MOON SURGICAL: Driving Robotics into High-Volume Surgery

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Moon Surgical believes it has the solution to an intriguing question in robotic surgery: If robotic surgery is so popular today, why are penetration rates still low in so many procedures?

■ For all of the current enthusiasm for robotically assisted surgery, penetration rates in laparoscopic surgery remain low. ■ The telemanipulation platforms pioneered by the major robotics companies are elegant in their approach to surgery, but many high-volume surgeons find the setup and time involved argue against the use of a robot. Moon Surgical is taking a different approach to robotics, returning the surgeon to the patient's bedside, augmenting surgeons by giving them control over all of their instruments throughout the procedure. ■ By adapting robotically assisted surgery to surgeons' regular practice efforts, rather than the other way around, Moon believes it can bring robotic surgery to high-volume surgeons.

t is a curious fact that despite all of the interest in and enthusiasm for robotics in surgery today, actual penetration rates remain surprisingly low except in a handful of procedures. In their earliest iterations, robotics systems were an elegant solution to a vexing problem for surgeons: how to perform the sometimes complex manipulations required for laparoscopic surgeries with the often unwieldy tools used in the early days of minimally invasive surgery (MIS). Robotics systems were certainly an improvement over the rigid tools used in the closed confines of MIS. But the highly sophisticated, highly articulable tele-robots developed by pioneers like Intuitive Surgical Inc. were almost overkill. Thus, while some surgeons took readily to the new platforms, many others stuck with a nonrobotic approach to the surgeries they perform most often. Now, Moon Surgical SAS, with offices in Paris and California, believes it has come up with a solution to the low penetration rates, generally speaking, of robotic surgery with a platform that, the company argues, promises to bring a robotically enabled approach to high-volume surgeons.

Out of a Paris Lab

The robotic system developed by Moon Surgical was born in an academic lab working closely with French liver and pancreas surgeon Brice Gayet, MD, PhD,

one of the early adopters of laparoscopic surgery and a surgeon with a reputation for doing complex laparoscopic procedures. "I've known him for about 15 years and worked with him on other projects," says Anne Osdoit, CEO of Moon and a partner at Sofinnova



Partners, home of MD Start, which incubated the company.

For the past decade, Gayet has worked with ISIR, a robotics lab at Sorbonned Uniersity in Paris, developing technology that as Osdoit describes it, "allows the surgeon to have complete direct control over the trocars and other instruments involved in laparoscopic surgery." Gayet and his team "had been working on this concept and prototyping it over the years, but as often happens in academia, hadn't really thought about how to turn his idea into a medical device," she says.

Visiting the lab, Osdoit was struck by two things: first, how far the project had advanced in a purely academic setting. "They had a fully functional prototype," she notes. "Nothing that we could take to a patient, but something that worked, which was pretty interesting." Second, and more importantly, Gayet's design was, to Osdoit's thinking, "a completely new approach to augmenting the surgeon in an operating room. It was something I had never seen before."

Indeed, the system didn't even look like a surgical robot as traditionally conceived, with the surgeon operating from behind a console, sending signals to robotic arms and performing tasks remotely. "It was the first time I saw an approach where the surgeon was central [to the procedure], controlling the whole scene." Though he hadn't actually formed a medtech company at the time of Osdoit's visit, Gayet had already created an entity into which he was going to transfer the technology out of the lab. With Osdoit's backing, MD Start funded the company, naming it Moon Surgical, and in the process transferred to it the IP and prototype. (See "MD Start III: Refining the Model," MedTech Strategist, November 16, 2021.)

Solving Surgeons' Needs

As she began the effort to turn Gayet's engineering project into a real company, Osdoit turned to two robotic industry veterans for advice. Dan Wallace was one of the first engineers behind Intuititve Surgical's da Vinci system and later co-founded Hansen Medical with Fred Moll, MD, before supporting him at Auris Health Inc., the robotics company acquired by Johnson & Johnson for just over \$3 billion in 2020. Among his contributions to robotic technology, Wallace, whom Osdoit calls "a kind of genius inventor, instrumental in bringing some of surgical robotics' platforms to the market," invented the highly articulable instruments that revolutionized suturing via da Vinci. (Wallace later was a co-founder of the mitral valve company Cephea Valve Technologies.) The other executive was David Schummers, who was VP of marketing and later business development at Auris. "They basically helped us formulate the positioning assumptions around the

the positioning assumptions around the technology and were instrumental in our decision to move forward," Osdoit says.

In the course of their roles as advisors, Wallace and Schumers led Moon, indirectly, to two other former Auris executives, David Noonan and Jeff Alvarez. After what Osdoit calls "an intense courtship" and "several months of weekly calls," both joined the company about a year ago, Noonan as chief technology officer and Alvarez as chief operating officer.





Noonan's interest in robotics goes back more than 20 years, to his days at university, and led eventually to five and a half years with Auris where he led the systems engineering team, the robotics controls team, and the algorithm team for the company's Maestro platform (see Figure 1). Like Osdoit, Noonan says he was taken by what he calls Moon's "different approach" to robotics, "putting the surgeon not just central to the operation, but keeping them at the bedside with the robot and the patient. It was something I was intrigued to get involved with."

Jeff Alvarez, for his part, has been in the medtech start-up world since 2004 and helped build several, including Auris. In 2006, prior to Auris, Alvarez joined Hansen Medical where he led advanced R&D projects and helped lead early product development on Magellan, Hansen's vascular platform system. He joined Auris in 2011 as one of its first employees and helped lead product development for the company's first four and a half years in areas such as cataract and retinal surgery before focusing on interventional pulmonology and lung nodules. (Between Auris, which he left in 2015, and Moon, which he joined in 2020, Alvarez worked on a couple of start-ups including Portrero Medical, a TheraNova company, where he led product management for two years.)

Alvarez notes that at Auris, "key to our approach was staying value-focused. We wanted to understand what the surgeon and patient need and how we could make sure that what we delivered creates value in the clinical environment for both. I think other companies might place priorities a little differently. But we were very user-focused throughout the entire product development life cycle." Adds David Noonan, "We always focused a lot on the lab work to test the system with doctors and their staff to make sure that what we were doing was solving their needs."

And that has translated to the work they're doing at Moon Surgical. "From a robotics perspective, we're always focused on patient safety as well as solving clinical need," says Alvarez. "As a robotics company, you're not changing robotics so much as changing how you're using motors and encoders and algorithms to build the product. But it's not about falling in love with your own solution; it's about putting the system in the hands of people who are going to use it to make sure that what you're building is actually valuable."

A Shared Control Paradigm

David Noonan contrasts what Moon is trying to do with the kinds of robotically assisted systems that Intuitive pioneered and that, more recently, companies like **Medtronic plc** and **Cambridge Medical Robotics Ltd.** are offering. "What we're doing is developing a system intended to be at the bedside with surgeons, augmenting them by giving them control over all of their instruments throughout the procedure." Moon's system also features a small, lightweight footprint that doesn't affect the surgeon's workflow and is able "to seamlessly integrate into the existing steps of the procedure by providing assistance to the surgeon," he adds. "To do that, we want to change the way in which the surgeon interacts with the system."

Noonan notes that with robotics' traditional "telemanipulation paradigm," the surgeon is located at a distance from the patient. "We don't think that supports the high volume of procedures done today typically without the assistance of a



robot," he says. Moon's goal: "to bring the surgeon back to the bedside, using a co-manipulation paradigm where our system utilizes mechanically transparent haptic interfaces as its primary manipulation tool." In effect, Moon's system allows surgeons to both wield their instruments on their own throughout the procedure and use the system to move the instruments if they prefer or need that. "It's basically a shared control paradigm, which is very different from what you get with a telemanipulation system," he continues. "Surgeons can grab any of the instruments held by the device, and move them wherever they need them to be-where they're using them or where they want to let them go and be stable." Noonan says the Moon system "is extremely transparent and follows what the surgeon is doing." And once the surgeon stops moving the instruments, the system remains stable, anchoring the instrument or scope in the needed position. "We're essentially equipping the surgeon with an extra set of hands and with full control over the laparoscopy operation,

but in a way that's light and nimble and very easy to use at the bedside," he concludes.

Jeff Alvarez acknowledges that large telemanipulation systems like da Vinci also offer surgeons control over their instruments and scopes so they can position them wherever they want. "Now, the trade-off is that they remove the surgeon from the sterile field," he says. "They take off their gloves and go over to a corner where they tuck their head in a console. But any time things change or don't go according to plan-for example, the surgeon needs to adjust the ports or take a slightly different approach—they have to yell across the room. They can't keep track of what their team is doing, and they're very disconnected." Some of the more recent iterations, like Medtronic's Hugo robotics system, address this problem by replacing the console control with 3D glasses. But, Alvarez argues, surgeons are still remote from the patient and their assistants in the OR. "Our philosophy is different. We keep that surgeon at the bedside. But we enhance their capabilities by giving them control over all of the instruments and all of the ports they need, while also giving them the ability to have control over the operating theater. They're at the center of it; they can see everything, and everything is within arm's reach. That's the power we can deliver," he says, characterizing the Moon technology as "a highly adaptable system that allows incredible versatility across a number of different indications in the end, because that surgeon is still there, still in control."

It's Just Not Worth It

One additional benefit of Moon's approach, says Anne Osdoit: the low, virtually "nonexistent" training issues. "Surgeons spend years training just to be surgeons and don't want to train more" when it comes to new tools and systems, she says. "The fact that we fit perfectly inside the workflow and that our system is über easy to use should be another plus." And earlier this year, the company announced a strategic partnership with King's College London to develop machine learning for what it calls computerassisted surgery.

Moon Surgical's launch comes at a fortuitous time, when interest in and enthusiasm for robotically assisted surgery is high and surging. The \$600-million round raised by **CMR Surgical** this past year is just one reflection of how hot the field is, while long-time market leader Intuitive Surgical has a market cap that now stands at \$125 billion and surgery giant Medtronic recently announced the launch of *Hugo* in Europe.

But it wasn't always that way, and the early days of robotics, just over two decades ago, told a different story—one of resistance and skepticism on the part of many surgeons and medical centers. Part of that had to do with the systems' high price tag; so, too, were lingering questions about whether robots Jeff Alvarez acknowledges that large telemanipulation systems also offer surgeons control over their instruments and scopes so they can position them wherever they want. "Now, the trade-off is that they remove the surgeon from the sterile field," he says. "They take off their gloves and go over to a corner where they tuck their head in a console."

actually improve outcomes or enhance the surgical procedure. But behind the resistance there was also concern on the part of many surgeons about the experience of robotically-assisted surgery. Fear of being replaced by robots was never a real threat to their adoption—or lack of it, but surgeons' worries about loss of control intra-operatively and, in this most tactile-oriented medical field, discomfort with the technology were. Indeed, it was a decade or more before Intuitive saw the take-off of its FDA-approved da Vinci system. (See "Intuitive Faces the Future of Surgical Robotics," MedTech Strategist, January 16, 2019.)

Acceptance of robotically-assisted surgery has undeniably come a long way from the late 1990s and early 2000s when surgeons were first introduced to the new technology, but issues around loss of control and disorientation were an early undercurrent in adoption. "A lot of it was about workflow," says Anne Osdoit who notes that MD Start conducted a number of surgeon interviews before making the decision to back Moon Surgical. "A lot of things came up during those interviews about setup time and complexity," she says. For those surgeons who haven't widely adopted robotics, "it just wasn't worth it to use robots for some of their high-volume procedures. We spoke with a lot of people in community hospitals and ASCs [ambulatory surgery centers], and they have other priorities. They want to deliver good care that is safe, efficient, and fast, and they want to work with a limited team providing the best assistance."

Reliability and predictability also emerged as important values "and were a driving force when we were developing our system," she goes on. "We want to allow the surgeon to have the best team with him or her for any surgery, and that means having the best assistants at the bedside," with a robot that is "perfectly reliable that they can drive themselves, so they can focus on their work without having to worry about workflow interruptions or directing others to do things properly or even having to take over when they get too frustrated."

Initial funding for Moon Surgical came in June 2020 with a \in 3 million seed investment from MD Start, supplemented by a grant from the French government for an additional \in 2 million, a total of \in 5 million (approximately \$5.7 million). The company plans a refinance and additional fundraising in early 2022. Currently, Moon has operations in both Paris, France, where Osdoit is located, and San Carlos, CA, where Alvarez and Noonan live (though Alvarez recently moved his family to Paris for a year).

Such binational arrangements aren't rare, especially when European investors are backing US-based companies, but Moon is a Paris-based entity, and Osdoit explains that the move was driven by the company's need to build its team with the right robotics expertise. "One of the things I quickly realized is that unlike many of the other MD Start projects, we had to staff Moon quickly with a fairly extensive and expert technical team," she says, hence the appeal of Noonan and Alvarez and their years of experience at Auris. Moon is "small compared to a lot of other robotics companies," she acknowledges. "But if you consider that we're a seed round company, it's a decentsized technical team." More, she notes, as she spoke with folks in the robotics space about the functions and expertise needed to launch a company in that space, "I soon understood that those people exist mostly in the US and that if we wanted to attract the best people and accelerate the company, which is the mandate at MD Start, we needed to hire in the US. It was a very pragmatic approach."

There are, of course, some very promising robotics companies in Europe in addition to CMR Surgical: **Robocath**, a French company, **Distalmotion SA** out of Switzerland, and **Medical Microinstruments** (MMI) from Italy, to name just a few. And Moon has tapped some European executives for its Paris headquarters. But the reality, Osdoit argues, is that there is a larger pool of potential hires in the US. "It was the middle of the pandemic, and we were all in lockdown and we just said to ourselves, 'We're going to have to have one facility in Europe and one in the US.' Because we also couldn't ask anyone to relocate and everyone is working remotely anyway." Noonan joined first, in November of 2020; Alvarez came on board in early January of 2021. Indeed, both worked out of their homes until Moon opened an office in San Carlos, CA, in March of this year. The arrangement, says Osdoit, "has been working remarkably well."

A Robot by Any Other Name...

As noted, Moon Surgical's launch comes at a time when interest in robotics is high, particularly among major strategics, a group of multinationals that virtually ignored the potential and opportunity in robotics in the field's early days. Today, as surgical device giants like Johnson & Johnson's Ethicon operating company and Medtronic are bringing their own robots to market and virtually all of the major orthopedic companies offer systems as well, even companies without a large footprint in surgical devices are trying to figure out how to incorporate robotics into their offerings—or at least adapt to the operating room of the future, which will be informed by advanced technology like robotics.

How do start-ups like Moon Surgical think about and navigate the burgeoning opportunities in robotics? Auris showed one path, with its mega-exit via Johnson & Johnson, though it's not clear that kind of deal will be available to other small robotics companies.

David Noonan cautions against an obsession with terms like "robotics" and offers a different way of talking about the technology that both broadens its scope and makes the description more precise. "A lot of people are using the term 'robotics' and it is, in a lot of ways, a valid term, but we think about the market in terms of 'smart tools,'" he says. "Yes, on one level, they're robots; da Vinci is a telemanipulation robot." But a fixation on robotics ignores a large part of the market "that doesn't need something as complex as that. You can call what we're developing a robot; you can also call it a smart tool or use some other term, but we're filling a need that has not been addressed by the more traditional robotics approaches."

That kind of distinction can be helpful for Moon Surgical as it tries to both ride the rising tide of robotics and also foster a sense of novelty and differentiation from other start-ups and their technologies. Even Intuitive, the company that has all but defined the notion of surgical robotics, steers clear of the term "robotics," preferring "robotically assisted surgery."

"If you think about our end users, we are in a space which is all about high-volume procedures in general surgery, across the spectrum from ASCs to community hospitals to tertiary care hospitals," says Anne Osdoit. "This is a market that is largely untapped and underserved" by the large telemanipulation systems sold by the robotic giants (see Figure 2). "It's not a market where da Vinci has a high market penetration." Da Vinci has a "very narrow and deep" market adoption, she says, and a lot of the new platforms coming to market target the same indications. "They're not going to solve the kinds of issues da Vinci has failed to solve. Nobody has a similar approach [to Moon's] and we're getting very consistent feedback on the value that we can deliver to [high-volume] surgeons and operating rooms," she adds.

A Category Creator

Osdoit notes the interest that large medtech multinationals are now showing in robotics. But rather than being a competitive threat to start-ups like Moon, she believes that interest is potentially a positive sign. "They've all placed their bets and the interest level has increased tremendously; it's now a hot topic," she says. "But those bets are not that disruptive and they're all taking the same approach. They each have their subtleties and nuances, but they all go back to a console. We don't see any of them solving the problems that telemanipulation robots have failed to solve until now." In fact, interest on the part of big companies sparks thoughts of acquisition activity to fill out product lines, pointing to a potential exit for Moon. "I think we could either be a standalone company with high, ambitious goals and raise a lot of money and do it ourselves, or corporates might realize that the bets they've placed with their internal programs or acquisitions are going to have their limitations, and they might look for something radically different," she says. "Everything is possible."

And within the robotic start-up space, Moon Surgical executives argue, their technology is truly different. "The key is that a lot of these other new entrants are very me-too," says Jeff Alvarez. They've broken up some of the components into smaller modules, he goes on. But that doesn't really change the fundamental value proposition of the technology or the procedures for which they're best suited. To create a meaningfully new approach, he says, you have to "build more adaptability in your system so that you can have versatility in going after various indications. That's very challenging with a robotic system because it is so intensive in its design and the investment that it takes to get there is so great." Alvarez's point: If you don't start from the outset with a vision of how your technology will be different, it's nearly impossible to adapt or adjust later. "If you don't understand the problem you're trying to solve early on, you end up with a system that's not hitting the mark." Like Auris, he says, Moon Surgical began not by trying to develop a robot per se, but by "asking questions like, 'What's the problem we're trying to solve with our system that will really change the game?' That's a very different approach than other companies are taking."

Anne Osdoit calls Moon Surgical "a category creator." "We've identified the problems and created new approaches to solve them. And that has nothing to do with" existing approaches to robotics taken by other companies. "We're creating something completely different," based on "the workflow and the pains" that have come with traditional robotic systems.

In effect, if the original robotic systems were themselves solutions to one technological problem for surgeons—having to perform surgery using unwieldy devices developed for the first-generation of minimally invasive surgery (MIS) — Moon Surgical executives believe those original systems were themselves limited solutions, in the sense that they didn't allow for deep penetration of high-volume surgeries. The company's initial target will be general surgery and specifically, laparoscopy. "We want to make the application as broad as possible, and we're designing a system that will be usable in many indications and procedures," says Osdoit. She



ROBOTIC ASSISTED PROCEDURES

Fewer than 7% of total potential surgeries across Europe, Americas, and Asia are performed with robotic assistance



Soft Tissue Robotic adoption has remained limited because current platform offerings do not adapt well to different procedures and environments.

A Large and Untapped Market

Figure 2

TOTAL SOFT TISSUE MIS MARKET

Exceeds 20M procedures between the Europe, Americas, and Asia

[Includes Abdominal, Urology, Bariatric, Gynecology, Thoracic Surgeries]

Source: Moon Surgical

Subscriptions, advertising, reprints, web posting, and distribution licenses are available. Contact Bridget Kelly-Stoll: 408-877-0133 | b.stoll@medtechstrategist.com Moon is hoping to reverse the paradigm: Rather than require hospitals to build surgical suites around large robotics footprints, it hopes to position Moon's technology as an essential piece but really just one more part of the broader armamentarium of any traditional OR."

acknowledges that Moon still has to prove its system works and has to clear regulatory hurdles. "But we're hoping to go broad very early on," she says.

And when Moon is ready to commercialize its technology, company executives hope that by taking a broader approach, focused on high-volume surgeries, Moon Surgical will be able to avoid the kind of direct competition with more traditional systems that would require it to wrestle with the issue of supplanting an installed base. Osdoit says Moon is targeting "different indications, different procedures, different surgeons, different settings, and hospitals as well."

A Different Business Model

In the process, Moon is hoping to reverse the paradigm: Rather than require hospitals to build surgical suites around large robotics footprints, it hopes to position Moon's technology as an essential piece but really just one more part of the broader armamentarium of any traditional OR, "just like the lap tower and the anesthesiology cart," says Osdoit. "We're bringing an embedded assistant and system augmentation to the operating room, and that's not something you build a separate room around in the surgical department. We view it as really something that people will use all of the time and that will be in every single room."

Such an approach will require Moon to come up with a different kind of business model than other robotics start-ups because the financial proposition for hospitals is so different from the way they currently think about robotic adoption. "We have to be creative in our business model and how we structure the offer and market it to hospitals," Osdoit says. "We have to have a different approach in our go-to-market because we believe this should really be in every single operating room." Osdoit notes it's still early for Moon to have fully formulated its commercialization strategy, but, she adds, "We know a couple of things: We want the system to be accessible. We want to have very low barriers as to how surgeons use the system," meaning Moon won't develop its own proprietary instrumentation, but will enable surgeons to use the instruments they're already using. "We think that will facilitate market penetration," she says.

Much of the planning around the go-to-market strategy is still a work in progress but it tees up the question of how Moon will ask hospitals to pay for its system—a big issue for a lot of startups now coming to market. Will it come with a large up-front price tag? Or a smaller per-procedure fee, especially if Moon is successful in positioning its system as one more tool in every OR? One thing Osdoit has already decided on: "There are a number of business models that avoid the intense up-front capital equipment spending. That being said, we need to think carefully about this. If you have a per-procedure model, people will think about the added cost for every single procedure where they're using the system," which can be a drawback for such a model.

Key for Moon Surgical: ensuring that whatever model the company comes up with allows for the broadest possible adoption and use in high volumes of procedures that is central to the company's vision. Jeff Alvarez notes that with more traditional robotics platforms, the up-front acquisition cost of a robot is only part of the story. "A lot [of the cost for hospitals] is in the recurring costs." Robotically assisted surgery increases per-procedure costs by around 135% he says. "And on top of that, it's about procedure volume," he goes on. "In using a robot there's a distinct [increased] cost in prolonged procedure times." Factoring in OR room turnover, traditional robotically assisted surgery typically increases OR time by about 36 minutes. "And that adds up," he says. As a result, hospitals "have to start thinking, 'This is a robotic procedure so let's make sure we have the right team in place to turn over the room as quickly as possible and block in as many procedures that can accommodate the robot in a specific time frame." That, too, is why adaptability is so important to Moon. Surgeons can decide at the last minute that they want to use the Moon system, says Alvarez, "and within a minute it's in place and they're using it." Up-front equipment costs or per-procedure models address only part of the cost issue for hospitals. "You don't just solve the cost problem with those kinds of business models," he says. Adds Anne Osdoit, "Sheer usage will facilitate adoption and address the financial burden."

It's all part of offering surgeons the optimum surgical experience. "We want to give the surgeon the best surgical team every time they go into the operating room," says David Noonan. "Because if they have the best team, they're going to want to use the system. That, ultimately, is what we're trying to do."

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