US Ankle Replacement: What's New and What's Next?

SmartTRAK discusses the latest trends and future state of ankle replacement in an interview with Steven Haddad, MD, Senior Attending Physician, Illinois Bone and Joint Institute

Lisa Mahan: This is Lisa Mahan with BioMedGPS. I'm pleased to have the opportunity to be speaking with Dr. Steven Haddad to discuss the state of ankle replacement in the United States today. Dr. Haddad is affiliated with the Illinois Bone and Joint Institute in Chicago, and is the current President of The Orthopedic Learning Center in Rosemont Illinois. He is a respected expert on ankle replacement and is a past President of The American Orthopedic Foot and Ankle Society.

Thank you for taking the time to speak with me today, Dr. Haddad. Could you give us a little bit of background on your experience with ankle replacement? When you started first doing that surgery and just give us an overview of where you're at?

Steven Haddad: Thanks Lisa. Yes, I began doing ankle replacements in 1999 on my own. I trained under Mark Myerson in Baltimore and did his first 20 ankle replacements with him back in 1996 when I was his fellow. And then I waited a few years just to sort of see how the technology was evolving and see if I thought it might have some usefulness. And by 1999 prostheses were sort of beginning to roll through the United States. Then more surgeons were adopting it so I flew out to South Dakota, spent some time with Frank Alvine who developed the Agility prosthesis and then took off from there.

So since that time I've done 825 ankle replacements over a variety of increasing and decreasing per year. I became involved with another company, Wright Medical, in about 2008. And have been heavily involved in development of ankle joint prostheses since that time. And I promise to not let my specific experiences taint what I say here today.

Lisa Mahan: What do you think are the big trends right now in ankle replacement? What are you seeing?

Steven Haddad: Well, I think if you look at the implants that are coming out in the market and some of the clinical testing that has been done, I think there's probably four or five separate issues which we continue to try to tackle or work with. One being lower profile implants that have better bone preservation about the ankle joint region as well as we're looking heavily into component wear. We worry about osteolysis or the cysts developing around the ankle joint. It seems to occur

earlier in ankle replacement than that what we see in the hip and the knee, probably about 15% of patients within three years develop it, which is a much higher rate than we see with other implants. So we're certainly working with that in trends.

We're also looking to try to develop a prosthesis that mimics the true center of rotation of the ankle joint. We're trying to make these prostheses a lot more physiologic in that sense and not simply just masses of metal to duplicate where an ankle joint is supposed to be or should have been prior to this. And we're also looking at methods to implant prostheses more accurately and predictably. And most important and more recently we're trying to develop and perfect methods to create revision ankle prostheses since there has been so many ankle replacements throughout the world. We have to now develop ways to revise them when they fail.

Lisa Mahan: And what do you feel are where we are in terms of clinical evidence? Especially related to newer implants that are on the market?

Steven Haddad: I think that in some sense we're better off than we were five years ago with clinical evidence. But in another sense we're still hampered by that specific element of ankle arthroplasty because really if we look at follow-up studies on specific ankle prostheses that are out there on the market today, we have a long way to go. Most of the current prostheses that are being used heavier today have only really been around for about two to four years and one has been available for 10 years and there's a few out there as well that are over that timeframe but if we look at long term clinical data, it's really hard to garner meaningful results at a two to four-year follow-up on these patients.

We don't have the conditional long-term clinical data that the hip and the knee surgeons have and most of our studies thus are done more in the basic science world with wear testing, done in a laboratory setting rather than clinical follow-up. We do have, for the current implants, a variety of short term follow-ups of perhaps two years or 2.5 years on average. This doesn't really give us any meaningful data for long term survivability on the current generation of implants.

Lisa Mahan: Even though there doesn't seem to be a lot of long term clinical evidence in patients, the number of ankle replacement surgeries seems to have been growing dramatically over the last several years. I know it's a niche market but BioMedGPS is projecting the market's likely to double in the next five years. What do you think is driving growth in this procedure? What types of things do you think is limiting growth?

Steven Haddad: Another great question. Especially how you phrase it will a lack of clinical evidence. If you look at, what I think is really is driving the growth is two things. The first being patient awareness. The patients out there are certainly having an interest now in noting that ankle replacements are available. There's a variety of social media outlets which suggest great outcomes with ankle replacement even though these are individual stories or more anecdotal. Patients are aware now this technology is out there and they don't want their ankles fused anymore. They worry about how it might affect their back or hip or knee in the future and hindrance of any potential or healthy lifestyle activities that they're performing. Certainly that's one.

The second believe it or not is surgeon awareness because basically now surgeons are understanding the better survivability in ankle joint implants and even more facile methods of how to implant them. Most surgeons who do a lot of ankle replacements have been doing a lot of them for years. That number changes somewhat or has some change in variability here with the statistics you're speaking of.

But really it's the numbers to escalate the levels you're talking about, have to come from growth of surgeons who may have been afraid to do ankle joint replacements before or really didn't think they could accomplish it technically or predictably. Now they are starting to do so as they see newer joint implantation methods and survivability of prostheses becoming more out there in the literature in some sense. That they begin to gain some confidence then starting to generate prostheses being implanted in the US.

Basically I think that's where the numbers are going to escalate are surgeons adopting this technology who had not adopted it before.

Lisa Mahan: You talked about surgeon awareness and how believe or not that can be an issue. How are they finding out about it?

Steven Haddad: I think a lot of surgeons find out about it the same, similar ways that you might guess through research articles in journals they might read and also more so through patient inquiry. Patients come in and say, "Hey, do you do this? Do you know about it?" That might scintillate some interest in them attending courses. There are certainly a variety of corporate courses out there at how to put in different ankle replacements. They might ask colleagues as to what they might use and also they have noticed a lot attention in our national meetings to ankle replacement papers and symposia.

I think that's where they're starting to understand the way it is growing. A lot of it is generated more so in the foot and ankle rather than the joint replacement

world but I do think that even joint replacement surgeons are gaining an awareness for it. Most of them were around in 1970s when prostheses had a least a 50 to 60% failure rate at two years. And they were discouraged by that and decided that may not be the best method to treat these patients and reverted back to fusion.

As this changes, as they start to see that patients are inquiring more and more about it, I think that's what is really generating their interest in going to these courses and understanding how to put these things in better.

Lisa Mahan: You see that shift of patients asking for specific procedures but also patients looking at where they have the surgery. If you look at procedures moving from an inpatient to an ASC or outpatient setting. Do you see that happening with ankle replacement? And what factors have had the greatest influence on that move?

Steven Haddad: If we look at outpatient centers or ASCs performing these procedures, that's certainly is happening both at a local level here in Chicago as well as nationally. I think that doing the simpler ankle replacements, those without significant deformity or those not requiring multiple simultaneous procedures, we're certainly heading that way towards outpatients because like you might guess, the real advantage is cost reduction. The lower infection risk of hospital acquired infections, those are driving factors.

But there are disadvantages to doing these procedures in outpatient setting. Basically, we worry about the critical follow-up of arthroplasties in that early postoperative phase if you send a patient out as an outpatient. For example, what we do here is we institute a physical therapy protocol beginning at about two days postsurgical working with compression wraps to decrease edema. Showing not only a decrease in wound complications by two thirds, but also promoting early range of motion which is critical to long term outcome in ankle replacement flexibility.

I think that if we are driving more towards an outpatient setting, I think a surgeon has to have a program not necessarily like mine but similar to it so that these patients aren't well, we'll do the surgery, you'll go outpatient, we'll see you back in 10 days, take out your sutures and see how you're doing. You have to make sure that these patients have a very proactive recovery in an earlier phase.

Another risk factor with doing these outpatients comes from the fact that about a third of the patients that we see with ankle arthritis have at least 10 degrees of deformity in their ankle joint at the time they present to the surgeon. These

patient require multiple additional procedures to balance the foot appropriately beneath that new ankle replacement. It's critical to have this pedestal to put the replacement upon. As you can imagine, if you increase the number of incisions and procedures done simultaneous, that also increases the risk that might tip the scales to make outpatient surgery in that case more risky than that done in an inpatient setting. When you can follow these patients for a couple of days in the hospital, make sure their pain is under control and make sure there's no trouble with their incisions and that short term element of those first few days.

I don't think that every ankle replacement's going to become outpatient or done in an ASC. I think that certainly there will be a percentage of them doing so. Probably initially the more simple ankle replacements but we'll have to see how technology evolves with managing these patients outpatient to see how those numbers will increase in future years.

Lisa Mahan: Are you seeing any change in the number of patients that are likely candidates for ankle replacement? Is there growth in the actual patient population or potential population? Do you see any changes in that?

Steven Haddad: Sure. I think there's a dramatic increase like you recognize in ankle replacements. Not only in the US market but also worldwide. It's really hard to predict the specific growth rate because we don't really have the surgeon's access to a lot of that data. If you look at, like I said before, surgeon interest as a guide, it clearly is growing exponentially. Our national meetings, like I said before, we used to have five years ago maybe a few papers or one session on ankle replacement. The room would rarely be attended and now we have three to four sessions of moderator ships and symposia and then on top of this multiple papers. The room becomes full.

If you look at my practice, it's significant growth but I guess you have to realize I'm a little different in many ways and a lot of the foot and ankle surgeons. I no longer do forefoot surgery. I stopped doing that about eight years ago and my practice really is focused on complex deformity correction and ankle arthroplasty. Because I spend a fair amount of time thinking about this and taking on these more challenging cases, my personal referral basis is really more national. A lot of orthopedic surgeons that may not feel comfortable doing these more complicated procedures.

If you look at my growth it's probably quadrupled over the past five years but again, it's a unique subset of patients that are driving that growth with respect to the more complicated aspects of arthroplasty.

Lisa Mahan: What do think are some of the issues that still need to be resolved with the ankle replacement procedure? What are some opportunities for advancement?

Steven Haddad: Well there's a lot of opportunities for advancement still as we see today because I think despite the fact we'll see a lot of these newer technologies out here, we still I think do have a long way to go. I think that opportunity is really come about through a couple of methods that are out there today. If you look at that sequentially, the first would be advancement in patient specific instrumentation, making it certain that we can implant these prostheses more predictable.

This is really not only fostering advancement on an individual level, of patients getting better outcomes because of the placement of the implant but also makes it further advancement with respect to surgeons exploring more challenging corrections because of it. That in and of itself is a major advancement.

Certainly there's other elements too and a lot of that comes down to revision ankle arthroplasty and where we are with this and trying to make sure that if you do have the confidence doing the arthroplasty in the first place, you have the confidence that if it fails, you can certainly do another operation to fix it. In the past we had a default to arthrodesis in those cases where we might stick a big allograft femoral head in that region and make up for this failed arthroplasty and the structural defects.

That led to about a 40 to 50% failure rate with graft collapse and subsidence and failure of these fusion attempts and so we need to have other elements and advancement in revising them to actual ankle replacements. That's really a critical element here. And that also would help these surgeons to gain confidence that during the index operations and the sort of the end stage for these patients, their next stage might be either a complex fusion or a below knee amputation.

Lisa Mahan: You mentioned the patient specific instrumentation. How much has that penetrated the ankle replacement? How do you see that being used now versus in five to 10 years?

Steven Haddad: Some of that data would be hampered. There's really only one company out there now that has true patient specific instrumentation. That company probably garners about I would imagine or I've been told, about 60% of US and international market in ankle replacement. I don't think all that penetration is coming from PSI itself. I think though a large percentage of it is with that confidence in the utilization of that technique. I think that's an isolated

example. I really feel that more and more companies now are trying to figure out different ways to utilize PSI and if they do that will become more so the dominant method that all companies use to implant the prosthesis.

Before you make that statement, you have to recognize that we really have a long way to go in PSI. Even the techniques that are out here today have some challenges with predictably handling complex ankle deformity with arthritis. There's just so many variables and adjustment to the foot and alignment of the foot afterwards that simply just putting in a prosthesis parallel to what is the predicted joint line doesn't really accurately reflect how we have to correct these complex deformities.

This is where PSI can be a dangerous element because a surgeon might say, "Well listen, I went through, I did the technique. I worked with the engineer. He showed me where the implant should go." And then they go ahead and they put it in and suddenly they note significant instability below the implant or significant deformity which wasn't really predicted. And they really know how to take care of that.

PSI can also be sort of a false security blanket for surgeons in the sense that they feel that it might make it easier to put in the implant but they really have to recognize in advance all of the other issues going on with putting in this prothesis before they feel that that's going to be the ultimate answer. I think that if that game is going to be played, the surgeon has to be involved in the planning with the engineer. Make sure that everyone understands where this implant should go and also what other procedures are required simultaneous.

As it stands today, it really does have a significant market penetration and certainly has the potential to become an even broader penetration of the market in the future if not doubling what it is now. But again, I say that with caution having used the technology fairly extensively. That you have to be careful with it. It's not the panacea as of yet what we predict it might be in the future.

Lisa Mahan: You talk about the opportunity for improvement with PSI technology or any technology and we've talked about the new implants that are on the market now. Do you feel that these next generation ankles are major improvement over previous versions? Why do you feel that is? And what kind of issues have they addressed over previous versions of these implants?

Steven Haddad: It's interesting, I think that I'm not really certain whether this so called next generation of implants coming in the next five years or whatever will be that much different from the current batch of implants that we have manufactured

over the past four years. I think that the generation of implants that we have now, these so called lower profile prostheses are all really starting to look alike in many ways. It's almost like the hips and the knees where they begin to look very similar even though different companies have manufactured them.

Low profile implants also are now starting to look very similar to each other and implantation methods, other than the patient specific instrumentation we talked about a minute ago, have also become very similar. We talk about is there is next generation implant? And can you preserve more bone as part of it? But when you think about it you really have to have a polyethylene or a plastic that is thick enough to limit wear rates. Because of that, you might be talking about in this next generation coming out, maybe a millimeter or two less bone resection from what we have now.

That really becomes more a marketing issue than a physiologic issue and really has to be seen as that. The patient might see that and say, "Wow, I've got this implant. It takes three millimeters less bone than brand X." But in the end that probably makes no difference when we look about subsidence or failure of these implants ultimately where many millimeters of bone are lost as these implants sink into the bone.

I'd be cautious about thinking that implants coming out in the next two to three years are that dramatically different. They certainly might have better fixation methods which would help with new technologies in metal, bone interface. That can certainly be something. But the design themselves, I just can't see it being that revolutionary given what we know about now about the current generation of implants which are already excellent the last couple of years that have come out with low profile stability.

Lisa Mahan: One of the things that's gained a lot of attention in obviously the hip and knee space of robotic assisted surgery. Do you ever see that moving into the ankle replacement arena? And why or why not?

Steven Haddad: Well I did think that back when I started in replacement back in the early 2000s when I had got my numbers going. I really came up to a number of these robotic assisted companies. This is before PSI was out there and I said, "Listen, this technology's big. It's going to be big and I'd like to work to develop methods for robotic assisted surgery." And basically just was a bunch of dead air coming back. They really weren't interested. They said, "Listen, you might be thinking you're a big deal or the numbers are big but you're talking 5,000 protheses where we're instrumenting 600,000 hips and knees a year." It became almost a financial issue for a company that it wasn't profitable for them to get involved in that technology.

Robotics is interesting. The companies certainly know they have to have a certain number to make it financially viable for them and they might be waiting for that number to occur. And the robotics themselves may not really offer a huge advantage over PSI but there might be other elements that we're not even thinking about where robotic assisted surgery could have value.

Lisa Mahan: When we talked about robotics, we talked about PSI, what do you think? Are there any biological repairs that you've seen that are being developed that might take over? Will there always be a need for metal implants? What do you see down the horizon for ankle replacement or patients that are potential candidates?

Steven Haddad: That's interesting. Obviously we all hope that's the ultimate answer is biology but if we look at where we stand today, we're really not even close. Right now we have a lot of hocus pocus out there without any real critical data supporting it. The patients come in after reading stories in the newspaper and think that these techniques might be possible but really we haven't figured out a way to generate cartilage on a broad scale and make it stick to bone for these large defects.

I think that biology certainly is going to be an answer at some point. Cartilage generation for massive levels. But I do think there's really always going to be a need for metal implants. It's almost like what we know with the hip and the knee which have been around for over 50 years in higher volume. I think a society that doesn't need those implants is something that you might see in a current sci-fi movie which is very cool but I'm not certain it's feasible within at least my lifetime.

Granted if you look at a 100 years from now, sure. That might be the way we treat it. But for at least the foreseeable future I think metal is still going to be on some level what we're replacing these arthritic ankles with.

Lisa Mahan: If there was one thing that you could put on your wish list as a surgeon for an improvement, what would that be?

Steven Haddad: Certainly some things that I do today if not a lot of things I do today might really appear archaic and pedestrian to the generation of surgeons 20 years from now. Really I'm jealous of that generation for I'd really love to be there working when some of these difficulties that I currently experience are solved and solved with ease. I think if you look what the future may hold, it'll probably be some sort of a low friction implant without wear characteristics which will more than likely take materials or metals that we're not currently using in ankle arthroplasty.

That would be the pipe dream. Some kind of Teflon or something out there that is more just an inserted disc spacer that relieves pain without sacrificing any bone. That really simulates cartilage or perhaps regrowth of cartilage themselves. If you look at that and I think about this a lot. Obviously being involved in development. This country it's hard to do that and I'm not being negative on the FDA because I do they provide a lot of appropriate protections but it becomes fairly onerous to try to have these revolutionary technologies.

If we look at newer metals or plastics required to achieve this type of evolution, they require these long term studies that cost these companies millions of dollars to garner the patient numbers that regulatory agencies consider acceptable. They take years to complete. There won't be any quick revolutionary product out on the market for it would really have to undergo significant testing. These different metals or low friction that I'm talking about are probably years away just in the fact that we have to go through the processes to make sure they're safe for patients which I fully support but some of these regulations make it difficult even for things that have been proven safe to get out on the market.

Biologics are probably the ultimate answer like you've suggested. Generating cartilage predictable and durable to last in the body. That would be the mainstay but if I look at it, something foreseeable that is possible that I could see as this major impact, I really think it's probably nothing that we have out there today. I think it's something that's going to be coming out probably in the next 20 years, hopefully sooner, that is made of different metals than we're using now, that is low friction, has no wear, provides pain relief and doesn't sacrifice bone. That's is what every company would love to have and no company has. I think it's going to require a lot of diligence not only on the engineering part but perhaps some willingness to invest the capital for this kind of a long term solution to ankle arthritis.

Lisa Mahan: So what's next for you?

Steven Haddad: For me? I love that question because I as you might guess by this conversation, I think about ankle replacement literally 22 out of 24 hours a day. When I'm sleeping I'll think about ideas with it because the cases that I take on these days are so difficult with, and I'm not bragging about that, I'm just being honest. They're these sad stories of patients that just have had either failures of implants that have been done or bad deformities and so I'll spend a lot of time trying to figure how to correct these problems. We certainly have a newer generation of revision implants out there now that are much more capable of doing these revision surgeries than they were in the past.

I think I've kind of been pigeonholed now to try to figure out how to predictably do these complex surgeries with massive bone loss and convert them to arthroplasty rather than arthrodesis which gives patients better satisfaction and surprisingly a quicker recovery. If I can figure out, if we can figure out ways to do this predictably, these complex deformities and these revision situations with bone loss then I would consider my career worthwhile on some level because then making a contribution to the future of arthroplasty. That's really where I'm focused a lot of my efforts now.

As a sideline I'm also working on methods to perform bone fixation with plates and things like that. I'm doing some patented material there I've done and also for me I'm trying to figure out metallurgy so that I can understand better potentially what I talked about at the very end of this conversation, how to make something truly revolutionary or low friction, low profile, that is different than anything that we see today. That's where I am. I'm spending the rest of my career working on that stuff. That's what I want to see done.