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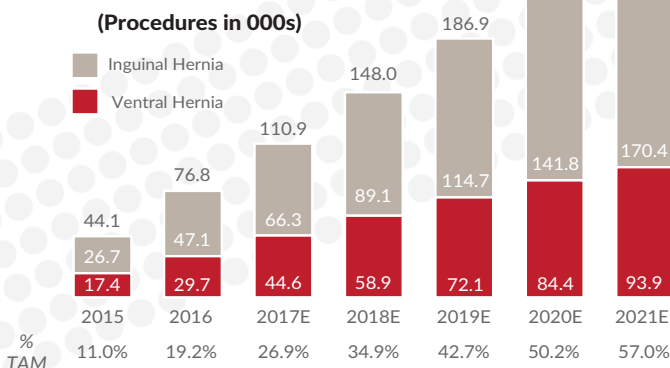
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Synaptive Medical: Connecting Surgery, Imaging, and Data to Improve Outcomes

KEY POINTS

- There is a need for richer information gleaned from imaging data to help surgeons at key decision-making points. Canadian company, Synaptive Medical, is working to address this need.

- Synaptive's point of departure is its expertise in improving imaging technologies and optics, but the company's ultimate destination is one seamlessly connected system that integrates all of the important information for safer and more efficient surgical intervention, from presurgical imaging to the OR.

- Two years after regulatory clearance of its first module, Synaptive has already sold over 20 *BrightMatter* systems to prestigious medical institutions across the US and Canada, and surgeons are extolling the workflow efficiencies and clinical improvements they've experienced.

- While making surgery more effective and efficient today, Synaptive is also laying down a framework for a future in precision medicine, where, the company hopes, the searchability and accessibility of the data in its platform, and its ability to create new sources of medical data, will help enable the right treatment for the right patient at the right time.

by
MARY STUART



Synaptive Medical Inc., a young company out of Toronto, Canada, has achieved some impressive milestones in a short period of time. Over the course of only four years, the company has grown from six to over 300 employees, created a multifaceted and integrated capital equipment and information platform for neurosurgery, and installed its system at more than 20 prestigious medical institutions in the US, Canada, and Pakistan, including Cedars-Sinai Medical Center in Los Angeles, the Swedish Neuroscience Institute, Henry Ford Health System, Emory University Hospital and Grady Health System.

In the process, it has attracted a young team of talented engineers and software experts in the mold of Silicon Valley, as well as an executive management team steeped in medtech, which all coalesced around the vision of company co-founder and CEO Cameron Piron, who colleagues say is an unusually selfless leader. Notes company Board member David Caluori, a principal at the global growth equity firm General Atlantic, which recently entered into a strategic investment partnership with Synaptive, "The quality of the team that has grown around Cameron is impressive. These are really seasoned executives in operations, sales, financing, and on the Board."



CAMERON PIRON

Caluori is not alone in describing Piron as “a mission-driven entrepreneur.” He says, “Not to sound clichéd, but he really cares.” According to Caluori, when Piron was asked about the company’s goals, he responded “I think we have built some amazing technology that can actually save people’s lives today, and I am entirely focused on getting this out to as many people as possible as quickly as I can.” That mindset is no small part of the company’s secret to success in such a massive undertaking.

The recent partnership with deep-pocketed General Atlantic, which invests more than \$2 billion a year across multiple sectors, is yet another positive indicator for Synaptive. Indeed, things are moving fast for the young company. Piron notes that in this early growth phase, Synaptive is outpacing the success enjoyed at that point by the surgical robotics company **Intuitive Surgical Inc.**, perhaps the most successful medtech investment ever. (See “Where do Surgical Robots go From Here? An Interview with Fred Moll,” *The MedTech Strategist*, February 29, 2016 and “Surgical Robotics: Assessing Growth in 2017 and Beyond,” in this issue.)

In certain respects, Intuitive Surgical is a model of success for Synaptive Medical, since Intuitive “demonstrated that it could bring automation and imaging technology together into a single integrated system to bring a new level of technology to surgeons. It was a fundamental paradigm shift on the integration of technology,” says Piron. The comparison ends there, though, because, while Synaptive Medical also has a robotics component in its surgical platform, its *Bright-Matter* technology is dedicated to positioning imaging devices, not enabling dexterity, and in fact, it is the founders’ expertise in imaging technology that led them here.

An Experienced Team Targets an Acute Need

The team that founded Synaptive also built Sentinelle Medical, which was founded in 2004 by Piron and Gal Sela to bring a combination of MRI coils and visualization software to the breast cancer market. Piron studied systems design engineering at the University of Waterloo, then went on to get a graduate degree in medical biophysics at the University of Toronto. Sela has a background in electrical engineering as well as a masters in medical imaging. He began his career by supporting intraoperative MRI systems for neurosurgical procedures at Toronto Western Hospital. Before they joined Sentinelle Medical, Synaptive co-founders David Gallop, an electrical engineer, and software engineer Wes Hodges both worked at a start-up acquired by Merge Healthcare, a leading provider of enterprise imaging systems that is now part of **IBM**.

Sentinelle had grown to 200 employees when **Hologic Inc.** acquired the company in 2010 for \$85 million (plus contin-

gent earn-outs). That experience only served to deepen the team’s mission. Says Piron, “My career and that of my co-founders has really been about how to get imaging to the appropriate points during a patient’s care cycle. We want to bring it to areas where it’s really vital, but for whatever challenge, it’s not able to be utilized.” Sentinelle was focused on that goal in breast cancer, where diagnostic imaging could find small tumors, but there was nothing that could guide biopsies to them with precision. “There we saw a gap between the imaging and the interventional world.” Even before the sale of their previous company, Piron notes that neurosurgery was already next on their list. “In neurosurgery we saw that the gaps were even larger and even more clinically significant. There, the need for better imaging in the OR was really acute.”

In talking with Piron, one gets the sense that he and his team think a little bit differently about imaging. While one might think of imaging devices in the context of specific tasks, like diagnosing a tumor or providing a look into a surgical site, Piron speaks of images as rich content for a unified information technology platform. He believes this information should be available to clinicians at all points of care and interactions with the patient, from preoperative imaging to postoperative evaluation, or, more specifically, across diagnostic imaging, presurgical planning, navigation, visualization, the electronic health record, and, in the future, databases that could be mined to determine the best treatment for a particular patient.

How did a small company think that it could wrap its arms around such a complicated information technology and capital equipment platform? Says Piron, “We have been uniquely focused on the areas between tech siloes, the integration of imaging and intervention. That is exactly the area everyone else has not focused on. And by thinking not just about products, but systems of products.”

Imaging: The Foundation of a Medical Information Technology Platform

Today, several imaging modalities are used as a patient progresses through diagnosis to surgery, but they’re disjointed and not always purpose-built to the tasks for which they’re used, says Piron. Imaging technologies tend to be siloed: diagnostic imaging technologies are offered by one group of companies—the likes of **Siemens**, **GE**, and **Philips**—while intraoperative optical technologies (e.g., surgical microscopes), have been the domain of companies like **Olympus**, **Leica**, and **Carl Zeiss**.

This disconnect between preoperative diagnostic images and the intraoperative view of anatomy leads to inefficiencies in surgery and less than optimal outcomes. Diagnostic

Figure 1

Synaptive Medical's Six Cleared (FDA and Health Canada) Products



PRESURGICAL PLANNING

BrightMatter Simulate: Training tool that enables surgeons to practice minimally invasive neurosurgeries and craniotomies on a life-like model of the brain. Designed to imitate the tactile properties and response of brain matter, presenting an anatomically correct cortical surface, and a realistic suturable dura. Available in different configurations to model different pathologies and anatomical structures (tumors, hematomas, ventricles, etc.)

BrightMatter Plan: Software for assessing 3D tractography and detailed anatomy to help surgeons automatically generate the data for surgical plans that help them arrive at a target pathology by a safe pathway through the brain. Seeing this whole-brain data allows surgeons to tailor approaches to a patient's specific anatomy.

NAVIGATION

BrightMatter Guide: Synaptive's surgical navigation platform. Described as "a GPS for the brain," gives surgeons a visual representation of the complex structures and associated tractography in the brain to aid them intraoperatively in finding the least disruptive pathway to the target pathology. Guide provides continuous tracking of multiple tools throughout a procedure for real-time location updates within the surgical cavity. Full feature set for corridor resection and port-based procedures.



SURGICAL ROBOTICS AND VISUALIZATION

BrightMatter Drive and Vision:

- Robotic system that provides automated positioning for optimized visualization during surgery; eliminates the need for manual movement, keeping a surgeon's hands in the surgical field at all times and creating greater efficiency. Allows surgeons to operate in an ergonomically neutral position
- Optimized optics provide high resolution and depth-of-field keeping the entire surgical field in crisp focus
- Easy room set-up, including multiple intraoperative positions for quick recall

INFORMATICS ARCHITECTURE

(web-enabled platform integrating a patient's digital footprint across their circle of care)

ImageDrive:

- A core database for Synaptive's solutions that drives efficiency by integrating patient data between medical devices, designed with centralization and collaboration in mind
- Combines a data structure foundation with a diagnostic-level, FDA-approved DICOM viewer to aggregate, search, and view both Synaptive-generated data and data from existing hospital systems (i.e., PACS, EMR, Pathology, etc.)
- Integrates and centralizes surgical-related data, thereby increasing efficiency by improving data accessibility and streamlining surgical workflow. Includes quality control and research collaboration features

Source: Synaptive Medical Inc.

quality images are often imported into surgical planning programs, but these aren't always in the right format to make them useful and patients frequently have to be re-scanned. Maps created during planning and imaging devices used during surgery represent two different systems that weren't designed to work together, which compromises surgical quality and efficiency. Finally, the pictures that are taken in the course of patient care aren't as accessible as they could be. "More than 90% of medical imaging data resides in hospital PACS systems, which weren't designed to be contextually searched," i.e., searched in the context of a particular patient, says Piron. Bridging these gaps is one of Synaptive's goals.

To date, Synaptive has created and launched six products for its *BrightMatter* platform, each designed to solve problems for surgeons at different stages of surgical workflow, but all designed to work together (see *Figure 1*).

The company starts by bringing a new kind of imaging into the surgical planning process, in its product called *BrightMatter Plan*. Synaptive's algorithms automate the creation of diffusion tensor tractography images from MRI data. This imaging modality shows the diffusion of water in the brain, a surrogate for the orientation of axons. Tractography images show the directionality of the fiber bundles in the brain, revealing pathways and anatomical connections that can't be seen by any other imaging modality. The company displays these over an anatomical image of the brain (see *Figure 2*).

At the presurgical planning phase, armed with this information, surgeons can plan safe trajectories to tumors, lesions, or clots that need to be removed so they can avoid damage to important white matter structures. The preoperative plan is transferred to their navigation system called *BrightMatter Guide*, and provides real-time interaction and visualization of white matter tracts during surgery. The system allows for a surgeon to determine the best approach for the patient, but also visualize their surgical tools as they navigate their plan during surgery.

Synaptive didn't invent diffusion tensor imaging (DTI) but recognized its value and importance in research and planning brain surgery. Processing these scans historically has been laborious and time consuming, and is often a subjective interpretation of the radiologist preparing the data, based on the region they choose to map out by individually seeding each tract, and the software being used. Acquiring DTI has often been lim-

ited to radiology departments in education and research institutions with moderate experience in processing these types of scans. According to Piron, Synaptive automatically creates whole brain tractography by mapping "every location in the brain to provide the clinician with a complete picture." This technique may be more resilient to false negatives than standard tractography techniques, he says, because it doesn't require the clinician to make assumptions to generate tracts. Moreover, he adds, "We can create that information without having to rely on radiologists, who are often busy doing what they do best, that is, diagnosing images, not processing datasets."

As noted, this type of image data is important, because it helps surgeons plan safe trajectories through the brain so they can avoid harming areas that control language, movement, sensory, and other vital functions. While neurosurgeons have generally been taught to take the closest route to a tumor, this new information allows them to take a personalized approach to the patient's anatomy.

Surgeons using *BrightMatter* are reporting that with this new information they're able to undertake surgeries previously considered too risky in terms of their potential to cause significant harm to structures along the way. Steven N. Kalkanis, MD, a neurosurgeon operating at the Henry Ford Health System in Michigan, Chairman of Neurosurgery, and co-director of the Hermelin Brain Tumor Center, is an early adopter of the *BrightMatter* system.

Kalkanis says, "We have had success in cases that were deemed inoperable by world-renowned surgeons at the greatest centers in the country, that were thought to be too risky because of the difficulty in approaching the anatomy where the particular lesion happened to be located." With this technology, he notes, surgeons can look for corridors that provide a safe entry point and trajectory to reach these "inoperable" lesions.

"The system reveals vascular anatomy and three-dimensional views of various structures that are impossible to discern in a standard preoperative MRI," says Kalkanis. He notes that the structural anatomy, the fiber tracts, eventually link up to important areas like the motor strip, which controls the ability to move the arms and legs, and sensory and language functions. "Once those fibers leave the surface of the brain and go deep, up to this point, we didn't have a good way to track exactly where they went. Now [with *BrightMatter*] I can literally see

Figure 2

***BrightMatter Plan*: 3D Tractography**



Source: Synaptive Medical Inc.

around corners,” he says. Surgeons are thus able to look for pathways that don’t interrupt critical structures. “Without that knowledge,” says Kalkanis, “no surgeon would take that risk.”

Kalkanis says *BrightMatter* is enabling his institution to convert a small percentage of inoperable to operable cases. “We are increasing the denominator of patients who can benefit from this. It’s not a huge number, but for those patients, it makes a big difference.”

For those tumors already deemed operable, the system might enable a safer surgery, perhaps smaller incisions, and direct visualization that might help surgeons perform faster and safer brain surgery. “Because the incisions are smaller, that saves time on the set-up and the opening and closing. We are often able to save enough time in a given operative day to add on another case, which brings in surgical volume and revenue to the hospitals.” Kalkanis also believes that the *BrightMatter* system attracts patients and surgeons to his institution, making it a marketing advantage for hospitals where it’s installed.

While the initial adoption of the system has largely been for brain surgery, the company’s robotic system has also been adopted by spine surgeons, ENTs, Head and Neck surgeons, or anyone who requires better visualization during a surgical procedure.

The Integration of Imaging and Intervention

In addition to its novel way of present preoperative and intraoperative images for the purposes of navigation, Synaptive also has replaced the standard surgical microscope with a robotic arm equipped with a camera that creates a superior image entirely in focus with a deeper depth of

field. The increased clarity and greater usable field of view enables surgeons and the entire OR to focus on the patient (see *Figure 3*). But beyond the advantages of more detailed images, the improved optics offer other benefits to surgeons.”

Synaptive’s website shows a video of a neurosurgeon performing brain surgery with the aid of the Synaptive *BrightMatter* system. It doesn’t even look like he’s operating because he’s not hunched over the patient; he’s not peering down into the surgical site through a microscope. Instead, he’s standing up straight in a relaxed position, looking at a large monitor across the table, and so is his entire surgical team. A robotic arm tracks the surgical instruments and automatically moves the optics and light source to keep them aimed where they’re most needed.

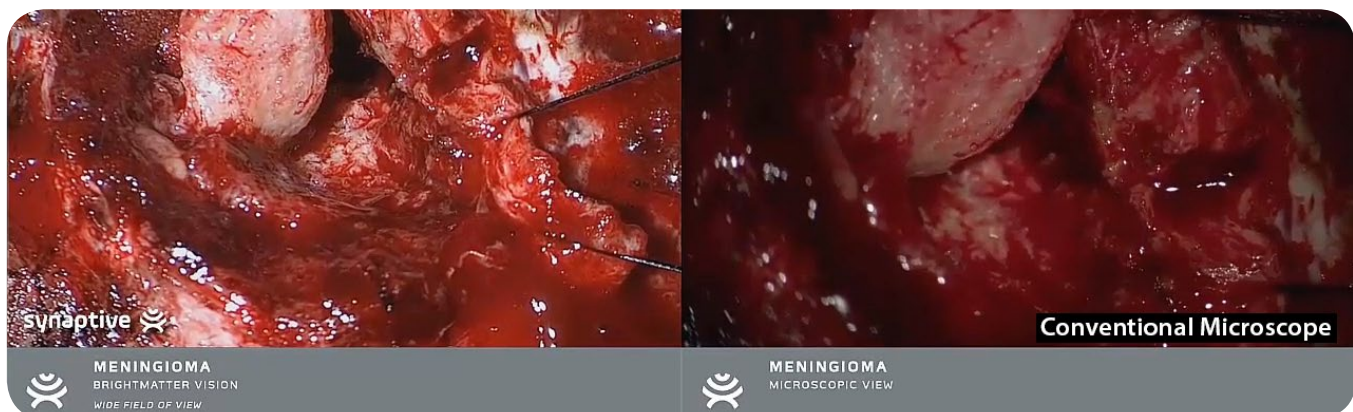
This feature alone creates efficiencies in the operating room, since surgeons spend a great deal of their surgical time repositioning light and optics. In addition, because everyone in the surgical suite can see the same image, surgeons have reported that techs are better prepared to hand over the correct instruments. Finally, the shared and detailed view of the surgery creates an excellent training tool.

According to Rod J. Oskouian, MD, Chief of Spine at the Swedish Neuroscience Institute, “The traditional way of operating is looking down a scope and having a narrow field of view. This way, surgery is done the way it should be; you’re relaxed, your shoulders are relaxed, your neck is straight, and you can visualize everything.”

Indeed, Piron notes that awkward and uncomfortable postures held for hours on end are an occupational hazard of neurosurgeons, who frequently suffer from back

Figure 3

Comparing the Surgical View From Synaptive Exoscope vs. a Standard Microscope



Source: Synaptive Medical Inc.

and neck pain. Synaptive was able to provide a solution for them, says Piron, “Because we send our design engineers out in the field to observe surgeons.”

Building Bridges

Synaptive’s improvements upon imaging technologies are perhaps the most straightforward and obvious of its innovations, but they’re only a part of the company’s story. Synaptive regards itself not merely as a medical device company, but also as a data-driven information company that operates in the same peer group as a Google or an Amazon, Piron says, the kinds of companies that are very good at managing and searching large amounts of data.

In fact, as it integrates information technology with conventional medical device technologies, one might compare what Synaptive has created to an iPhone. Phones, digital cameras, electronic notepads, and the Internet all existed before, but the power of the iPhone lies in the integration into a single platform of these technologies with software and apps.

Indeed, the components of the *BrightMatter* system—planning software; navigation technology for guiding instruments based on imaging; the *Drive* system, which is the robot that delivers the optics based on the location of the surgeon’s tools and instruments; and the data product called *ImageDrive*, which links all that information together—each existed separately in other forms. “But other systems take a lot of time and effort to make them relevant. We have linked them together to make them synchronous and automated. We take care of the background so the user can fully enjoy the functionality of the system,” says Piron.

Thus, a large part of Synaptive Medical’s vision is integrating technologies that are siloed today into one seamless platform, as well as the ability to connect disparate departments and functions across the hospital and even among different institutions. As noted, the company’s *ImageDrive*, which integrates patient data between medical devices, is the platform that connects it all. *ImageDrive* is a core database that combines a data structure foundation with a diagnostic-level, FDA-approved DICOM viewer to aggregate, search, and view both Synaptive-generated data and data from existing and future hospital systems (i.e., PACS, EMR, third party pathology reports, and even, in the future, genomics data).

It’s this connectivity piece that enables Synaptive’s future vision for patient data. Says Piron, “Medicine is really the practice of the accumulation of data and decisions based on data, whether that’s on an individual basis—a surgeon working with a patient from their experience—or the advent of big artificial intelligence systems that are beginning

to scour large databases to find associations.” The underpinning is always data, he says. “We provide better and more data that can be used more appropriately to help facilitate what we think will be a really exciting future with the advent of artificial intelligence systems.” The company will be able to play in that ecosystem, Piron says, by providing better and more timely information to make decisions across the detection, diagnosis, treatment, and monitoring of diseases. “The combination of imaging and intervention applies to each of these areas.”

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Small Company with a Grand Vision

It all sounds like a daunting undertaking, particularly for a small company; it involves capital equipment and a systems-wide approach to surgery, and there is no way to do it piecemeal, since the system has to work as a coordinated whole.

But the company is doing it, as evidenced by increasing sales to some of the top ranked neurosurgical programs in the US. The platform doesn’t fundamentally change the way surgeons operate, and it has been easy to demonstrate clinical relevance, in terms of the conversion of “inoperable” to operable procedures and other metrics, which the company is gathering. For example, says Piron, “In the context of spine surgery, recently one of our users had a series looking at dural tear rate reduction. Because you can look at an entire field in focus, the entire dura [the structure covering the spine], you are less apt to damage it.” That has a direct impact, Piron notes, because even a small nick in the dura requires a patient to come back for additional care, including longer OR procedures, longer ICU recovery, and/or the need to have the dura repaired.

Finally, the price of the *BrightMatter* system is not a barrier, since it costs no more than the technologies hospitals use today, if its components are considered separately, according to chief commercial officer Jim Cloar. Cloar has 25 years of leadership experience in the medical device industry, including 14 years at Medtronic, where he led the navi-

gation and imaging division that brought the O-Arm to market. He notes that the hospital pays a certain sum for the company's bundle of products—in the ballpark of a million dollars for a basic installation—that can be further customized to meet the needs of hospitals and surgeons. "It wouldn't be an added cost to what they would need to equip their operating room," Cloar says.

But what is different in Synaptive Medical's approach is the benefit of bundling the components together. "We are looking at how we can address the challenges that are the biggest cost components for procedures, whether it is re-scan rates, potential neurological deficits that arise when surgeons don't have the information they need, or time efficiency savings in the OR,"

says Cloar, who notes that Synaptive is working with its clinical partners to quantify some of these savings.

Getting back to the question of how a small company can execute on such a grand vision, Synaptive Medical also doesn't plan to do everything itself; it has a strategy of acquiring and partnering to gain the resources it needs. The foundation for *ImageDrive* came from ClearCanvas, an imaging informatics company Synaptive acquired in 2014, and the company will continue to explore outside partnerships. Moreover, Synaptive has a very long pipeline of products that will continue to expand its ecosystem of point-of-care imaging systems and the interconnectivity between those systems. Although it is not yet prepared to discuss these systems, they expand on the use of MRI and advanced optics at inaccessible points in the patient care cycle.

Beyond initial applications in brain and spine surgery, *BrightMatter* has the ability to enhance any surgical procedure—performed in an open or minimally invasive manner—where better information could help surgeons avoid harming important structures along the way.

Indeed, one of the biggest challenges Synaptive Medical faces is to keep a creative team with an ambitious plan focused on a manageable set of goals. Says General Atlantic's David Caluori, "Every business that is growing as fast as Synaptive has a lot of opportunities to execute. The breadth of opportunities they have is a constant challenge and they have to prioritize the highest-value activities because they don't have a billion-dollar budget right now." He adds, "But if they did, I'm sure they would put it to good use."

For now, says Caluori, it's important for the company to grow its business and create positive reinforcement within the organization, "to create a long-term sustainable company. That is the blueprint we are working off of right now." 🟡

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