

THE THIRD ANNUAL  
CODMAN SHOULDER SOCIETY MEETING  
SATURDAY, JUNE 25, 2016 (4-10PM)



*“Give me something that is different, for there is a chance of its being better.” EA Codman, 1934*

## *Report of our Third Meeting*

Dear Colleagues:

I would like to thank all of you for attending the third annual Codman Shoulder Society Meeting. For those of you who were unable to attend, I welcome your thoughts (as well those from attendees) after you read this report. Enclosed is a brief summary of the topics we covered. I will also share my thoughts about the potential for this organization. As you read this, ask yourself what value this might hold for you and your colleagues, and do so taking into account all the other competing educational activities which demand your attention. The real question is, does this activity add value in a world already overloaded with CME events, compliance requirements, family commitments, etc. Is this just one more thing to do? What should we be as an organization? Should I open this meeting to a broader group of interested shoulder surgeons? Should we keep this small? How will we sustain this endeavor? Please don't be shy with your input.

Please pay particular attention to the end of this document as it considers these issues in more detail.

Please consider this thought from my good friend Christian Gerber who is probably one of the most important innovators in shoulder surgery in our generation: “Education is difficult to pass down to the next generation, but this is not the case for enthusiasm.”

This year we were lucky to have esteemed experts speak to us on several topics. This meeting was actually more than lectures. It was a true “think tank” as we discussed and debated important concepts about innovation and treatment of shoulder problems. Our invited guests were:



Ronald Navarro



Jim Esch



JP Warner



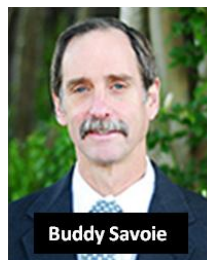
Mohit Bhandari



Matthew Provencher



Asheesh Bedi



Buddy Savoie



George Athwal



Joaquin Sanchez-Sotelo



# Codman Shoulder Society Meeting 2016 Group Photo



**Back Row (from left to right):** JD Werthel (Mayo) Gregory Alberton (San Diego) Asheesh Bedi (UMichigan) Amon Ferry (Phoenix) Mena Mesiha (Fall River) Paul Dowdy (Orlando) Sommit Dan (Australia) Tyler Fox (UKansas) Uma Srikumaran (Johns Hopkins) Michael Freehill (Wake Forest) Orsa Britton (Zimmer)

**Middle Row (from left to right):** Ed Yian (KP Anaheim) Brett Sanders (Chattanooga) Lewis Shi (UChicago) Albert Lin (UPMC) Arnold Alqueza (Brigham and Women's) Peter Vezeridis (UCLA) John Macy (Vermont) Amit Sood (New Jersey) Jeremie Axe (Delaware) John Hoyt (Smith & Nephew) Danny Goel (British Columbia) John Goff (Northern California)

**Front Row (from left to right):** Bassem Elhassan (Mayo) George Athwal (Western U, Can) Felix "Buddy" Savoie III (Tulane) Mohit Bhandari (McMaster U.) Jon JP Warner (MGH/Harvard) James Esch (San Diego) Joaquin Sanchez-Sotelo (Mayo) Philippe Valenti (Paris) Ron Navarro (KP So. California) Jonathan Ticker (Merrick, NY)

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*"Give me something that is different, for there is a chance of its being better." EA Codman, 1934*

- [4:00-5:00](#) Welcome cocktail reception (Cobalt Foyer – 5<sup>th</sup> floor) **Meeting in Room 520**
- [4:50-5:00](#) Group Photo
- [5:00-5:10](#) **Jon JP Warner:** Welcome and introduction; Recap of the last two meetings

**KEYNOTE SPEAKER**



**Mohit Bhandari, MD, PhD**

**SESSION I: EVIDENCE & VALUE: CAN WE ALIGN THESE? SHOULD WE TRY?**

**MODERATOR: JON JP WARNER**

- [5:10-5:25](#) **Mohit Bhandari – Keynote Address:** Driving Better Decisions – What Evidence Do We Need?
- [5:25-5:35](#) **Felix “Buddy” Savoie:** Strategic Approach to Value-Based Care: AANA’s Strategy
- [5:35-5:50](#) **Panel:** Evidence and Value – How to align with CMS and payers (Bhandari, Savoie, Ticker)

**SESSION II: HOW CAN WE IMPROVE VALUE/OUTCOMES IN SHOULDER ARTHROPLASTY?**

**MODERATOR: RON NAVARRO**

- [5:50-5:58](#) **George Athwal:** Stemless Implants and other advances... What does the future hold for B-2/C glenoid Rx?
- [5:58-6:06](#) **Jon JP Warner:** PSI --- Really makes a difference in outcome and value
- [6:06-6:14](#) **Joaquin Sanchez-Sotelo:** The indication and expectation for Reverse prosthesis is expanding
- [6:14-6:22](#) **Ron Navarro:** Registries will change what we do
- [6:22-6:37](#) **Panel:** (Athwal, Warner, Sanchez-Sotelo, Navarro)

**SESSION III: INSTABILITY – BONE LOSS...THE BIG QUESTION: TREATMENT?**

- [6:37-6:45](#) **Felix “Buddy” Savoie:** Evidence for Remplissage
- [6:45-6:53](#) **Asheesh Bedi:** Evidence for Latarjet
- [6:53-7:01](#) **Matthew Provencher:** Evidence for Bone grafting
- [7:01-7:10](#) **Mohit Bhandari:** Is the evidence adequate?

**SESSION IV: BUSINESS/PLANNING/FUTURE CONSIDERATIONS**

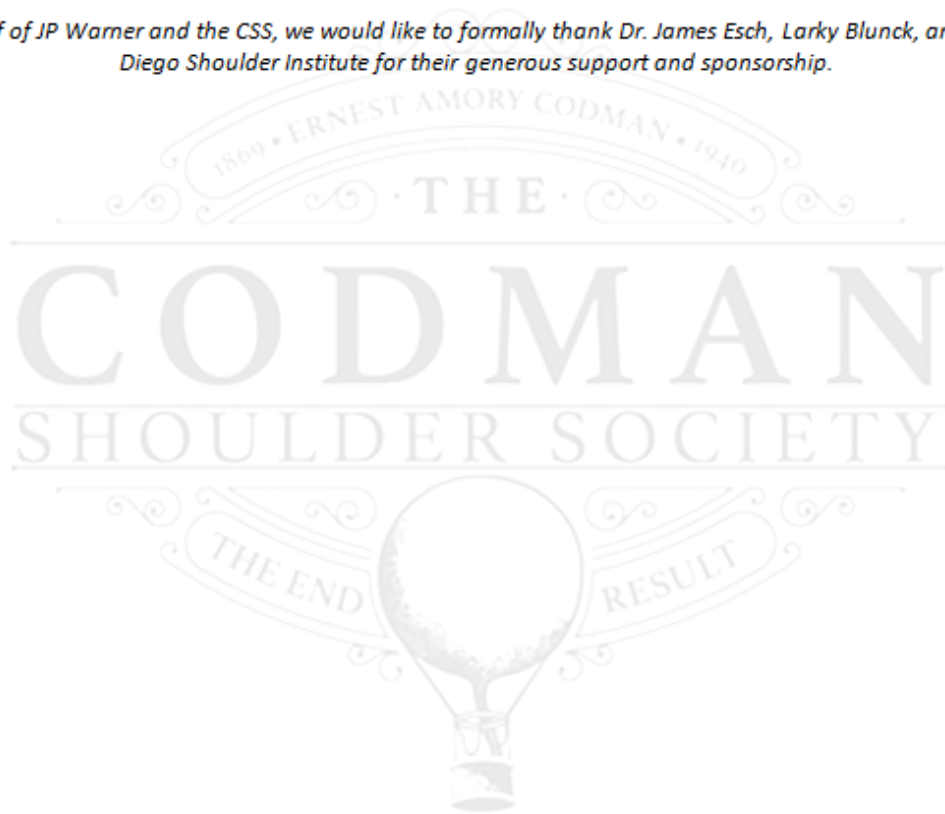
**MODERATOR: JON JP WARNER**

**7:10-8:10** Discussion among CSS members and others who are interested

- What do we want to be going forward?
- What are we willing to do?
- Next Steps

**8:00-10:00** Dinner

*On behalf of JP Warner and the CSS, we would like to formally thank Dr. James Esch, Larky Blunck, and the San Diego Shoulder Institute for their generous support and sponsorship.*



*Enclosed is a brief summary of our meeting.*

## **I. Evidence & Value: Can we align these? Should we try?**

*With the first ever Codman Society Keynote Address from Dr. Mohit Bhandari, we considered the current state of evidence and related challenges in orthopaedics research. Within this context, we worked to define the role that the Codman Society can play in advancing evidence-based research and treatment.*



**Dr. Warner:** We've got a logo, we're an entity. We have the enormous opportunity to be a think-tank and grow and make a difference with ideas and research. We can facilitate everyone's good ideas. Providing money for it is another matter.

- Motto: "give me something that is different, for there's a chance of it being better." From E.A. Codman. I think this saying should be at the core of everything we do. We can be self-critical here and design something better. Evidence should be the driving methodology of this goal, which is why we're so lucky to have Dr. Bandari speak to us.

### **Mohit Bandari: Driving Better Decisions: What Evidence Do We Need?**

*He shared his evidence-based practice experience from the past twenty years, as his group has grappled with trying to move evidence and meaningful research forward. The ultimate goal in this pursuit is to "help people make better decisions."*

- "The truth is, nothing important comes easily.
- C.S.S. must ask itself several questions:
  1. "What is our End goal...Regionally, Nationally, Internationally?"
  2. "How committed are we as an organization to research?"
  3. "Who in the group will lead, moving our mission forward?"
  4. "Do we want to collaborate, lead, or do both?"
  5. "What is our strategy to differentiate ourselves from other organizations?"
  6. "Are we prepared to say that some things don't work if they've been used regularly until now?"
- Some Advice:
  1. "Leaders....Anticipate change; have diverse networks of relationships; are courageous enough to abandon practices that may have made them successful in the past"
  2. "Outside the box" thinking may not be the best way!" For impactful evidence....

- a. Ask BIG QUESTIONS (matter to many)
  - b. Ask SIMPLE QUESTIONS
  - c. Embrace Failure of your hypothesis
  - d. Collaborate for the greater mission
  - e. Be pragmatic and set realistic milestones
  - f. “Saying is not doing....doing is DOING”
3. The majority of what we’re doing is incremental, and does move things forward. But big innovations happen with the simplest ideas, in which everyone buys in.
  4. When we started the FLOW study, it was so simple that people were wondering why we were even doing it, and we had \$3 million for it. Simple questions that seem intuitive should be challenged. Dogma should be challenged.
 

Bhandari M. *et al.*: [A Trial of Wound Irrigation in the Initial Management of Open Fracture Wounds](#). NEJM, 373.27 (Dec 2015): 2629-641.
  5. “If you’re asking big questions you must be ready to fail.” (Robert Leftkowitz, 2012 Nobel Prize)
  6. “Science is 99% failure, and that’s an optimistic view.” (Robert Leftkowitz, 2012 Nobel Prize)(But failure is information—we often learn from it.)
  7. What can this group do that would challenge dogma and do something that hasn’t been done in shoulder surgery. You should find the zone between your comfort zone on one side and recklessness on the other.
  8. When we started trials for the soap-washing study, the statement was “you just won’t get surgeons to do it.” Then medical people said surgeons won’t work together, and then it was “Canada can’t work with America,” then “we can’t do it outside North America.”
  9. Commit to research that matters: that’s significant for everyone, creates a global connectivity, grows the team, and contributes to wellbeing of all people.
  10. **The challenge:** There is a severe noise to signal ratio issue in orthopaedics. The value of this collaborative is combating this issue by bringing together a large group of skilled surgeons with a large pool of patients for recruitment. When the N is big, the problem in question becomes simpler.
    - a. Remember why randomization is so powerful. The only way we can assure whether treatment A or B is different or the same, is if the study groups are actually the same.
    - b. We characterize a bunch of factors, but do you honestly believe that two groups of 30 patients per arm are actually balanced? If we had 10,000 per arm, we have a pretty good balance across groups.
    - c. It may not always be feasible, but always ask, “Can we do a RCT?”
  11. **SAMPLE SIZE ISSUE** is why no one wants to get involved. In our FLOW study we were stuck at 80 patients. We had to really grit it out and expand to get to our desired sample size. We finally got to 2447 patients. And even this pales in comparison to some cardiology trials, such as the OASIS 6 RCT, which enrolled 13,000 patients across 447 hospitals and 41 countries. These are hard to do, but you get generalizability and impact.
  12. Another problem: meta-analyses, the “Gladwell phenomenon.” Since 2005 we’ve seen a massive increase in meta-analyses. There were more meta-analyses published

- in 2005 than there were in all years combined before then. This contributes to even more noise in the system.
13. You can create knowledge, and you can disseminate it. “Evidence does not cease to exist because it is ignored” (-Aldous Huxley).
    - a. Widely spreading whatever new information we come up with is also important—we can contribute to translating evidence.
  14. In summary: small studies risk erroneous conclusions, we need larger studies by design, these will require collaborative efforts, and then if you want to go from good to great, you’ll go from successful (footprints on individuals) to significant (footprint on society).
  15. Example of Jack Welch, who transformed GE into a \$450 billion dollar company. How’d he do it? He found really smart people, and gave them resources and money. How do we continue on this pathway? “My main job is developing talent” (Jack Welch)

**Felix “Buddy” Savoie: *Strategic Approach to Value-Based Care: AANA’s Strategy***

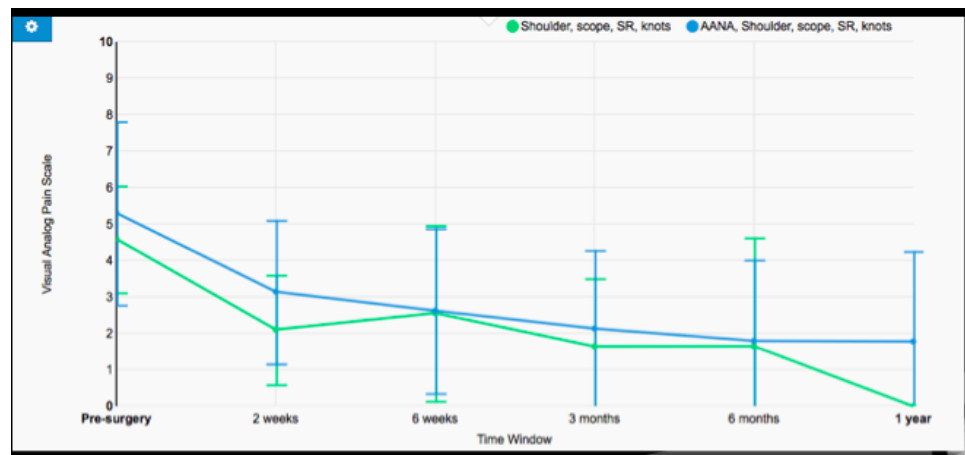
*“There is a war out there in Medicine. The ammunition is data. The doctors have none”*

*- Lanny Johnson*

- Update on American Arthroscopy Association of North America (AANA) initiative to collect evidence, representing the presentation of President of AANA, William Beach.
- Value cannot be determined without measuring outcomes.
- The future as we may know it?!:
  1. End of Fee-for-service by 2020?
  2. 50% of CMS payments will come from alternative payment models by 2018
  3. There is a commitment is to change from VOLUME to Value
  4. *WE MUST MEASURE OUTCOMES?*
  5. Creation of Value Metrics is the issue....who will determine this?
    - a. Who determines the metrics? (Provider vs. Payer)
    - b. Who will collect the data? (Provider vs. Payer)
    - c. How will this affect your “Administrative Burden”?
- Getting going with the AANA data collection project took 30 years.
  - Other societies (AJSM) have no interest in data collection, others (ASES) are resistant. It’s unclear where AAOS stands. But CMS expects us to have data: mortality, complications, and numbers of patients returning to the hospital.
  - CMS also wants patient reported outcomes (PROMs). In one study, *the number one predictor for how patients evaluated their doctor’s office visit was depression*. The government that’s rating you wants to know how the patient feels.
- “Data is power.” We need to integrate good sources of data, including RCTs. Members must buy in. AANA was first society as a whole in the U.S. that started collecting data. In next 2 years ASES will likely follow suit. It’s a pain in the ass but it’s crucial in order to avoid negative coverage decisions. With evidence we can change this.
- “Where are the main problems”. Surgeon Buy-in is number 1. Expense is number 2.

- Arthrex came to the plate after AANA’s request to create a database, Surgical Outcomes System (SOS). Every AANA dues-paying member gets it for free. The goal is to make it less expensive, with minimal burden for surgeons and no excessive regulations.
- Concerns about SOS and relationship with Industry:
  1. There is a HIPPA “Communication Mandated” wall between data collection and company sales personnel.
  2. The business/sales people are “blind” to who the surgeons and patients are who are participating in SOS.
  3. Currently, this is the only organization which has offered such a service at no cost.
  4. Every AANA SOS user has access to a global de-identified average which can be used for comparison for outcomes of any surgical procedure.

Example of SOS data report for Single Row RCR:



- Hopefully, more societies will follow suit.
  - 2 models within the database.
    - 1: Research model. This is what we want. (collect more data, options for data collection, IRB approval written patient consent).
    - 2: Healthcare Operations (HCO) side, which is what we’ll need to give to government or insurance when the government starts ratcheting down.
- What JP wants to know is, is this system working? He wants everyone involved. This will help your patients, this will help you. Should SOS be a shared data collection method for members of the Codman Shoulder Society?
- Parts of the survey equation: 1) administrative assistant who has time 2) telling Pt. its important, getting their email, explaining two-year commitment. The surgeons do the surgery, input diagnosis and treatment, and follow up with patients. Then you get the data for analysis. All this goes to JT Tokish’s group, where S. Carolina has put up \$20m dollars to establish a data repository. ABOS also very interested.
- 30% of AANA membership has started process of signing on. First year was 5%, now about 10-15% are actually getting reasonable data. You’ll need a full-time assistant that is responsible for keeping the research going. ASES looking around, trying to follow lead of JP Warner and Larry Higgins in pushing a value agenda and emphasizing data collection, but progress is slow.



### *Comments from the Group:*

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**Ron Navarro:** Question to Buddy. The means of data collection is appreciated (with industry providing us platform) but are these industry partners Trojan horses that will interfere down the road? Will it be a problem to pull this data back from them?

**Buddy:** This is a valid concern, but Arthrex doesn't maintain this data (SOS). Arthrex can access it but the AANA database information is stored at JT Tokish's group. Even if Arthrex walks away, it's still our data. However with ASES we don't know where we are on that, it's a concern for a smaller society. DePuy has another system, but its more expensive and they're not willing to give it for free. The Rush group (Chicago) Rothman Institute (Philadelphia) and maybe HSS (NYC) use OBERD, which is at least \$5000 per doctor per year.

**Brett Sanders:** Our group developed one in-house on Athena platform, which builds into the workflow of PT. The therapist sees the patient and, day 2, again day 14, and every time they touch person they add a survey.

**JP Warner:** The problem is that in order to see a therapist, the patient needs to visit. Research Assistants are affordable, and they can look in the database and follow up if someone doesn't fill out a survey. They key is getting meaningful data over time, with fewer dropouts.

**Mohit Bhandari:** What JP's talking about is a big challenge with large data sets. Without a 100% buy in, getting a complete data set is challenge. And another challenge is funding. For example, with only 5 years of funding, it's not sustainable. With these systems you're not asking questions before you start, you collect data and ask post-hoc questions. So it's tough for funding.

**Baseem Elhassan:** As Phillippe Valenti has said, the French Orthopedic society will sign people up and will pay for them to do the study.

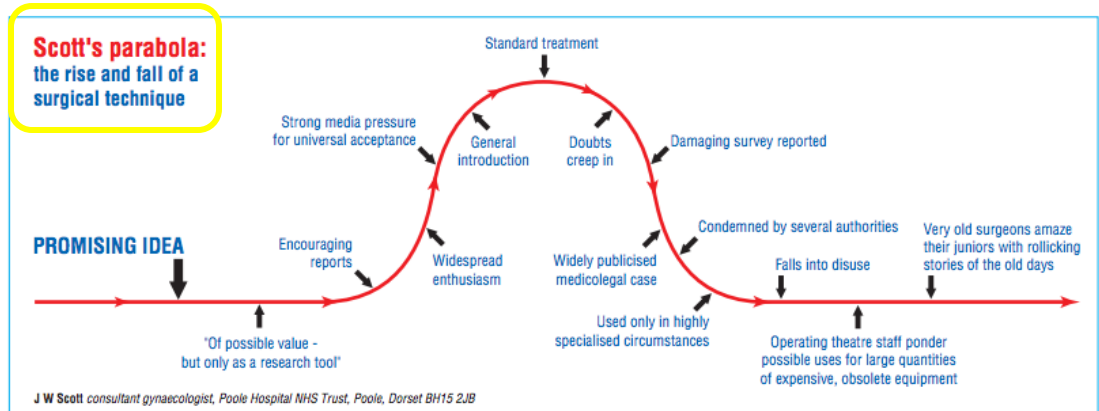
**JP Warner:** That just won't happen here. As president of ASES I changed the society's by-laws to have value-based approach. Buddy is still carrying the torch as ASES President. But we don't have the money to do that.

**Phillipe Valenti:** With Pascal (Boileau), we decided to select 15 centers to look at fractures with reverse prosthesis. The French society paid to travel, but no more. You spend a lot of time collecting data, but all the French society pays for is travel.

**JP Warner:** That comes back to the point about funding—at the end of this meeting we'll talk about our future direction and potential funding sources.

## II. How can we Improve Value and Outcomes in Shoulder Arthroplasty?

With Scott's Parabola in mind, we discussed recent advances and current topics in shoulder arthroplasty.

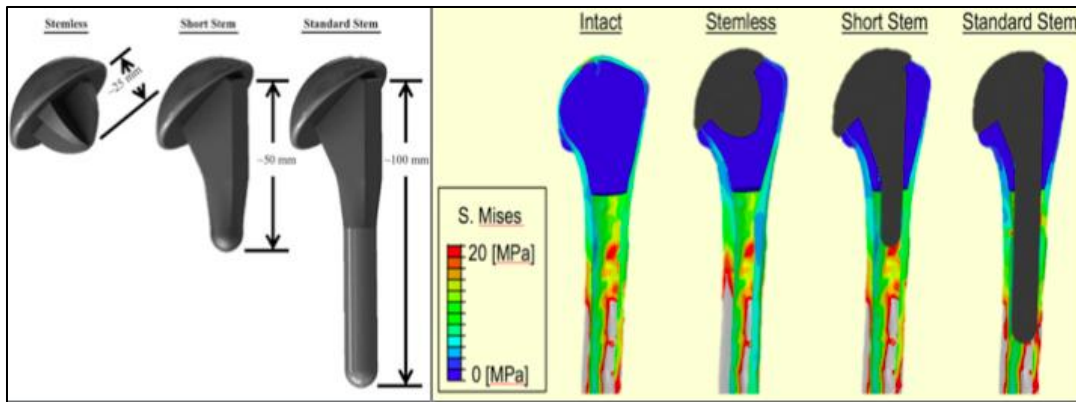


### George Athwal: Stemless Implants and other advances...

- Outline: design rationale, why “canal-sparing,” a few commercially available systems, my experiences, other advances (pipeline products in the future)



- People calling them “canal sparing,” but they all have metaphyseal characteristics of some type.
- Is this new technology? Not really. I put my first one in in 2007. There have been >16,000 implanted since 2004.
- What’s the hype? It allows for anatomic humeral head reconstruction, independent of canal/stem position. No broaching, no reaming.
  - Companies describe them as “bone preserving.” But you’re still putting in a metaphyseal characteristic, so this is contentious. JP what are your thoughts on that?
  - **JP:** This comes down to pure marketing, though there are real advantages: perhaps not just short term but long term when it comes to possible revision.
- Some other advantages: easy access to glenoid, and they’re good for addressing humeral deformities.
  - Athwal, G. *et al.*: [Comparison of proximal humeral bone stresses between stemless, short stem, and standard stem length: a finite element analysis](#). JSES 25.7 (Jul 2016): 1076-083.
    - We looked at stemless, short stem, and standard stem implants. Comparing the cortical stress distribution of normal intact bone to stemless, we see they’re virtually identical.

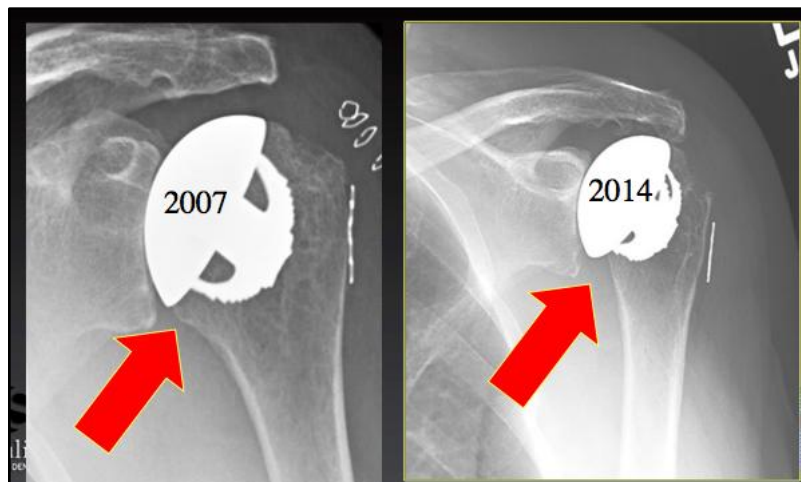


- The short stem and the standard stem implants actually have some serious stress distribution changes.
  - While the stress between cortical bone for intact and stemless are similar, the metaphyseal bone stresses are substantially higher in a stemless system.
- Some systems available on the market:
    - 2 types of metaphyseal characteristics: thin types vs. cage system (by Arthrex)



- State of stemless in 2016, worldwide.
  - Biomet system: first one put in. Designed in '04. Only system early on that had anatomic and a reverse. This is only still around in the EU.
  - Arthrex system first in 2005, IDE still ongoing, 80% done, forecasted to finish in 12 months. Still around 3 years away from FDA approval in the U.S. The only one with threaded cage design. No predicate exists in the shoulder; only predicate is spinal hardware so FDA wanted a big IDE (~280-300 patients.)
  - Simplicity (Wright/Tornier) is the only one with FDA approval.
  - Zimmer Sidas: it finished its study a few months ago. Will be approved in next 24 mo. by FDA. It's not convertible, there's no primary reverse, and it has a male taper (hoping for female taper in second generation)
  - FX solutions—no experience with, but it's the first convertible one. Can decide if you want anatomic or reverse, without revising the metaphyseal characteristic.
  - Biomet Nano: also a convertible system.
  - Lima: also convertible, came out recently, no experience with this system.

- Experiences with these
  - Case in 2007, 55 YO female with OA and RC tear. Back in 2007, would've done hemi and RCR. Balanced on forward elevation so did a TESS hemiarthroplasty
    - 2014: pain and pseudoparalysis, likely ruptured superior cuff, failed subscap, proximally migrated. Comparing '07 and '14, one can see stress shielding and bone remodeling occurring at the medial calcar. This seems very common with stemless implants. May have to do with force distribution (aforementioned study, where more force transmission/pressure at the metaphysis for stemless.)



Revised her due to improper placement. In total have revised ~25 stemless implants, only one was revised for fixation issues. All others were for infection or placement. So the stemless design is a solid design.

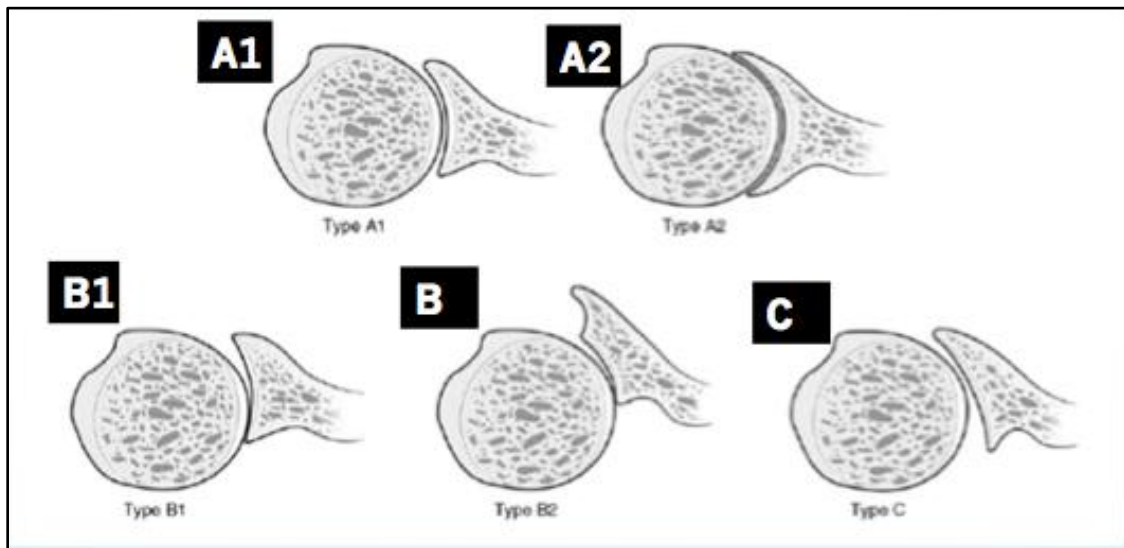
- Stemless implants are getting the reputation as being “nice and simple,” but I’d warn that nothing is ever simple, and to be wary of the marketing. New innovations create new problems, like taking them off as just one example.
- Other current/upcoming advances:
  - Pre op planning and understanding glenoid OA.
  - In the near future: patient-specific implants and implantation
  - Needs further study: Alternate bearing surfaces, tissue sparing arthroplasty, understanding implant failure, and understanding *P. acnes* and infections.

### **JP Warner: Patient Specific Instrumentation (PSI)—Really makes a difference in outcome & value**

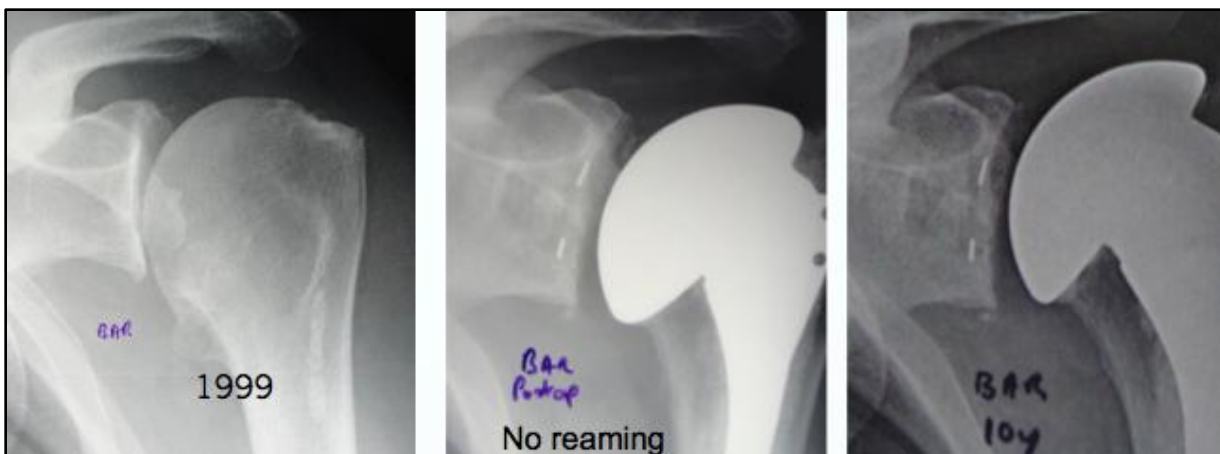
- This is an area that could have an enormous impact on reproducible outcomes which are durable in TSA.
- Salvador Dali: “have no fear of perfection, you’ll never reach it.” Hypothesis though is that PSI will get you closer. At the very least we can show it makes a difference in planning.
- Gilles Walch has been important in understanding this. Christian Gerber has said, “An operation can fail even before you get to the operating room.” If you have no plan or a poor plan, the chance of providing success (value) is low. G. Walch and Cofield et al,

have shown that glenoid (radiographic) loosening occurs in 50% at 10 years and 80% at 15 years even if the patient is asymptomatic.

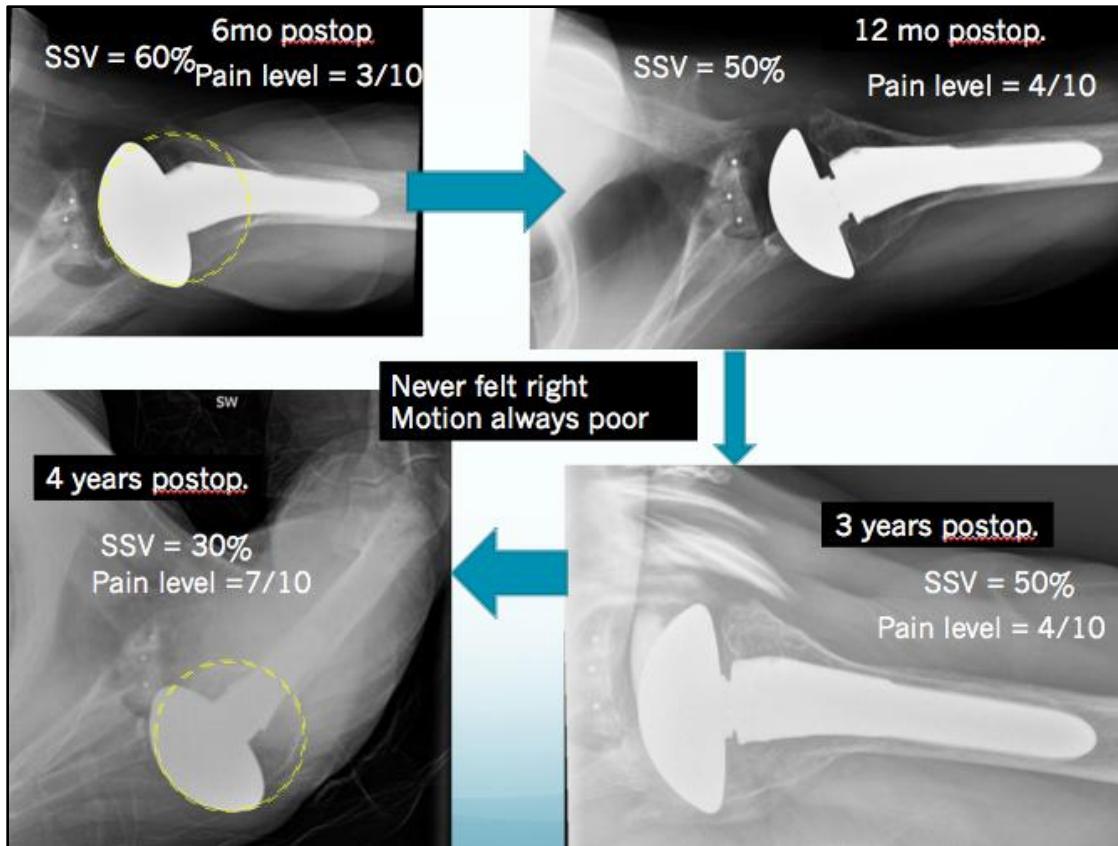
- What we know from literature is:
  - If the glenoid is placed in retroversion  $> 10^\circ$  it will likely lead to failure.
  - If seating of the glenoid component is less than 80%, it will loosen.
  - Excessive reaming of subchondral bone will likely lead to failure.
- We still don't know impact of superior inclination and how to use this information. We know that degree of superior inclination probably has an effect on the rotator cuff, may presage failure
- Glenoid Morphology predicts failure if we don't consider it (G. Walch Classification of Glenoid anatomy):



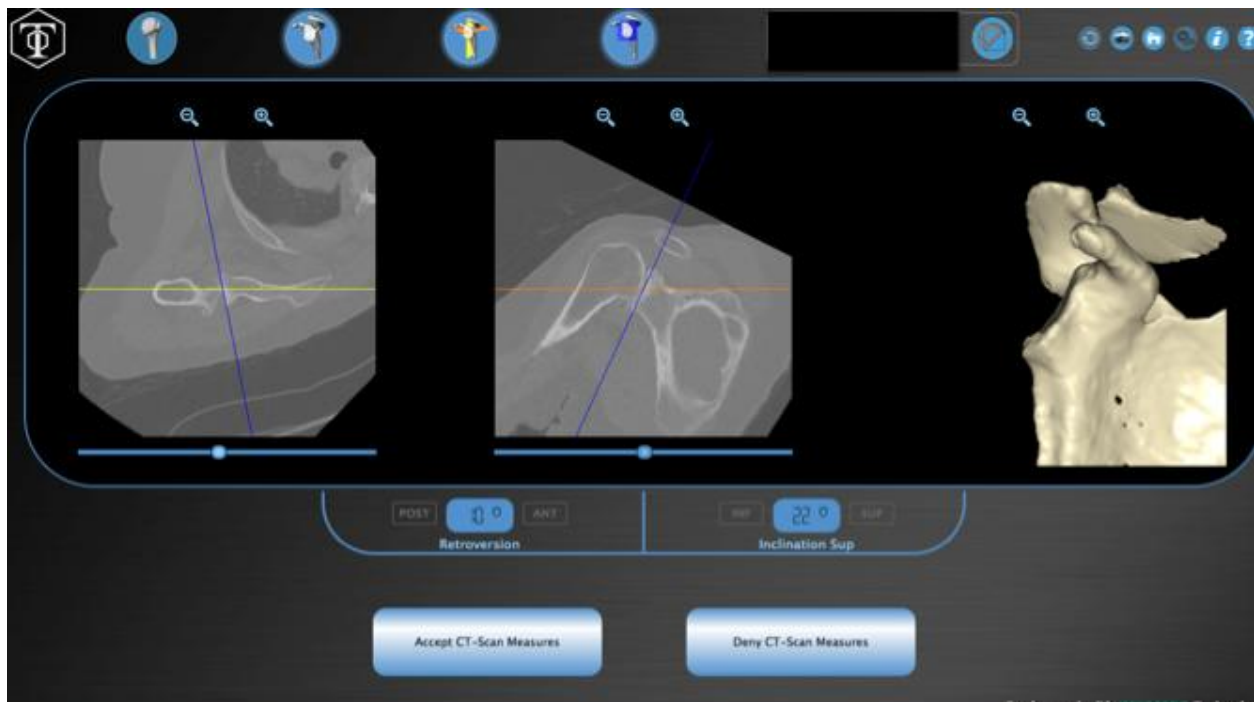
- Poor implant positioning is a cause for failure.
  - PSI may help avoid incorrect glenoid placement and excessive reaming
- Example: Patient followed for 10 yrs, absolutely perfect glenoid, no symptoms. I've seen some of Neer's patients twenty years out that looked this perfect. Why? Perfect patients, excellent surgeon, minimal glenoid reaming, balanced RC envelope. Placement and skill is more important than design.
- 10 year follow-up with no loosening (Courtesy G. Walch):



Case #1: Failure to recognize a B-2 Glenoid and consequence of excessive anterior reaming to place a glenoid component:

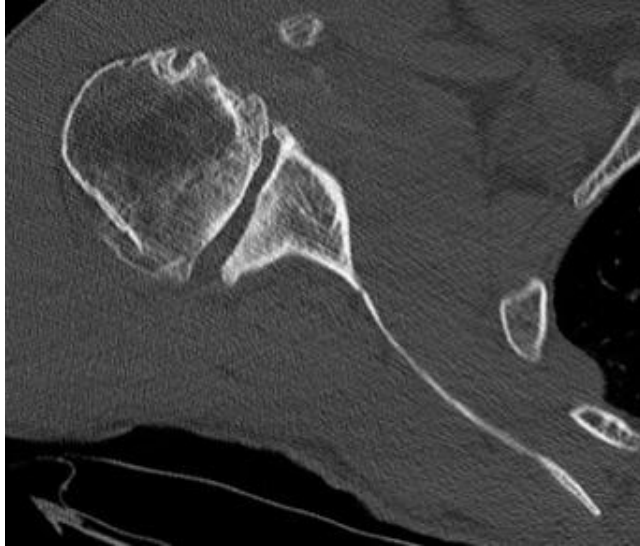


Case #2: 64 YO woman with excessive superior inclination (using Blueprint™ planning system).

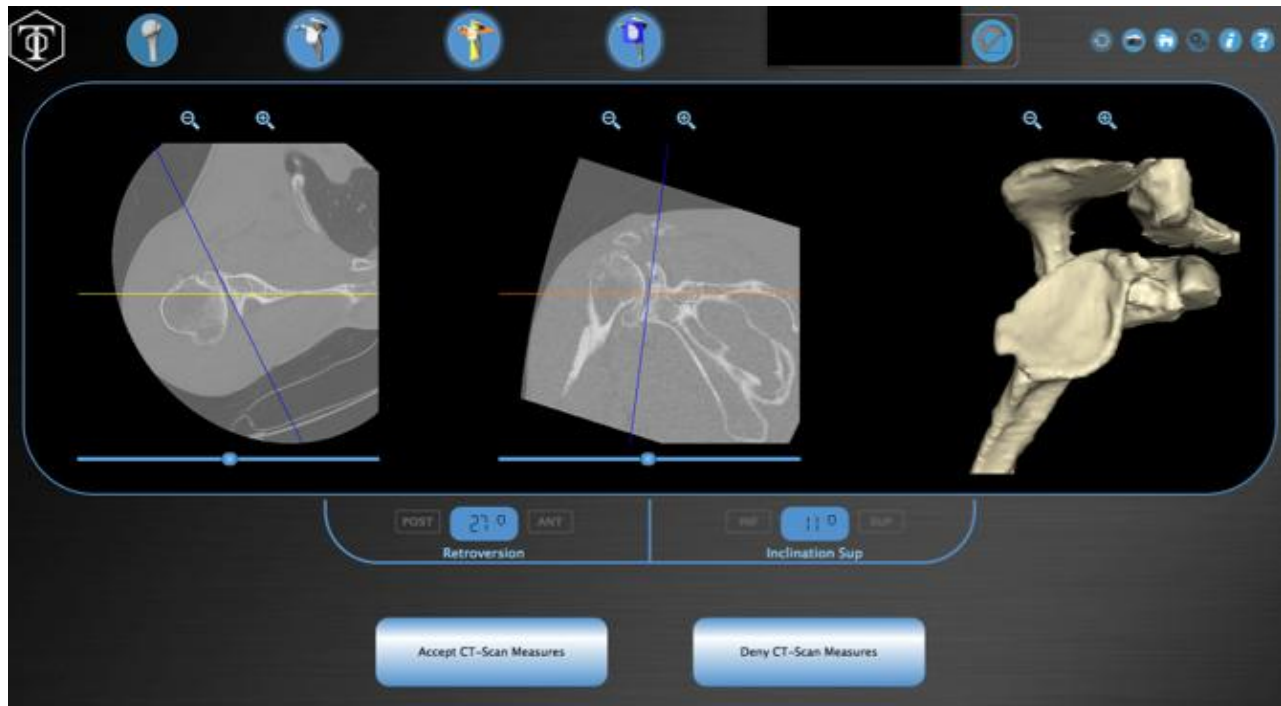


Is this a problem?

Case #3: 50 YO man with severe retroversion and prior instability surgery. Is this capsulorrhaphy arthropathy? Will a conventional TSA work?

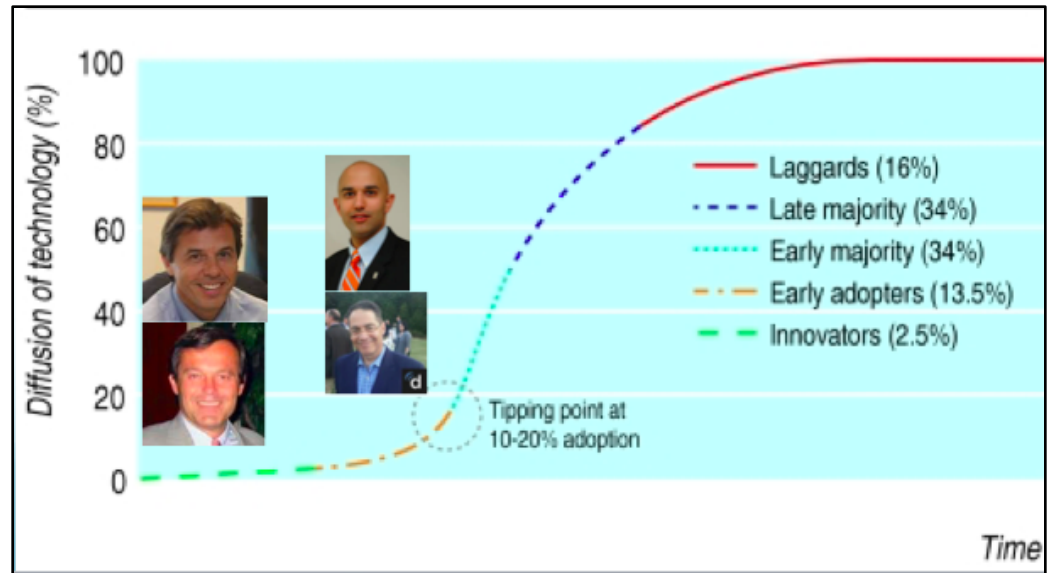


Does 3-D Planning change your mind? (Blueprint™)



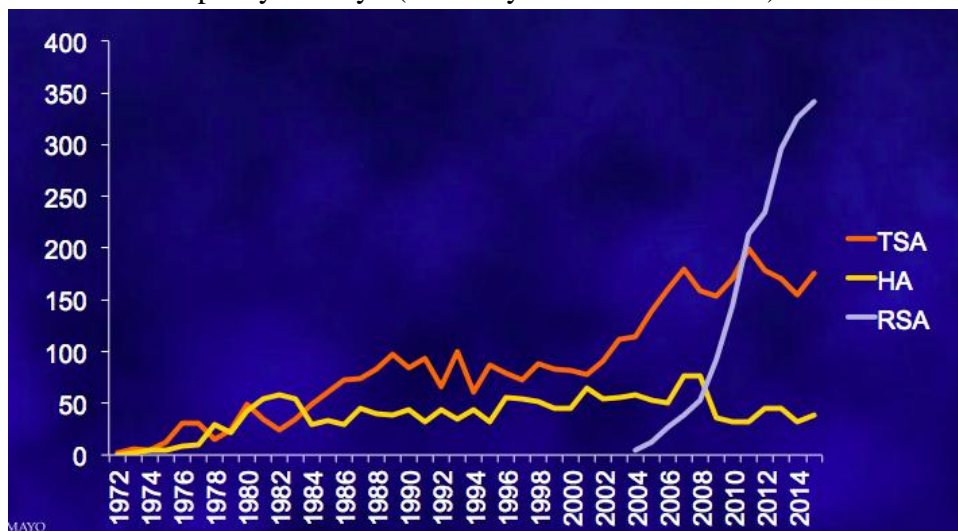
- We need the insight that PSI planning can give us in order to plan surgery before we actually do it. If we come up with options A, B, and C, then we can plan for each of these with inventory and contingences. The question isn't "do we need this." All companies now have it available. **The question is, "what is the evidence that this changes what we do and that it results in better patient care?"**
  - I'd like to prove that there's a rationale behind this technology and we can bring it (and the evidence-based decision making) to the majority.

The Impact of PSI will be huge!  
Where will you be on the curve?



**Joaquin Sanchez-Sotelo: The indication and expectation for Reverse is expanding**

- Shoulder Arthroplasty at Mayo (Courtesy J. Sanchez-Sotello)

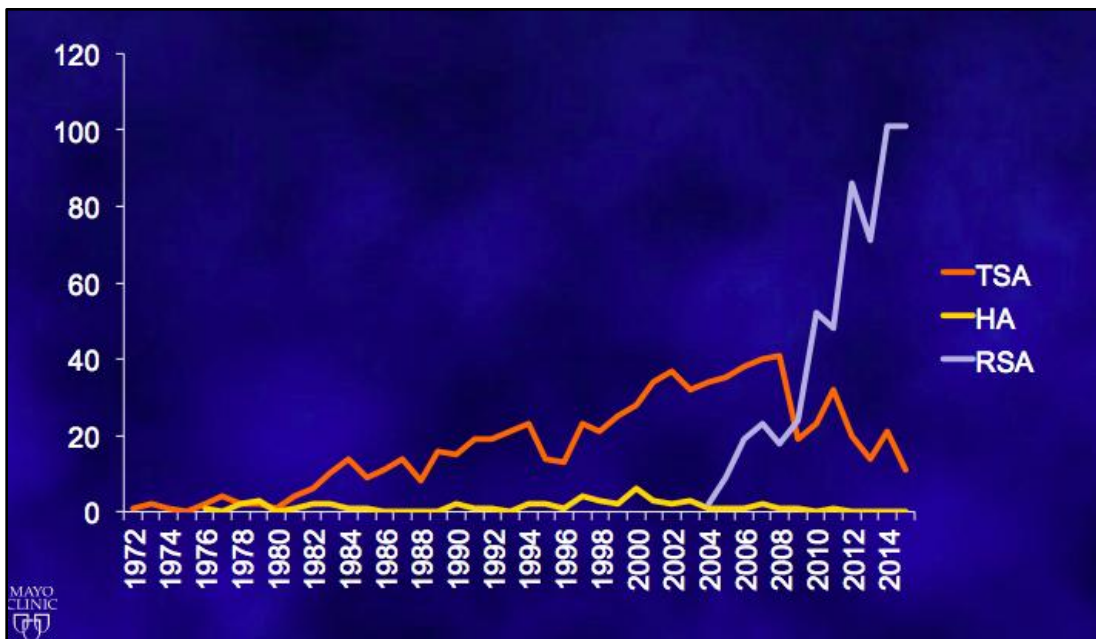


- Indications expanding, expectations are expanding, what's the value?



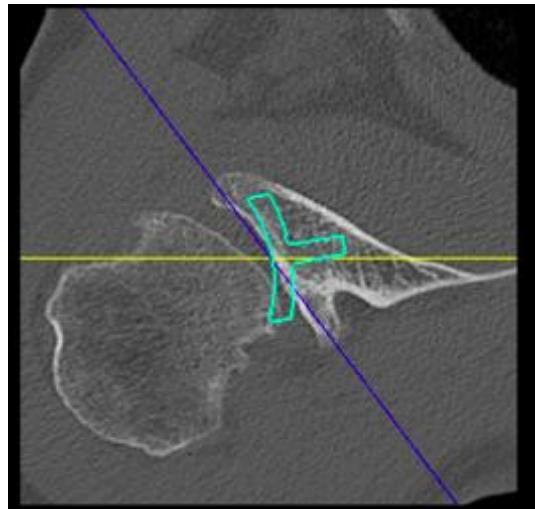
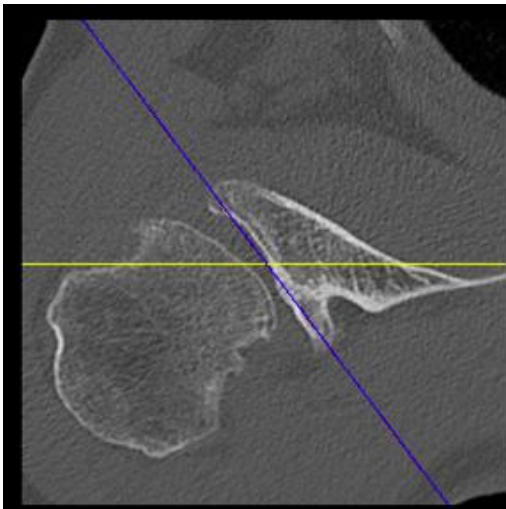
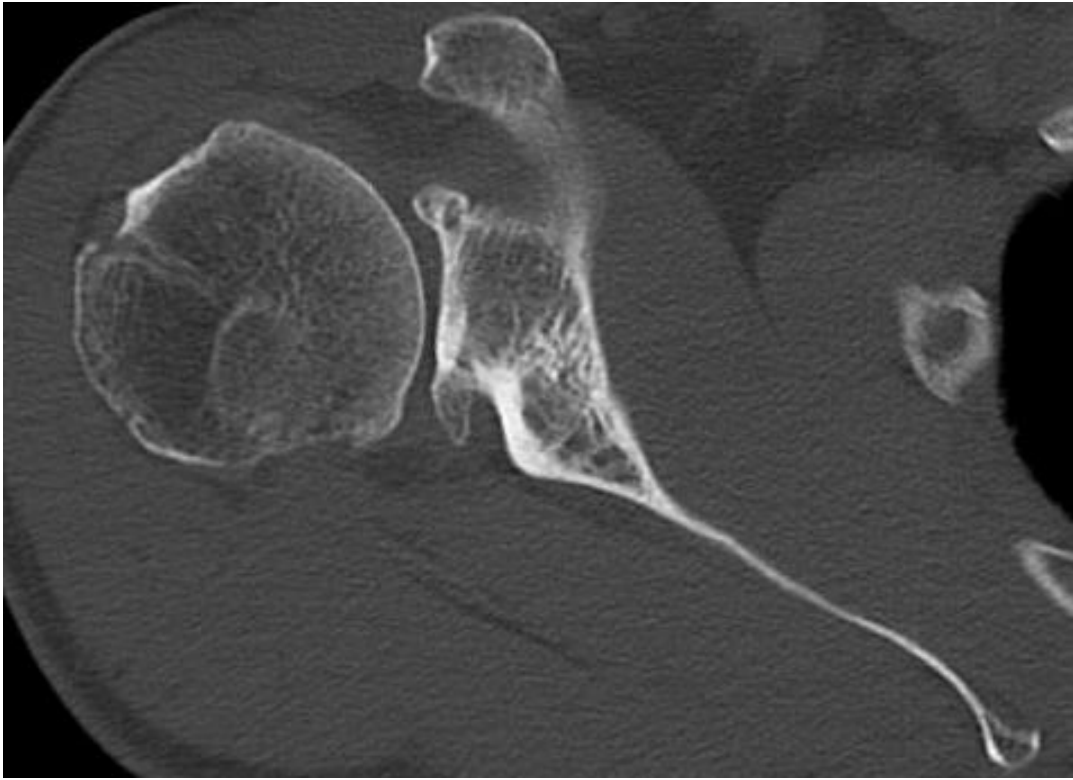
- Dr. Paul Grammont: when he designed the reverse prosthesis he changed the world. Since then there have been waves of expansion.
  - First, only used after cuff tear arthropathy. Then used for no cuff, no OA, then used for proximal humerus fractures, then for revision shoulder arthroplasty.
  - The indications kept expanding: primary OA with intact cuff (B glenoids) and now it's used for younger and younger patients.
  - Plenty of studies looking at U.S. experience in volume. Just look at registry at Mayo. 7000 arthroplasties collected, and there's been huge growth in reverses. At Mayo we're doing about 350 primary reverse shoulders every year. About 120 revision reverses a year.

Revision Shoulder Arthroplasty at Mayo (Courtesy J. Sanchez-Sotello)



- Case: 55 YO gentleman. Back when I was a fellow, to be honest, I would've thought that there's nothing that we can do for this patient. He has an intact Rotator cuff and CT scan and 3-D planning. tell the story....my solution....

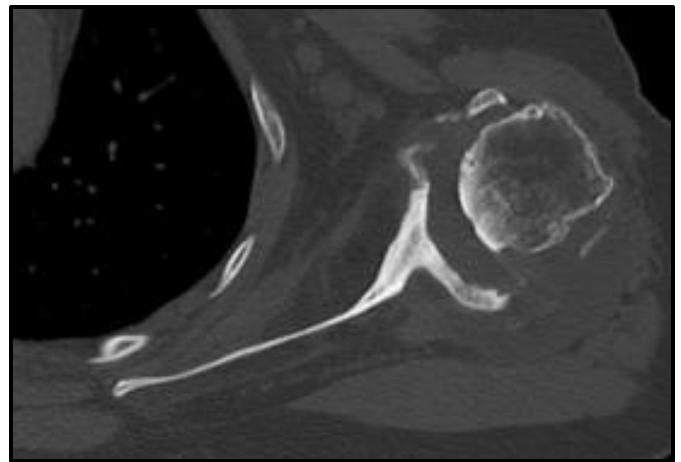
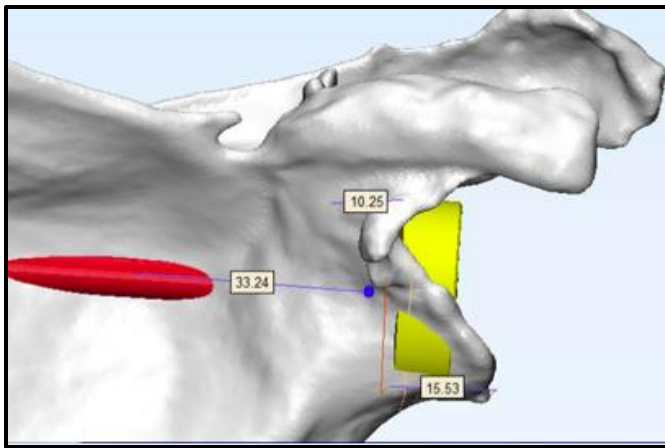






- #1, Indications are still expanding.
- #2, expectations are huge on patient side and surgeon side. Reverse can be intoxicating, when patients come back in a number of months with restored function and ROM. We tend to forget that we only get these results in patients with cuff tear arthropathy and in patients with primary OA.
- However, patients expect these incredible outcomes with everyone. Boileau won the Neer Award in 2005 when he showed that the outcome is pretty much dependent on the underlying diagnosis. (Boileau P, et al, JBJS 2005)
- I get frustrated with my fracture patients. The patients do well, but they don't have the results of those outcomes from a cuff tear arthropathy.
- In our minds we think, "If I go reverse we'll get that 165 deg. motion." But that's not true in every diagnosis.
- Second thing is we're really pushing the envelope on the glenoid and cubital side.

- Case: 78 yr old women with severe bone loss. Should we even try? Will PSI help us to solve such problems? What are the risks?



- 69 yo woman with humeral insufficiency and stem of implant into elbow. Are we “pushing the envelope” too far on humeral side? Allograft proximal humerus + Reverse + TSE.



- What about value? Not a lot about it.
  - Article from Mark Frankle. 55 primary RSA- Fu 4 yrs. Mean total cost \$24,000, 5 fold reduction in pain, 70% improvement in function, complication rate (cost) was 10%. Frankle, M. *et al.*: [Preparing for the bundled-payment initiative: the cost and clinical outcomes of reverse shoulder arthroplasty for the surgical treatment of advanced rotator cuff deficiency at an average 4-year follow-up](#). JSES 22.12 (Dec 2013): 1612-22
  - Another article: used complicated suspected value analysis to show that you can get cheaper gain in quality of life with reverse. But they assume that RSA outcome is worse if you’ve had previous surgery, and their complicated suspected value equation completely changes. Shows you how complex people can make this question when their study parameters change. Makhni E., Swart E., Steinhaus M., Mather R., Levine W., Bach B., Romeo A., Verma N.: [Cost-Effectiveness of Reverse Total Shoulder Arthroplasty versus Arthroscopic Rotator Cuff Repair for Symptomatic Large and Massive Rotator Cuff Tears](#). Arthroscopy. 2016 Apr 28 (ePub).
- Reverse is wonderful. Allows survival outcomes that previously were going to be failure.
- The reverse glenoid is winning. At 10 yrs., mechanical failure is decreased (doesn’t seem to loosen).
- Functionally, I think the best anatomic is better than the best reverse because you get such a nice range of motion, it’s so functional. Especially internal rotation.

- Don't forget, RSA's can get us in trouble. Catastrophic glenoid failure, fractures spine/acromion, brachial neuritis, dislocation, revision. Reverse is tempting (and forgiving). Many people have low threshold to "bail out" to reverse.

***Comments from group:***

**JPW:** Larry Higgins just looked at Quality Adjusted Life Years (QALY) for treatment of rotator cuff tears and reverse prosthesis, it's very cost effective. The single situation where there is no value is revision of a failed rotator cuff with a complication. So the value delivered has a lot to do with your "batting average" and the problem is that registries don't reflect the records of individual surgeons, it's blended together as an institution. For instance, Mayo clinic and NYU Orthopedic programs report their outcomes, but it's all aggregated. So on the individual level we need to be able to boil it down for the patient as a consumer.

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**Ron Navarro: *Registries Will Change What We Do***

- Dr. Bhandari's talk made me think registries, registries. But there are limitations.
- Why registries?
  - Surveillance of implants (early failure detection) data for quality improvement (failure, infection, VTE, readmission, mortality) cost effectiveness (better outcomes, lower cost).
- The "How" of Ortho Shoulder Registries
  - Have to define what the measures are. For Kaiser Permanente (KP) it's implant failure (don't look at downstream x-ray findings)
  - No patient reported outcomes (PROs) in KP, something they're working toward.
  - Want to make reporting burden low for surgeon.
  - Minimal data set that all can live with.
  - Trouble with the costs of registries.
    - Went from something that industry paid for, then turned into something that they would pay money into KP and pay for, now the KP medical group and healthplan pay for it jointly. They're always asking, "Is there value to this?" So it's always at risk of being shut down.
- There are many different national registries. In the U.S. there's Mayo, HSS, Kaiser, other regional U.S. registries. An international registry was discussed as a new effort, at the First International Shoulder Arthroplasty Consortium in 2014.
- KP Shoulder Arthroplasty Registry
  - Developed in 2009, now all KP regions participate and over 1000 cases are added annually.
  - Surgeons complete intra-operative form including procedure performed and diagnosis.
  - Data collected:
    - Patient data: Age, BMI, ASA, Race, Gender, Diagnosis, Comorbidities

- Surgery data: procedures, components, cement, approach, graft, subscap repair, complications
    - Surgeon data: blood loss, operative time, cases/year, fellowship, length of stay, anesthesia type
    - Within EPIC health record, computer prompts surgeon to fill out form.
  - All complications and revisions are validated via chart review.
- How can registries help with behavior change?
  - Risk adjusted Medical Center Reports
  - Confidential Individual Surgeon Profiles
  - Peer group discussion meetings
  - Patient risk calculator (For registry, in development for shoulder)
  - EBM influence
- Patient safety
  - Ongoing evaluation of device performance
  - Prevent implantation of devices with higher than expected adverse event rates. (ex. Decreased implantation of keeled components, went with pegged based on lit.)
- Quality Improvement
  - Quarterly reports, process improvement. Surgeon and hospital.
  - Feedback and change via data
    - For example: the chief from one of the KP medical centers, if he sees his complication data is trending high, can ask about seeing individual data with the surgeon. No surgeons' data can be shown to any one else, which ensures surgeon participation to some degree.
- Identify Modifiable Patient and Surgeon Risk Factors
- Yearly SAR registry goals.
  - ID reasons for ED visits post-surgery, reduction of OR/pain mgmt. variation.
  - Reduced LOS, adverse events?
  - Continue to increase patient participation
- Understanding registry research
  - Not the “end all, be all,” at best it’s high-level observational work.
  - Internal validation and bias control strengthen the data.
  - Prospectively collecting data, doing retrospective analysis after. So it’s not a one large, single-harvest database study.
- What can we do as a group?
  - Can we drive a national American shoulder arthroplasty registry? Or an instability registry? Dr. Bandari has shown we need large data sets. We’re interested in international comparisons—aggregating data is best and can bring out rare complication event rates. The idea of “add a 0 to your N” is critical, can get us closer to answering a question.

- Must be wary of the challenges of harmonizing data across regional/national databases. Difficult to compare data. For example the Australian OA Registry and KP have different terminology (RC insufficiency vs. RC tear, dissociation vs. glenoid component loosening).
- International Society of Arthroplasty Registries (ISAR) 2016, Manchester England. Bringing groups together to start large data analysis.
  - Invitation to attend and contribute to the 6<sup>th</sup> ISAR Congress in 2017, in San Francisco. (May 20-22<sup>nd</sup>, 2017).
- Conclusions: Registries emerging, adding to the value of the care, EMR can add with data collection, registries contribute to literature, National Registry in U.S. is a hope, International collaboration is a hope but harmonization is a challenge, registries can help with surgeon performance and change what you do in arthroplasty.

*Comments from the Group:*

**Mohit Bhandari:** This all comes back to making a decision. What is it you want to do as a group? Registries are important and get big numbers, but to do it well is really hard and money is going to be a factor. A big factor is, where money will come from, either to drive a registry or a hypothesis-driven study or maybe a bit of both. Look at questions you want to ask, figure out most compelling way to answer that. The question drives the design.

**JP Warner:** Best way to do something meaningful is to ask an important question. The literature is full of answers to questions that aren't important. It's a lot of filler in the journal. And every now and then you come across something that could make a real difference. One of the things we can do (as a group) is firstly ask important questions, and then we need to formulate studies that are doable, and can be answered in a manageable amount of time. Even if we asked one question a year, really get data on it, and publish as a group, it'd be a validation of the organization. Its one thing to come up with a bunch of "pie in the sky" study ideas, but coming up with a study and actually getting it done is what matters.

### *III. Instability—Bone Loss...The Big Question: Treatment?*

**JP Warner:** Now we'll ask a question that's had some controversy. This is our last structured topic. How do we manage bone loss and instability, and what is the evidence for it? At the end, hopefully Dr. Bhandari can share some perspective with us on what we're using as evidence.

**Felix "Buddy" Savoie: Evidence for Remplissage**

- When do we do it?
  - Moderate bone loss patients—Bernageau view most helpful
  - Visible Hill-Sachs defect that "engages"
  - Posterolateral shift needed



- Does it help?
  - Yes—Excellent for primary moderate bone loss, not as good in revision cases with bone loss.
    - Looked at moderate bone loss patients. At least 10% on glenoid side, significant HS lesion on X-ray. Did this operation with primaries and it went well, but a 40% failure rate in revisions. McCabe MP. *et al.*: [Primary versus revision arthroscopic reconstruction with remplissage for shoulder instability with moderate bone loss](#). *Arthroscopy*: 30.4 (Apr 2014): 444-50
- Remplissage vs. other approaches
  - Why not just do a coracoid transfer and restore the glenoid to normal?
    - You guys are all great surgeons so you've probably never done a patient like this (x-ray with nonunion of coracoid, broken screw).
    - I do a lot of revision reconstructions and they get more difficult regarding what to do.
    - We all know JP's original paper on Latarjet with a 28% complication rate. He no longer has that, you guys no longer do, but the primary guys do have that rate or higher.
- Humeral Option 2: Remplissage
  - Remplissage to fill in defect, make it extra-articular
    - Need to pick your spots carefully
  - Works best with a primary surgery, not revision (*McCabe et al., above*)
  - Soft tissue procedure with minimal risks
  - Does not make up for significant glenoid bone loss.
- Remplissage Results
  - McCabe *et al.*: 36 shoulders with moderate bone loss (10-20% glenoid defect with “medium” HS) patients treated with Bankart and remplissage= no recurrent instability
    - How did we quantify “medium”: larger than small, smaller than large...
    - Revision reconstruction is a similar group, but had a 36% failure rate. Five of these patients had apprehension or instability overhead.
  - These are all level 4 studies, no level 1's on this.
    - Kelly JD *et al.*: [Outcomes of the Remplissage Procedure and its Effects on Return to Sports: Average 5-Year Follow-Up](#). *Am J Sports Med*: 44.5 (May 2016): 1124-130
    - 50 patients, 60 month follow up.
    - WOSI 79, ASES 89
    - 6 redislocations (3 traumatic, 3 atraumatic)
    - 65% of throwers had problems throwing
  - Cho NS, Yoo JH, Rhee YG: [Management of an engaging Hill-Sachs lesion: arthroscopic remplissage with Bankart repair versus Latarjet procedure](#). *KSSTA*. June 2015.
    - 37 bankart + HS remplissage vs. 35 Latarjet
    - No difference in any parameter, including recurrence (2 in each group)

- What is the role of remplissage?
  - Useful in the mild to moderate bone loss patient
    - Combined reconstruction and remplissage allows for excellent results in most instability patients, including those with moderate bone loss.
  - Not necessary in the absence of instability
  - Significant bone loss (> 20% glenoid, >30% humerus) will require bone procedures.
  - This can be another arrow in your quiver but it's not the "end all" for every patient.

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**Asheesh Bedi: Evidence for Latarjet**

- Good opportunity to be critical when we look at evidence in literature.
- Two types of evidence: we have biomechanical studies vs. clinical series to look at whether its good for instability (primary vs. secondary)
- Strongest papers: Biomechanics side?
  - Yamamoto N., Steinmann SP *et al.*: [The stabilizing mechanism of the Latarjet procedure: a cadaveric study](#). JBJS 95.15 (Aug 2013) 1390-7.
    - 8 fresh-frozen shoulders, with a 50 N axial force.
    - Intact shoulder, shoulder with bankart lesion, glenoid defect after latarjet, then after they remove the bone block to isolate the sling effect
    - Showed that the latarjet is powerful for restoring translational force for decreasing back to intact condition.
    - When they separated sling effect vs. effect of isolated bone block, the sling effect was particularly contributory for range of motion. Emphasized importance of repairing the capsule.
    - Biomechanic studies have largely directed our knowledge on this topic.
  - Payne B., Lee TQ *et al.*: [Biomechanical comparison of the Latarjet procedure with and without a coracoid bone block](#). KSSTA: 24.2 (Feb 2016) 513-20
    - Tried to isolate effect of whether you could get the same result if you don't take the bone, and simply transfer the conjoint tendon and get the sling effect.
      - Wasn't bad at lower anterior and inferior loads at lower translational loads, but as the loads got higher, it wasn't as effective as true latarjet construct.
  - Kleiner MT. *et al.*: [Biomechanical Comparison of the Latarjet Procedure with and without Capsular Repair](#). COS: 8.1 (Mar 2016) 84-91.
    - Concern of capsular repair (as Walsh has taught us, the concept of incorporating the CA ligament)
    - Didn't find that incorporating it made a difference, actually may lead to stiffness: "the capsular repair from the CA ligament stump to the native capsule did not significantly affect translations relative to the Latarjet

condition; however it did cause a significant decrease in external rotation in both the scapular and coronal planes.”

- Strongest papers in the Clinical Literature
  - Interesting to see what Dr. Bhandari may have to say here, because on his study pyramid for randomized controlled trials, I found zero.
  - Gerber C. *et al*: [The Latarjet procedure for the treatment of recurrence of anterior instability of the shoulder after operative repair: a retrospective case series of forty-nine consecutive patients.](#) JBJS: 94.11 (Jun 2012)
    - 49 patients with previous stabilization surgery. Looked at constant score, SSV, activity level.
    - 88% of these good to excellent, looked at final follow-up.
    - Learned that lateral overhang can be negative.
    - Conclusion was that it was effective in revision setting, but pre-op pain meant poorer outcomes.
  - Boileau P. *et al*: [The open latarjet procedure is more reliable in terms of shoulder stability than arthroscopic bankart repair.](#) 472.8 (Aug 2014): 2345-5.
    - 93 patients. Retrospective cohort-comparison. Arthroscopic bankart vs. open latarjet.
      - Groups weren't equivalent (latarjet group had higher number of recurrences and glenoid defects).
        - Concluded that latarjet had decr. risk of recurrent instability, but reop rate was similar. Patients who were younger had higher risk
        - Conclusion was open latarjet was better (less recurring instability, better outcome scores.)
  - Arciero RA *et al*: [Recurrent Anterior Shoulder Instability with Combined Bone Loss: Treatment and Results with the Modified Latarjet Procedure.](#) Am. J Sports Med 44.4 (Apr 2016): 922-32
    - Level 3 evidence: 52 patients, 2 groups, disproportional groups
      - Looking at severity of bone loss.
      - One group less than 25% bone loss, group with more than 25% bone loss had only 12 patients. Engaging HS lesion.
      - Found latarjet was relatively effective by reducing recurrence in both groups, but the group that had more bone loss had inferior outcomes (ROM, external rotation).
  - Burkhart *et al*.: [Results of modified Latarjet reconstruction in patients with anteroinferior instability and significant bone loss.](#) Arthroscopy: 23.10, (Oct 2007).1033-41.
    - Level 3 study, 102 patients with open latarjet procedure.
      - Follow up was the challenge (only 47 were examined with physical FU, rest were telephone).
      - 5/102 had recurrence of dislocation (primary outcome measure)

- As best could be assessed, ROM was found to be good.
  - Conclusion was broad: Latarjet can successfully restore ROM and stability in patients with bone loss.
- Walsh G. *et al.*: [Long-term results of the Latarjet procedure for anterior instability of the shoulder](#), JSES, 23.11. (Nov 2014): 1691-9.
    - Retrospective review of 68 Latarjets at mean of 20 yrs PO follow up
    - Looking at OA change. 60 patients did not have preop. OA, but 12 (20%) of those had developed OA at final follow up.
    - Conclusion was that older age, higher demand sports, and lateral overhang were contributory for OA,
    - Latarjet provided excellent long-term soln.
- Example of concern for systematic reviews and meta-analyses: Trantalidis J. *et al.*: [A systematic review and meta-analysis of clinical and patient-reported outcomes following two procedures for recurrent traumatic anterior instability of the shoulder: Latarjet procedure vs. Bankart repair](#), JSES 25.5, (May 2016): 853-863.
    - Meta-analysis of 8 comparative studies, 800 patients, about 400 open or arthroscopic Bankarts, around 400 Latarjets. Primary and revision procedures
    - Challenges here: Not similar groups (because of different indications for these two operations).
    - Conclusion was that Latarjet is viable and possibly superior alternative to Bankart repair (based on grouping all of this data)
    - The question is, is this valid?
      - Or it because of selection bias (in North America, Latarjet selected for greater severity of pathology and bone loss.)
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### **Matthew Provencher: Evidence for Bone Grafting**

- Complications for Latarjet are real: Griesser MJ *et al.*: [Complications and re-operations after Bristow-Latarjet shoulder stabilization: a systematic review](#), JSES 22.2 (Feb 2013): 286-92
  - 45 studies (1,904 shoulders) age=25.8 yrs.
  - Complication rate= 30%
    - Recurrent anterior dislocation and subluxation rates were 2.9% and 5.8%, respectively.
    - Most occurred in the 1<sup>st</sup> year (73%)
    - 7% had unplanned reoperation
    - Overall nonunion rate of 9.1%.
- Giacomo *et al.*, [Coracoid graft osteolysis after the Latarjet procedure for anterior shoulder instability: a CT scan study of twenty-six patients](#), JSES 20.6 (Sept 2011): 989-95.
  - 26 patients, FU=17.5 months
  - One of two studies to use CT evidence (in 50 yrs of doing Latarjets).
  - 59.5% showed coracoid graft-osteolysis.

Building Block Approach: is there a better way?

- Articular contact pressure, Latarjet versus ICBG with different pressures.

- Provencher *et al.*: [Normalization of Glenohumeral Articular Contact Pressures after Latarjet or Iliac Crest Bone Grafting](#). JBJS 92.6 (June 2010): 1478-89
  - Latarjet vs. ICBG.
- Decided to look at Articular Contact Pressures, Latarjet vs. Distal Tibia Allograft (DTA) Provencher *et al.*: [Comparison of GH Contact pressures and Contact Areas After Glenoid Reconstruction with Latarjet or distal tibia osteochondral allografts](#) Am J Sports Med 41.8 (Aug 2013): 1900-8.
  - Conditions:
    - Intact glenoid, 30% defect, reconstruction with a dTA, reconstruction with a dTA or Latarjet bone block.
  - Number of other studies showed that forces and contact pressures worked well with DTAs.
  - Provencher *et al.*: [The Effect of a Combined Glenoid and HS Defect on GH Stability](#). Am J Sports Med 43.6 (Jun 2015): 1422-9
    - 144 patients:took their CT scans, median average of HS volume. Took median and created 3D model, recreated this exactly in cadaver.
    - Tested= just 4 mm of glenoid bone loss led to poor fixation after Bankart repair.
    - Meaningful results using some new technology.
- Outcomes following bony allograft procedure to treat instability: ICBG, DTA, other.
  - Not a ton of evidence, dealing with challenging problem to reconstruct glenoid.
  - Warner *et al.*: [Anatomical glenoid reconstruction for recurrent anterior glenohumeral instability with glenoid deficiency using an autogenous tricortical iliac crest bone graft](#). Am J Sports Med 34.2 (Feb 2006): 205-12
    - Looking at ICBG: 11 patients, 33 months follow up. No recurrent instability, demonstrated incorporation of bone graft. All patients returned to pre-injury level of sport.
    - All patients did report some level of discomfort over bone graft site.
  - Kraus N. *et al.*: [Arthroscopic anatomic glenoid reconstruction using an autologous iliac crest bone grafting technique](#). JSES 23.11 (Nov 2014): 1700-8.  
Looking at ICBG:
    - 15 patients, 20 month follow up.
    - No redislocations or subluxations post-op. SSV 84%, WOSI 76%.
- But, morbidity associated with ICBG.
  - Polluck R. *et al.*: [Donor site morbidity following ICBG for cervical fusion: a comparison between minimally invasive and open techniques](#). Eur. Spine J 17.6 (Jun 2008): 845-52
    - 24 patients open, 52 patients minimally invasive harvesting.

- 8.3% in open group had minor complications, 11.5% in minimally invasive group.
  - At 14 weeks, 30% of all patients were still complaining of pain.
- Case Presentation: patient with over 100 dislocation/subluxation events, failed 2 prior arthroscopic surgeries, with continued instability.
- DTA= first case in 2008, now have 24 patients. [Outcomes of Distal Tibia Allograft Reconstruction for Recurrent Anterior Shoulder Instability](#) ISAKOS Congress Presentation, Jun 2015.
  - Scores in the 90s, diligent about getting CT scans at a minimum of 5-6 mo.
  - Management of capsule is still a challenge. Haven't seen instability issues, did have one infection
- AAOS 2017 submission: looking at 30 matched Latarjets vs. 30 DTAs
  - All 20% mean bone loss, 3 yr. follow up with CT scans on all
  - Scores are very close together (SANE, ASES, WOSI all within 2.5% between groups.)
  - But, only 30 per group is a limitation.

Looking at these bone grafts there's not a whole lot of high level evidence. Another place where we can be innovative and ask some important questions.

### *Comments from the Group: Possible Study Ideas*

**Mohit Bhandari:** I am naively looking at what was just presented, why hasn't there been a randomized trial? Can one be done?

**JP Warner:** If you're talking about randomizing Latarjet and Bankart, there are 2 issues. Firstly, there's a big incision (open surgery) with one and a small incisions (arthroscopic) with the other condition. It will thus be difficult to recruit patients. Secondly, can we ethically do this over time when we know what little we have in the literature reflects the failure of Bankart over time. And Gerber is about to publish with 6-10 yrs follow up showing patient satisfaction is much better with Latarjet over Bankart. Finally, the risk for adverse outcomes is greater with Latarjet than arthroscopic Bankart.

**Mohit Bhandari:** Clearly the current standard is a Latarjet, but the data you're showing is back and forth.

**Buddy Savoie:** It actually changes country to country, society to society.

**Mohit Bhandari:** So why can't we do a Randomized controlled trial? There's the individual surgeon, and in order to do a study they must have equipoise, which is basically, "I don't know which one is better." You can also have equipoise on a community level. If one nation says Latarjet is better, another country says otherwise, you can use "community level equipoise."

There is global uncertainty around what is the optimal procedure. This is how we sold many of our big trials.

**JP Warner:** Maybe the bigger question is, for small amounts of bone loss, doing a prospective randomized study looking at Bankart plus remplissage, versus just Latarjet.

**Buddy Savoie:** Do we have to randomize those without our own practice, or can we do me versus another guy?

**Mohit Bhandari:** You can do a “cluster-randomized” procedure. Or you can do “expertise-randomized trial” Patients are randomized to treatment A or B, and the corresponding procedure is done by a surgeon who believes in the treatment he’s doing and is good at it. But that means that you must have someone at your institution that’s willing to do procedure “B”.

**George Athwal:** We have a protocol in place together for randomized prospective study for comparing arthroscopic latarjet to arthroscopic Bankart for moderate bone loss. The problem where we are is that it’s a migrant population, you can’t get people to come back. We were targeting 96 for that study, but seems like we should add a zero to that number.

**Mohit Bhandari:** I won’t belabor the point, you’ve all presented the data and identified the challenges when there’s no true comparison. With meta-analysis you have to be really nervous about the data. If you truly believe that there is an argument to be made that the current perceived standard could in fact be based upon data that isn’t robust, a clinical trial would help resolve that. Either way a clinical trial could help resolve that. Could you have numbers to get that trial into the hundreds.

**Basem Elhassen:** If you have a 20% versus 6% complication rate for the two operations you’re looking at, what do you tell the patient who you’re trying to get into the study? If you had a family member who wanted to be in the study, what would you say?

**George Athwal:** You, as a scientist, would really have to believe that you do not know which one is better.

**Mohit Bhandari:** This could really be one of the questions where you could figure it out. In other specialties like neurosurgery RCTs have completely reversed treatment methodologies that were well established and believed to be benefitting patients.

**Buddy Savoie:** Bassem, to me it’s the opposite of what you said. My success rate with Bankart is around 97%. My complication rate with Latarjet is much higher than with arthroscopic Bankart.

**Basem Elhassen:** Ok so latarjet it’s a high complication rate, so how can you randomize a patient into a procure that has a much higher complication rate?

**JP Warner:** The broader question is, how confusing is the literature on Bankart repair? There’s never been a large enough study.

- **Provencher**= the number of Bankart in the world literature in the past 10 years is less than 1500 total cases. That's sad.

**JP Warner:** If we just agree on the key steps. As long as we agree and we do the same operation, same patient position, do videos to analyze that we're compliant.

**George Athwal:** I disagree. You do the procedure that you're best at.

**Mohit Bhandari:** depends on what you're going for. Think about a really simple clinical trial on a very common problem and do it really big.

**JP Warner:** This fulfills that criteria and we talk about this silly topic at every meeting. The key is we could start this (Arthroscopic Bankart Repair), follow it annually at this meeting, and look at how the data is going and how the numbers are going.

**Mohit Bhandari:** The principle is to get to the crux of what matters, what simple things can you start engaging in together. The question has to be one that you can sell as really important and could really change the practice. If you do that, you come together with a group like this, you will get grants. There's a real opportunity there for this group.

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### *Future Directions for the Group*

**JP Warner:** I'll float a few ideas for you and then Asheesh Bedi will talk to us and suggest a PSI study group.

- We've already talked about what we can do; it has been so valuable to have Dr. Bhandari here.
- There are a few other ideas:
  - Perioperative antibiotic use in TSA (Steve Parada)
  - Uma suggested looking at Liposomal Bupivacaine vs Interscalene Nerve Block after TSA.
- What should this group be? Help me understand. To keep trademark we must fulfill charge of educational and research group.
  - Create a website? Chat group? Not-for-profit? We've been living off the SDSI generosity (James Esch and Larky Blunk), but we should be more for that.
  - How will we coordinate our research? I don't mind if we have a few studies going on. Then we can review our research at future Codman meetings, rather than discuss current things.
  - This meeting really does help Identify gaps in knowledge, and this helps me with formulating the content of the following year's SDSI meeting.
  - In the end we can make a difference. Wouldn't it be cool if we could get grant funding?



- There are several barriers: one would be taking time from your institutional commitment through our collaboration.
- Financing our endeavor is something we must also consider.
- I invited industry because I wanted them to see what we do. What we're doing is very different than the SDSI.

### **Asheesh Bedi, Study idea: PSI:**

- Based on case studies, it's clear that PSI can make a big difference with difficult glenoids.
- We could start simple and define where PSI can help.
- Proposal: Existing series from Prof. Walsh. Group higher volume surgeons, lower volume surgeons. Take these 50 cases for which we have radiographic series and CT, we can have 3D series built from them, we have blueprint w/ plan. We also have implanted components, postoperative x-rays.
  - Selectively provide this info to surgeons, see how they would do this plan and how it would affect their judgment.
- Part 1= surgeons provided plain films. Measurements (version, inclination, Walsh classification, provide subluxation). Look at variable based on standardized x-rays.
  - Based on this, what humeral characteristic or glenoid might be used? Would you have to use grafting, what reaming, maximum depth, etc.
  - Add in the selective and incremental value of 3D imaging.
    - Same q's with additional info of CT scan.
    - Then, give them the planning software. Look at the changes in their plan with this additional data. Does it make the lower volume surgeon closer to the higher surgeon?
    - How does that compare to what Walsh actually did? (we have postop x-rays, what he did).
- Phase 2: Evolve from retrospective to prospective.
  - Take 100 (or add 0) patients
  - Preop x-ray/CT
  - Randomize to standard instrumentation versus blueprint-guided technology
    - assess, do they make us better? Do they make us better for particular types of glenoids?
  - Primary outcomes=
    - Revision/failure, loosening/wear (serial XRs, PROS (ASES, WOSI, constant))
    - This would have to be over a long time range.
  - Great thing to do together because severe glenoids are rarer.

**Mohit Bhandari:** You may not need to do a huge number of patients here because this is more of a pilot study.

**JP Warner:** And a pilot can be the basis for grant funding. But we need a good hypothesis, it needs to be hypothesis driven. Is there any literature that shows that pre-op planning does make a difference? Pre-op planning and decision making is an important question. George and I did something like this, 100 cases. 30-40% of the time the planning changed what our actual surgical plan was. It could have pretty substantial implications.

**Joaquin Sanchez-Sotelo:** This is very interesting but what questions do we want to answer? I want to know, what is the added value of using the guide? Is the process of thinking through the operation good enough, or do I actually need this guide?

**JP Warner:** That seems a further downstream question. How about decision-making and planning before you get there.

**Sanchez-Sotelo:** What I was thinking is, comparing what I come up with on the pre-op planning versus what I actually did in surgery. In other words, I was planning for 17 degrees, what did I actually get when I put the hardware in? I want to know does the software help me.

**Zimmer-Biomet Perspective (Orsa Britton):** 3 cohorts. Plan without the guides, big difference in the angle. This was pre-submission work on 90 cadavers. It did show a massive difference.

**Asheesh Bedi:** That's related to this proposed study. Phase 1 would show that it does provide an improved road map. And in Step 2, it may suggest that that guides make you a better surgeon to execute that task.

**George Athwal:** We don't know what the target is, and to look at this prospectively, in terms of angle, is where the value really is.

**Asheesh Bedi:** This study is looking at with or without instrumentation. This is where you'd put it. Your hypothesis depends on power analysis for this. If you're trying to look at outcomes score for the patients, its very different than if you want to look at a primary measure like loosening over time.

**Mohit Bhandari:** It depends on the outcome you're in which you are interested. Exploratory versus otherwise.

**Ron Navarro:** Were you sufficiently compelled with the breakout session about normative data? Is the normative data for Hispanic females in San Diego different than the data for Asians in Japan? Many of us have done with work PSI and planning. Could there be preliminary work together in order to figure out what the normative data is? This would determine if we can dial in demographic data and where we need to put this, which could make a difference.

**JP Warner:** That's making it really complicated.

**Mena Mesiha:** After 2.5 yrs. in practice, I want to know, am I putting it where I planned on putting it? 2 steps:

- 1) protocol for CT.
- 2) reading of the CT.

That would be something we'd agree upon. I want someone to tell me, "you did this (this amount of retroversion, etc) but you actually planned to do this, you were way off" (or not).

**George Athwal:** This seems like a cadaver study. We don't want to waste patient resources. The question is, you want to know if you're putting it where you planned. You can answer this with a cadaver study. The problem to me is, no one truly knows where the "right place" to put it is. For us to say, "are the guides acceptable"—I think that's already been proven. We just don't know what the best placement is. And that's a more important question.

**Audience:** You can ask: you take 50 CT scans and the question is "would software template change your surgical platform?" So you look at the CT before, you say, "I would do a total shoulder, anatomic, I'd ream this amount, put in this hardware," etc. Then you're given the software in addition and see if/how your plan changes. If it changes your surgical plan then I think it's valuable. It's a simple question. And it doesn't require x-ray follow-up or anything.

**Asheesh Bedi:** That is essentially the Phase I of that study I proposed.

**JP Warner:** That's very interesting. And in that framework the planning may change the surgical plan but we may change our plans in different ways. I think we're making this very complicated. Once we choose an important question that's going to yield valuable answers and that takes off, we can use it as a launching point and work from there. We'll get something done and it can lead to other studies.

*THANKS TO ALL—SEE YOU NEXT YEAR!*

