

Editorial

“In My Experience...A New Age of X-ray-based Patient Specific Instrumentation”

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Keywords: Total knee arthroplasty, Total knee replacement, Patient Specific Instrumentation

<https://doi.org/10.60118/001c.122985>

Journal of Orthopaedic Experience & Innovation

Vol. 5, Issue 2, 2024

The author writes about his experience with modern Patient Specific Instrumentation.

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Patient Specific Instrumentation (PSI) is not new. It's been around for 20 years or more even, and there's been several iterations of what this initially was intended for. I was an early adopter, not on a global scale in my practice, but I would use it in those situations where there may be a femoral nail in place or a tibial nail and I didn't want to take it out. But my experience was a little bit tainted, in the sense that I didn't feel as if it added enough for the effort of getting the CT scan, of waiting for the blocks to arrive, and we still needed all of the other instrumentation because it really only told us where to put the pins. So, in other words, all the 5- and 4-in-1 blocks needed to be there. And all the instruments still existed, so the number of pins really wasn't diminished because of this technology and it really didn't speed things up all that much. So for those reasons, to be a situation where this would be adopted for every single knee, primary knee, in my practice, probably this is why it never happened, at least in my mind. You look at the overall adoption rate, it never did become what everyone

thought it might be. And that probably was the reason, or at least certainly some of the reasons.

In addition to that, as things evolved even more with insurance companies denying the CT scan, because there was not 100% certainty that it brought value to the operation. And so when that happens, insurance companies started denying the CT scan. And so now you have to do a peer-to-peer just to get the CT scan ordered. In other words, each and every case was painful and what happens is human behavior, you're just going to quit doing it. In other words, you put a bunch of roadblocks up and surgeons are going to react, and if it's not efficient you're not going to use it. And that over the last three to five years, I would say, has really changed and really diminished the chances for generation 1, 2 of standard PSI to ever take hold in knee replacement surgery going forward.

With that being the case, that there's also then a switch from a lot of the primary knee replacements now being done in a surgery center, and priorities to a surgery center

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are efficiency, reprocessing is difficult they don't have this huge master reprocessing capabilities like we have in our hospitals. And so, to take all of these instruments, two or three trays of instruments, several trays, and to reprocess those each and every case became very burdensome and costly. One of the priorities for surgery centers is to have their reprocessing fees reduced.

I just started thinking, I'm like, I like the concept but the original again just only told us where to put the pins. And we still needed all of the other instrumentation to be opened and up on the table for the most part. And so, how can we accomplish getting rid of those two things? So, in other words, improve our reprocessing and the efficiency and improve the utilization of what we're trying to get done.

One of my goals over the last many years was to make all five of the cuts with a given block. Leo Whiteside, back with ProFix, 25 years ago had this, and it was very efficient and very accurate. All the cuts were linked. And so I started thinking what if we had (a) the ability to make a 3D printed block based on just x-ray, not CT, so we didn't have to fight insurance companies every step of the way; and what if we can make all five of the cuts with one block. So then the picture would look like this: you go in and see your patient that had an x-ray taken in your office, you're showing them on the computer screen, you're reviewing their exam, you're talking to them about the operation, they elect to have the operation, you walk out of the room with the surgery form filled out, and your nurse clicks a button, a single button, and it gets pushed to the company that will make a 3D printed block based on two-dimensional digital x-rays. Three weeks later that block shows up and you open the knee, you put the block on the patient, pin it down, make all five cuts, throw the block away, move on with the procedure and perhaps the tibial cut as well.

And so if you can imagine then, zero time lost for the surgeon. If you're working at a surgery center, all those instruments that typically are reprocessed do not need to be open now because you're making all five cuts with this block. So, the trials could be disposable. The four-in-one blocks are all gone. The rod and the distal femoral cutting apparatus, gone. The sizing apparatus, gone. So not only are you more efficient with your surgery, in other words, it improves time, improves potentially accuracy, but it doesn't need to be more accurate, it just needs to be as accurate. And so to save with reprocessing, save with time, and not add any more burdensome roadblocks for the surgeon to tackle in the process of getting this done, this was my vision. And until we had the ability to do it with a regular x-ray versus a CT scan, none of this is possible, because when you hit the roadblock of having to call the insurance company just to get a CT scan approved, surgeons are going to stop.

Secondly, the counterpoint to that may be, "Well, why don't you just tell them, go ahead and pay for it. Create a \$300 charge for them to come in and just do the technical component but only with a CT scan and just charge the patient." Yeah, there's going to be a lot that would just say, "Yes, for sure, I want it, I want it." But there's going to be

another faction that's all of a sudden, now you have to talk to son, daughter, "Would you do it? Was it worth it? Would you pay \$300?" "I don't know. Let me call you. Can I call you? Can my son call you?" And all of a sudden what do you do after that happens? Human nature says, "I won't do it anymore." And all of a sudden it's gone.

With the X-ray, where you don't have to change any behavior to make this happen, this is why I think this has a possibility. And it does not add cost. In other words, whether this has tech with a cost or tech that's built into the implant, it shouldn't add tons and tons of cost.

And again, I certainly have the utmost respect for any robotic surgery that's being done and I know there are colleagues that embrace it and it's growing in its nature and I certainly am supportive of their opinions and their choices. But to me, there's going to be, and there already are roadblocks being placed for the CT scan for the robotic surgery. So that's another thing that's going to get in the road of robotic surgery having adoption rate perhaps to what they think it's going to be unless that is tackled.

So, these are the main goals that we have with x-ray-based PSI. It is to be able to create our garden variety, primary knee replacement surgery being done anywhere. It's more efficient anywhere with regards to reprocessing time, perhaps accuracy, and without creating hassle, and without creating a lot of cost to the actual operation itself.

Production of these blocks is interesting. They are 3D printed. There is an algorithm that is done with the surgeon's preference with regards to your distal femoral cut angle and your slope within the tibia, on the tibial side. The size is chosen. And once that has all been completed, then it is pushed to a 3D printer and the block is made. Again, within three weeks we're able to do it. Right now, this technology is only available with United Orthopedics.

We're in our first 50 cases, just to tell you exactly where we stand. And I can say that the beautiful thing about patient-specific instrumentation is that the next case potentially is going to be better than the last case. So you're able to exponentially speed the process of getting down to what is necessary, what works, what doesn't work, and that's why I love that part of it.

I mean, if you think about the major companies, they come out with a new system probably every 15-20 years, right? Now there were iterations, but the iterations come ever so slowly when it's metal blocks and there's thousands of sets that have to be changed, updated if a change needs to happen. So with this, the beautiful thing is that the next case can be better. It can be different. And that's what I have really, really enjoyed.

So literally, in the last six weeks, the changes that we made are light years ahead. The other users on this team, just this week, we've had a huge breakthrough of keeping the block super stable while the cuts are made. I'm using literally cementless femur on these cuts with the same tolerances and the same fit and feel as the block is put on. The x-rays you would never know. There's no lucent lines or cuts that are off or anything like that. We had a little bit of that early on and we had some that we had to abandon. We initially made the cuts, in other words, we scored the bone,

took the block off, and then went with standard instrumentation to ascertain that this was absolutely dead on. And that is what gave us the confidence to then go on and say, "Hey, I think we're there." And then went ahead and then completed the operations, and then look at the x-rays and the feel and the fit of it, not having to violate the femoral canal. I mean, it's a small thing, but it's something we all try to avoid. My last quotes to the company and to the other

users was I think we're extremely close and to having this to the point where we could offer this to the world.

Submitted: August 26, 2024 EST, Accepted: August 26, 2024 EST



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