THE FOURTH ANNUAL CODMAN SHOULDER SOCIETY MEETING

SATURDAY, JUNE 17th, 2017 (3:15-8 PM)
Hilton San Diego Bayfront, Conference Center Room 310

Meeting Theme: Shoulder Arthroplasty— How Can We Provide Better Value?

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

This year we are honored to have Robert H. Cofield as our Keynote Speaker, Special Guest and provocateur. As such I have placed a quotation after each lecture to acknowledge the wisdom of Charles H. and William J. Mayo as published in a small book called "Aphorisms."

3:15-4:00 Welcome cocktail reception *(Conference Center 3rd Floor, Aqua Terrace Foyer)*

3:50-4:00 Group Photo

4:00-4:10 **JP Warner: Welcome & Overview of the Codman Shoulder Society®**

KEYNOTE SPEAKER

Robert H. Cofield, MD

SESSION I: SHOULDER ARTHROPLASTY

MODERATOR: JOAQUIN SANCHEZ-SOTELO

4:10-4:30 **Robert Cofield – *Keynote Address:* The Mayo Experience: What I've learned works and what does not.**

"In the study of some apparently new problems we often make progress by reading the work of the great men of the past..."- Charles H. Mayo

4:30-4:40 **Ron Navarro: Registry Update—the Kaiser Experience**

"Once you start studying Medicine you never get through with it – Charles H. Mayo

4:40-4:50 **Kyong Min: Presentation and Discussion of the C.S.S. Value of Preoperative Planning Study**

"That which can be foreseen can be prevented." And "There is no excuse today for the surgeon to learn on the patient." - William J. Mayo

4:50-5:00 **Markus Scheibel: Stemless Implants**

"The scientist is not content to stop at the obvious"- Charles H. Mayo

5:00-5:10 **Joaquin Sanchez-Sotelo: Reverse Shoulder Arthroplasty**
"Experience is the great teacher; unfortunately, experience leaves mental scars, and scar tissue contracts."
- William J. Mayo

5:10-5:20 **L.D. Higgins: Value Proposition: The Big Picture**
"Medicine gives only to those who give, but her reward for those who serve is 'finer than much fine gold"
- Charles H. Mayo

5:20-6:00 **DISCUSSION (Moderator: J. Sanchez-Sotelo)**

6:00 -6:20 **Emilie Cheung: Codman's Paradox (Success & Failure) Case Presentations: Arthroplasty - Ground Rules? Both Failures & Successes….what do we learn?**
"Age carries mental scars left by experience which shortens vision, but age carries wisdom."- William H. Mayo

SESSION II: INFECTION AFTER ARTHROPLASTY—HOW CAN WE DO BETTER?

MODERATOR: ED YIAN

6:20 -6:30 **Larry Gulotta: Current State of Disagreement and Evidence for Best Practices**
"If two people agree, one is not a surgeon" – C. Gerber

6:30-6:40 **Joaquin Sanchez-Sotelo: Presentation and Discussion of the C.S.S. Infection Questionnaire**

6:40-6:50 **Stephen Parada: Presentation and Discussion of the C.S.S. Infection Questionnaire**

6:50-7:00 **Ed Yian: What the Registry Experience Teaches Us**

7:00-7:15 **DISCUSSION: Can we come up with a consensus statement on best practices? (Moderator: Ed Yian)**
"Medical Science aims at truth and nothing but the truth." –William J. Mayo

SESSION III: WORKING DINNER DISCUSSION—Future Directions for the C.S.S.

MODERATOR: JP WARNER

7:15- 8:00 *Dinner will be served as we discuss our strategic vision, future research goals, and organizational structure.*

- Research- Where are we and what are we doing
- MyOrthoEvidence.com opportunity
- Our Website: Web Committee, Funding
- NFP Status: What is our Vision, Mission, Strategy?
- BOD: Shahian, Esch, Herndon, Bhandari, Porter
- SOS Registry; Study Groups: Infection, SCR, other?
- Plan for 2018: Theme- Rotator Cuff (Gerber & Walch)

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

Codman Shoulder Meeting 2017
Group Photo

Front Row (Left to Right): Neal Chen MD, Markus Scheibel MD, Matt Provencher MD, Bassem ElHassan MD, Laurence Higgins MD, MBA, Robert Cofield MD, Jon JP Warner MD, James Esch MD, John Costouros MD, Emilie Cheung MD, Laurence Gulotta MD, Ed Yian MD, Josef Eichinger MD, Jeff Martin (Arthrex)

Back Row (Left to Right): Dan Hatch MD, Tyler Fox, MD, Stephen Parada MD, Asheesh Bedi MD, Michael Freehill MD, Kyong Min MD, Eric Wagner MD, Cory Stewart MD, Joaquin Sanchez-Sotello, MD, Peter Vezeridis MD, Matthew VanHorn (Smith & Nephew), J.R. Romanowski MD, Danny Goel MD, Timothy Hartshorn MD, Lewis Shi MD, Jeremy Axe MD, Greg Mallo MD, Jeffrey Zanni (Wright Medical), Vincent Fath (Wright Medical), Orsa Britton (Zimmer-Biomet)

Welcome & Overview of the Codman Shoulder Society®

JP Warner: Thank you all for coming. The point of this organization is to meet, listen to each other and to ask meaningful questions that have the potential to change the quality of shoulder care and offer value to our patients, our colleagues, and society. This is, after all, what Codman would have wanted for his legacy. Our first meeting was an Alumni reunion for the Fellowship at

MGH & BWH; but it quickly became apparent that we had an opportunity as a "Shoulder Think Tank" to do something bigger.

I think we are all, by our nature, committed to finding better evidence and solutions to provide value-based shoulder care. That is our craft and our passion. John Ticker proposed what has become our motto, and these are the inspirational words of EA Codman: ***"Give me something different, for there is a chance of it being better."***

Last year, our Keynote Speaker and Provocateur was Dr. Mohit Bhandari. He showed us that most of the evidence upon which we base our clinical decisions is woefully inadequate and even inaccurate. This is not just due to study design but the small cohort analysis we do which lead to what is called 'fragility' in a study. The conclusions we derive from these small retrospective studies are often proven wrong. Thus, there is real potential for bigger thinking and bigger studies to provide more robust evidence. To be sure, other organizations are trying to do this. But in my opinion they may be fettered by political impedance of their members and also a certain scientific correctness, which waters down their resolve to ask difficult questions. As a group, The Codman Shoulder Society can do better. For this reason, I try each year to invite speakers who will help us focus on particular areas so that we better understand what we really don't know. This way we may formulate meaningful questions worth answering as a group. This is only our fourth meeting and we are gaining enthusiasm and starting to roll down the runway at a greater pace. I will need everyone's help to get this society up in the air and break the gravity of talking without doing anything meaningful.

This year, it is my great pleasure to introduce Dr. Robert Cofield as our Keynote Speaker and Provocateur. Dr. Cofield is one of the greatest shoulder surgeons of our time and he has much in common with Codman. He has done the one thing we all need to do in order to improve care. That is measure and analyzes results. The Mayo Clinic Shoulder Arthroplasty Registry has produced meaningful study after study, which have set the bar for the Evidence-Based approach we use every day to help our decisions and to deliver value for our patients. Today he will share his life-experience in measuring and analyzing shoulder arthroplasty treatment and outcome.

Session I: Shoulder Arthroplasty (Moderator: Joaquin Sanchez-Sotelo)

Robert Cofield, MD: Keynote Address – The Mayo Clinic Experience: What I've learned works and what does not
(Click here for PDF)

"In the study of some apparently new problems we often make progress by reading the work of the great men of the past…"- Charles H. Mayo

- Key Points:
  - Hip surgeons, then knee surgeons and finally shoulder surgeons started to use a registry and measure results.
  - You need to consider a minimum data set & the times for periodic follow-up
  - You need a dedicated team to do this follow-up
  - Our registry first started to look at TSA & hemiarthroplasty and we found about 20% of hemiarthroplasty didn't get good pain relief. TSA, however, had consistently good pain relief.
  - We found over time that RA and Trauma cases went down while arthritis cases went up.
  - Posterior wear, posterior subluxation and rotator cuff tears had worse results.
  - We found no difference in outcomes between monoblock stems and modular stems, sadly.
  - In the case of fractures we observed 20% of cases with tuberosity resorption and poor outcomes. We realized how important it was to securely fix the tuberosity and not move patients early.
  - In the case of post-traumatic arthritis it was always better to avoid greater tuberosity osteotomy.
  - We learned how to expose and avoid deltoid injury. You can free up the anterior deltoid without worrying about its insertion or flexibility.
  - There was no difference between pegged and keeled glenoid components in our analysis.
  - Metal-backed glenoid components proved to be a dream that didn't last.
  - We studied rehabilitation and found 4 weeks of immobilization was the threshold to avoid problems after shoulder replacement. 5-6 weeks may be even better to protect the subscapularis.
  - We learned about radiographic glenoid component failure vs clinical failure.
  - We observed infection was associated with younger age, male gender and increased OR time.
  - The revision rate for total shoulder replacement, after the first two years is 1%/year. It seems there is no value to seeing patients at 5 years due to small incidence of problems.
  - We found it was best to separate our own revisions from those referred in from elsewhere. The latter were much more complicated compared to the former (ours) which were much more focused. Referrals from elsewhere included complex problems like humeral component malpositioning and errors in sizing of components, failures of the subscapularis and instability.

Dr. JP Warner giving Dr. Robert Cofield, our Keynote Speaker, the plaque.

Edward Yian, MD: Shoulder Registry Updated – The Kaiser Permanente Experience
(Click here for PDF)

"Once you start studying Medicine you never get through with it"—Charles H. Mayo

- Key Points:
  - The Kaiser Shoulder Registry is one of the smallest of KP: 15,500 Patients enrolled to date.
  - The registry started as a research initiative but is now under quality & safety.
  - 70 shoulder surgeons participate, mainly in California and expanding into the NW region.
  - There are five goals we stress for our surgeons:
    1. Notify surgeon recalls
    2. Clinical best practices
    3. Evaluating risk factors for complications
    4. Assessing Implant effectiveness
    5. Setting a foundation to answer research questions
  - Our Current registry: Epic, one page, integrated operative report on type of procedure, type of implant, bone graft, etc.
  - KP registry is part of 90 recalls of over 25,000 implants.
  - Best Clinical Practices:
    1. Hemiarthroplasty failures > TSA failures in young patients. This led to increased utilization of TSA vs Hemi- in young patients.
    2. Surgeons receive score cards: revisions, complications, infections, loosening, etc.
    3. We can track all patients in KP network.
    4. We are planning to implement PROM's, Subjective Shoulder Value, etc.
  - We plan to compare our registry data with others: *International Society of Arthroplasty Registries led by Liz Paxton and Steve Graves are looking at standards for quality data and minimum follow-up for new registries in the future; Cooperating with the Australian Registry.*

- ***Comment (Cofield):*** This should help us all think about how we want to follow our patients.

Kyong Min, MD: Patient-Specific Planning Reduces Errors Before Surgery & Potentially Improves Outcomes
(Click here for PDF)

"That which can be foreseen can be prevented." & "There is no excuse today for the surgeon to learn on the patient."—William J. Mayo

- Key Points:
  - Only 3% of orthopedic surgeons who perform shoulder arthroplasty do more than 10/year. So most shoulder arthroplasty is performed by less experienced surgeons (Tier 3)
  - There is an association of volume and outcome in shoulder arthroplasty
  - Many complications are errors in diagnosis and treatment selection and technique
  - This study evaluated Tier 1 surgeons (> 40 cases/year) vs Tier 2 surgeons (10-40 cases/year) vs Tier 3 surgeons (< 10 cases/year)
  - 59 members of C.S.S. & N.E.S.E.S. (New England Shoulder and Elbow Society) & Shoulder Fellows participated in the study
  - Tier 3 surgeons were helped most by Patient-Specific planning with a 3-D program, but this type of planning led to more consistent decisions about treatment for all surgeons.
  - Future study may consider the role of Patient-Specific planning on inventory management

Markus Scheibel, MD: Stemless Implants
(Click here for PDF)

"The scientist is not content to stop at the obvious"—Charles H. Mayo

- Key Points:
  - Why stemless rather than stemmed?
    1. Preserve humeral bone stock
    2. Excellent access to glenoid
    3. Good for post-traumatic deformities
  - 10 Years of experience with Stemless in Europe
  - Two different fixation techniques:
    1. Eclipse™ (Arthrex): Screw fixation with cage & Trunion insertion first, then humeral head on Morse taper.
    2. Sidus™ (Zimmer-Biomet): Impact Nucleus as central core and then apply humeral head
  - Track record for stemless implants:
    - Osteointegration is complete after 3 months (Berth et al, JSES 2015)
    - Simpliciti is only stemless implant available in USA
    - Midterm results of stemless implants:
      - TESS Group (Huguet et al, 2010): 45 month follow-up with excellent outcomes and no loosening
      - Eclipse system: also excellent outcomes
      - Bone grafting for metaphyseal defects can also work (Eclipse experience)
      - Stemless reverse: European study has shown good outcome in short and mid-term

- Questions about Stemless implants:
  - **Larry Gulotta**: Thank you very much for the presentation. I've had experience in the U.S. with two clinical trials that studied Eclipse and Simpliciti. They compared and contrasted the impaction system and the screw-based. For the Eclipse trial, we have to get good investigators assessment to improve trials. I was very encouraged to treat bony deficiency by bone grafting technique. Why are we pushing the envelope and avoiding the short-stemmed implant? What's the upside?
  - **Markus Scheibel:** So your question is, why not go to the short stem but do a bone graft? (Gulotta: "yes, why take the risk?") *We have not done stemmed implants for primary osteoarthritis over the last twelve years in our institution.* So we always did stemless, and the reason was because in many cases the eclipse was without bone grafting stable enough to do it at least from a time zero point of intraoperative observation. *In cases where we have bone deficiency, weak bones, we always did bone grafting (with Eclipse).* We look at patients with two years, there was no difference in terms of range of motion and on radiographs, and I have to admit that in three or four patients, I cemented the screw. I would not do this again, but I did it at this time, these were incomplete metaphysis and the humeral side was also very weak, so these were very rare cases where you probably would already go to a reverse. We are really in favor of stemless due to our experience with the bone grafting in such cases. I'm not sure if you really can do it with the impaction system (like Simpliciti), and I'm not sure if I'd do it with the primary short stem reverse. I don't think that's possible.
  - **Larry Gulotta:** My next question is, do you have a rough sense in Europe of what percentage of anatomic arthroplasties use metal back glenoids?
  - **Markus Scheibel:** I think (the percentage of metal back glenoids) is down below 10%. You know there was a time when Peter Habermeyer cemented back with a screw-in metal fixation like the same kind of caged crews on the market, but these phases were very early off, three to five years. These were retrieved from the market, and now there is a new implant that is also available in the U.S. for the reverse that he is using, but altogether for the anatomic replacements, most of the surgeons would use cemented, either keeled or pegged implants.
  - **JP Warner:** Bob, would you comment on this? You have the world's greatest, longest experiences with stemmed implants, why are we even thinking about stemless? Or is it just a fad?
  - **Bob Cofield:** I think that's something to think about. I want to see if it could work. *Again, the major problem is going to be with osteolysis after polyethylene wear with proximal resorption. You don't need too many to fail to loosen, because the (newer) stemmed implants now are better than the old ones*. But I think it's worth it to do the study (stemless).
  - **Bassem Elhassan:** What do you say is the main difference between surface replacement and stemless implants?
  - **Markus Scheibel:** You're talking about surface replacement right? For us, the papers that are published, from the Copland and Phillip groups, show the same results as the stemmed implants. However, I did visit them previously and it's not very easy to access to the glenoid. So if you try to remove the cartilage (but keep the head intact) and have a good exposure to the glenoid, that's not very easy. This is one advantage to use the stemless (humeral replacement). Second, most of the previous designs that were on the market lead to overstuffing of the joint because you just remove the remaining humeral cartilage and then you add this kind of humeral resurfacing. The X-rays did look more like hips compared to the shoulder. You can modify this technique, but I think proper (anatomical) surface replacement is much more difficult (to achieve) compared to a stemless prosthesis

- **Bassem Elhassan:** Because I think the stemless implants are resurfacing, and for me that is shorter than stemless I think the metaphysis is around the suture, and number two, all the trauma surgeons do filling and they put the stem in some of these patients that are young with three- or four-part fractures and resulted in completely sealed shafts.

Joaquin Sanchez-Sotelo, MD: Reverse Shoulder Prosthesis
(Click here for PDF)

"Experience is the great teacher; unfortunately, experience leaves mental scars, and scar tissue contracts."—William J. Mayo

- **Key Points:**
  - "Provoke" (definition): "to stimulate an emotion (often unwelcomed)". This is my provoking thought with which you might agree or disagree: ***Contemporary, well-performed reverse shoulder arthroplasty will outperform the old polyethylene shoulder arthroplasty in every age group in terms of mechanical failure***. The rate of aseptic loosening in reverse shoulder arthroplasty is going to be less than in the old, polyethylene cemented arthroplasty.
  - Initially, we thought keeled components had perfect X-Rays at 2 years with no lucent lines. You can see how over time the component migrated. When we examined the pegged component, we found the same results in the X-Rays. By 7 years, the rate of revision was 8%, but the rate of (radiographic) loosening was 40%.
  - Thinking about this, we have two solutions: 1. Come up with a successful cementless non-polyethylene component to outperform anatomic TSA in terms of mechanical failures, or 2. Do RSA for everyone. The volume for RSA keeps increasing; (the Mayo) registry by now includes 3000 RSAs.
  - Question is, if it's a 62-year-old patient with classic primary OA with no major B3 glenoid, why don't we do reverse for everyone? The reason for me used to be that the glenoid would be more likely to fail, but now I think the glenoid actually fails more often in an anatomic TSA with cemented poly. The reason I don't do it (reverse prosthesis) now (in everyone) is because you don't get good internal rotation in every single patient. So, I tell patients that if you do a reverse, you may or may not be able to put your hand in the back. The second reason I won't do an RSA is because I hate the complications, which unfortunately do happen. Even though people say that acromion fractures are not that important, my patients after a fracture do not do the same (as those who do not have acromion fractures). They lose motion and have pain. If the fracture is more proximal and in the spine of the scapula, the result is even worse. The third is because it violates so much glenoid, and the fourth is because it doesn't respect the rotator cuff very well. We all know that the reverse is more forgiving for the rotator cuff, so it is tempting to eliminate the rotator cuff if we need to, but then if it fails, you may need the rotator cuff.
  - As a society (The Codman Shoulder Society), I'd like to see if we can (determine how to) get reliable internal rotation in every reverse and decrease the rate of fractures of the acromion, because these are the two main reasons why I don't do a reverse.
  - This is a patient I saw last week a year postop, who has excellent internal rotation. In another case, the patient had the same implant a year out, but had no internal rotation. I don't know why the outcomes are different with the same implant surgery. Maybe it's the scapula? Soft tissue? I don't know.
  - Study: 31 patients who had reverses on both shoulders, questionnaire about activity and internal rotation. They did well clinically, but about 70% patients cannot bring their

arm to their lower back, and about 30% of female patients cannot put on their bra. So clearly, limitation of internal rotation does have an effect on function. Questions to the group: are you getting internal rotation or not? If you do, what do you do to get with rehabilitation to achieve this?

- Stress fractures: These are increasing, affect outcome, and while the acromion (stress fracture) may not be as important, scapular spine (fracture) is very important. This is a male patient who's very tall and doesn't have osteoporosis; I did a primary reverse and was pretty happy with the X-Rays, but 3 months later, he had a fracture of the spine in scapula. Bad situation: terrible pain and complete loss of motion. I fixed the fracture, and luckily he healed. Looking at X-Ray, why did he get the fracture? Maybe it's the combination of lengthening and lateralization that's transferring the stress more medial to the scapula. The other thing was that the screw is pretty long. Maybe I have filled the lateral scapula with so much metal, that it's very stiff, so it's in the red zone (stress concentration), whereas the rest of scapula is not so stiff. Just the screw or the metal, but the reality is that this problem is increasing in incidence, and I want to understand what you all do to decrease the fractures in spine of the scapula?
- Bone preservation: it's interesting that we want to keep shortening the humeral side, but we tend to forget the bone is missing on the glenoid side. It worries me that in primary reverse, we're using implants with titanium that violate the whole glenoid wall, and there are studies that show that as you do that, you really lose more and more bone. We have to move into implants for primary arthroplasty that do not violate too much bone.
- For discussion: What do you do to avoid poor internal rotation in primary reverse arthroplasty? What do you do to decrease the chance of fracture of the acromion?

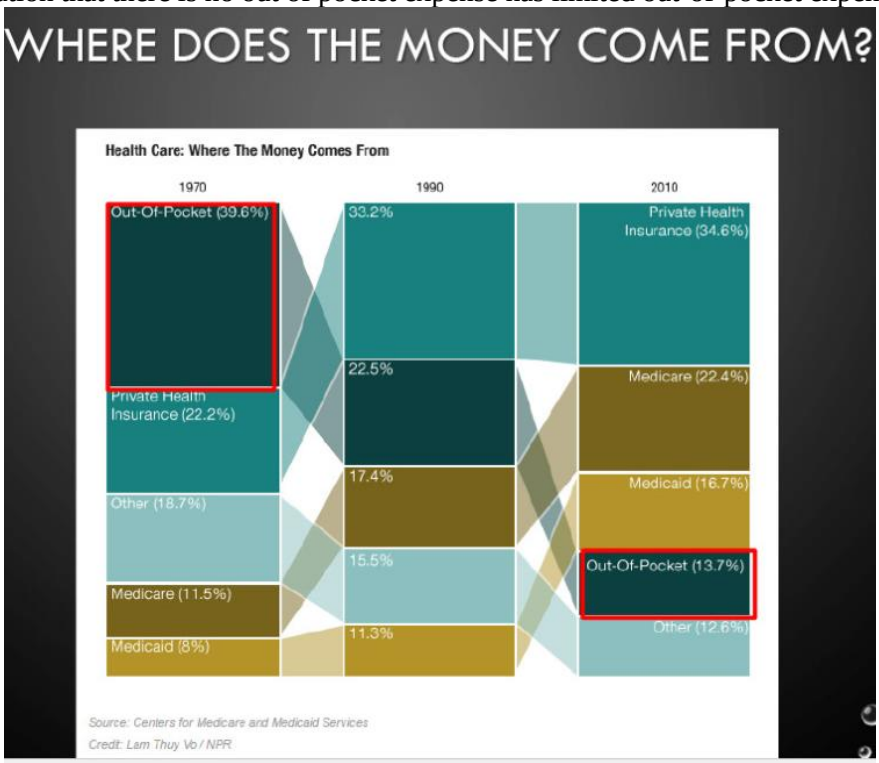
Laurence Higgins: Value Proposition: The Big Picture
(Click here for PDF)

"Medicine gives only to those who give, but her reward for those who serve is 'finer than much fine gold'"—Charles H. Mayo

- **Key Points:**
  - I want to take a higher level view of the value proposition and present the big picture. Albert Einstein said that ***"the perfection of means and the confusion of aims seem to be our main problem."*** Nothing can summarize this better than the efforts that we have spent on ICD-10, which has amazing and very important classification systems, that you can classify someone very carefully that if they've been struck by an Orca, if they had an unspecified spacecraft accident, they were sucked into a jet engine, or they were struck by a car as well. There's also one for a parrot as well, and my personal favorite is a burn due to your waterskis which caught on fire; I'm personally confused about that one. I think nothing epitomizes the medical economics and the efforts that we spent to improve them better than a short video **(click here for video)**.
  - So where are we in the USA? Well, we're not in a good place. The US spends more on healthcare with worse results than all of us can possibly imagine. We recently passed the 10,500 USD per person limit on the annual cost of healthcare. What does this give us? We spent 17.8 % of GDP on healthcare, more than any other country. The USA spends 44% more of their GDP than Sweden, the country that has spent the second largest of their GDP, and we're not doing as well as them. Let's take a look at healthcare spending per capita: We're averaging about 9,000 USD per capita, which means Switzerland has about a 30% discount (compared to us), and the other OECD countries have about 60%

discount compared to us. And what do we buy with this great healthcare? We rank in the lowest 20% in the world for our quality of life and our life expectancy. We rank between Estonia and Chile in terms of life expectancy, who I don't think are well distinguished by their healthcare. We spend 2.2 times as much as Chile and 2.7 times as much as Estonia to actually achieve that distinction.

- Japan, with the highest life expectancy, spends about 10% of their GDP on healthcare and compared to us this is a 70% discount. Some of their aggregate costs, for example is $7,500 for cardiac bypass, and in New Zealand the cost is $4,000. We are only 87% more expensive for this than New Zealand.
- Where is the money going? Interestingly, it hasn't really changed a lot since the 1970s to 2010. There's been a slight upshift in the dollar amount going to the nursing homes and caretakers, but otherwise the hospitals are still down a bit from 43% to 37%. And interestingly, between 1970s and the present day the pay for physicians really hasn't changed, staying about 9% or 10% of all healthcare spending. What has changed is out-of-pocket expenses (for patients). In 1970, about 40% of all dollars spent has been out-of-pocket, and in 2010, it's about 13%. More robust insurance coverage and patient expectation that there is no out of pocket expense has limited out-of-pocket expenses.



- What does this mean for us and our tax dollars? We are now the largest single item of expenditure in Medicare and Medicaid in healthcare 23%. Compared to the other countries, our private healthcare spending is over 560% more than the next closest country, which might be okay if our public healthcare spending wasn't essentially at the highest level as well.
- And what's our compounded annual growth rate? About 13%, and it's expected to be at that level until 2020. So what we have is an unsustainable problem: they have to cut down all the trees to create all the bail out money needed to create a green job that saves the environment. So I think there has been a real misalignment of our goals as Einstein said; our aims are incorrect even though we're trying to improve our means. And if you

do believe, as I've adopted, clearly, Porter's philosophy about value-based healthcare, bundled payments and measuring costs are the (only) ways to get there.

- Right now, our fee-per-service system has to change; that's our existing reimbursement world, and there are two potential paths that we can go. We can go to an ACO and a global capitation system – we've done that experiment in the past, and that means care for life. Or we can go to the bundled payments, which means caring for a specific condition. I'll encourage people to learn more about this, to go back to July and August HBR (Harvard Business Review) journal, which had excellent articles on these two points. This is the article from Robert Kaplan and Michael Porter about how to pay for healthcare, and a really elegant description of the bundled opportunity.
- Just real briefly, bundles as we all understand: the longer term, the longer time horizon that we look at the bundles, the more savings we are going to get. You can't really cut down savings with an arthroscopic rotator cuff repair as a procedure if you are just trying to cut implant costs; you need to look at the one-year cost of the entire event, and therefore we can include opportunities like PT and saving on implants, and saving on other costs that aren't creating positively impacts. That's how we're going to innovate on this.
- In the end, the aspirational goals that we've said about earlier are important for us to model what we do on. One thing that all of us in the room can do is to do the one thing that is hard for us to swallow and look at our results sometimes, but it is the singularly most important thing we can do, and I think everyone in this group agrees with that, and that's what's great with this group. I think we have a commonality of goals, and if we can all encourage transparency and outcomes, we're going to be further off than we were because if you can't measure, then if you can't manage it; if you can't manage it, then you can't improve it. Thank you.

- **Discussion:**
  - **JP Warner:** Larry, question to you, and then to everybody else. What do you think is the biggest barrier (to achieving what you suggest) where we work? People can comment where they work, on getting to this approach of doing bundles or bending the cost curves. Why are we stuck here? Why can't we get there? Even Mayo Clinic, in a recent article I saw, started to emphasize certain payers over other payers because their margin is suffering. How do we manage our margins so we can maintain our mission?
  - **Larry Higgins:** My thoughts about it, I think, align very carefully with Bob Kaplan's and others; and, as Mike Porter was saying, we have a complete lack of alignment in our goals. And I think that encompasses our current paying structure, lack of transparency, and accountability for outcomes. I think those are the high-level issues that we see. The current system is unsustainable, so there's a lot of legacy investment though, in the way fee-per-service works. And hospitals that have complication rates generate higher volume and higher revenue, and in many cases a lot of them aren't penalized for that. That is a real dis-incentive for systematic improvement and engagement of the physicians. Groups like OrthoCarolina are really moving much more aggressively in the bundle marketing. They are starting to innovate because they're getting the bundled payment, and then they are going to contract the hospitals, rather than the hospitals getting the bundled payment, and then trying to figure out what the physicians get out of bundled payment. You have to rely on everyone, and the only way to do that is to go to a bundled-market place.
  - **JP Warner:** So Bob (Cofield), maybe you can comment. Surgery and technology have gotten more expensive. What about the expensive technology that we're coming up with now? We're adding expense to new technology, the implants cost more, you showed us that there wasn't a difference between second and third generation shoulder implants

when you studied this (though the newer generation implants are more expensive). How do we make this a value-based proposition when every surgeon wants to use what they want to use (the implant of their choice), the same way as every golfer wants to use their specific club?

- **Bob Cofield:** Well, it's very difficult in terms of people having relationships with companies. In the shoulder specialty, Mayo Clinic uses products from five different companies. It's very hard to negotiate. We have hip and knee surgeons who use three companies. People will say that "you can use this, but it cannot cost more than that." Try to have more volume, space cost is the same, human cost is the same. You have to be careful about the contracts – 70% of the population in Georgia is covered by government-contracted care.
- **Ed Yian:** I have a question for Larry. You showed that slide of how much healthcare cost for one country. How much does it cost for the implants of different companies? Has that changed over the last thirty years?
- **Larry Higgins:** It's been relatively flat for the last fifteen, twenty years. One of the things I get frustrated about is that they (implant costs) are very easy targets. They represent, for example, in the case of rotator cuff repairs – 19% of the cost of the entire value-chain (over a one year episode of care). Whereas (over the same time period) 72% of the cost is personnel expense. So we spend all this time trying to drive down the price on implants, and we keep on focusing on discussions about that, whereas if we were really aligned, the possibility exists for the physicians to actually benefit from cutting costs and being more efficient. Then I think we should have an easier realignment in our overall delivery of care. I do think that there are conflicts, and I think those people with such conflicts have to be recused from the decision-making process. Loma Linda went through something really dramatic – They actually went into a single arthroplasty provider for hip and for knee. That was a big deal for them. They did that by having anyone who had a conflict of interest recuse themselves, so they could go into a single vendor, except for special circumstances like complex cases.
- **Audience 1:** How do we negotiate with companies?
- **Larry Higgins:** The reality is that the companies will actually offer a substantial discount when they control about 80+ percent of the market. So getting down to 2 insurers and vendors doesn't even help you that much. It actually has to be with one provider at 85% of the market or more, and that's what they want. Some of the trauma companies, like Synthes or Smith & Nephew, are trying to negotiate contracts where they can control 80-85%. Getting down to 2 providers is a little better, but it's really the volume discount that's actually going to change the game for pricing. And that is really hard because there are so many people who have conflicts. I have a conflict; I work with Arthrex. So (to audience) just raise your hand… How many people have some type of conflict (with a company relationship)? So if you just look around this room, more than half the people have some type of conflicts. I think most of us are involved, so I think it is a problem (for all surgeons who seek to innovate.) These relationships create conflicts. Unless we can committ 85% of our business to a single vendor, you're not going to get a great discount.
- **Audience 2:** We have reached the origins of research involved in healthcare economics. In the big picture, implant cost is small in the overall cost of care. Yes, we can lower that, but I have to attest that there are so many realities that we can also focus on. If we're careful though, as we create savings by bringing down the cost of care from say $26,000 to $24,000, that means that if you narrow it down, and you keep bringing down the cost by incentivizing those of us who are working hard to do so, and maybe to some extent ration other care services, including PT, ancillary services, etc.

- **Larry Higgins:** This is a really important point. Here would be a perfect example of this. I was at Mount Sinai last week giving Grand Rounds, and they are becoming more aggressive about the bundled opportunity costs. So they enacted a bundle in hip and knee arthroplasty. The hip and knee arthroplasty bundle generated a nice margin. What did the hospital do? Well, the hospital experienced a major deficit in the stroke (care) bundle and wiped out the arthroplasty bundle cost (by taking it to offset their losses in the stroke bundle). That is the best way of dis-incentivizing physicians of working together, right? The free market will dictate the right price, and we will have innovations so that we can drive down the price because there are a lot of ways for us to save money, and I think all of us can think of ways to save money for the system; but we're not incentivized and the system isn't flexible in most cases, to respond to what we see and what we want to do. And until that happens, we have legacies (in terms of price).
- **Buddy Savoie:** At least in our area, the physicians don't incorporate the bundle. It has to do with the hospital systems. We hire administrators to manage the bundle, and there's really nothing there that helps motivate us to get there. Say that we're saving money, five thousand dollars for a joint replacement. That money just goes straight back into administrative costs immediately (without benefit to us). So you save a million dollars and half comes from the top and half of those go to your bottom line, and they manage the numbers in them and share that information and it all looks like just a bad year. That happens all the time.
- **Larry Higgins:** That happens all the time, and it's part of the root problem of the system in which many of us work; and that's why going to bundled payment is the only way we as physicians are incentivized to participate and be rewarded. I don't think physicians should get paid less, that's not my argument, my argument is that let them get paid well, and cutting costs to improve efficiency will optimize it.
- **Buddy Savoie:** I think the only way that works is if you take the bundle out, and then let them come back to you and say "hey bring it back" you'll be just fine.
- **Larry Higgins:** OrthoCarolina is doing that. They're getting the bundled price. (For example) they're getting $26,000 per year for a knee replacement, and they're going to bill the hospitals and track their records. And I'll pay six thousand dollars to have my patients' study here, and then they negotiate with the hospitals. (They are proactive in controlling the dollars and dealing with the hospital. Most of us work in environments where it is the other way around).
- **Ed Yian:** Yeah, so like what you were saying, the system is unsustainable, and change is here, and more changes will come. And we have a choice as to whether or not we can set the guidelines for the administrators, the lawyers, or whoever else who has historically dictated our fate. To continue to do so, we're going to take charge of our situation, and find our own value in our situation. That being said, the one thing that's barely been talked about are thoughts on clinical expansion. You automatically say that it's a bad thing. Why is it such a bad thing? I mean I understand that when you have your money's worth that we have a pretty low life expectancy. Genetically and socioeconomically, patients are much worse than other countries. Why is it that the administration continues to grow, provides jobs for people, provides revenue –why do you see that and say, "that's bad"?
- **JP Warner:** Can I just add something? Larry you can comment on this. Unless I'm mistaken, the Brigham and Women's Hospital offered 1600 nurses early retirement for these jobs so they could cut costs. Am I wrong?
- **Larry Higgins:** No, you're right. It's just that you can't sustain it if your inflation is running under 2%, and you've got a 12.8% compound annual growth rate – that's not sustainable. ***Albert Einstein said the most powerful force in all of nature is compound interest***, and that's we're having – we're having compound interest.

- **Lewis Shi:** Thinking about all the players in the game, at my institution, we have access to a database that contains about 20% of US population, and I did a study looking at 40,000 rotator cuff repairs on date of surgery, one year before, inclusive of all the cost of MRI, PT, injections, and then one year after surgery. It turns out that $24,000 was this entire episode of rotator cuff repair. Of this money, 14% of that cost was paid to a surgeon. This is not looking at implant companies and their costs. So when you look at PT money, anesthesia money, MRIs ordered by primary care doctors, there's only a limited amount of what the surgeon can control, only 14% of payment is to us. Obviously, from a political perspective we can make some changes, but when you talk about bundle payment, obviously a lot of players have to be included in the conversation.
- **Buddy Savoie:** The one thing that you have to remember is that they are your patients. We've given up, so not like it never happened. Thirty years ago, Bob Cofield said these patients need one year of therapy, they've got one year of therapy, right? We've given up our control in everything, and all of the people who have hospital jobs have more control, and they have less access to the medical knowledge. We control the patients – you don't go to a hospital, you go to a doctor.
- **JP Warner:** Yes but we're not allowed to unionize.
- **Buddy Savoie:** 75% of people who have hospital jobs are unionized, you know, they have control over it.
- **JP Warner:** For me, it's very interesting because one of the biggest barriers to innovation is where it happens (the environment in which you work). And so, Bob told us about Mayo Clinic; Larry and I are at academic medical centers in Boston; Larry told us about the OrthoCarolina situation. We see things that work in certain circumstances and many of the Harvard Business School case studies reflect this reality. The question is, why can't we extrapolate some of those? And the answer is, it's the environment in which we work that defines this possibility. Some places are willing to reinvent themselves, and some places not. And when you start to lose money on a billion dollar businesses, that becomes problematic. How they respond and adjust accordingly will determine whether or not we can go our way. I suspect, and I may be wrong in this, that in Europe with its social systems, academic centers suffer greatly, and it was the private institutes that became able to provide lean management. Thus they were really able to provide value and manage the margin, and also innovate at the same time. I don't know if that is possible going forward in our academic medical centers here in the USA. Just as in Europe, the Academic Medical Centers may not be able to compete on value offered.
- **Sanchez-Sotelo:** Any other questions? Or comments?
- **Jeremie Axe:** JP Warner – for the study (Patient-specific planning) that we filled out the survey for, it was sent to NESES (New England Shoulder and Elbow Society), so these are all very specialized people. How does this help Tier II or Tier III surgeons?
- **Kyong Min:** I think I should explain – it actually did help everyone. But when comparing, who it helped more? It helped the less experienced surgeons more in their decision-making.
- **Buddy Savoie:** If you (Joaquin) do revision shoulder arthroplasty, it can be a huge problem when it creates stress fractures. The second thing is, I would think about if it doesn't work, what would be our next operation – you asked why not do a reverse with 62 years old. If I had a TSA now, then I could do a reverse as a revision operation.
- **Sanchez-Sotelo:** No, quite the opposite, the person I mentioned, I would use an anatomic because I could get a better clinical outcome in the first two years. Reason for failure of RSA would be stress fractures, and not sure the reasons and outcomes of

having stress fractures. I don't know if it has anything to do with the screws. Have you seen any increase in your fracture rate, JP?

- **JP Warner:** No, not from our database. What I see is, it just makes it a whole lot harder when you lateralize on the glenoid and distalize the humerus; it really is challenging. I know that when Gilles Walch did a planning surgery in an industry session recently, and he put the glenoid in such a lateralized and inferior position, and I was like, "Oh my God, I don't know how in the world would you do that?" So I think you can optimize certain elements of geometry and it can be very hard to manage the soft tissues, but I haven't necessarily seen high instances of fractures.
- **Sanchez-Sotelo:** So what can you do to achieve better internal rotation and make reverse be more predictable?
- **JP Warner:** What I would say is this: first of all, there is no question it's the geometry. But, if you don't fix the subscapularis, there's no chance for internal rotation.
- **Bassem Elhassan:** The tricky part is, I challenge everyone to plan before surgery. Nobody can predict for the patient after surgery that they get internal rotation.
- **JP Warner:** Bassem – here's my challenge for you: you've got a perfect model to do it. Take that as a biomechanical study in your lab – dynamically and statically what you're going to do to achieve optimum Internal rotation.
- **Bassem Elhassan:** I understand – the point I'm getting at is that there are certain surgeons that are adamant about talking about subscapularis for internal rotation. It's about the surgeon doing subscap repair all the time, they're getting some internal rotation, but unpredictably. I challenge you to compare the two and see the difference. We can do the biomechanics of it. I'm just saying that subscap, because we're still thinking about it anatomically. The concept is completely different, but for deltoid, most of the patients the scapula does not heal completely. No matter how much we look at that, there is a difference between the two. Maybe we can both do a bigger size, she can wing her scapula up, but the anatomy is different. The scapula is not moving in anatomical rotation. If you don't wing the scapula, you don't get internal rotation
- **JP Warner:** Maybe we just define something very important.
- **Buddy Savoie:** You can see the pictures that Joaquin showed. The girl's scapula is winging when she gets internal rotation.
- **JP Warner:** So here's what we find: You can absolutely know the range of motion. I just don't know if it correlates with Dr. Yian's data. So you can certainly model the mechanical movement of internal rotation with the baseplate and decide what position. What I don't know is to do what you just do with that data. Is it the geometry? Can you change things? Can you make a difference? That's a study to do, we can do it on every patient-specific planning and maybe see where it goes. Let's table that till the end and we'll discuss about what we can do.

Emilie Cheung, MD: Codman's Paradox (Success & Failure) Case Presentation — Ground Rules

(Click here for PDF)

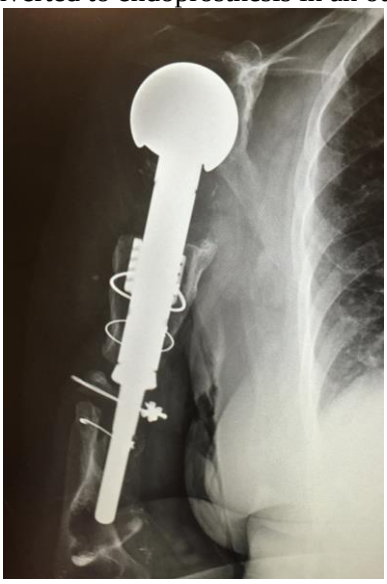
"Age carries mental scars left by experience which shortens vision, but age carries wisdom."— William H. Mayo

- My definition of "paradox": "A statement that seems absurd or contradictory but yet can be true, or at least makes sense. Paradoxes are often contrary to what is commonly believed and so play a part in furthering our understanding in literature and everyday life, or simply an entertaining brain teaser."

- Codman's paradox – a specific pattern of motion at the shoulder joint. It asked how a mysterious axial rotation about the longitudinal axis of the arm occurred during two or three sequential arm rotations that did not involve rotation about the long-axis.
- My interpretation of that is that 1) there are always things that are not easy to explain, and 2) the best teachers are time and experience.
- The objective of my talk is to go over 6 case examples of paradox that are somewhat challenging cases for forum or discussion to enlighten and educate each other.
- Case 1: 53 yo F with pain, exquisite shoulder pain, limited mobility, somewhat pseudoparalytic, had a humeral hemiarthroplasty for fracture 11 years ago at an outside institution.
    - You can see the stereotypical appearance with the absence of the greater tuberosity promontory that would suggest that it was in a setting of a fracture. You also see some suggestion of superior wear of the glenoid and erosion of the glenoid in a concentric pattern.

    - In my mind, I was thinking that this patient was not satisfied with their current function to revise this into a different type of arthroplasty. How many of you would revise this into a reverse shoulder arthroplasty? CT scan showed adequate glenoid bone stock. Who would revise to anatomic total shoulder arthroplasty? Who would treat this patient conservatively?
    - I told the patient that since she was 53, she was relatively young. I wanted her to think about it because I knew the stem would require probably humeral osteotomy, and it would be a big revision. So I actually told her to think about it, and for a while, she couldn't decide what to think about it. We sent her to therapy, and actually she became very dedicated herself with the therapy, and she came back to see me 6 months later.
    - My thinking behind is that somehow, she is able to get good periscapula compensation; she has an intact coracoid, acromial arc, and she was able to develop a compensatory motion and avoid the revision surgery. (click here for videos)
- Case 2: A 48 yo male who had avascular necrosis. He underwent total shoulder arthroplasty by a hip surgeon many years ago, and failed due to glenoid component loosening. They treated with resection of the glenoid component, but he continued to have pain and was treated with a resection arthroplasty by another doctor, which happened two years before I started at Stanford about thirteen years ago.
    - Remarkably, he had no pain. Video of his range of motion showed that his cuff was intact, and I guess hips surgeons are good at doing shoulder surgeries sometimes.

- Case 3: I see this about once or twice a year. This is a 53 yo female with a failed proximal humerus fracture, open reduction internal fixation, and then she developed a periprosthetic fracture and failure of the fracture to heal; eventually this was converted to a hemiarthroplasty, and later converted to endoprosthesis in an outside hospital.



  - Things that go on in my mind when evaluating X-Ray are: 1. She's in a lot of pain, so she's desperate to have something done, 2. She looks like she has an impending fracture at the tip of the stem, it's windshield washing as you can see here. She has painful symptomatic hardware, her radial nerve is actually intact, and if you look closely, she actually has glenoid insufficiency as well.
  - So different options: 1. leaving alone is not really an option because eventually she's going to have pain come back, 2. ORIF is not really an option because there's not a lot of bone left, 3. There are newer endoprosthesis options that may be a consideration in this case. I didn't think so because the bone stock is ballooned out. 4. Resection arthroplasty: certainly a realistic option that you can have pain relief, 5. APC.
  - Philosophically, one of the greatest things we can do to patients is to give them hope.
  - Technical points: I found the nerve, and she had a shell of bone distally, and I preoperatively planned this with my tumor partner. It's important to save the pseudocapsule as a superior restrain because she had insufficient glenoid and I wasn't

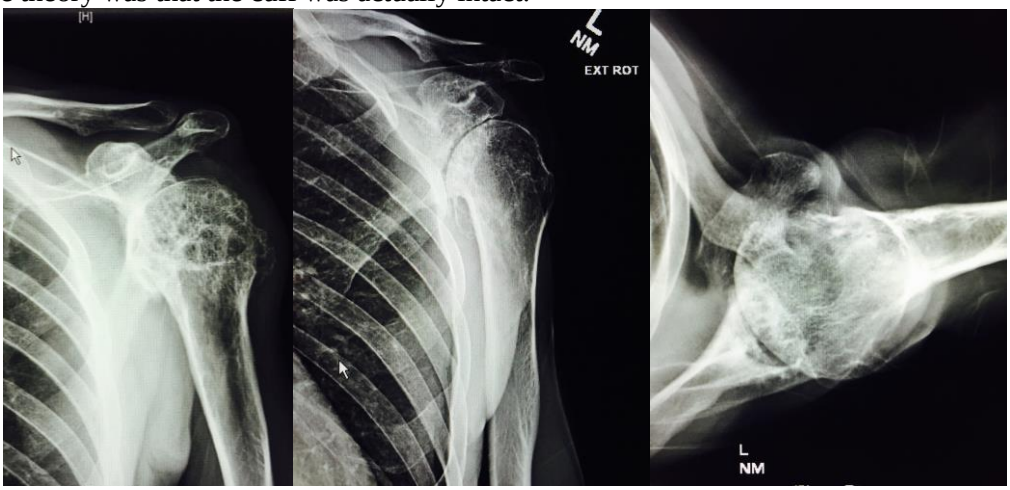
optimistic about putting a reverse in her. I saved the shell of bone, which I learned from Dave Moller, one of my tumor colleagues. Anything that's live, we try and save, and we'll wrap around the allograft later on. We try to achieve as much bony contact as possible with femoral or humeral allografts- these big defects that are segmental. I used BMP at the interface between the allograft and the host bone.

- This is the pre-existing prosthesis (see image below); this is the portion that was windshield wipering out of the distal humerus. Basically, we took a humerus with some cuff attached, and used it to contour this into a potential biologically viable solution. Our options were really limited and this was a salvage case.

- This is what I ended up doing: I used a CTA head because I didn't think the glenoid was going the support the glenosphere and base plate. We ended up doing dual plating, and we got to the shell of bone around that had gloomed out so much to wrap around some of the inner prosthesis and up here we saved that shell of bone. With dual plating, it actually ended up pretty well, and that's some of the bone. I've actually been pretty lucky doing some of these over the years. (click here for video)

- Case 4: An interesting case. 53 yo male who had a complete axillary nerve palsy and complete deltoid atrophy. Thes was secondary to childhood trauma. He was a thin guy, completely concave around the deltoid from his axillary nerve palsy and was able to actively abduct to 80 degrees, much of it was scapulothoracic compensation. He had excruciating pain and crepitus due to this post-traumatic arthritis. But again, no deltoid and I showed his pre-operative video to everyone, including Gilles Walch, Pascal Boileau, Yamaguchi, and other

people about four years ago. Everyone had a different reason because he had no deltoid, but the theory was that the cuff was actually intact.



- What I elected to do in this patient who had an intact rotator cuff, but no axillary nerve or deltoid function to consider these options: TSA, hemi, fusion. I think the stakes were too high to do a total shoulder because of the risk of glenoid loosening. Hemi or resurfacing would probably be the lesser of all the evils because the rotator cuff is intact, and I didn't want to fuse him. So I ended up doing the resurfacing on him because he was at a relatively young age, and I got this four-year post-op video: he couldn't do that before the surgery secondary pain and he had no deltoid but his cuff was intact. When you see later on with this video (click here for video), you can see how much atrophy on his deltoid that he has. All of the motion is generated from the intact rotator cuff. When he turns, you can see his lack of deltoid. He gets fatigued because his rotator cuff is doing all the work, but he can get there. He is better than he was before.

- Case 5: 62 M who has gone through a lot. He has chronic pain. I saw him earlier on in my practice when I was more aggressive and naïve. As you can see here (see X-rays below), he has an erosive pattern of arthropathy. On his shoulder, he has glenoid erosion. You can see the degree of glenoid erosion looks to be medial to the base of the coracoid on the X-Ray. CT scan shows very little glenoid to work with, and again he is articulating on the base of the coracoid. I used a superiorly augmented component, so this happens to be ExactTech component that has a superior augment on the baseplate to substitute for that. I also did BIO-RSA, so I used humeral head autograft, and I looked into the glenoid, it wasn't a live bone, so I perforated it with the drill and tried to get a bleeding surface, so that the humeral head

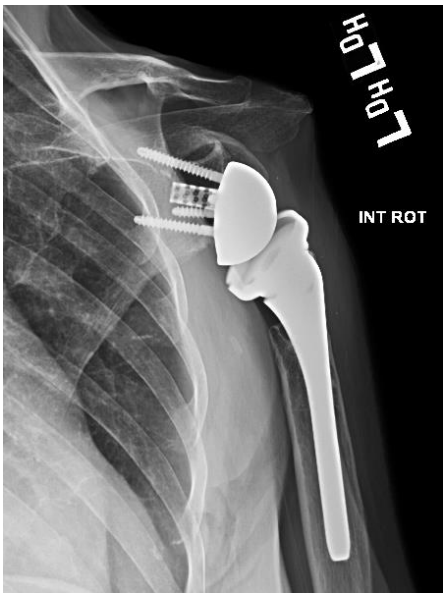
autograft had something to heal onto, and then I put the reverse in. You can see the long-post to the middle there on the X-Ray.

- Sure enough, I thought it went well. But three months post-op, he didn't ingrow and the forces were too great so it failed. And I would convert that to hemi.

- This is the quote that JP gave in the handout: "Age carries mental scars left by experience which shortens vision, but age carries wisdom." I'm less aggressive now doing BIO-RSAs for reasons that I just showed.

- Case 6: 55 yo F, over 300 lbs. She was operated by my partner in the trauma department. She's painful and pseudoparalytic. You can see that she has failure of fixation, had some screw perforation, flattening of the humeral head consistent with post-traumatic arthritis and avascular necrosis. I did what most of you would do in here – I did a reverse shoulder arthroplasty, and there's a little gauge wire there, and I thought it was okay to do a press-fit because I thought there was good digitation even if the gauge wire was there.

- At 8 mo post-operatively, she had insidious onset of shoulder discomfort, but she had lost 50 lbs because she decided to lose weight and have a bypass surgery. She dislocated, I took her back to the surgery and gave her a humeral tray, and a bigger polyethylene liner. Two weeks after that, unfortunately, she had a hematoma. I took out the wire, the cultures were positive for *Staph epi*, and she had a 6-9 week treatment with IV antibiotics.
- 10 months after that, she continued to have pain: this foam was starting to resorb, and it was followed that two years out, she lost 110 lbs and continued to have aching pain. Her bypass turned out to be working out, and she was half the woman as she used to be (literally). You can tell that she has complete deltoid atrophy because she lost all the weight, and it's now apparent that she's had an axillary nerve palsy all along.
- She continued to stay reduced. 3.5 years post-operatively, she continued to lose more and more bone along the prosthesis, and she's getting pain from the humeral side of loosening, which I didn't appreciate before.



- So I learned something from this case, and she was miserable all the time, so I ended up doing a resection on her. She is actually happier now than she has been in the last five years from the very beginning when her fracture failed under multiple surgeries. She's actually happier now because she's not suffering from the pain anymore.
- It's ironic: I got a phone call last week from Arizona, and her name came up.

- In conclusion, our profession we know that we often experience the epitome of success and also the utter failure sometimes too. We all recognize in this room that "the heights by great men and women reached and kept were not attained by sudden flight, but they, while their companions slept, were toiling upward in the night" – Henry Wadsworth Longfellow. Thank you.

Session II: Infection after Arthroplasty—How Can We Do Better? (Moderator: Ed Yian)

Larry Gulotta: Current State of Disagreement and Evidence for Best Practices

(Click here for PDF)

"If two people agree, one is not a surgeon."—C. Gerber

- I'll start by talking about what I think we know, and then move on to what we don't know.
- What we know is that infections occur. We know that P. Acnes is particularly problematic in the shoulder, and this talk is geared towards talking about P. Acnes because that is really the black box in the topic of infection.
- I think there are three groups of patients that come with P. Acnes: those who form a purulent infection; the vast majority are those who have no overt signs of infection, but bacteria is pathologic – implant loosening, rotator cuff is falling apart; those who are colonized with P. acnes and are fine.
- What we don't know:
  - How do you tell the last two groups apart? How do you tell that the infection is indolent and pathologic vs. indolent and benign? It will come down to diagnostic skills and tests in order to figure this out.

- Why do they present differently? Is it because they are various bacterial strains? Host factors? Influence of varying hormonal levels?
- How do we treat them? Benign neglect? Single vs double stage revisions? Role of IV Abs? Role and duration of PO suppression?

- One of my favorite quotes from Mark Twain: ***"What gets us into trouble is not what we don't know, it's what we know for sure that just ain't so."*** So we should keep that in mind.
- What's the evidence for diagnosis?
  - We know that *P. acnes* is the most common pathogen in revision arthroplasty. There is ~50% positive culture rate for revision shoulder arthroplasty.
  - Due to its indolent nature, infection can be difficult to evaluate and diagnose. It could be subtle, non-specific clinical picture with delayed, chronic presentation. It could be a patient with pain or stiffness.
  - Our diagnostic workup for patients with a painful shoulder arthroplasty includes history & physical, imaging, serum ESR & CRP, preoperative aspiration, intraoperative culture and pathology, and newer diagnostic tests, which I am going to talk about that might help with our sensitivity and specificity.
  - There are risk factors for periprosthetic joint infection. In particular, we talk about males being prone to *P. acnes*, postoperative hematoma, prior surgery, age, humeral and/or glenoid component loosening, osteolysis that you see on X-Rays are signs of indolent and pathologic infections once you start to see implant loosening.
  - We know that there is a low sensitivity of standard serum markers due to indolent pathogens, but pretty good specificity. We got 21-42% sensitivity for ESR, 0-63% sensitivity for CRP, but it can get up to 90% in terms of specificity.
  - Part of the problem to determine what the literature and the evidence is that under sampling is very common in the literature, and there are other factors that impact our ability to culture our *P. acnes*, such as: preoperative antibiotic hold, fluid vs. periprosthetic tissue specimens, culturing technique (anaerobic, implant sonication), culture length is 7-28 days. There is so much variability in the literature that makes it hard to give concrete evidence.
  - Another issue is what is the optimal intraoperative culture protocol? I think the consensus is that more cultures are better, 4-5 tissue specimens, 14-17 day culture hold, which increases our yield based on past literature; if you hold them too long, eventually they'll grow *P. acnes* and become false positive.
  - What's the evidence if you do have positive cultures? If the cultures come back positive, how do you determine between false positives and real positives? Here's a study by Frangiamore et al, JBJS 2015 of 46 revision shoulder arthroplasty cases with more than one *P. acnes* positive culture and they categorized into two groups – one as probable true positive group, and one as probable contaminant (false positive) group. One of the factors that differentiated these two groups was that 1. When did the culture actually become positive? True positive became 'positive' on day 5, and false positives became 'positive' around nine days. Cases with higher number or proportion of positive cultures are usually true positives as well.
  - How about frozen sections at the time of surgery? How useful is that for us intraoperatively? It depends. If you look at the literature, there's a lot of difference in terms of what people use for criteria to become positive for infections with the frozen sections. You can see here, if you use the newest criteria, which is a total greater than ten PMNs in the 5 most dense high-power fields, you can raise your sensitivity to over 72%, which is good but certainly not great.
  - What about the newer diagnostic tests? The synovial fluid biomarkers have been identified as part of the innate response to pathogens – there is some evidence that shows that it can get up to 100% in sensitivity and specificity for hip and knee

infections. But what's it in the shoulder? Two studies in particular talk about the synovial IL-6 and synovial alpha-defensin. Sure enough, the sensitivity (76%) and specificity (90%) are high in IL-6, but the sensitivity in alpha-defensin remains low (63%), but they can be positive in *P. acnes*, so it is encouraging.

- There are a number of different factors that you can combine to help you diagnose better. But there are challenges to these tests, such as the lack of commercial test or point of care test for intraoperative use and decision making. Preoperative aspirate possible to send for analysis prior to surgery, but often dry tap or low volume with indolent pathogen. So it doesn't really become too practical for us at least as of now.
- People have talked about some leukocyte esterase strip test, urine analysis, and there has been some evidence in hip and knee but in shoulder it's been very poor in terms of sensitivity and specificity.
- Building on the future: organism-specific testing? It would be interesting to look at your take on PCR pathologic genes. If you start to use PCR testing, we're going to find genes for *P. acnes* that come out positive in our serum. It's really identifying the ones that become a problem that is really challenging.
- Algorithm for diagnosis is going to be a combination of pre-operative risk factors, plain radiographs, CT, serum CRP, ESR, synovial aspirate (culture, alpha-defensin, and other biomarkers). Intraoperative diagnoses include synovial fluid, multiple (5) tissue biopsies for culture and frozen section of capsule, glenoid & humerus fibrous tissue, and a combination of these factors altogether.
- What about the role of diagnostic arthroscopy? It can be useful in terms of figuring out what you are dealing with. My personal experience has only been about ten patients, so I'm sort of on defense, and often times those patients come back with perhaps some mechanical cause for their failure, but you aspirate it with routine and you get back a positive *P. acnes* culture and I don't really know what to make of that. So I scope all of them, and seven of them have come back confirming with positive *P. acnes*, but three of them are negatives, so I put them as two-stage explanation of re-implantation, which we can talk about there in a bit as well
- What is the evidence for treatment in terms of single-stage vs double-stage? This is a meta-analysis that came out of Rothman, what they looked at patients who came out on-stage vs. two-stage. A lot of these turned out to be unexpected positive cultures, so patients who inadvertently had single-stage and compare with patients who had two-stage, and the success rates are about the same, somewhat about 90% in terms of the ability to eradicate the infection. Antibiotic suppression or I&D with implant retention had poor eradication rates.
- The problem is that these are all meta-analyses with very small numbers, and there's a lot of heterogeneity in terms of treatment protocols and choosing one- vs. two-stage revision.
- My practice is that if I do have positive cultures, I still feel obligated to do a two-stage explantation and reimplantation, and I'd only do single-stage if we had an unexpected positive culture, and typically that works out.
- I think the evaluation of infection of shoulder arthroplasty remains a challenge due to the low virulence of the common offending organisms. We need better diagnostic testing to be able to detect infection. New perioperative testing in combination with existing tests may increase the ability to detect infection.

- Standardized protocols for perioperative testing are needed and may help to clarify diagnostic criteria for shoulder PJI. This may impact clinical decision-making and lead to more well-defined treatment algorithms. However, we still have a lot more to learn here

Joaquin Sanchez-Sotelo: Presentation and Discussion of the C.S.S. Infection Questionnaire
(Click here for PDF)

- Thank you very much again. So the reason for this paper is that we have seen a review paper about infection, and then I talked to JP Warner asking permission to contact you to see if we could understand better. Then I sent the same surveys also to the ASES members. We sent about 752 surgeons, and 218 (30%) people responded.
- Survey results:
  - How long in practice? Very even distribution between <5 years (22.9%), 5-10 years (23.9%), and 10-20 years (22.9%).
  - Fellowship trainings: 72% trained in shoulder and elbow, and there are also 18.3% who trained in sports.
  - In terms of evidence: do you feel that the currently-available data clearly supports the use of infection prevention strategy? 82.1% responded no, and 17.9% responded yes (218 responses).
  - Before surgery, 80% routinely assess for the adequacy of diabetic control.
  - Before surgery, 60% routinely screen for MRSA or MSSA colonization.
  - Only 20% surgeons require tobacco cessation for > 30 days prior to surgery.
  - 3 of 4 surgeons (75%) request patients to use a special soap or scrub prior to surgery.
  - If cementing, do you routinely use antibiotic-impregnated cement? 70% yes; 30% no.
  - If yes, which antibiotic do you mix into your cement (check all that apply)? 43.7% tobramycin, 54.3% gentamycin, 24.5% vancomycin, 4.6% other
  - Do you irrigate the wound with antibiotic-laden solution? 35% yes, 65% no
  - Do you routinely use any sort of dilute iodine solution for wound irrigation? 28% yes, 72% no
  - Do you routinely use topical vancomycin powder? 27% yes, 15.3% sometimes, 57.7% no
  - Which of the following best describes your use of a closed suction drain? 29.8% "I always use a drain," 32.6% "I never use a drain," 36.2% "I use a drain selectively"

Stephen Parada: Presentation and Discussion of the C.S.S. Infection Questionnaire
(Click here for PDF)

- Thank you very much. Thank you Dr. Warner for letting me to be a part of this.
- The impetus for this study was that we started growing *P. acnes* in our lab down with Augusta. We started looking through the literature, and there wasn't really a consensus on even the antibiotics to treat known *P. acnes* infections, so I sat down and talked with our infections disease staff and they have different opinions and we really thought the first step of this was going through and getting some more information with questions asked first. This was very exciting that this was the index study of Codman Society, and we presented the results to the Orthopaedic Research Society this year.
- None of the authors have any relevant disclosures related to this topic.
- *P. acnes*, as we have talked about, clearly it's been shown to be frequently responsible for shoulder arthroplasty, but again, there is no best practices that are out there. Different papers, if you look through the literature, they'll say different forms of cefazolin, and penicillin G have been found to be very effective and almost no one is using that prophylactively or to treat *P. acnes.* And then there's different things that showed vancomycin only have "fair" effectiveness, and then there have also been several strains that have been found to be resistant to clindamycin and other antibiotics.

- There are a variety of techniques for infection but no consensus, and so we thought the first step was taking a look, and looking at the best practices by coming up with the questions, first of all, and that were the purposes, we just wanted to see what our group was doing, what you all were doing, what other preparation protocols that you had that you were using for *P. acnes.*
- We hypothesized that marked variation in *P. acnes* prophylaxis practices exist among a cohort of similarly fellowship trained shoulder surgeons
- We tried to keep this very short, and thought that we would have better interactions if we kept this short. It was under 10 questions, and we sent this out to 84 members of the Codman Shoulder Society
- We had a fantastic response rate (64/84; 76%), and I wanted to thank everybody for participating because this is very unusual for surveys to get over 75% response rate. Just like Dr. Sanchez-Sotelo showed, the same thing, we had a lot of heterogeneity in the distribution of surgeon experience by years since fellowship and also by the surgeon volume. We were just asking about primary arthroplasties, not anything having to do with revisions.
- When we were asking people about the antibiotics that they were using preoperatively, cefazolin (90%) was the most common, but almost two thirds of people use more than one antibiotic. Postoperative antibiotics pretty much followed the same distributions; most people used cefazolin (82%), some people adding vancomycin (27%), some people use clindamycin (16%). Just within our group, we have a lower percentage of surgeons using vancomycin powder, with just under 40%. We did let people write in any other comments, so one surgeon did report that they are using gentamycin powder.
- We then asked people about other surgical preparation protocols. Most are using ChloraPrep (85%) for the skin prep that you can see. We asked people if they are doing pre-scrubs, and you can see that 61% of people are using pre-scrubs. Most are using the Ioban (81%), about a third of people are using sterile hoods (37%), space suits, laminar airflow (37%).
- Interestingly, we asked people about topical benzoyl peroxide ahead of time, and in fact when we were coming up with this survey, Dr. Higgins kept emailing me back to tell me that "you didn't add the question about topical benzoyl peroxide," and I kept emailing him and telling him that "I think you are talking about something different," and he kept asking me to include benzoyl peroxide. And of course, there has been more and more literature about this. Other people added other responses about glove changes, different kinds of irrigation solutions that they are using, and different kinds of dressings. But again, no one in the survey reported using benzoyl peroxide. I wanted to ask, this has obviously about a year now since we last surveyed you. Does anybody here use any type of benzoyl peroxide preoperatively ahead of time? It's interesting that there is more research about this very new, obviously skin colonization is higher in men (80%), and still present if we use ChloraPrep. So there has been some studies showing that preoperative topical benzoyl peroxide in reducing preoperative culture of *P. acnes* to the postoperative cultures on the skin. There are only two studies that are out there about benzoyl peroxide (BPO): one used just about 5% BPO, and the other one added clindamycin. So I think as we talk about things in the future, this is definitely one of the topics that maybe we can look into.
- We asked surgeons have they had culture-confirmed infections, and you can see 37% reported *P. acnes*.
- Interestingly, we asked when they could choose as many reasons as possible, what are the reasons for perioperative antibiotic protocol? We all kind of learn things from the same teacher, yet we all do things differently. You can see almost everybody said that they learned this from their fellowship. One explanation is that we all did the same fellowship and we all do things differently. I think one of the obvious reasons is that things change, and lots of things change and we try to continue to evolve. We didn't use vancomycin powder at the beginning of my fellowship, and Drs. Warner and Higgins had look through a lot of available

literature, and sparked some of the different studies that have already been referenced, but as we look through that, then that was something during our fellowship that we started doing. So I think Drs. Warner and Higgins have continued to adapt and evolve as the literature is showing different things that are beneficial, so I think that's why we all did the same fellowship, we still are doing things differently.

- Future direction of research:
  - Pre-surgical steps such as topical scrubs (BPO?) is something that is going to be more effective. Certainly, the ChloraPrep that we give to patients preoperatively is not effective for *P. acnes.*
  - Prevention of intra-op contamination from dermis to the deep layers, whether that is through things like how we change the use of our scalpels, maybe not using scalpels to go through skin, there's a lot of different things.
  - Intra-operative antibiotic powder with better susceptibility profile than vancomycin (Pen G?)
  - *P. acnes* grows with biofilm formation. Implant specific coating to reduce biofilm formation to reduce *P. acnes* growth?
- Conclusion:
  - *P. acnes* remains a known cause of post-operative infection after shoulder arthroplasty
  - Despite growing literature on identification of *P. acnes*, there is surprisingly little consensus on infection prevention
  - Opportunity exists to create an evidence-based best practice guidelines to limit post-operative infection after shoulder arthroplasty
  - Limits: low infection rate, significance variance in labs, regional variance in strains
  - What better to take on this challenges in looking into this than here at the Codman Shoulder Society? Thank you very much.

Ed Yian: What the (Shoulder) Registry Experience Teaches Us: The Kaiser Permanente (KP) experience
(Click here for PDF)

- I'm tasked to talk about the topic of what the registry has taught us about the infection after arthroplasty, the prophylaxis measures, and then we can hopefully have a discussion on how we can do better on this.
- We know that the incidence of infection has been reported to be between 0% and 5% and probably close to 1% for anatomic replacements. What's interesting is that this has not changed, if not increased, probably from a better understanding of disease processes over the last decade or two. We're going to get to a point where there's zero events of infection? Probably not, but hopefully we can strive towards this.
- When we look at factors for infection risks, we can break them down into modifiable and non-modifiable, and these can be sub-categorized into procedures specific, surgeon specific, and most commonly studied is the patient-specific (host) factors. As Larry talked about *P. acnes*, the number cause of infections as demonstrated by the Mayo registry, 35% of all the organisms. Our registry showed 30% of all organisms were *P.* acnes, most would probably report 30-50% *P. acnes* for their infections.
- What do we know about patient specific risks? The Mayo registry has highlighted the male gender, the younger age, obesity (particularly BMI > 49), diabetes is controversial – both the Mayo and Kaiser registries have not shown association with the infection risks with diabetes, but recent national administrative databases have shown that hemoglobin 1C and 1A have shown associations, and other factors such as smoking, HIV/Hep C has shown associations as well.

- Procedure-related risks including reverse shoulder replacement has a 6 times higher risk at our organization, 3 times higher risks with trauma fractures, 5 times higher risks with revision surgery, and the Mayo group showed twice as higher risks with nonarthroplasty surgery history.
- The most actively under our control, but probably the least studied factors are surgeon-specific risk factors. What can we do as surgeons to minimize this risk? Time of duration is looked at by the Mayo registry and recently our registry as well. The threshold is probably 2.5-3 hours. We also showed time-sensitive component with reverse shoulder arthroplasty.
- Antibiotic cement is controversial: Dr. Nowinski's group showed reduced risks in primary reverse shoulder arthroplasty from 3% to 0% with the use of routine antibiotic cement. 0% infection rate is probably not realistic at this time, but perhaps maybe possible in the future. Now in this registry when we looked at it, we did not find any association at all with the routine use of antibiotic cement in the primary arthroplasty setting. This actually parallels most registry findings in the lower-extremity arthroplasty literature as well.
- How about surgeon space suit use? This as well has not been found any significant associations with infection risks. We think it can influence infection risks but it has not been shown out clinically.
- Antibiotic irrigation has been looked at sparingly. The only other citation that I could find was a total knee literature from a single surgeon and his experience over ten years. We looked at that in our lower-extremity registry and we found that we reduced infection risks with some antibiotic irrigation but we had multiple surgeon practices using different antibiotics, so we were unfortunately unable to show an optimal antibiotic in our studies.
- So is there a magic bullet to prevent infection rate? Probably not, but perhaps a multimodal approach. This is something that the arthroplasty has looked at. They looked at a meta-analysis of, perhaps have been correlated with infection. They looked at preoperative, intraoperative, postoperative factors, and even by incorporating all of these factors, they were only able to reduce the infection risks from 2% to 1%, so there still remains a discrete unknown of how to reduce infection, despite all these measure, and surgeon-driven prophylaxis.
- So where do we go from here? As we even eluded to, we often times do things, as far as antibiotic prophylaxis, based on what we're taught. We'll probably answer one of three reasons why: one is that that's how I was taught originally, or that's how I would do things now because that's all I have, and the least cited reason is the scientific evidence of this is why we do things – we just don't have the evidence of why we do things for infection prophylaxis. This is the thinnest area of evidence (Husted et al).
- Why can't we just look at the lower extremity literature? Well often times it's because the total knee risk factors are different than shoulder replacement risk factors. In addition, the presentation and management of treatment are different as well. The organisms at risk, the pathological organisms are different between total knees and total shoulders. Even within hip replacements and knee replacements, the risk factors are different and the organisms are different as well.
- This article by Dr. Ring: he compared experts surgeon opinion with a large database statistically driven model to try and predict infection risk after total shoulder replacement. He found that the large database statistical analysis was five times better able to predict infections or complication risks after TSA, so perhaps the time is now that we start using large datasets better to perhaps identify factors that we just don't know about with expert opinion.
- So registries can help perhaps or even large databases to answer questions that are rare events. Most of the infection studies right now only enroll a few hundred patients that carry very low power to detect differences, and randomized controlled trials are just not possible at this time.

- How can we do better? For example, we often use antibiotics for short-term gain, but we don't know the long-term effects, so antibiotic resistance, changes in organism profile over time can occur and we don't know about it. So large databases can help detect these changes, and from this, perhaps we can establish guidelines for best practices to use.
- Where can we start from here? We need to look at the literature, come up with a consensus or recommendations or guidelines on prevention measures, and then if we're not able to come up with these based on the evidence, we need to come up with questions that we need to answer before making any guidelines. There's already a few infection work groups starting, for example, multi-centered ASES, our work group, as well as the consensus forum established by Dr. Parvizi next year.
- Perhaps we need to collaborate with other subspecialties as well. For example, the spine field has commented on *P. acnes* infections after lumbar disc herniation. They've reported 5% *P. acnes* cultivation, positive culture rate for patients undergoing primary discectomy, so they can also help to compare *P. acnes* speciation to determine significance of these *P. acnes* infections.
- We probably can't rely on administrative guidance, for example, the SCIP measures have not been effective as far as impacting and reducing healthcare costs. The WHO just came out with prophylaxis guidelines in *Lancet* last year, and these are based on general surgeries that were 20 years old, so we probably need more region-specific guidelines as far as shoulder.
- J.P. sent us a link to Dr. Gerber's comment on a case example. Even among our international shoulder experts, antibiotic infection prophylaxis methods are inconsistent, and there's a wide discrepancy on what is effective or not. Thank you.

DISCUSSION: Can we come up with a consensus statement on best practices? (Moderator: Ed Yian)

- **Ed Yian:** JP perhaps you could start it off by commenting on whether we are able to come up with a consensus statement on best practices?
- **JP Warner:** Just leading up to the concept of infection, and why it happens, and all of that, we have wonderful questions and insight on how we don't all agree. There are lots of organizations working on this at a more diffuse approach, maybe ASES is going to do it for shoulder. I guess the question is what questions can we answer that would be meaningful? And how can we do that as a group, assuming that we have the will to do it, because you can ask a lot of questions you just can't answer, like the vancomycin powder in a million patients, that's not going to happen. You know it's cost-effective in Larry's study, but we don't know if it works, so that would be for me the biggest issue. Number one is, I think at the very least, our organization should have some kind of summary of where we are currently. We just showed beautifully about where we are. I don't know if we can come up with a consensus statement. We can come up with a lack of consensus statement – that would be kind of interesting. But, the most important thing is how can we bring clarity to this? Is there any way, we can agree that things that might be done, we can all agree, should be done, to improve? For example, how many of you change your gloves frequently during the surgery? How many of you, you know, make your point to change your gloves before you touch the implant? Okay, so, we can kind of do cultures, before and after, to look to see if that makes a difference, and there have been studies like that. We know that there are studies that looked at cultures of dermis and subdermal layers, studies that look at irrigation immediately after going through the dermal layer, hand off the knife and then irrigate. Gerber made that comment that he always takes the skin knife and gives it away. He changes his gloves, irrigates, and goes on. Is this a useful practice? I've no idea what his infection rate is – there's a problem too because do all of you know your infection rates? I must say, we looked at the Top 30 U.S. News & World Report of hospitals, almost all of them do not report infection

rates of shoulder arthroplasty. Larry and I try, I mean, Larry what do you think our infection rate is now from what we've looked at? We've looked at cohorts, we report every year, but the problem is we report everything that we do but in arthroplasty. I'm not sure, I haven't been understanding for the last five years, which we should do. What's our infection rate? And how do you follow up with a patient to know that they have an infection? Because we've seen cases where biopsies done years later are positive, and that's something that someone pointed out too. So it becomes a very difficult proposition to determine what is really an infection, and when it would happen, and what's our end point. And when we interpret the literature, you know that you may be missing a bunch that were just sort of trickling along that appear years later. These are just some of the questions that would be amazing that you don't have to answer now to think about, because if we can think of one question that we can answer that gives clarity to one part of this big mess, that as far as I see it, that would be a contribution. I don't really know where to go with that, but I'm open to any suggestions.

- **Neal Chen:** I think the fundamental piece that we need to find is to define what an infection is, especially for this case in point. The reason why is that we need a hard line for statistical analysis. And if you want to look at the data to say this is infection and this is not infection, once you have the outcome, then you can start applying the statistics. If we don't define that, take that exact outcome, then everything that we do, all the data we collect, we can't have a way to study.
- **JP Warner:** So is that where we should start? Should we come to a consensus of what the hell is an infection? Or how long we should follow up to be safe to say that there is one? Or is there a definition there? Because I don't know it and I might have missed it in the literature. You study this so much, what does the literature say about this?
- **Ed Yian:** There are limited studies on that. I think there are different definitions of possible infections, probable infection, and definite infection, but that's something we can look into. I do think that as far as research studies, ASES work group met two months ago, and one of the things that was agreed upon was that there is a need for more foundational research, so possibly, how do we standardize labs? Because often times, labs are different. We use cultures as our only determination of infection, and a lot of centers have different labs, different agars – chocolate agar, blood agar, different types of agars. Even then, we don't know our false positive rates, so one of the questions brought up was that we should get more centers to determine our false-positive rates in our labs just sending raw specimens from the OR.
- **JP Warner:** That's a reasonable study to do, right? To bring clarity? There's a question that we can actually ask and we can potentially answer it that we don't have to ask for the IRB that we ask. Okay, so that's good.
- **Joe Eichinger:** I was just looking through the literature, and some of the problems in these newer studies right now that compare to the historical things that they found in the literature, I found that, if you read the methodology of how they did it, just like what you were just saying, there is so much variability in the labs, you can't compare it, even multi-centered studies using multiple labs would be tough. And certainly, comparing that to any of these historical studies, does the pre-wash matter? The positive culture at the time of the surgery, things like that. I found that those studies, scientifically, did not seem very valid to me, so I think it'd be hard to do multi-centered lab studies – it just introduces so much variability.
- **Ed Yian:** That's a statement on point – standardization is needed if we start doing multi-centered studies.
- **JP Warner:** Just a thought, I'm leaving with more clarity about what we don't know, that nothing seems to matter, and more importantly, that we don't measure to the degree that we can to have some clarity about what we're doing. At least, I don't know, Bob you've got a big registry, what is your end point? How confident are you if you reported infection rates, that's what it is?

- **Bob Cofield:** I'm pretty confident.
- **JP Warner:** Okay. In the end, what is it now?
- **Bob Cofield:** It's 1% infection rate, every year, every surgeon, every procedure by procedure. However, there's a lot of variability in surgeon experience.
- **Sanchez-Sotelo:** We can work with infectious diseases department and figure out what's a false positive vs what's a true positive… can pull data from Mayo registry to analyze infection rates
- **JP Warner:** So, I'd be really interested to know how we all measure outcomes. Wouldn't that be interesting? I mean, that would be really interesting, and this is a group of people who are really focused and dedicated to shoulder. If that's our benchmark, how are we doing? And I mean, how do we collect our cases?
- **Sanchez-Sotelo:** I don't mind the same idea. Does the patient need another operation for infection?
- **Bob Cofield:** One of the things we do is to ask those who work in the registry. So if a surgeon asks – anything that's a hint of infection, they put it in the registry – and then we have to go back to see which ones are the false-positives vs true-positives
- **Bassem Elhassan:** Again, this is because of the regulations at our institution, so for example, how often during the surgery, we take the biopsy for infection. How often? Even during the implant? How often do we go back to the revision? Very very low.
- **JP Warner:** Can we find that in the registry?
- **Bassem Elhassan:** We can find out. But it's not that simple that even for bone infection. We must be careful about how we define what an infection is.
- **JP Warner:** It's something worthwhile to think about.
- **Sanchez-Sotelo:** The infection rate is so low, it's difficult to prove.
- **JP Warner:** Yeah but Larry is that worth doing? The vancomycin powder?
- **Larry Higgins:** Yes. It's not worth studying, but it's worth committing to as a potential way of diminishing your infection rate. And if you look at the spine literature and the trauma literature, it is very compelling.
- **JP Warner:** How many cases did they have to do before they conclude?
- **Larry Higgins:** Well their infection rate in traumatic spine injury is as high as 15%. So, that's part of the issue, right? Dan worked on this and probably has more details about this than I do because he was so integral in working through this, but the reality is that the predicate is so strong on some of those, and those were prospective studies, and these were randomized prospective studies that were done with very high quality data. In response for us to talk about trying to do something like that, we can collect data and agree within this group, this is what we think our best practice is, and I think you can stop there, once you agree on best practices. So, it may be said that we hash out and we have a best practice consensus, and we just try to commit to that. And I think that's probably the appropriate way to approach this.
- **JP Warner:** Mohit Bhandari said that the evidence is so fragile in literature.
- **Sanchez-Sotelo:** Evidence is very hard to collect for infections.
- **Bassem Elhassan:** Bone graft, always use vancomycin
- **Gulotta:** We don't standardize vancomycin.
- **Stephen Parada:** basic science literature – vancomycin is no better than others, specifically for *P. acnes.*
- **Lewis Shi:** antibiotic resistance is rising if all joints are using it.

SESSION III: WORKING DINNER DISCUSSION—Future Directions for the C.S.S. (Moderator: JP Warner)

- **JP Warner:** After the fact, we will email everybody about where we are. I have a few ideas about where we might go in our organization. Let me tell you first about what my intention is. I met, in the last year, with Mohit Bhandari, Michael Porter, and David Shahian, who is an expert in quality and safety in Cardiothoracic surgery, and they all expressed interest to serve on the board of directors if we choose to make this a non-profit organization. If we do make a non-profit organization, there are several things that we have to do: We have to submit a fiscal plan for the organization; We have to have an advisory board, an oversight board, and we have to do things that are meaningful and consistent with our mission. I am open to discussion as well why we want one more organization, and the biggest thing you have is your time, and you are all very busy people. The question is does that add value? And my thought was being at this institution where I have worked for twenty years now where Codman worked, and on Codman's gravestone which the ASES and American College of Surgeons put there after many years following his death was buried in an unmarked grave, and it was because of what he believed. A hundred years later, his gravestone said: "Perhaps one hundred years later, my ideas will be accepted." Now I can tell you, in my twenty years at Mass General Hospital, they have not been and they will not be. The only chance that I have to honor Codman is to create an organization like this, and why do I care? I know why I won't care in the first place, I think we should probably all care about what we believe in. We all try to do what we believe in, I think, but can we do something that may have seem to be a worthy endeavor, but I will leave that all to you. My intention is to move in that direction, and I'll get some legal advice, as is the name is trademarked, my only trademark, it's trademarked under the guide as a think-tank of a group that gets together for educational purposes, and then to do research and advance shoulder surgery. We have the MOON group, we have ASES that are trying to get into this area, one thing that we could potentially do, is to avoid politics that are inherent to a specialty society and the variation of leadership that goes with years. Maybe that's overseeing, but I think that's something that we can do that we're all like-minded. The other thing is it gives an opportunity for all levels of shoulder surgeons to be involved in meaningful things, and I thought that that was a great thing to give back for former fellows and anybody else who would love to – the opportunity to contribute meaningful work when you're not at an academic medical center. And frankly, I think it was Asheesh who told me, we can publish as an organization with names, with five authors or whatever. Me personally, I don't need to be on anything. I'm just interested in meaningful work, so that's how I would like to go – I want all of your input. The fastest, most impactful is if you would like to do it. I'm open to any comments that anyone who wants to make, or you can table it and tell me another time. All of these people I told you about work together, and if we are part of this involvement this can be value-focused. We've got Bhandari, we've got the evidence-medicine based focused, and if we've got David Shahian involved who has written enormous amount of quality who's already got something that changed the face of cardiothoracic surgery in terms of benchmarking. Why not start measuring ourselves? So that was sort of what I wanted to bring up.
- Now, there's a whole bunch of studies that we can think about, and there are two things that I want to make you aware of, one is that Bhandari has an organization called MyOrthoEvidence.com, you can all go to it, but they systematically evaluate Level of Evidence in different areas. They asked me last year if our group would be interested in consulted with and try to benchmark the Levels of Evidence in certain areas. We were just talking about infections and things like that. They were very willing to allow us to look for best evidence outside of Level I, since it's so hard to get to Level I, and in so doing we may do a service by helping to outline where we are. I can tell you that when you look at evidence-based medicine treatment, which was written about in 2003, orthopaedic surgery

didn't make the list. We're just not there in the way we provide evidence. That's potential collaboration that can put a face on our organization and advances care, and I just thought that out to you as one opportunity.

- The next opportunity is an organization called Avant Guard Healthcare. It was created by a gentleman whom I've met at the Harvard Business School when I was taking classes there. Really smart guy. And he created an organization that looks at value analysis of hospitals and groups, etc., and they have access to all sorts of interesting analysis. For example, they looked at Medicare costs for all shoulder arthroplasty at the Mass General Hospital, they looked at the four busiest surgeons who were doing it, and they were able to tell me what my average costs are compared to the other guys. That was really interesting because the hospital said to me that you use the most expensive prosthesis, so we've got to cut you off. The reality was when they looked at 90-day post-acute care hospital care, I was half the cost of the low volume surgeon, we use a different prosthesis. We can drill into why that is, but that's a wonderful organization in terms of keeping us grounded in some of the value in what we do, and that might be the answer for all of us. Anyways, if you wonder how you can make an impact via powerful friends, and I think he gives us tremendous credibility in research publishing, or have some analyses done that get published on Harvard Business Review or something like that, that would really make a difference.
- So those are two opportunities, and so of you out there may have thoughts on either of those opportunities. Anybody has any comments?
- That was just an idea. We talked about inventory management, which I think is something that is probably worthwhile to do. I have no interest into being in one particular company, we use a system that I use, and those who are happy to use that system can be partaking in a multi-centered study, but if somebody uses another system, I don't have a problem with the concept that this works just as well for inventory management. We can do a cost-benefit analysis with our Harvard Business School colleagues, looking at the potential implications of pre-operative planning on the overall cost of care. What does it do? It gives us more over the process we were talking about it. If you make it an argument to the administrators of how much we can save to do this, we obviate some of the control they put over us. And a quote Bernard Morrey who was someone who became a mentor for me, "design processes to get where you want to go, don't just say where you want to go." So this is one way we can carve and leverage into something meaningful with someone who we can collaborate with. And guess what? The insurance companies too. Just want to let you know, that Larry and I have done a demonstration project with the Harvard Business School –we came up with a single bundle rotator cuff repair that built in an increased margin for us because we guaranteed outcomes. And when we took that to the hospital and proposed that to them, they turned us down. The reason they turned us down was because their margins were so high in facility fee. That said, that was also because they didn't want control to leave them, so anything you can do to lower your position you gain more control, publishing about whatever, you can make a big impact. And since then Larry and I have consulted with several hospital chains around the country about how to build bundles, which I think is an important way to keep control. And by the way, Larry Johnson did this twenty years ago, when he and his friends went in Michigan and came up with a guaranteed bundle outcome or arthroscopy with HMO, and the next year he got something like a 30% increase in margin, so it can be done. As we're moving away from fee-for service and others, and if we're going to help our hospitals, maybe we can nudge them in the right direction and help our own case. That's something that we might all agree on for a study idea.
- In addition, I think if we do become a group, we can start to vet different studies and ask if we reach the threshold of what we want to achieve in meaningful ways in evidence and in value. That's one good way to really looking to make a difference. I've been trying to find that difficult balance without spending a long, long time to do it, and that's a tall order in

finding we can find answers to in relatively useful way to make a difference. One thing we talked about last year, for some of you who weren't here, Bhandari was our provocateur and we asked a bunch of questions, including instability treatment, so several guys took their best shot at providing the evidence. Bhandari pointed out that our evidence was really poor, and when we looked at the literature out there in terms of numbers, they were all fragile studies, so the potential to do large studies as a group are things that we do every day that are simple. So we can talk about Bankart or Latarjet or whatever, you get meaningful numbers when you start taking hundreds of cases. Now there is a French multi-centered study group that do what they do, but you know there's national pride, all sorts of other biases, now one thing that Bhandari can do, if we do decide to do these things, is to help us create things is to maximize the elimination of bias before we start. How do we deal with what's going to be criticism in biases before we even start? Which I think would be very useful.

- **Bassem Elhassan:** JP, since we're talking about topics, now there are certain things in orthopedics shoulder surgery, that we used to, when we talk about rotator cuff tear – this is a topic, we have a lot of publications about that rotator cuff tear – repairable or irreparable. Especially with this meeting, the definition of what everything has been published, and the outcome of "irreparable rotator cuff repair" that we're talking about, I'm not sure as a group what we can do because now we are essentially questioning all the publications done in the past. Bhandari said our studies are poor in general. We're talking about definition in our specialty. Rotator cuff is the most common. And up until now, I don't know if there's one thing that we can all decide about to decide what is "irreparable." Yesterday, we had a discussion, and people were talking about "no, this is not irreparable, we're talking about fatty atrophy." I wonder as a group if we can work together and come with a true definition based on science.
- **JP Warner:** So I don't know if you're familiar with the Philip Collin's study where he asked fifteen surgeons how do you determine what's irreparable? 4 of them decided before surgery, 11 decided in surgery, or something like that. So they could even decide how they make the decision – did they have to go to the OR the figure it out, or did they do it with certain criteria. Now things with tall order are worth trying to do, there will always be naysayers but there are strengtheners. I think it would be a great thing to do to come up with the evidence-based consensus statements. We have a board with someone like Bhandari – we can ask them this question and vet it, and Bhandari is an orthopedic surgeon so we can say "fine, this is our dilemma, what do you think? What can we do? How can we get there?" Because he's done a lot of it. So I'm looking for things that we can do that will have impact. Anyone else have any ideas?
- **Asheesh Bedi:** We started a little bit last year at this meeting, we can finally start again with Mohit Bhandari's group. He asked me to speak little bit about Latarjet and evidence of Latarjet – as he pointed out after culminating the literature, even today, the quality of literature, particularly in terms of standards of evidence, almost all of them are Level III and Level IV studies. Even Gilles Walch's long-term follow-up studies are still case series. And Buddy you were here, there was a discussion about mild bone loss case they defined as "mild," there is an opportunity to treat the Bankart plus or minus the Remplissage. Many of the surgeons were polled - even though academic council talk about mild bone loss, 10% glenoid bone loss being treated potentially now more aggressively with the Latarjet, the survey study suggests that most surgeons, particularly the young population, would still treat that arthroscopically. So to that end point, we try to run a trial with Mohit Bhandari, on a study that would look at mild bone loss. So if I find a CT in the so called 10-20% range, the idea being less than 10% wouldn't get surgeon ~ in the North American population that would typically do a primary Latarjet, or the 20% that most would agree would do a bony procedure, and to specifically focus in that group, and randomize patients into a Bankart plus or minus the Remplissage at the discretion of the surgeon, versus a Latarjet procedure, and to

do a true prospective study to really look at recurrent outcomes, and other metrics beyond recurrence of failures and patient-reported outcomes. I do think that's a meritorious study, we're trying to find, even to get a grant support for that from the Canadian Institute of Health, I think it would be potential to do with a group like the Codman Shoulder Society, just to see the power of that, to look at the numbers of that, enrolling somewhere around 75-100 patients in each group.

- **JP Warner:** That's not insurmountable at all. I thought it would be bigger than that.
- **Buddy Savoie:** So could you say – for instance, you and I can do a study, and I can do all Bankart, and you can do all Latarjet? Or do we have to randomize it for surgery?
- **Asheesh Bedi:** Yeah so, we can do it that way, that of course has some in terms of quality of study to be negative, because theoretically the surgeon doing all Latarjets may execute a better technical operation, and the ability bias or technical bias comes in, and here's the question. The best study is while done by a group of capable surgeons, equally poised to do both operations. But if you're unable to achieve it that way, it still would be okay if we're able to at least compare groups – in that case, it would bring the level of evidence down because it's more comparing cohorts than confounded technical expertise for surgeons selection bias. 10-20%, it has to be quantified by a CT with a standardized measure – the perfect circle technique, or best-fit circle technique, whatever we choose to define.
- **Matt Provencher:** How about the on-track, off-track as inclusion or exclusion criteria?
- **Asheesh Bedi:** That could certainly be a reasonable way. I think at the time, this was a year ago, we started to divide. The one challenge about the on-track, off-track is that it still hasn't been totally validated, I think, so it's a mean to at least incorporating the bone size. But we have a preoperative CT, there's no reason that we couldn't do it that way.
- **Neal Chen:** I think it's a good study to do together. It may be worthwhile to set up a study – let's try to define what bone loss is on CT scan, and all of us prospectively determine what to find on the CT scan, and maybe do a survey to try to define bone loss. And then have a second portion to demonstrate the feasibility, and then you can go to NIH and say that you have this study that you want to do this, and if you have enough preliminary evidence to show that we can function as a group, we're more likely to get more funds. You're talking about potentially a very large study that could find funding to support.
- **Asheesh Bedi:** That's totally spot-on. I didn't know that you knew that. Even as part of this grant that we're trying to involve, the first part is like what you said, which is a feasibility study, so you have to demonstrate that everyone in Codman would be able to conduct the study, but it's included in that initial grant, the first twenty-five patients that would then be reviewed that you could standardize. With regards to the input of the study design, I'm happy to circulate what has been articulated to date on that front, and there may be a way to get those numbers to front that's very hard to get in any one institution to answer that question with Level I data.
- **JP Warner:** So maybe as a to-do, you can send something to everybody with all the input on it, start a dialogue, and then maybe get something rolling. Again, my goal is to get everybody invested in something that they are interested in doing so that we can actually do, provide everybody the opportunity to produce something meaningful. There may be resources that come from outside, from inside, I don't know. The theme is we do something meaningful that is worthwhile and not just replicate what we already think we know or don't know.
- **Stephen Parada:** To that end, the measurement system that we came up with that hasn't been published yet that showed for defining glenoid bone loss, it would be an easy way to standardize it. The system that we came up with was to show interobserver and intraobserver reliability.
- **JP Warner:** So I think once we start a dialogue about this we can comment on it, there'll be a bit of back and forth, I encourage everybody to start weighing in on it. I really am hoping that we can do something meaningful that's more than just how we get together and chit chat

every year. Now things may change that will stimulate us, and the way we've done this is that I tried to take advantage of my position at the San Diego Shoulder Institute to get people like Dr. Cofield available to us, which is a wonderful thing. And things may change, but that doesn't mean that we change that we don't our focus, in fact, if we have enough work here, part of this meeting is to review where we are and how we're doing. We create reports about our progress and to invite criticism for the people who are actually coming to the meeting. It would be the real work of Codman. Anyway, I'm going to take executive privilege and say that we're done. Thank you all for staying and have a great rest of the evening.