Will COVID-19 Permanently Alter the Surgical Products Market?

COVID-19 had a devastating impact on elective surgery procedure volumes in the first half of the year. Although hospitals have bounced back sooner than expected, surgical capacity remains strained. Returning to pre-pandemic levels is likely to be a multi-year challenge, according to Ethicon Endomechanical's Tom O'Brien, who says the emphasis now is on safety, efficiency, and cost-control. Ethicon is relying on real-world data to help make the case for its surgical devices.

▶ MARY THOMPSON

COVID-19 has taken a toll on healthcare providers, and hospitals that rely on elective surgeries to bring in much needed revenue have been particularly hard-hit. As a result, medical device companies that supply surgical products are also feeling the pain; but some are rising to the opportunity and are taking specific measures to help their customers address the current elective surgery backlog. (*See "Navigating Beyond COVID-19: What Device Companies Can Do to Survive and Thrive,"* MedTech Strategist, *May 21, 2020.*)

In the following Q&A, Tom O'Brien, Worldwide President, Ethicon Endomechanical (part of **Ethicon Inc.**, a subsidiary of **Johnson & Johnson**), discusses the impact the pandemic is having on the surgical products market and how the company is helping its customers meet today's unprecedented challenges.

Pre-pandemic, Ethicon invested in an ongoing series of studies designed to collect real-world outcomes data on its endoscopic surgical devices, and it is now using that data—showing improved surgical efficiency, the potential for reduced complications, and lower overall costs for various devices and procedures—to promote the benefits of its devices in today's challenging hospital climate, where OR efficiency and cost control are primary concerns. Ethicon is also taking steps to help its customers deal with safety issues in the OR and understand how to reach out to patients who may be hesitant to reschedule their surgery due to safety concerns.

The goal of all these efforts is to help hospitals address the current surgical backlog and eventually return to full capacity, which O'Brien concedes could take a while. The pandemic's impact will be felt for some time to come, he says, and a few of the changes it has wrought could be permanent.

MedTech Strategist: What are some of the biggest challenges facing your surgical customers right now when it comes to performing elective surgeries in the COVID-19 era?

Tom O'Brien: I think the first thing to clarify, and this is eye opening for me as well, is this term "elective" surgery. We often think about elective surgery as something like cosmetic surgery. But elective surgery, in the definition that was used in most healthcare systems throughout the first half of the year, was any procedure that could be postponed. So, what wound up being included were nonacute procedures like bariatric cases, but also many cancer procedures, where delays are more problematic. In March, many US hospitals were required to shut down all those procedures, and they only started to reopen them in June.

As a result, one of the biggest challenges our customers face is obviously the cost structure. They are treating all these COVID patients, with all the additional expenses that come with treating COVID, and at the same time they're not doing as much surgery to bring in revenue.

Fortunately, in the latest wave of COVID, hospitals have made huge strides. They've learned how to more effectively treat people who have COVID, so fewer people now wind up in the ICU. And those who do have shorter ICU stays. So they've been able to maintain at least a fraction of their surgical volumes at the same time that they're treating COVID patients, which is really encouraging.

But they're still finding that the social distancing and the cleaning requirements have had a negative impact on hospital capacity. Instead of 100% normal capacity, they may be operating at more like 80% to 90% at best. Limited capacity is one of the big challenges right now. It's a challenge for the hospital, and it's also a challenge for patients who are trying to reschedule procedures and get them done.

But remember, it was only a couple of months ago that they were shut down. And now they're learning how to run procedures while COVID patients are still coming to the hospitals. That's a tremendous improvement from where we were before, and I really applaud the hospitals for some of the measures they have put in place.

How is Ethicon helping providers deal with these challenges?

One of our roles in this is to make procedures as efficient as possible. And the best way to do that is to reduce total operative cost by reducing complications so that procedures are not as long and patients don't have to come back. The worst thing that can happen for a patient in this environment is a complication that requires them to go back in for a re-op. Our goal is to bring the technology, bring tools and bring evidence that demonstrates those tools can improve overall operative efficiency and potentially reduce complications.

That's what you're trying to do with these real-world studies that came out recently on your powered stapling devices?

Well, this effort actually started long before we were all aware of COVID. These are devices used in critical surgeries. They're used in lung, gastric, and colorectal cancer cases, and they're also used in bariatric cases. And we've learned a few things over the years. One of them is that while we all like to think that complications are rare in surgery, they're not as rare as we think they are. Particularly when you get to cancer cases, where there's a lot of variability, patients are often much less healthy than anticipated and complications can occur.

We believed, and it was borne out in the work that we did, that we could make a difference in the complication rate. What we set about to do with our devices was to recognize some of the unique tissue differences found in patients with cancer. For example, a cancer patient undergoing a lung lobectomy may have very friable, fibrotic lung tissue that does not behave elastically. So when we're designing a device to minimize complications, we need to think about how we can prevent complications in that environment.

And we also need to think about how we can validate that in human trials. One of the best tools to do that is real-world evidence, because it reflects the current practice in surgery. That's what is so exciting about the

results we've seen—all the effort we had previously put in to trying to understand those unique differences in tissue was borne out once commercial use began with pretty strong associations with fewer bleeding complications and lower total operative cost. These studies typically involved thousands of subjects, and when we looked at a tally of the actual cost of those procedures, it was dramatic to see the kinds of improvements that you could make in terms of cost reduction.

Were those cost reductions primarily due to fewer complications?

Actually, if you just added up the cost of the complications, it would never equal the types of cost reductions we were seeing. And then we realized what was going on is that in surgery, when somebody is using a device like an endocutter, if it's performing well and it's avoiding complications, great. But the other thing it can do is alleviate the need for small interventions, such as inserting an extra clip onto a staple line or getting a hemostat. What happens is those things add time and they add cost. So it turns out that it's a combination of reducing complications, which is a direct contributor to cost, and then also an indirect impact on cost by making the procedure more efficient, eliminating all those 'micro steps' of intervening—whether it's addressing bleeding that may be occurring or accommodating other things that may be happening in the staple line. Those wouldn't be classified as complications, but they impact the overall efficiency of the procedure.

That's interesting. Was this a surprise to your customers as well?

Overall, our customers have responded very positively to the data, in part because we're bringing them data, which is helpful. But also, because it corroborates some of their experiences and their intuition. Sometimes they'll say to us, 'I suspected that was happening. I noticed that.' But they may not have actually quantified it with data.

What's the full extent of the evidence you've accumulated thus far?

At this point, we have seven different published studies that have been completed in different geographies. And we have another study that's coming out for our *ECHELON CIRCULAR Powered Stapler* later this year. A lot of them are US studies, but some have been done in Korea, Japan, China. And they involve different specialties, including bariatric, thoracic, and colorectal. They represent about 40,000 to 45,000 patients overall, and the consistency of the results is remarkable. Economically, the results range from 7% lower median total hospital costs versus what they had been doing before to upwards of 13% lower costs. The bariatric study was about 13%; the thoracic study was about 9% in the US, 12% in Korea. I suspect we're probably somewhere in that 10% range in terms of cost reduction overall, but they tend to bounce around between high-single digits and low-double digits.

One of the most recent of these studies involved a diabetes cohort of bariatric patients. Anywhere between 25% and 30% of bariatric patients have metabolic disease, so they either have active diabetes or they have the beginnings of metabolic disease. And what we know is in patients who have diabetes, the tissue doesn't heal in the same way. It doesn't heal quite as quickly. So you can wind up with higher rates of complications—that's been documented and our data confirmed that on average, patients with diabetes have higher rates of complications. But what we were so excited about is that when you filter out those cases in which our powered *ECHELON FLEX GST* System endocutter was used, that effect was equilibrated. When you compare a patient with diabetes and a patient without diabetes, where the surgeon used our *ECHELON FLEX*, there was no difference in complications. And to me, that's what we shoot for—to take at-risk patients who desperately need surgery and mitigate those risks.

The other study that recently came out demonstrated the importance of our powered endocutter in reducing bleeding complications. We always suspected when we did our design work that having a powered cutting device is an important component of minimizing complications. But it's not the sole component. When you're dealing with fragile tissues—and I'll use the lung example again—with that highly fragile emphysemic lung tissue, it's all about stabilizing the tissue. The more you stabilize it, the less likely you are to tear it or cause trauma that might trigger a complication like bleeding. Adding a powered endocutter minimizes lateral tissue tension so the device stays really stable when you fire.

But I truly believe it's a combination of several factors that essentially stabilize tissue. One of them is powered firing so that the tip of the device doesn't place lateral tension on the tissue when you're trying to fire the device. Number two is pre-compression. Before you fire the device, if you can squeeze the tissue and squeeze out some of the fluids, compress the tissue down, that helps stabilize it. And then third, and probably almost as important as the powered firing, is the gripping surface that holds the tissue in place and prevents it from moving when the staples are being deployed and the knife is going through the tissue. When you put all three of those together, you're able to stabilize the tissue so you don't inadvertently tear it.

When we were able to finally get enough real-world data to do a more detailed, apples-to-apples comparison of two powered devices, we did indeed find that the powered device with our GST [Gripping Surface Technology] reloads was associated with 73% less bleeding and bleeding-related complications. And on top of that, you saw those same reductions, in this case it was about a 7% reduction, in median total hospital costs.

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These are all real-world studies you're talking about, which I find interesting. Is real-world evidence more important now in the surgical device market than it has been in the past?

It's another tool in the arsenal. When you do a real-world evidence study, you're trying to understand if there are differences associated with how people generally practice medicine. And you can get really large numbers of patients; in the case of the studies we've done, we can get 20,000 or so patients. We've used real-world evidence recently because it enables us to get this picture quickly. But we don't rely solely on it; we've funded traditional randomized, controlled clinical studies as well. We've got a number of different tools and we try not to rely too heavily on one versus another. What we try to do is put together a picture that gives us the most realistic understanding of how our device is performing and what kind of differences we're making for patients. That said, I don't think there's a better study than a real-world evidence study to look at cost.

Can you walk us through some of the pandemic-related challenges your business has faced over the past five or six months—are you starting to see the light at the end of the tunnel?

Well, obviously in Q2, our device sales were impacted as a result of market conditions. Hospitals had halted most procedures, and nobody knew what was going to happen. And then in June, we started to see some changes in the marketplace. We started to see cases such as thoracic cancer procedures coming back. And that was reassuring because when you're talking about cancer, it's dangerous to wait. A thoracic case needs to do be done in a timely manner. It was really reassuring to see that hospitals were comfortable treating these patients.

Then we started to see the other surgeries returning, such as colorectal cancer procedures. And then in the beginning of July we actually started to see bariatric cases come back, which was a very positive sign. We expected bariatric cases to perhaps take a little longer to come back because they probably have more flexibility in terms of when they're done than, say, a colorectal cancer case, but they came back sooner than we expected.

There are still a lot of questions about what the impact of the high unemployment rate is, what the impact of not having insurance might be. So as we go forward, there's still some uncertainty, but we are reassured by two things. One is that the procedures have come back faster than we anticipated, and the other is that hospitals seem to have figured out how to conduct surgery and treat COVID patients at the same time.

What additional steps can device manufacturers take to help address the unique challenges hospitals are facing today?

Well, I already mentioned what our products and our evidence can do in terms of helping our customers manage efficiency and reduce complication rates. So that's one thing we're doing. Number two, we're trying to help them with some of the concerns around OR safety. As you probably are aware, there are concerns both in bronchoscopy suites as well as surgical suites about aerosolized virus and other potential safety issues. We're helping to educate clinicians on the importance of smoke evacuation and provide solutions that address this need to reassure our customers and give them pointers on how to most safely use those devices in surgery.

And then the other thing we're doing is a broader campaign to help hospitals bring back the patients whose procedures have been delayed. I'll give you an example. You probably have seen a lot of work that the hospitals have done trying to educate patients about the importance of getting treatment if you need it and not avoiding the hospital system during the pandemic. Hospital systems have been doing a nice job of using social media within their communities and talking about how it's safe to come back to their hospitals now to make sure people take care of their health. We have also done some market

research, and we conducted studies around the world to understand patient attitudes. And interestingly enough, we discovered that one of the most powerful ways to convince a patient to come back and take care of a procedure that was delayed was to personally contact them—which means the doctor gets on the phone and says, 'Hey, we had your procedure originally scheduled in April, but we had to postpone it. I think now is the right time to do it and let me explain why it's safe.'

That personal connection means more than anything. But what we found that's interesting is that only about 50% of hospitals and practices currently recognize that. That's been pretty stubbornly fixed in the data. So we're trying to give them some tools to be able to reach out to their patients and reassure them so they come back in for procedures. It's a principle that I think, as you look back at it, makes sense. People need somebody to turn to and trust, and they're going to trust the people that they have the closest relationships with, and that's their personal doctor, their surgeon. We believe one of our missions to help the healthcare system is to help hospitals recognize the importance of the personal touch and personal communication.

I know you don't have a crystal ball, but can you speculate on how long you think it will be before hospitals are able to gear back up to 100% elective surgery capacity?

That's a hard question. Hospital systems are going to slowly make progress in overcoming some of the constraints that limit capacity. And then some of them are going to be very difficult to overcome. For instance, some of the social distancing requirements, some of the cleaning requirements between cases and so on are going to just naturally diminish that capacity. How much, I don't know. The ideal case would be that they get to 110% of capacity so they can actually start taking care of the backlog. But I don't know that we'll get that high. I think it's going to be a while [before we reach full capacity], and I think even once the vaccine comes, it's not going to happen overnight. I think we're facing a multi-year challenge.

Will this pandemic result in some permanent changes to your business? And if so, what does that new normal look like for medical device companies?

Yes, I think it will. For example, the way we interact with surgeons in the OR has already changed. We're launching a product right now called *ECHELON ENDOPATH Staple Line Reinforcement*, used largely in bariatric procedures. And for probably half the cases being done, we're providing support for our surgeons remotely. That's very different than it was before. I suspect even after the virus is gone, a portion of our cases are still going to be handled remotely. People now recognize that there is additional risk with many other infectious diseases, beyond COVID-19. As a result, I suspect some of the cleaning measures are going to become more permanent, especially as data comes back showing that some of these measures can reduce infection rates and complications. We just don't know which ones yet.

But the changes we're most confident may be lasting involve the kind of unfettered access to the OR we used to enjoy. That has changed, and in fact, that has been changing over the past several years. But I think this pandemic has ensured that OR access [for medical device reps] will never again be the way it was a decade ago. MTS

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