Surgical Staplers: Kirk Reichard, MD

Intro

So my name is Kirk Reichard. I'm a pediatric surgeon here at Nemours in Wilmington. I am also the surgical director of our operating room. And amongst my responsibilities there is I oversee the value analysis team for new products. And I also am Surgical Director of our bariatric program where we use a lot of innovative stapling devices.

Why do you use a surgical stapler?

Surgical staplers allow us to do a lot more with the laparoscope. So they're very tiny incisions. You know, when I first trained when we made big incisions, a lot of our surgery was done with hand cutting and sewing. That's by and large, impractical, if not impossible, with the laparoscope. And so it's really helped us to minimize the incisions and the amount of time. It certainly takes less time to do the same work with a stapler than it does by hand sewing. And there's some evidence that it may actually be safer. And I think over time the stapling devices have become really engineered to the point where they're far safer than anything that we would do by hand.

How do you utilize a surgical stapler in bariatric surgery?

So in bariatric surgery, everything we do currently involves rearranging the intestine somehow. And when you do that, you have to not only cut the intestine, but you have to seal it back up. And you have to do so, so that that seal doesn't leak because that can make patients very sick and even kill them. So the two most common bariatric procedures right now are the gastric bypass, which I think most people think about when they think, when they hear that. And it involves several steps that require us to decrease the size of the stomach. We use a stapler for that. And then we have to create a bypass so that we bypass part of the intestine. And all of those connections, which we call anastomoses, are facilitated greatly by having various kinds of staplers and there are different designs. And then the sleeve gastrectomy, which is what we do here and is the most common bariatric procedure now involves removing literally three-quarters of the stomach with the longest staple line that exists in surgery. And again, a leak there is devastating. And so we have to have a very high degree of certainty of that staple line, and that tends to be much more reliable than hands-on techniques. And takes probably a quarter of the time.

Compare circular vs. linear staplers.

Circular versus linear staplers. So probably a 100 years ago and I don't think I have it my office, but the old style surgeons used to use a little, almost looks like a spool on a sewing machine. And they would take two pieces of intestine, literally clamp it together with a metal ring. And over time the tissue in-between, would necrose- would die- and seal, and that's how and then the patient would pass that ring out in their stool. Forward 20 to 30 years, we began developing better suturing techniques. And so that was by and large, supplanted by hand suturing. Probably in the 70s, I think, maybe a little earlier was when people first started talking about using staplers instead of suture. And we used wire suture at the time. So it wasn't a big leap. And I can't say when the very first ones came out. I began training in 1988 and we were already using sort of the more rudimentary types of staplers at the time. Many of them would be able to put a suture, a staple line on the tissue, but wouldn't cut the tissue. The next generation would both put a staple line and cut the tissue. Then we added more staple lines. And now we've gotten to the point where instead of it being a manual technique which leads to some variability and problems with the staple line. It's, most of them are now powered with battery power and the speed is very well set and leads to an extremely reliable staple line. So the circular stapler really recapitulated the spool that I talked about a 100 years ago. But now it allows us again to create a circular staple line that works for the colon and rectum. It works well for the gastric bypass. And literally it just pulls the two pieces of tissue together,

fires two or three rows of circular staples and then cuts it. And that is a very commonly used stapler. Now we even have a powered version of that.

Firing staplers has always been a little bit of a guessing game. In the past. The sounds and the feels were not really clear, so you never really knew whether you had a good staple line until it was too late. Much of that has now been engineered out of the newer products so that really all of this is automated and the surgeon really just needs to be sure that everything's in place, pulls the trigger, and everything else is done. So that's, you know, that's the evolution. The linear staplers, so-called, just do the same thing that the circular stapler does, but it does it in a straight line. That's for example, how I remove a lot of stomach and a sleeve gastrectomy. Many of the small intestinal anastomoses we do, we use a technique called a functional end-to-end, where actually they're side-to-side. And that linear stapler does a nice job. It creates a little bit of a bigger opening so that there's no problems with scarring. So that's the essentially the difference between the two.

When or why would you choose a powered or non-powered stapler?

When staplers were first designed, it was very manual. The linear staplers you used to literally have to squeeze with your thumbs and the better your hand strength was, the better you were at that. You know, people that had arthritic conditions or had other issues really couldn't use the stapler. And as we began to use the laparoscopic staplers, now you're adding 30 centimeters of really disadvantaged length. And so the amount of manual force that it required got to the point where as we began to develop 45 and 60 centimeter long staples, it was just impossible to provide that much force no matter how strong you were. So that's when we began to think about powering staplers. Some of the early techniques there were to have three fires. So you had a mechanism to kind of divide it up. But the other thing that became very clear early on in the lab- and I've worked a lot with Ethicon over the years and actually had a good relationship with one of their product developers who developed their powered stapler- was that he found that there was an optimal speed at which the staples are fired and the knife goes across at the same time. And if you exceed that speed, then the staple line begins to lose its safety. So if the tissue is cut before the staple complete the forms, that staple won't completely form. And they would teach it and teach it and teach it and say, you know, I gotta go slow. And then I give it to a resident- pfft. So usually you get away with it. But I think probably when I first went with him- had to be in the early 2000s- and that's when they began to develop what's now called the Echelon stapler, which is the Cadillac of their product line and we use that. So I would say that in 2021, I use a powered stapler whenever it's available. The staplers that we use for open surgery, because we do a lot less open surgery now, I'm not aware of any that come as powered staplers. There may be a few out there. But almost all of the laparoscopic staplers have now been supplanted with a powered version. Ethicon just updated their powered version one this year. So you can, you can hear how the motor's running and you can know that, what speed it's running, you can know when it's hitting thicker tissue. They've done a lot of work in staple length, which turns out to be enormously important, although it's not intuitive. It's actually probably better to have too long of a staple than too short. But within limits. The Ethicon device closes to a standard length based on pressure. The Covidien version does something slightly different, but either way, there's the staple length needs to be tailored to the thickness of the tissue. And there have been a lot of advances recently, particularly with our sleeve gastrectomy. I met with the National Product Development Team with Ethicon just a couple of weeks ago talking about some of their new ones. And it's hard technology to keep up with. Most of my colleagues weren't aware of that. Honestly, some of the some of the product reps weren't even completely up to speed on that. So they continually change and continually improve. So now the staple lines are- I really don't even worry about them.

What is the process of setting up a surgical stapler?

The staplers now are very intuitive. So they come in a packet. I'll take, for example, the Echelon Ethicon stapler, which is probably the most technically savvy one that we use, comes with its own little battery

pack. You don't have to recharge it. It lasts for, I think at least eight or 10 fires before you have to switch, which certainly lasts through an operation. You take that out, you put that together. They do not come with the staple cartridges anymore- they used to. And so now we have the staple cartridge array and we choose the one we want. The staple cartridge fits in very securely. You can tell by the click that it's in. It's very hard not to do that correctly. And at that point, the stapler's ready for use. If you're going to put a staple line reinforcement, that's added very quickly. Ethicon's design was really pretty ingenious, I thought. We used to have to slide little sleeves on and there were laces holding it together. And if the tech put the laces on the wrong side, that was a disaster. If you forget to pull the string before- there were so many steps. Now it's very simple- it comes on a cartridge, stuck to the cartridge. It's sticky on the other side. You clamp it. It automatically comes off the cartridge. It's very foolproof. So I think that was a really ingenious improvement in a product. And so it's pretty intuitive. And now it takes our good techs probably 20 to 30 seconds between firings to get the staple ready to go again.

What happens to the stapler after surgery?

They throw it in the bin. It's all disposable. The battery's disposable. There are companies that reprocess. We don't use that service for a variety of reasons. But it's completely disposable. And because it has a sharp- you typically dispose in a sharps bin. And I assume the battery gets put someplace where it's safe to recycle a battery? I hope so.

What factors influence seal integrity?

There's a lot of debate about that. The way the staples are formed, as they come down, they form into sort of- not an S, it's almost a W. And that, I'm told by the engineers, is very important. We also believe that the number of staple rows has become quite important. So now routinely if we're going to do vascularized tissue stapling, we'll typically use three rows of staples, and I will always choose that device if I can. And you can actually visually see the staple line once it's done and you can look for defects. And if there are no defects in the staple line, you can be pretty confident that it has good integrity. There have been dissolvable reinforcing meshes that had been developed. Gore right down the road, had one of the early ones, and now Ethicon has actually developed their own. We use those routinely in bariatric surgery where I do the gastric sleeve- it helps mainly with stopping bleeding. So hemostasis and bruising and hematomas that occur in the staple line. Because we do know that if there's a blood clot in the staple line, the body pretty routinely dissolves it at five to seven days and that's probably where we see most of the leaks nowadays. It's not an initial failure of the stapler, it's a failure in hemostasis. So that's an important thing and staple length has to do with that. Number of rows of staples. And then we think this reinforcing device- Many of us believe that that's important. Not everybody, but there's some pretty good data on that.

When do you know if there is a problem with the device or staple?

Well, the answer used to be you didn't know until there was a complication, and the complications are often devastating. So I think a lot of the improvements recently have come around, sort of real-time feedback. To the point where staplers just won't misfire by and large. I can remember a terrifying time as a resident 30 years ago where we had one of the very old linear kind of staplers. It would staple but it wouldn't cut. And we were taking a lung out, so we were in the big pulmonary artery that leads to the heart. We fired it. Fired the way we expected. We cut it, and it hadn't stapled, and that did not go well. So that- it is so critical to have that feedback. In that case, we found out almost immediately, and it was too late. But a lot of the improvements that we've been asking for are around that failsafe mechanism. It won't fire if the tissue's too thick or too thin for what you've put in. It won't fire if it's already been partially fired. So we try not to find out the hard way from a complication, and I think we're getting much better at that.

What are your preferred features of a stapler?

The most important part is the powered part that we talked about because I think it really standardizes how you do your staple line. We actually have a little chart on the wall now so I know which color of staple insert to choose. Ethicon, for example, has at least six or seven different colors. The frustrating part is that the colors mean something different in their endoscopic powered than it does in some of their other ones. We've brought that up to them and they're working on that. Many of the staplers now have the ability to articulate, which means that instead of being, having to be completely tangent to what you're doing, you can articulate- it would be nice if they articulated more, but again, you know, the mechanics of it are that you can't really articulate more than you do. So that's an important component. Not all staplers do that. But most of the time I will choose an articulating stapler if I can, so the staple line is anatomically more correct. And then I think that the fact that while the device does make noise, but they have tried to standardize the noise that you hear so that once you've used it a few times, you're used to what it should sound like, and if it doesn't sound like that, you know there's an issue. And you can usually solve the issue before there's a problem with it. So those are some of my favorite parts of it. Many of the staplers now are very easy for our Surgical Technologist to use. And just with a few times, and they're pretty foolproof. There's a lot of safety mechanisms- so you can't fire a second time. A lot of different safety mechanisms.

What challenges have you encountered with surgical staplers?

So some of the challenges, as I said, sometimes we like more articulation than we can possibly get. I would say one of the other real challenges- and I just talked about being able to choose a variety of different staple lengths- the problem is it's hard to know prospectively how thick that tissue is going to be when you crush it. It's a little bit easier with a piece of intestine because it doesn't crush as much, but I use these a lot also to do lung resections. Lung tissue, a big lung like this can crush down to a very small piece. So we still- we're talking with their folks about trying to figure out how to do that better so that either the staple device tells you that it's too thick for what you chose or too thin for what you chose or something like that. I think those are those are the main challenges honestly. We- since we do pediatric surgery, there are specialty companies now that are creating smaller and smaller staplers. Again, you get to- well maybe not with your team- but you get to a point where, you know, once the diameter is small enough, the mechanical advantage is gone. But to be able to use it for neonates, in particular. There's a company now that makes a five millimeter in diameter stapler. Our current ones are 12 millimeters or ten, right in that range. So that's something that we're really looking forward to. As you can imagine, the development of that device has happened in fits and starts. There was one company that came out. I was very unhappy with how it performed. We stopped using it for a while. Another company has taken it over, made a lot of great improvements. And so we still interact a lot with their reps. Their reps try to come in every time we use them because we do a lot of it. And we give them product improvement recommendations real-time. And I think they've all been very open to that.

How do we approach the innovation of surgical staplers?

I think that there's still room for improvement. We talked about a few of those. I think developing a partnership between the clinicians who are seeing the issues and engineers are the right way to move forward with innovation. It doesn't need to take 10 years to develop a new process, a new product. I find that, like with the staple line reinforcement- subtracting features often helps. You think about subtraction. You think about addition. You think about multiple use. A lot of the staple improvements have been through subtraction at this point.