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Mynosys and the Science of Market Penetration:

A Case Study from Navigant Consulting

by
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Mynosys developed a device that automates the only manual part of cataract surgery, the world's most common surgery, thereby increasing its precision and improving outcomes. But that wasn't going to be enough to gain market adoption of a premium product in a bundled procedure already offering slim margins for physicians. Working with the consulting firm Navigant, the company implemented two successful strategies for market penetration.

When ophthalmology industry veteran John Hendrick was tapped to lead **Mynosys Cellular Devices Inc.** as CEO in 2013, he found a promising product destined for a large market—a device that would automate and increase the precision of the most difficult step in the most commonly performed surgery in the world—cataract surgery. (On a global basis, there are 26 million cataract surgeries each year.)

At the time, Mynosys was a two-man operation run by its founders, David Sretavan, MD, PhD, the former head of ophthalmology research at the University of California San Francisco, and engineer Christopher Keller, PhD. The two began working in 2006 to develop a novel device for performing a capsulotomy, the process of creating an opening in the eye's natural lens capsule through which the cataractous lens is removed and the artificial replacement lens inserted.

In 2012, after the founders tested a working surgical prototype in a rabbit model, they began knocking on doors looking for venture capital and angel funding, without much success. They needed an experienced CEO, they were told, so they recruited Hendrick, who had just finished a seven-year run as CEO of Neovista, the developer of a novel device therapy for age-related macular degeneration. Hendrick had also held executive positions at Allergan Medical Optics.

Hendrick says he spent two weeks on his own due diligence to determine if Mynosys' product was a worthwhile undertaking, and decided it was.

The capsulotomy has been described as the lynchpin of cataract surgery; get it right, and procedural success will follow; get it wrong, and there will be side effects and compromises to a patient's visual acuity. Indeed, if a clinician inadvertently breaks the lens capsule during the capsulotomy, says Hendrick, the procedure can turn into a vitrectomy, and a 10- to 20-minute case runs to an hour. As such, it is a pain-point for clinicians, especially when they're operating on complicated patients. Mynosys hoped to reduce their stress with an easy-to-use device that would achieve reproducible results.

The *Zepto Cataract Capsulotomy Eye Surgery System* Mynosys' founders developed replaces manual continuous curvilinear capsulorhexis (rhexis, for short), which is skill-dependent, and femtosecond laser technology, which is expensive (starting with upfront capital equipment costs of $500,000) and associated with higher rates of certain complications.

Zepto consists of a hand-piece attached to a laptop-sized console to deliver fast, low-energy pulses of direct current to create an ablative phase transition of water molecules (*see Figure 1*). The tissue cutting

action is delivered by a ring, so the capsulotomy is created in 360 degrees within 4 milliseconds. Using *Zepto* for this step shaves at least 10 minutes off the cataract procedure in comparison to rhexis and femtosecond lasers. *Zepto* would allow ophthalmologists to quickly and more easily create a precise and centered capsulotomy, allowing the intraocular implant to be centered on the visual axis of the eye. (If the lens is not centered, the patient will experience visual problems.)

By late 2015, when Mynosys won CE mark approval for the *Zepto* device in the EU, it was clear that it had a system that offered cost and clinical benefits over the two other major capsulotomy approaches.

But one major risk still remained on the table. In his experience, says Hendrick, "Many people come up with good ideas that could be beneficial to patients, but at the end of the day they have to be financially viable. And it's as true around the world as it is in our medical system, if physicians don't have a way to make money out of it, it won't get universally adopted. And it's also difficult to raise money in that case."

Mynosys faced the next adoption hurdle: market risk. Hendrick had, in previous companies, worked with Dymedex Consulting, now part of Navigant Consulting Inc., so he engaged the medtech practice of Navigant to conduct a strategic market assessment.

Specifically, Mynosys faced the challenge of introducing a new device into a procedure that is generally reimbursed as a bundled payment. In the US, for example, the majority of patients are covered by Medicare (because cataracts tend to occur with aging), which makes a one-time payment to the facility and to the physician for doing a cataract procedure. Everything that is part of the description of a cataract procedure is included in the bundled payment, i.e, an innovative device for creating a capsulotomy would be part of the bundle. "That means if the facility or the physician buys that product, it reduces their income. That was a major blocker," says Hendrick.

Mynosys turned to Navigant because "We needed to understand the different demographics of the market," says Hendrick. "What could people with cataracts afford to spend, what would doctors do with a product that did not have reimbursement? Was there any arena in which they would use it?" And one final question: could *Zepto* get reimbursement? Navigant was able to find the answers to these questions and set Mynosys on the path to success.

The Science of Market Development

Navigant is a global consulting firm operating across several industries including life sciences. Its medtech practice, led by director Michelle Edwards, helps companies realize the full market potential of their products. Edwards says that Navigant is especially well known for its data-driven methodology, called "the Science of Market Development," which looks at 14 critical factors to identify, assess, and reduce market risk and accelerate commercial adoption.

Navigant uses quantitative tools to figure out how a technology fits into a market and to analyze barriers that might hinder adoption. "We put that data into a proprietary model [in which variables are weighted to various degrees] to figure out what a likely adoption curve would look like, how the company can influence uptake, and where they should spend their money to get the biggest bang for their buck," Edwards says.

Navigant's client list includes 22 of the top 25 global life science companies. Large companies might engage Navigant to develop clinical trial or commercialization strategies for new products, or to develop a strategy to deal with a product on the market that is under-performing relative to expectations. But Edwards says about half of the business comes from companies like Mynosys; VC-funded medtechs that are "looking at investing in a single technology and want to validate the market. They want to know that their precious dollars are being spent as wisely as possible."

In 2015, Mynosys was in just that situation, and Navigant's task was to validate the market opportunity and value proposition for investors and potential acquirers of the *Zepto* capsulotomy system. Navigant set five primary objectives for itself and began by analyzing the cataract treatment landscape to gain clarity on *Zepto*'s market potential, areas of opportunity, and market penetration strategies (*see Figure 2*).

In the process, the team reviewed more than 200 articles, including clinical literature, physician forums, and patient online resources, and integrated the data with over 70 peer-reviewed published sources and Medicare procedure data

Figure 1

Zepto Capsulotomy Handpiece

Source: Mynosys Cellular Devices

Figure 2

Navigant's Strategic Assessment Goals for Zepto

- Quantifying the net addressable market potential, both overall and in each market sub-segment, for the US and the European Union, and assessing the adoption potential of Zepto in each of those sub-segments
- Assessing the barriers, investments, and time required to access the full market, which included defining the road map to becoming the standard of care for appropriate patients—both in guidelines and in actual practice—and prioritizing strategies and investments based on short- and long-term impact
- Providing strategic insights necessary to effectively prioritize target market segments and key barriers to adoption
- Determining the expected rate of market adoption under different growth investment scenarios, for instance, full investment vs. targeted or staged investments, and under different business model assumptions
- Synthesizing everything into a clear, concise, and compelling market assessment to support strategic discussions and enterprise valuation

Source: Navigant Consulting

to analyze cataract prevalence, incidence, longevity, and treatment age, among other factors.

Mapping the Patient Landscape

Navigant concluded that the cataract surgery market was mature, stable, and fully penetrated—nearly 100% of cataract patients requiring surgery were getting surgery. But the surgery rate is an age-driven dynamic and market growth was slowing as baby boomers aged out. Also, industry marketing efforts had increased the number of surgeries per year to a high baseline, so it would only grow 2.1% annually over the next 15 years. In other words, the overall surgical volume showed some promise for market increases, but not as much as the start-up originally anticipated.

In addition, Navigant's research and analysis revealed that while several factors favored the adoption of *Zepto*, superior technology alone would not be enough to propel it past the current standard of care for all cataract surgery patients. There were several promising sub-segments, however. Challenging clinical cases presented as compelling opportunities, because in those situations physicians would be highly motivated to adopt a new, risk-mitigating option. It turns out that 23% of surgery patients have high-risk ocular morbidities that cause intraoperative complications in standard-of-care cataract procedures. Hendrick notes that India provided a good point of entry, because that country sees higher rates of complications due to small pupils, shallow chambers, white cataracts, and pseudoexfoliation.

Navigant also identified another promising segment in low-volume surgeons who treat cataracts infrequently; they would benefit from the reduced surgical variability and risk *Zepto* offers.

Finally, in the US, the premium lens market presents an opportunity. Here, patients pay out of pocket for premium lenses that promise spectacle-free vision correction. As noted, to achieve the best results in terms of visual acuity, intraocular lenses need to be centered on the visual axis, a potential benefit that only *Zepto* offers (compared to manual capsulorhexis and femtosecond lasers). In the US, 14% of patients choose premium lenses, and these patients might benefit from *Zepto*'s superior precision and consistency.

Analyzing Barriers to Adoption

After defining the patient landscape, Navigant's team analyzed the barriers to adoption (again, according to factors that go into its scientific methodology, such as the degree to which a product is reimbursed, whether or not its use is already dictated by clinical guidelines, or what preponderance there is of clinical evidence to support its use). Several barriers were identified that could inhibit broad adoption, the most critical being cost and pricing for *Zepto*.

Research showed that little incentive existed for high-volume physicians performing routine manual capsulotomies to incur even the minimal incremental cost required to adopt *Zepto*, because 95% of their procedures already went smoothly.

These same physicians were also a barrier to adoption in premium-lens patients. Even though research indicated that premium-lens patients could afford to pay a little extra out of pocket, they would only do so if the technology was recommended by their physician.

These new insights indicated that initial success would be driven by the niche market of challenging cases. Edwards says, "From our work, we know that if the doctor successfully solves an unmet need in their first use of *Zepto*, say in a patient with an ocular co-morbidity that makes their eye very fragile, they will work to find more patients in which to use the device." If Mynosys could compel physicians to adopt *Zepto* for challenging cases, they would be more likely to begin using it for general cases too.

Finally, there was a lack of definitive clinical evidence validating *Zepto*'s

superior efficacy over the standard of care in any patient segment. And *Zepto* wasn't yet included in any practice guidelines, which are essential for engaging the broader clinical community. Without clinical evidence or guidelines, far fewer physicians would try the new treatment option.

To address these barriers, Navigant recommended that Mynosys conduct a small, targeted clinical trial to demonstrate how *Zepto* reduces the complication rate and works well in complex or co-morbid patients. Navigant also recommended the publication of the recommended clinical patient stratification to document the benefit of *Zepto* in high-risk patients to help gain initial inclusion in guidelines for selected high-risk patient groups. Mynosys took the advice and invested in the suggested clinical studies to demonstrate the inherent advantages of *Zepto* in cataract surgery patients with high-risk co-morbidities and in need of premium lenses, as well as to reinforce the superior procedural ease and precision for the general patient population.

Finally, Navigant recommended that Mynosys pursue a reimbursement strategy to compel providers to prescribe the technology. Navigant created forecasts for six different investment scenarios for Mynosys, each taking into consideration the response surface of market dynamics and the application of specific business strategies to address various adoption barriers. If Mynosys stayed on its existing commercial launch course and did no additional investments to address adoption barriers, Navigant's analysis forecasted up to a 53% market penetration valued at $221 million in revenue by 2030 in the US alone.

If major barriers were overcome through targeted investments and strategies, however, *Zepto* had the potential to rapidly grow globally to more than $600 million by 2030, according to Navigant's model.

Reimbursement: Removing the Barrier to Broad Adoption

Mynosys worked with Quorum Consulting, now a part of Navigant, to create the strategy and work through the long and arduous process of gaining a Category III CPT Code from the American Medical Association to provide a reimbursement option. The Category III code allows the physician to collect payment for the novel procedure.

Navigant's strategy involved leveraging the unique ability of the *Zepto* capsulotomy to center on the visual axis of the patient. "We studied the architecture of the current bundle, and it was clear that aligning on the visual axis was *not* within the definition of a cataract surgery procedure," says Hendrick.

The first submission was turned down. Mynosys had to hit the road to educate members of societies like the American Society of Cataract and Refractive Surgery and the American Academy of Ophthalmology, and applied once more, only to be rejected, again. The third time was a charm, however. "I felt very strongly that the definition of aligning on the visual axis was clearly outside the bundle," says Hendrick. "I brought along doctors this time [Vance Thompson, MD, and Kevin Waltz, MD], and they did a great job of presenting the clinical benefits and the fact that it was clearly outside the bundle." Mynosys got its Category III CPT code, which became effective last January.

"So now we create a safer environment for the physician, it is quicker, it allows them to center the lens, and he or she can get paid for it. I can't emphasize that enough. They need to see that it provides a clinical benefit and makes them money. Those are the two factors that drive it," Hendrick says.

With the CPT code in hand, Mynosys also enlisted Navigant to provide insight for pricing to help guide and encourage physicians on the value of the technology. "We can't tell physicians what to charge, but we can give them recommended ranges of what to expect," Hendrick explains. "I had a gut feel of what to recommend, but now I *know* what to recommend."

"The strategic market assessment project pointed us clearly in the direction we needed to go," Hendrick recalls. "We now knew better where to focus our marketing efforts.

Mynosys Today

Zepto has now been used in over 30,000 cases worldwide.

A series of clinical studies published in 2018 validated the superior results of cataract surgeries performed with *Zepto*, including an article published in the *Journal of Cataract & Refractive Surgery* (JCRS) that received the prestigious 2018 Rosen Award, which is given to the authors of the best technique article published in the year, as voted on by the editors. (See Vance Thompson, MD, "Streamlined method for anchoring cataract surgery and intraocular lens centration on the patient's visual axis," *JCRS*, May 2018.)

Another notable clinical study was performed by Doctors Massimo Camellin, Umberto Camellin and Luisa Frizziero in Italy, the results of which were published in *Visco Chirurgia*. The study concludes, "The technical skills and early results of *Zepto* show promising data that could support an increasingly widespread use of this technique, also and especially in cases of cataract with increased risk of complications." Many similar results are being reported from surgeons around the world.

Now that Mynosys has reached its commercialization phase, Hendrick has stepped down and ceded the helm to former board member Thomas Dunlap. Now CEO of Mynosys, Dunlap previously held executive positions at HOYA Surgical Optics, Allergan Medical Optics, Bausch & Lomb Surgical, and Surgilase among many other experiences in the ophthalmology industry. On January 1, 2019 the Category III Reimbursement code became effective for *Zepto*. Dunlap says: "The market response has been very encouraging. In fact, we see *Zepto* being used on challenging cases, premium cases and standard monofocal intraocular lens cases. The technology delivers a clinical benefit and the economics make sense for patients and surgeons alike."

Patented worldwide, *Zepto* technology is available in 29 selected markets, including the Americas, Europe, Africa, Asia, and the Middle East, through local distributors, and is gaining in use among ophthalmologists worldwide, especially for challenging cases. In testimonials, physicians have noted the consistency, precision, and safety the *Zepto* capsulotomy system provides—at an accessible cost.

Said Richard Lindstrom, MD, a leading cataract surgeon in Bloomington, MN, "Given the choice, I would use *Zepto* on every patient."

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