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Editorial

"In My Experience...the InSpace Balloon

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The author reviews the history of and his experience with the InSpace balloon.

I am going to review my experience with the InSpace Subacromial Balloon Spacer. I will start with a little bit of the background. In 2013, I was in England at a meeting and Assaf Dekel, the inventor of the balloon, was exhibiting. His company was called OrthoSpace. Assaf is an orthopedic surgeon, actually a hip and knee surgeon, and a serial entrepreneur. At the time I first met him, he was in the back corner of the exhibit hall. He had this novel product there and he was like, “Hey, you want to see this thing?” I’m like, “Oh, what is this?” He’s like, “Oh, it’s a balloon. You put it in the shoulder. I’ve done X number of these and these are my videos.” He started showing videos of patients and they’re doing well. And I’m like, “Oh, that’s interesting. It’s a very novel idea. Never seen anything like it.”

I thought to myself, this will never get approved in the USA given our stringent FDA, etc. So, I go on my way and then two years go by. Orthospace was starting to put together an FDA-IDE. At Rothman, we have a pretty robust research arm, and our research director said to me, "Hey, there’s a group here that’s meeting to see if any of us are interested in doing this IDE using OrthoSpace. So I’m like, “Wait a minute.” I go to the meeting and immediately I’m like, “Wow, I can’t believe they’re going to do a trial.” So, I’m like, “This is amazing.” “Yes, I’m definitely interested.” To get training for the study, you had to fly down in July to Orlando to do cadaver training, and do all this stuff to be able to get our site onboarded as far as the FDA-IDE. So, I get trained and the IDE gets started. I put in one of the first IDE balloons. Early on we were also assessing location of the balloon using ultrasound so I had to get trained by an ultrasonographer on how to use ultrasound in the office and assess where the balloon is in the subacromial space.

So it was pretty exciting. It was ground-level real clinical science seeing translational medicine happen. What was exciting was, this was a patient population that is not a patient population that’s a good candidate for a repair and that’s not typically at a point where they need a replacement. So these are tweener patients that come in and you see them and you’re like, “Let’s try an injection.” They say “It’s not really working anymore.” “I don’t want to replace it.” “I’m not bad enough.” So for me, what I’ve been excited about is it created a new avenue of treatment for patients who are in that sort of subjective value score that’s above 50%, but not higher than 70%. So they have this 50 to 70% satisfaction with their shoulder, and not bad enough for a replacement. So all of a sudden, I have this option to treat patients in a way that’s minimally invasive, does not create an implant burden on their shoulder because, this balloon you may or may not know is resorbable. After a period of several months to a year, the balloon disappears.

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Dr. Abboud graduated Summa Cum Laude from St. Joseph’s University and received his medical degree from Georgetown University School of Medicine where he was promoted with “Distinction.” He earned membership in the Alpha Omega Alpha (AOA) Honor Society and graduated with honors in 1998. He went on to residency in orthopaedic surgery at the University of Pennsylvania, and subsequently completed two fellowships there in advanced Shoulder and Elbow surgery and orthopaedic biomechanics. In addition, he has recently completed the general management program at the Harvard Business School.

Dr. Abboud maintains a full clinical practice and an active academic and teaching schedule. He has 20 years of experience in shoulder and elbow surgery. He actively participates in regional, national, and international orthopaedic societies and serves on various national committees in leadership positions. His passion for teaching has been acknowledged by the Sidney Kimmel Medical College at Thomas Jefferson University, Deans Award for Excellence in Education. He has routinely been recognized for excellence in patient care by his peers.

Dr. Abboud performs a wide variety of simple and complex surgical procedures on the shoulder and elbow, including arthroscopic surgery, comprehensive fracture care, as well as shoulder and elbow replacement (arthroplasty) procedures. His goal is to always provide each patient with exceptional personalized care.

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Conflicts of Interest Statement for Dr. Abboud

All of a sudden I was pretty excited about the opportunity to participate in this study. This was a randomized prospective blinded study. The patients would come into the office, they'd have a massive cuff tear that was considered on the cusp of being irreparable. They had to meet the stringent inclusion-exclusion criteria. Then they would sign up for surgery and I would tell them they would undergo surgery and in the OR we would decide if they were to be randomized to a repair or balloon. In the OR, we would randomize them after reassessing everything live with arthroscopy and being sure that they met the inclusion criteria, meaning a two tendon tear, no arthritis, intact subscapularis, and what would classify as a massive cuff tear. Once they met the criteria, an observer for the study would then use a computer that would randomize the patient. Patients were randomized to a repair or a balloon. There was no combination of repair with a balloon.

It took us probably five years to finish the study because we had close to 180 patients to enroll and then we had to get two-year follow-up on all of them. I enrolled the very last patient in the study as well. We collected this data over two years. A very rigorous study. To this day, I say it was the most scientifically rigorous study I've been involved with. In August of 2021, the balloon was approved by the FDA and I did the first FDA-approved balloon in the United States. At this point, I've done 105. I would say close to maybe 50 a year. I've been studying them prospectively, from their demographics, their pre-op PROM, their function, range of motion. I'm trying to follow as many of them out for two years as possible.

I have 5 patients from the IDE that are six years out that are doing very well. It's been very interesting and enlightening because you have this device that at some level makes sense, at some level doesn't. Because I think we as orthopedic surgeons tend to be very concrete. So here we are, putting this balloon in and inflating it to a certain level. You put this balloon in, takes about five minutes, and then they're in a sling for comfort. You see them in the office and get started on therapy. The recovery is reasonably minimalistic. Now, as you know, like anything, like a cortisone shot, patients have variable pain. Some patients you give them a cortisone shot, no reaction. Others go to the emergency room. They've got awful pain. So obviously you have that variability still with a balloon like any other procedure. But if you take my average balloon versus my average cuff repair, their postoperative pain is much less. Their postoperative recovery is much less taxing because I didn't fix anything. I just put a balloon in there to give the remaining muscles around the shoulder a mechanical advantage to do their job. What I would say, when people ask me, "How does this thing work when it dissolves?" I say, "You're taking a decompensated tear and recompensating it." We know lots of patients who have large tears on MRI that have nearly full function, minimal pain, and good strength. That's what you're trying to recreate through this temporary balloon spacer. My experience has been range of motion improves, strength probably mildly, but what really improves a lot is pain.

When I look at my VAS scores, most of my patients who have surgery start with a VAS of six or seven, and they go down to a VAS of about 1.5. And you see the VAS gradually decline and sort of hit its peak of decline at around six months and stay there. Now as I follow my patients at a year out, they're still kind of in that 1.5 range VAS versus pre-op where they were six or seven. Which is, to me, fascinating because I think of all the things it does it improves their quality of life through pain relief. We see that in the American Shoulder and Elbow Society (ASES) score because the ASES outcome score has a big portion for pain. And you see their ASES scores go from somewhere in the forties to typically somewhere in the seventies or eighties. The interesting thing also is I've re-operated on some of these patients who have needed conversion because they didn't do well. I had one patient at six years start to have similar symptoms to their pre-op. I put the balloon in again. And when I've re-operated on them, there's no evidence of the previous balloon. There's no fibrosis. There's no excessive scar tissue. There's no evidence of anything having been there. It's kind of nice you're not dealing with tons of scar burden or post-surgical burden of implants, etc.

That's kind of the beginning of the story. I say now, "Where are we?" I think we've sort of continued to try to understand the mechanism of action and we're trying to further understand and refine the indication. Because like anything else, there's a tendency to abuse things and use them the wrong way. As a shoulder surgeon that does 500-600 surgeries a year, I told you that I only do this 50 times a year. Therefore, it's 10% of my practice. I am considered somebody who has a lot of experience with this so people refer patients to me. So if it's greater than 5% of your practice, you're probably over-indicating it. You're probably using it in the wrong patient. The wrong patient is a patient with significant arthritis, a subscapularis that's torn, or a patient who can't elevate past 85-90 degrees of forward elevation. Those patients are not going to be good candidates for the balloon. Those patients need something else. They're definitely not indicated for the balloon. The other challenging thing is cost. So initially the device was not reimbursed. Now, in a hospital, it's reimbursed by Medicare. And in a HOPD, it's also reimbursed by Medicare through HCPCS code in the range of $14,000 for a hospital and $8,000 for an ASC.

Where are we going with this technology? I think the burden on the device manufacturer is educating the surgeons for the proper indication and making sure we educate our patients preemptively before surgery so they understand how this is going to work, what are the sort of short-term and long-term benefits, and are there any downsides. To be honest, at this point, I haven't seen a significant downside for the patient other than if it doesn't work, it was a waste of time and resource, but it didn't set them back. I have not seen any surgical site morbidity from this. People sometimes talk about balloon migration, which is pretty minimal, but if it does happen, worst-case scenario, you can pop a balloon. It's not like, "Oh my gosh, what are we going to do with the balloon now?" That has not been a big issue. I think the thing we still need to refine is, when do

we use it in conjunction with partial repairs. What does it add to that? Because I can tell you that currently about 35% of the time, as opposed to the initial FDA study, I actually will do a partial repair of some of the cuffs plus add the balloon or sometimes even add the balloon on top of a repair that I think has a high risk of retear. We consider these cuffs at risk, high risk factors for recurrent tearing. Does it help? Does it not help in those situations?

Those are things that are yet to be decided and determined that I think are the next phase of application of this device. People have talked about, should the balloon be more of a permanent structure? Should the balloon have different geometry? Would the next generation of it be either a different structure or you can inject something else in it instead of saline, which is what it's approved for by the FDA now? Do you inject a biologic in it, like PRP or fat or BMAC? What could you add to it that would make it more efficacious longer term? I think those are things that are good questions for the next generation to sort of think about as we come out with a generation 2 balloon.

Going back to the story about the inventor, Assaf Dekel, I said to him one day, "How'd this come about?" He said, "Honestly, I was on the board of a urology company. They were developing a balloon to help with protection from radiation to the prostate. When you're radiating the prostate, they don't want to irradiate the bladder. So, they're using this balloon to protect patients from radiation." He was thinking to himself, where else could you use a balloon structure? I don't know why he came up with the shoulder. But he said to himself, the shoulder's not truly a weight-bearing joint and increasing the space, that acromial humeral interval that narrows when patients have rotator cuff disease, if you could re-expand that space, would that be beneficial?

He talked to some of the board members and the chairman of the board said to him, "That's a really bad idea. I would not do something like that." He actually went and did a bunch of cases in Slovenia and had really good results. Then he came back and reported to the board of this urology company, and they fired him. Then he ended up telling some potential investors in the US who then invested with him. This was a startup from Israel. They start the process, they released it in Europe, they had something like, I think 6,000 - 7,000 cases before the IDE was started in the United States, and then halfway through the IDE, Stryker purchased them for I think $220 million. So that's how Stryker became synonymous with InSpace. So, it's an interesting backstory.

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