

Slow and Steady Recovery Likely for Axogen

Companies: ABBV, AXGN, HSIC, IART, SYK

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Research Question:

Is the stronger-than-expected second-quarter demand Axogen experienced for its nerve regeneration products sustainable?

Summary of Findings

- Sources were mixed trending positive regarding [Axogen Inc.'s](#) (AXGN) ability to sustain the stronger-than-expected Q2 demand for its nerve repair and regeneration products.
- Three surgeons, three sales professionals, and an Axogen partner expect demand for its products to continue to expand. Growth will be driven by demand from university and sophisticated hospitals performing larger nerve gap procedures with Axogen's flagship products, [Avance Nerve Graft](#) or [AxoGuard Nerve Protector](#).
- Three surgeons and an industry specialist expect Axogen to be challenged to grow because most nerve repair and regeneration procedures are small gaps, which Axogen has not been successful in penetrating deeply. These repairs are typically performed by direct repair (suturing with tension) or the gold standard, autograft tissue (a patient's harvested nerve tissue) surgical reconstruction.
- Three surgeons noted that Axogen could significantly expand its use case for small gap repair if its products were not so costly. Two sources noted that Axogen needs more and better data to effectively communicate its value and expand sales, something it has yet to effectively accomplish.
- The nerve repair and regeneration markets are well established and not likely to experience significant expansion. Axogen's growth will take time as more surgeons are informed and educated about its products. One source said residents and fellows exposed to the products during training are some of their future users. Axogen's online programs and sales focus on expanding use of its products in existing accounts is considered a positive.
- Axogen's biggest competition comes from surgeons performing autograft procedures. [Integra LifeSciences Holdings Corp.](#) (IART) and [Stryker Corp.](#) (SYK) are also strong competitors. Integra was discussed by one source as working on breakthrough nerve conduits that will allow nutrients to be absorbed by the nerve.
- Blueshift Research reported positively on Axogen on [April 3, 2019](#). The company's leadership changes and sales team expansion were considered positives and necessary to reignite passion within the company for its products. Growth was expected to be slow and steady. Our current findings are similar to the April 2019 report, excluding the obvious impact of the COVID-19-related slowdown. Sources acknowledge Axogen as a leader in the nerve repair space with high quality products. Continued slow growth is expected.

Silo Summaries

1) Surgeons

Six surgeons offered mixed opinions on Axogen's growth opportunities and its ability to sustain its Q2 sales surprise. **Three think growth opportunities exist for longer nerve gap repair procedures, where there is limited competition for Axogen.** University and larger sophisticated hospitals are the major consumers of Axogen products, as opposed to smaller hospitals. **The other three sources acknowledge Axogen's high quality but see limited growth opportunities, as its pricing is prohibitive and the market for its products is small.** Another challenge faced by Axogen is the preference of many surgeons to perform an autograft or simply stitch the damaged nerve for small gap repair procedures. Integra LifeSciences is considered a strong competitor and is working on a potential breakthrough nerve conduit that allows for the damaged nerve to absorb nutrients, which will aid in the regeneration process.

2) Surgical Supply Sales Channel and Competitors

Three Axogen competitors expect its growth to continue. One source said their company's Q3 numbers are within 10% to 20% of pre-COVID-19 numbers after almost a total shutdown in Q2. This source still expects some regional slowdowns as different geographic regions struggle with a COVID-19 resurgence. Another source said elective procedures are continuing to increase and are only at 25% of pre-COVID-19 numbers, but trauma procedures have not been impacted. The third said nerve procedures will continue to increase and Axogen is well positioned to progress with its recovery; however, additional supportive data is needed. Two of the three sources commented on Axogen TAM as accurate, but one said Axogen's strength is with long nerve gap repairs, which is less than half of the total stated TAM.

3) Axogen Partners

This sales representative with key account responsibilities sees sales trending up for his company and the companies to which they sell tissue regenerative products, including Axogen. Axogen should be back on the growth track and meet its goals.

4) Industry Specialists

Axogen has overestimated its total available market, according to this source, who states there are fewer than 25,000 cases for peripheral nerve repair and most are 30 mm or less. No company can officially claim FDA approval for peripheral nerve repair, but **Axogen has the strongest data.**

	Sustainability of Axogen's Strong Q2	Axogen TAM	Axogen Reputation
Surgeons	➔	Inflated	⬆️
Surgical Supply Sales Channel and Competitors	⬆️	Accurate	⬆️
Axogen Partners	⬆️	Accurate	⬆️
Industry Specialists	➔	Inflated	⬆️

Background

Blueshift Research's [April 3, 2019, report](#) found that Axogen's executive leadership changes in late 2018 were necessary and considered a positive by the medical community. The C-suite changes were expected to improve the corporate culture and reignite passion for Axogen's products while leading to the slow and steady adoption and sales growth of its entire nerve repair portfolio. Surgery sources interviewed for that report noted that the patient population for many nerve repair and regeneration procedures is limited and that recovery, if successful, would take as long as a year.

Blueshift's ongoing research found Axogen, the leader in the development and commercialization of technologies for peripheral nerve regeneration and repair, experiencing a strong rebound in growth following the late Q1 and early Q2 2020 sales declines due to COVID-19. With a leaner organization due to COVID-19-related cost mitigation initiatives and a sales and support team retooled for limited direct hospital and surgeon face-to-face encounters, building on the Q2 success is a primary goal. Axogen is focused on expanding utilization of its products in the extremity trauma market segment and driving deeper penetration with its existing surgeon customers. It remains to be seen if the underlying demand for these unique products is truly growing and will deliver Axogen's future growth.

After posting mixed Q1 2020 results due to a significant drop in sales because of hospitals reallocating resources to prepare for and treat COVID-19 patients, and as shelter-in-place orders reduced the incidence of traumatic injuries, Axogen experienced stronger-than-expected Q2 results. The company reported a Q2 loss of \$0.20 per share on revenue of \$22.1 million. The consensus estimate was a loss of \$0.33 per share on revenue of \$11.2 million. Revenue fell 17.2% compared to Q2 2019. Karen Zaderej, chairman, CEO, and president of Axogen, said, "We are encouraged by the performance of our commercial team and the demand for our products over the course of the quarter as surgery schedules opened and hospitals quickly moved to complete nerve repair procedures." Zaderej added that Q3 and Q4 performance will likely trend below prior-year results because regional COVID-19 resurgence may continue to negatively impact the incidence of trauma and surgical procedure volumes in certain geographies.

Despite the sales decline, Axogen generated Q2 highlights, including ending the quarter with 112 direct sales reps vs. 100 the year before, increasing its active accounts by 4% to 789 vs. 762 in Q2 2019, and ending Q2 with 126 peer-reviewed clinical publications featuring Axogen's nerve repair product portfolio. The company also announced the completion of enrollments in its RECON Clinical Study—a pivotal study supporting the company's Biologics License Application (BLA) for Avance Nerve Graft. In June, Axogen expanded its digital marketing capabilities, allowing it to more fully engage with surgeons electronically.

Axogen is optimistic regarding its total addressable market (TAM), which it recently estimated at \$2.7 billion, with trauma representing the bulk of the opportunity at \$1.5 billion and 700,000 procedures. However, some on the street question whether this may be overstated. A [report](#) now available from Market Research Engine projects growth for the nerve repair biomaterials market in the United States at a compound annual growth rate (CAGR) of 11.2% for 2020 to 2025, totaling \$834 million by 2025.

Current Research

Blueshift Research assessed whether the stronger-than-expected Q2 demand Axogen experienced for its nerve regeneration products is sustainable. We employed our pattern mining approach to establish five independent silos, comprising 11 primary sources (including one repeat source) and two secondary sources focused on nerve repair and regeneration products and procedures. Interviews were conducted September 20 – October 5.

- 1) Surgeons (6)
- 2) Surgical supply sales channel and competitors (3)
- 3) Axogen partners (1)
- 4) Industry specialists (1)
- 5) Secondary sources (2)

Next Steps

Blueshift Research will continue to monitor Axogen's growth trend to determine if it is sustainable. We will try to determine how successful Axogen is at penetrating deeper into its existing accounts. We will research surgeon willingness to use more of Axogen's products for small and mid-gap nerve repair.

Silos

1) Surgeons

Six surgeons offered mixed opinions on Axogen's growth opportunities and its ability to sustain its Q2 sales surprise. Three think growth opportunities exist for longer nerve gap repair procedures, where there is limited competition for Axogen. University and larger sophisticated hospitals are the major consumers of Axogen products, as opposed to smaller hospitals. One source said Axogen's ongoing growth will come from fellows and residents exposed to its products during training and then continuing to use those products in private practice. The other three sources acknowledge Axogen's high quality but see limited growth opportunities, as its pricing is prohibitive and the market for its products is small. Another challenge faced by Axogen is the preference of many surgeons to perform an autograft or simply stitch the damaged nerve for small gap repair procedures. Integra LifeSciences is considered a strong competitor and is working on a potential breakthrough nerve conduit that allows for the damaged nerve to absorb nutrients, which will aid in the regeneration process. [BioHorizons](#) (a majority-owned subsidiary of Henry Schein Inc. [HSIC]) and [Strattice](#) (of LifeCell Corporation, an AbbVie Inc. [ABBV] company) were discussed as having investigative products in the nerve repair space. [BioXclude](#) was mentioned as an Axogen competitor in the oral and maxillofacial surgery sector.

Key Silo Findings

Axogen Use Case and Growth

- 3 of 6 said continued use and sales growth for Axogen is likely.
- 3 said growth for Axogen will be limited because of its products high cost and surgeon preference for using the gold standard of autograft procedures.

Axogen TAM Opportunity

- 5 think Axogen's TAM is dominated by large gap nerve repair, which is a fraction of the total nerve repair and regeneration market.
- 1 did not speculate.

Axogen Sales, Support, and Training Online Overhaul

- 2 were positive regarding Axogen's online focus.
- 1 said university hospitals have restricted sales rep access for some time so the COVID-19-related pullback is a non-issue.
- 1 said sales reps and procedure support professionals are not allowed back in their hospital.

Competitive Landscape

- Axogen has limited competition for long gap nerve repair.
- Stitching and autograft procedures are a primary competitor for Axogen for small gap nerve repair.

- Integra LifeSciences is considered a significant competitor and is working on a breakthrough conduit.

1) Actively practicing plastic/hand surgeon at a major academic medical center in the Southeast

Axogen is this surgeon's "go-to" vendor for nerve regeneration products. He considers the company the leader in the nerve regeneration space and said it is experiencing increased use at academic and sophisticated surgical centers, but not in smaller hospitals. The nerve regeneration market is well established and stable, with limited overall growth due a lack of new developments in the space. Academic institutions have limited pharma and device sales rep access, so Axogen's shift to online interaction has had little or no impact. This surgeon is not aware of any serious Axogen competitors.

Axogen Use Case and Growth

- "Axogen is the only company that has human allografts available off the shelf. It's my go-to company both for allografts and for the porcine nerve tubes."
- "Axogen is the clear market leader. I am not aware if they even have any real competitors."
- "Growth is occurring in academic and other sophisticated centers but not in smaller institutions."
- "The primary uses [by far] are in trauma cases. Nerve repair is also fairly frequently used by ENT surgeons when repairing mandible fractures. This is rarely indicated in carpal tunnel procedures. There really aren't any other significant applications."
- "It is fully done on an outpatient basis now."

Axogen TAM Opportunity

- "This market is very stable [with little growth]. There haven't been any significant new technological developments in several years. Further, the use of these procedures are also well established."

Axogen Sales, Support, and Training Online Overhaul

- "The use of sales reps has been severely curtailed over the past several years, in my experience, as the large academic centers have felt that their presence was too prominent."
- "COVID really hasn't impacted my exposure to sales reps."
- "I email reps when I need them to be in the OR to provide guidance in the use of a new plate or product. They show up to make sure that all of the necessary materials are in the OR pack. They also provide education to the OR nurses."
- "I haven't used their web-based programs."

Competitive Landscape

- "I have had virtually no contact with any company that is a competitor to Axogen. I trust them, as do my colleagues."

Axogen is the only company that has human allografts available off the shelf. It's my go-to company both for allografts and for the porcine nerve tubes. ... Axogen is the clear market leader. I am not aware if they even have any real competitors.

Actively practicing plastic/hand surgeon at a major academic medical center in the Southeast

2) Chief of staff of a major children's orthopedic hospital

This chief of staff specializing in hand and upper extremity pediatric orthopedics describes the Avance use case as for repair of sensory nerves no longer than 40 mm, preferring 10 to 20 mm repairs be done with sutures or conduits. Autografting is the gold standard. Though this source is not a big user of Axogen products, they have a good reputation and should be back on the growth track, although the numbers of procedures in the Axogen estimate may be a bit inflated. Axogen and Integra are best positioned for the future where this source believes the allograft product laced with nerve growth factors may one day supersede the autograft and reduce donor morbidity and OR time.

Axogen Use Case and Growth

- "I think that Axogen will continue on their growth track. Some nerves respond better than others to transplantation. Facial nerves do better."
- "The use case for the Avance product is a small defect in a sensory nerve no longer than 4 cm [40 mm]. Any longer than 4 cm [40 mm] would not be advised. In injuries where the defect is 1 to 2 cm [10 to 20 mm], conduits or sutures would be the preferred procedure. In our hospital we don't use much of this product."

- “If the injury is a clean cut, we’ll just suture it and not use any kind of transplant.”
- “Allograft procedures would be for relatively small deficits in a sensory nerve.”
- “The animal data shows a significant drop off in successful results after 3 to 4 cm [30 to 40 mm] with allografts.”
- “The [Ranger Registry](#) published in February 2020 tracks outcomes of over 600 nerve repairs using the Avance allograft. Axogen has cherry-picked the data to make their results look better than it really is.”
- “Key in the surgery is to get maximum imbibition [absorption of the nutrients] with sustained inosculation [vessels growth]. Conduits and other allograft materials can often impair this from occurring.”
- “Autograft remains the gold standard for nerve transplantation. The industry sees the numbers of procedures and knows there is tremendous financial potential for introducing better materials that would reduce the morbidity of patients for the autograft. They are all over this area.”
- “Our procedure is to harvest the sural nerve in the lower leg and reserve conduits and allografts for situations that can’t be bridged otherwise. I recognize that future research in allografts may supersede the autograft, especially as nerve growth factors are identified and synthesized. A conduit or allograft laced with nerve growth factors may ultimately be superior and reduce donor morbidity and OR time.”

Axogen TAM Opportunity

- “The estimate of potential nerve repair operations of 900,00 and the breakout seems a bit inflated to me. I think the more important factor is whether the nerve product is applicable to the type of nerve injury.”

Axogen Sales, Support, and Training Online Overhaul

- “We’ve had the sales reps back in the OR since sometime in late June—for about three months. We allow just one rep per procedure. In past there were often two reps but [they are] now limited.”

Competitive Landscape

- “Integra is very big in this field. They are actively working to develop a better conduit to enable the nerve to absorb the nutrients and better regrow the nerve. The company that can turn on the growth factors and sustain the activity of the growth factors, not just in the early stages of recovery, will have tremendous impact on this area.”
- “Integra and Axogen are the companies most active in nerve regeneration and they would be the most likely company to break through in this class.”

3) Hand and orthopedic surgeon practicing at a teaching hospital and level 2 trauma centers

This surgeon predicts that Axogen will grow as residents and fellows who have been trained to use Axogen products continue to use them when they go into practice. He previously used other nerve repair biomaterials but Axogen produced superior results. For the last three years, his Axogen usage has been going up due to hand trauma cases. Surgeons in other specialties are using more Axogen products.

Axogen Use Case and Growth

- “I’d say [the use case for Axogen] is growing. My use of it has been growing in the last three years.”
- “Yes, [the Q2 demand for Axogen is sustainable]. No one else has come out with the nerve allograft. It’s the biggest part of their product line.”
- “[As for the use trends in trauma, carpal tunnel, cubital tunnel, oral and maxillofacial, breast, etc.,] they are just using more [Axogen for all of those].”
- “I have a huge catchment area of trauma that’s referred in and life flighted in. We have three hand surgeons. Two of us use Axogen exclusively and we have a residency program which I teach in.”
- “I do at least two [Axogen procedures] of some sort and it can be as many as seven or eight a month. It’s growing for me because of its use in hand trauma.”
- “I don’t think the coronavirus has made any difference in the usage of Axogen because, even during when we closed the office down, I still had hand trauma [patients]. That’s the main use for it. You can use it on the lower extremity for nerve repairs. You can use it on any kind of nerve repair that’s kinetic.”
- “The problem with Axogen is pricing for surgery centers. Axogen can do well in hospitals or specialty hospitals. Surgery centers, because of the pricing of it, they generally won’t use it.”

Yes, [the Q2 demand for Axogen is sustainable]. No one else has come out with the nerve allograft. It’s the biggest part of their product line.

Hand and orthopedic surgeon practicing at a teaching hospital and level 2 trauma centers

Axogen TAM Opportunity

- “I have no idea [how big the nerve repair biomaterials market is]. I used to [use other nerve repair biomaterials]. I got better results with Axogen.”
- “I have no idea how Axogen estimated their numbers [for TAM]. I can’t tell you [if it’s realistic].”

Axogen Sales, Support, and Training Online Overhaul

- “Just recently, Axogen had a teaching course like a month or so ago. They provide good resources. Online works better for me because of the scheduling. So you don’t have to spend a day or half a day traveling to someplace to do a workshop.”

Competitive Landscape

- “There is no one that makes the allograft, so that means Axogen is the exclusive provider. There are others that make tubes.”
- “More allografts are being used in our teaching residency program. And [if] you have a resident who is now a hand fellow, as they go out and practice, they are going to use the product. So you are going to get growth [in Axogen usage] through their earlier experience in their training program.”
- “[This is also true for the other surgery subspecialties like breast and trauma] because you use whatever you were taught to use.”

4) Comprehensive peripheral nerve surgeon in the Midwest

Large gap nerve repair is a fraction of the total market. The greater limiting factors for Axogen are the number of surgeons qualified to perform a long gap repair and the cost of its products. Although its use case is compelling, the outcomes data is based on animal models. Some surgeons are skeptical whether that data directly correlates with functional human outcomes. Axogen cost is an enormous impediment when autograft procedures are a fraction of the cost.

Axogen Use Case and Growth

- “Although there are varying definitions, when we talk about large gap peripheral nerve repair, these are gaps more than 3 cm [30 mm]. There are plenty of patients that need nerve repair products and plenty of product available, but there are only a small number of surgeons in the U.S.—less than 1,000 and perhaps less than 500 total—who are qualified to perform these surgeries with Axogen products. If we use the high end of 1,000 qualified peripheral nerve repair surgeons, and every single one used Axogen, we would be looking at nearly 1,000 procedures per surgeon per year to get to their TAM estimate.”
- “Most patients will only need one to two grafts but a very small minority of severe, complicated traumatic injury patients may need up to 20.”
- “There are a significant proportion of nerve repair surgeons who are skeptical about the research Axogen uses to justify using their products. There is a good use case, and their animal model data is compelling, but a significant percentage of surgeons doubt that the animal studies directly correlate with human functional outcomes. I would estimate, however, that at least half of the qualified surgeons use Axogen products for long gap repair in at least some instances.”

Axogen TAM Opportunity

- “Cost is an enormous impediment to expanding the use of Axogen products. It is a recurring theme. A surgeon will commonly opt for an autologous graft. Sure, the patient may suffer from numbness in the ankle, but they will not be saddling them with \$15,000 in Axogen product charges and will not have the hospital administrator jumping down their throat about spending so much money on the surgery.”
- “Axogen has a lot of potential to move its product into use for shorter gap repairs but the biggest challenges are the number of surgeons qualified to do this type of surgery and the cost of the Axogen products.”
- “The majority of surgeons using Axogen products are hand surgeons who are disproportionately associated with academic medical centers. Because they are research oriented, those facilities are typically less concerned about cost.”

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Comprehensive peripheral nerve surgeon in the Midwest

Axogen Sales, Support, and Training Online Overhaul

- “All companies are in the same position now.”

Competitive Landscape

- “Axogen is really the only company that has a product for long gap peripheral nerve repair.”

5) Reconstructive and maxillofacial surgeon and biomedical engineer

Total market estimates for nerve repair are likely accurate, but large gap repairs are a fraction of the total. Axogen does not have commercial competitors for large gap repair; the alternative options include autograft and allograft. If the cost for Axogen products were lower, it could probably capture a percentage of the small gap nerve repair. Newer xenograft technologies (currently only available as a research tool) could be a competitor in the future. Prior to COVID-19, digital training would be wholly insufficient for surgeons—but the situation has changed. Axogen’s online education is effective for initial exposure and technical understanding.

Axogen Use Case and Growth

- “There was a [Markets and Markets](#) research report done, which is how I assume Axogen is estimating their market size. Although I have no way to validate those numbers, it is certainly true that the large gap nerve repair cases for which Axogen products are well suited is a fraction of the total nerve repair cases.”

Axogen TAM Opportunity

- “The cost of the Axogen products is their biggest limiting factor. If they could lower the price, at least for the higher volume shorter repairs, they would be able to grow their available market and increase utilization with existing Axogen customers.”

Axogen Sales, Support, and Training Online Overhaul

- “If you asked me this last year, I would have said there is no way to effectively train surgeons virtually. But the environment is very different now. People understand the situation, accept the virtual options, and enjoy the convenience of learning on demand. I expect this will be the norm for the next six to 12 months at least. Virtual education efforts certainly work for initial exposure and technical understanding.”

Competitive Landscape

- “Axogen products are expensive and are not always needed. For short gap repairs a graft is not needed at all. For one to five cm [10 to 50 mm] gaps, which are the majority of them, we typically use conduits. But for less than five cm [50 mm] repairs, the options are autograft, allograft, or Axogen.”
- “With autografts we typically use a sensory nerve from the calf. This is not optimal for repairing a motor nerve, which has a different anatomical structure [such as bundle sizes, number of fibers, not fitted for the axon size, etc.]. It is the wrong modality. Additionally, the patient experiences a permanent numbness in the calf, which is an acceptable tradeoff but it is not pleasant. For these reasons, my first choice is donor allografts but there seems to be little difference in clinical outcomes. But if price was not a factor, Axogen would be used for the shorter repairs much more frequently.”
- “In the research environment, we are using [porcine] xenografts. We de-cellularize and re-cellularize to essentially convert an animal nerve to a human nerve. Although it requires tissue cleanup, once that it is done the graft does not get rejected. To my knowledge, this is currently a research only procedure. BioHorizons and Strattice have porcine tissue matrix products but, when it comes to blood vessels and nerves, there is no commercial porcine product available, as far as I know.”
- “From a research perspective, large gap is the holy grail of nerve repair. But there are relatively very few cases. It is an orphan designation situation for gaps more than 15 cm [150 mm]. It may simply be that there is not enough demand for other competitors in that segment.”

The cost of the Axogen products is their biggest limiting factor. If they could lower the price, at least for the higher volume shorter repairs, they would be able to grow their available market and increase utilization with existing Axogen customers.

Reconstructive and maxillofacial surgeon and biomedical engineer

6) Oral and maxillofacial surgeon in private practice

This surgeon uses the Axogen Axoguard Nerve Protector less than once a month and frequently finds that it can salvage the nerve. He refers patients requiring Axogen nerve grafts to oral and maxillofacial (OMF) surgeons who do that procedure. His friends and colleagues have told him that the graft is very useful and works quite well. BioXclude is the only product he knows of that directly competes with Axogen in oral and maxillofacial surgery.

Axogen Use Case and Growth

- “[Axogen] is primarily for nerve regeneration, and it’s in lieu of taking a graft, typically. ... It’s been fairly successful. I don’t really see that many cases that warrant it. I have lots of friends who ... say it’s really useful in terms of not having to take a nerve graft. So you save a second surgical site.”
- “The only [Axogen product] that I personally use is the protector. I have never used the graft before but I’ve just heard from my [OMF] colleagues that it worked really well.”
- “[In OMF,] I think one of the most common uses is actually iatrogenic, particularly if you have a dentist try to take out a wisdom tooth. That tooth is often right near the nerve. There are two nerves right near it. ... So my most common contact with a person who would need a graft like that is not trauma—it’s iatrogenic. A dentist or somebody would actually injure that nerve, either compress it or literally cut it. And so then you would use the nerve graft to put that nerve back together again.”
- “I don’t even do one [Axogen procedure] a month. The cases that it’s mostly warranted on, I refer because you have to do a lot of them to really be proficient at it. I use the Nerve Protector to try to protect the nerve and, if it’s in a particularly vulnerable area, we will definitely use it when we have to, but it’s just not that often. I send [the nerve graft cases] off.”
- “A lot of times you can salvage the nerve by just putting it in [the AxoGuard Nerve Protector]. It keeps the pressure off that nerve and keeps it from being injured—hopefully, anyway.”
- “Elective surgery is still not back full speed yet. The hospitals still want their ORs relatively clear, because they don’t want the patients after the surgery on the ward where they want to keep their COVID patients. So they still haven’t let elective surgeries back full swing in the hospitals yet. I think that’s pretty much in most places. There are a few places that are back full swing but I think there are still some limitations on what you can do electively, probably in most hospitals.”

Axogen TAM Opportunity

- “I don’t think [the nerve repair biomaterials market] is real big, at least not in oral surgery. I just don’t think that those products are used that commonly. They definitely have a niche. I mean, there is a time when you just really need it and it’s great to have but, for the most part, those cases aren’t ubiquitous. Literally, I see probably maybe two to three patients a month who would be suitable for any of those products in oral and maxillofacial surgery.”
- “I think that [Axogen’s projected TAM] is kind of a high mark. I think that it’s achievable. I just think that’s kind of on the high end. This is just opinion—I don’t have any data—but I just talk to a lot of people and, seeing what’s being done, I would not be totally surprised, but I’d say [Axogen] is doing really well if they do that much. I’m talking about everything [including OMF surgery].”

Axogen Sales, Support, and Training Online Overhaul

- “I have looked at their website. They have fairly decent online protocols. I just kind of looked at it to see what they have and I think they are good.”
- As for whether more OMF colleagues are using Axogen’s products: “Not a lot.”

Competitive Landscape

- “I think they have a pretty good market. I don’t think there is a whole lot of competitive products out there. There is something called BioXclude. You can use that for a nerve protector, too. ... That’s the only one I really know of that is a real direct competitor of them in my field.”
- “I don’t hear much talk about [Axogen’s] competition. I really don’t. I have heard a pretty good bit about [Axogen]. ... I think they have done a fair job marketing. You hear the name out there a pretty good bit. I don’t mean like you hear it every day, or anything like that, but you just will hear the name. You know, people talk about it.”
- “I just don’t hear enough about [Axogen] to say that everybody wants to use that. You know there are all these cases that we need to use it for. I just don’t hear it—like breast and plastic surgeons doing it, orthopedic surgeons doing it. I talk to them all the time. I come in contact with them all the time but we just don’t discuss that very much.”

2) Surgical Supply Sales Channel and Competitors

Three Axogen competitors expect its growth to continue. One source said their company's Q3 numbers are within 10% to 20% of pre-COVID-19 numbers after almost a total shutdown in Q2. This source still expects some regional slowdowns as different geographic regions struggle with a COVID-19 resurgence. Another source said elective procedures are continuing to increase and are only at 25% of pre-COVID-19 numbers, but trauma procedures have not been impacted. The third said nerve procedures will continue to increase and Axogen is well positioned to progress with its recovery; however, additional supportive data is needed. Two of the three sources commented on Axogen TAM as accurate, but one said Axogen's strength is with long nerve gap repairs, which is less than half of the total stated TAM. Axogen is executing a solid conversion to online sales and support, along with the rest of the medical/healthcare vendors. Also, its focus on expanding deeper into existing accounts is considered a positive. Axogen's primary competitors are surgeons performing autograft nerve procedures and Integra and Stryker.

Key Silo Findings

Axogen Use Case and Growth

- 3 said Axogen's recovery and growth will continue.
 - o 1 said Q3 has recovered to within 10% to 20% of pre-COVID-19 levels but expects some geographic regions to experience slowdowns due to a resurgence of COVID-19.
 - o 1 said elective procedures are only at 25% of levels prior to COVID-19 and they are increasing. They added that COVID-19 did not impact trauma cases.
 - o 1 said nerve regeneration procedures are increasing and Axogen is well positioned to continue its recovery.

Axogen TAM Opportunity

- 2 said Axogen's nerve regeneration TAM estimate is accurate.
 - o 1 said larger nerve gap repairs, which are Axogen's strength, are less than half of the total TAM.
- 1 did not comment.

Axogen Sales, Support, and Training Online Overhaul

- 2 said the online shift for sales support and training is the industry standard, due to COVID-19.
- 1 said Axogen's focus on expanding sales in existing accounts is a solid strategy, as it is difficult to get new products on a hospital's formularies during COVID-19.

Competitive Landscape

- Surgeons performing autograft procedures, Integra, and Stryker were the competitors discussed.
- 1 said Axogen has no competition for longer gap nerve repair situations.

Miscellaneous

- 1 mentioned that physicians are getting burned out on the amount of online interaction from all of the pharm and device companies.

1) 15-year sales representative with competitor company

The nerve reconstruction market Q2 sales were awful, but in Q3 have rebounded to about 10% to 20% less than previous quarters. Axogen's focus is on its Avance product for nerve gaps of 20 to 70 mm, where it is on formulary and surgeons believe in the advantages of one recovery site, not two. Like all of its competitors, Axogen's promotions and education are all done virtually—online and digitally—but, because everyone is doing this, there is some physician burn-out. The advantage in the virtual approach is that the key messages will be exactly communicated on every program. This source agrees with the new strategy to pursue current users where Axogen products are on formulary. Due to the pandemic environment, it is extremely difficult to conduct an evaluation to gain formulary inclusion at a non-user institution. Axogen's new approach is strong and will gain this lower-hanging fruit.

Axogen Use Case and Growth

- "For short gaps between nerves (due to the trauma), when the gap is one to two cm [10 to 20 mm], surgeons will typically use a conduit—a number of companies have these—and allied products to support the procedure. It is a competitive market."

- “When the gap is greater than two cm [20 mm], then the surgeon makes the decision to do an autograft procedure and harvest from the patient or potentially use an allograft, such as a cadaver nerve transplant from Axogen. Avance can bridge a gap of up to seven cm [70 mm] by five mm. Longer transplants would have to be an autograft.”
- “Where the nerve damage is a clean cut—often seen with kitchen accidents or less overall disruption—a conduit is usually the solution. The nerve ending tends to retract when stretched into the conduit, so that is where the two cm [20 mm] or maybe two-and-a-half cm [25 mm] gap is the limit. If the damage is more crushing and not a ‘clean cut,’ they will have to remove more of nerve and potentially surrounding tissue and analyze the gap. Integra and Stryker conduits are better suited for the longer gaps within the two to two-and-a-half cm [20 to 25 mm] range. Axogen conduit is limited to smaller gaps.”
- “Surgeons deciding [between] autografting vs. the Axogen allograft is driven by cost and personal preference. Axogen’s transplant is good to a max of seven cm [70 mm]. At many public hospitals, harvesting from the ‘host’ and suturing the harvest site and the transplantation is far less expensive—the cost of sutures and the time in the OR vs. a \$1,000 or more product. Many trauma surgeons prefer the host harvest method. Not as many are convinced that eliminating the harvest site is that important.”

Axogen TAM Opportunity

- “Regarding the number of procedures and the percentages of trauma vs. carpal/cubital tunnel vs. OMF vs. breast, these percentages seem about right, with most of the procedures in trauma and tunnel syndrome repair.”
- “Q2 sales were awful starting in mid-March. Q3 seems like it’s back to where it was but there are patient questions and concerns regarding having the procedure now or waiting six months.”
- “I’d estimate there is a drop-off of 10% to 20% of nerve reconstruction procedures but in other parts of the country it may be worse. In the Northeast metro areas, we shut down in Q2 and have rebounded but we know other areas are still struggling.”
- “What tends to happen is the trauma surgeons put the patients together and stabilize their injuries. After the trauma procedures, these patients typically get referred to the specialty for their injury, often waiting a few weeks before their procedure. This is when the upper extremity, hand, foot, or plastics surgeon would get involved.”
- “Every hospital is a bit different as to which specialist do what procedures and where it starts and stops.”

Axogen Sales, Support, and Training Online Overhaul

- “Every company in this market has had to make the changes from personal promotion to online and digital. There are different seminars—45 to 60 minutes—and approaches for educating on advances and techniques. Digital training is dominant. In the past, we would fly a healthcare professional in or to a site to do a seminar and hands-on practice. Now it’s virtual and digital. Doctors will tell you everybody is doing it this way.”
- “Many of the hospitals are still banning rep visits to the procedure rooms.”
- “Regarding the effectiveness of the virtual programs, they can be effective but there is significant doctor burn-out on them because so many companies are doing them. The advantage to the virtual programs is that you can get the exact message you need to convey every time but, essentially, it’s all about receptivity and the opportunity to conduct these programs now six months into this new environment.”
- “Axogen’s announcement to go to their current users seeking deeper penetration of their products makes perfect sense. They are focused on their nerve transplant product. Due to the pandemic, it is very hard to get products added to formularies, as opportunities for evaluations—mini-trials at the hospital—are extremely limited. Much of the staff is working remotely. Cost of new products is being closely scrutinized. If the new product potentially increases the budget of purchasing, the less likely it will be approved.”
- “Taking a product already approved by the hospital or ASC [ambulatory surgery centers] is the low hanging fruit: grow[ing] your existing base has more immediate opportunity.”

Axogen’s announcement to go to their current users seeking deeper penetration of their products makes perfect sense. They are focused on their nerve transplant product. Due to the pandemic, it is very hard to get products added to formularies, as opportunities for evaluations—mini-trials at the hospital—are extremely limited. Much of the staff is working remotely. Cost of new products is being closely scrutinized. If the new product potentially increases the budget of purchasing, the less likely it will be approved.

15-year sales representative with competitor company

Competitive Landscape

- “Integra, Stryker, and Axogen are the main players in this market.”

Miscellaneous

- “ASCs now seem to be doing about 50% of the procedures in the greater Philadelphia area. Hospitals are shedding a lot of these procedures where their margins are not as good. They are not big money makers for hospitals. Five or six years ago there was a drop in reimbursement on many of the nerve repair codes.”

2) Senior executive at a competitive medical device manufacturer

The total Axogen market estimate for peripheral nerve repair is probably accurate, but the large gap repair segment that Axogen serves is much smaller—less than half of the total. Elective surgeries are still only 25% of pre-COVID-19 levels, although this would not impact emergency trauma cases. A strategy to organically grow its procedure volumes in smaller gap repair could be a good one, if the hospital is already carrying its product and can save procedure time by using Axogen. There are no direct large gap repair competitors, but companies like Integra LifeSciences and Stryker carry collagen conduit products for shorter repairs. In terms of digital education, everyone is in the same boat.

Axogen Use Case and Growth

- “The Axogen market estimate [of \$2.7 billion/900,000 procedures] sounds right for total nerve injuries, but those that require allograft are a much smaller number—probably less than half. In the case of traumatic injuries, most are relatively small, whereas the Axogen allograft is optimized for repairing longer gaps in the nerve.”
- “There is a limit to the number of Axogen suitable procedures. The demand for nerve grafting is not as big as bone grafting, for instance. The TAM for large gap nerve allograft is probably in the range of \$100 to \$250 million vs. a \$30 billion market for bone grafting.”

Axogen TAM Opportunity

- “Although Axogen’s product is specifically designed for larger nerve gaps because it is anatomically correct [vs. a hollow collagen tube], the strategy for increasing demand at existing facilities could be a good one. Shorter gaps can be repaired by a nerve conduit or meticulous suturing alone but hospitals are not always willing to carry multiple products. So if a facility uses Axogen for long gaps, they may be convinced to use the same reliable product for short gaps, even if it is not absolutely necessary. And using Axogen in place of a longer surgery time could result in a big savings to the hospital.”

Axogen Sales, Support, and Training Online Overhaul

- “In terms of the need to educate virtually, everyone is in the same boat. It is important to keep in mind that the so-called elective surgeries are still at about 25% of pre-COVID levels, which impacts all of the relevant product suppliers.”

Competitive Landscape

- “Primary competitors offer collagen products more suitable to short gap repair, including Integra LifeSciences and Stryker.”
- “Stryker does not put a lot of focus on this business segment. I estimate they do about \$1.8 million in sales. Integra is a bigger player, but I would estimate their annual sales at less than \$8 million.”

The Axogen market estimate [of \$2.7 billion/900,000 procedures] sounds right for total nerve injuries, but those that require allograft are a much smaller number—probably less than half. In the case of traumatic injuries, most are relatively small, whereas the Axogen allograft is optimized for repairing longer gaps in the nerve.

Senior executive at a competitive medical device manufacturer

3) Area sales manager in nerve reconstruction market

This source intimate with the market believes nerve repair procedures will continue to increase, in part driven by patient demand to alleviate pain and the decline in the use of opioids. Axogen is well positioned to share in that growth. The Avance product best case is where the nerve replacement is 20 to 70 mm and the patient is not a good candidate for host harvesting. This source believes that surgeons need to see more clinical data demonstrating the advantages and superior outcomes with the Avance allograft procedure.

Axogen Use Case and Growth

- “Doctors make decisions on whether to use Avance based upon location of the injury, the gap length, the time lapsed from the injury, the condition of the surrounding tissue, and the type of nerve. Grafts up to seven cm [70 mm] are best for Avance. A nice and clean and short gap [up to 20 mm] is better suited for a conduit. Where there is more clean-up, bigger gaps, and more damage to the nerve and surrounding tissue, there is greater need for the Avance.”
- “For more orthopods to buy in to Avance they need more clinical data seeing the outcomes and advantages on the allograft approach.”

Axogen TAM Opportunity

- “I believe the pain and nerve procedures will increase. Most of these patients have significant pain and the opioid use has been steadily declining, giving more opportunity for these procedures.”

Axogen Sales, Support, and Training Online Overhaul

- Did not discuss.

Competitive Landscape

- Did not discuss.

I believe the pain and nerve procedures will increase. Most of these patients have significant pain and the opioid use has been steadily declining, giving more opportunity for these procedures.

Area sales manager in nerve reconstruction market

3) Axogen Partners

This sales representative with key account responsibilities sees sales trending up for his company and the companies to which they sell tissue regenerative products, including Axogen. Axogen should be back on the growth track and meet its goals. Regarding Axogen's change in focus, he perceives the entire market is playing the virtual game and that going focused and deeper is a change all the companies are making. However, physicians are tiring of the virtual format and face to face is necessary to grow your products. Surgeons may equate the Avance cadaver product with tissue cadaver products that failed in the past, presenting a barrier Axogen must overcome to expand its user base.

Key Silo Findings

Axogen Use Case and Growth

- 1 of 1 said the use case for tissue regenerative products is growing and Axogen's growth will resume.

Axogen TAM Opportunity

- 1 said Axogen's market opportunity is growing after being flat earlier in the year.

Axogen Sales, Support, and Training Online Overhaul

- 1 said Axogen's shift to online and its focus on expanding sales in existing accounts is the industry norm.

Competitive Landscape

- Did not discuss.

Miscellaneous

- Physicians are tiring of the virtual sales and support efforts and face to face is now necessary to expand sales.
- 1 said the past failure of cadaver products is a headwind Axogen must address to significantly expand its usage.

1) Area sales manager for biotech company selling tissue regenerative products and Axogen partner; repeat source

April 3, 2019, interview: Axogen has excellent technology in its Avance Nerve Graft and very competitive products with its porcine-based AxoGuard line. Still, Axogen has limited presence in this region, likely because of poor sales and marketing execution. The sales retool will help get surgeons aligned with the Axogen's products and could help the company reach 30% to 40% growth. The source said a compelling product story is needed but is not yet happening.

Axogen Use Case and Growth

- “We sell products to companies like Axogen and products that are used when tissue repair and reconstruction is being performed. We are trending up, as are the companies that use our products.”

- “I know of one perspective that some surgeons have regarding tissue regeneration. There have been cadaver products used in skin grafting that were not good. They would not grow with the healing and would often dry up. The Avance product may have some problems to overcome due to the clinical experience with skin grafting. That may be a reason why surgeons would harvest live tissue from the host and transplant it vs. using an allograft.”

Axogen TAM Opportunity

- “The market for these products is trending up after being flat or worse earlier this year. Some of the growth is probably backlog from when we were shut down. Generally, things are growing and this market area is growing. I think Axogen will meet their growth goals.”

Axogen Sales, Support, and Training Online Overhaul

- “Our company did a complete overhaul as well and does virtual and digital training and selling. It is what we had to do. I still make calls and work in the OR—I had 20 cases in the last month and a half—but also contact more remote customers via virtual environment.”
- “The virtual environment is different in ways I did not expect. First, as opposed to a face-to-face call where the tendency is to talk, the virtual call more often is controlled by the doctor and they control the conversation and direct where the discussion is going. It makes the salesperson shut up and listen and is a good lesson for finding out what the customer really needs. The other aspect of it is that surgeons are getting a little tired of the phone call and sometimes make you feel like you are just playing a game. Face to face is where we need to be, but I have to do a mix.”
- “Axogen’s announcement of sticking with users and going deeper is what we are all doing. That is how we are going to grow, especially given the pandemic. It works—we’re all there.”

Competitive Landscape

- Did not discuss.

The market for these products is trending up after being flat or worse earlier this year. Some of the growth is probably backlog from when we were shut down. Generally, things are growing and this market area is growing. I think Axogen will meet their growth goals.

Area sales manager for biotech company selling tissue regenerative products and Axogen partner

4) Industry Specialists

Axogen has overestimated its total available market, according to this source, who states there are fewer than 25,000 cases for peripheral nerve repair and most are 30 mm or less. No company can officially claim FDA approval for peripheral nerve repair, but Axogen has the strongest data. Axogen does compete in short gap nerve repair with Cook Biotech’s bovine collagen product, which is used by some surgeons for mid-length gap repair.

Key Silo Findings

Axogen Use Case and Growth

- 1 of 1 said Axogen has the strongest data supporting large gap nerve repair and also competes in small and mid-length gap repair.

Axogen TAM Opportunity

- 1 said Axogen’s TAM is overstated, as the majority of the nerve repair procedures are autograft or direct repair (suturing with tension) and only 20% are allograft, including Axogen Avance or [AxoGuard Nerve Connector conduit](#).

Axogen Sales, Support, and Training Online Overhaul

- Did not comment.

Competitive Landscape

- 1 said [Cook Biotech](#) is a strong competitor.

1) Product development executive with expertise in the nerve repair market

Axogen Use Case and Growth

- “The vast majority of peripheral nerve repairs are autograft or direct repair [suturing with tension]. Less than 20% are allograft, including Axogen Avance or AxoGuard conduit.”

- “Axogen competes in small gap repair with Cook Biotech in two ways: 1. the Axogen AxoGuard collagen conduit Nerve Connector, 2. Axogen Avance is used by some clinicians for mid-length gap repairs [of 20 to 40 mm].”

Axogen TAM Opportunity

- “900,000 cases is way too high for peripheral nerve repair. I would estimate there are less than 25,000 and most are 30 mm or less.”

Axogen Sales, Support, and Training Online Overhaul

- Did not discuss.

Competitive Landscape

- “I do not believe any company, even Axogen, can make an FDA-cleared claim on nerve gap repair.”
- “Axogen has the strongest clinical data that supports large gap repair in its RANGER registry.”

Secondary Sources

These two secondary sources focused on an Axogen patient's recovery to resume pursuit of his dream and a market report addressing the size of the nerve repair and regeneration market.

September 85086 Magazine [article](#)

Dylan Harvey is getting another chance to pursue his dream of repairing race cars because of Axogen's Avance Nerve Graft following a motorcycle accident.

- “It turned out Harvey suffered significant injuries and damage to the nerves in his brachial plexus. Left with an arm that was essentially paralyzed, amputation seemed likely.”
- “Fortunately, Harvey's family connected with Dr. David Adelson, the chief of pediatric neurology at Phoenix Children's Hospital.”
- “Dylan Harvey spent time as a teen at Universal Technical Institute furthering his education in automotive craftsmanship, after which he moved to North Carolina to attend NASCAR Technical Institute. He now works for a Tempe performance shop that builds race cars. (Photos by Pablo Robles) Adelson, who is skilled in microsurgery, was able to repair Harvey's nerve injury using Avance Nerve Graft, a human nerve allograft, restoring movement to his arm and the possibility of pursuing a lifelong dream.”
- “The eight-hour procedure involved an off-the-shelf processed human nerve to fill the gap between a nerve to help it regenerate over time.”
- “The biggest challenge had been he suffered this really bad injury and the arm was not working,” Adelson says.
- “He was given a very poor prognosis, and they could have amputated his arm. It's important to get these children and adults referred early (to specialists). This gives us the best opportunity to try and intervene and see if we can improve their overall function.”

Sept. 28 Medgadget [article](#)

Report Ocean has made a nerve repair or regeneration report available estimating a growth rate of more than 9.15% over the forecast period 2020 to 2027. The report also addresses the negative impact the COVID-19 pandemic has had on the biomaterials segment of the nerve repair and regeneration market.

- “Global Nerve Repair and Regeneration Market is evaluated approximately US\$ 5.72 billion in 2019 and is estimated to expand with an elevating growth rate of more than 9.15% over the forecast period 2020-2027.”
- “Based on product, neurostimulation and neuromodulation devices segment estimated to dominate the market, owing to their traits related to drug-free solutions and high success rate of relief over other treatments. While on the basis of application, the neuroorrhaphy segment holds the largest market share in 2019, owing to its property of rapid reinnervation and faster return of function. The postoperative risks and the limited graft availability may hinder the expansion of nerve grafting segment.”
- “North America is the leading region for Nerve Repair and Regeneration Market owing to the growing recognition of the treatments available for nerve repair and deep-rooted healthcare support in the region. Whereas, Asia-Pacific is also anticipated to grow over the forecast period 2020-2027, due to rising geriatric population and increasing prevalence of neurological disorders.”

- “COVID-19 has adversely affected the healthcare services in most countries around the globe; the worst affects could be seen over the US, Italy, India, Spain, the UK, Russia, Germany, and Iran. Its major impact is on the biomaterials segment of the nerve repair and regeneration market due to possible reductions in the demand as a result of reduced cases of peripheral nerve injury. According to PubMed studies, vehicular accidents are major drivers of biomaterials in the market as these are the most common cause of peripheral nerve injuries. However, due to the restrictions in the movement as safety precautions to control the spread of COVID-19, vehicular traffic has greatly reduced and, so has the frequency of road accidents. Due to increasing number of COVID-19 patients, other ailments and procedures are not getting as much attention and many healthcare units are postponing such treatments, which is affecting the market for neurostimulation and neuromodulation.”

Additional research by Pam Conboy, Jim Boland, Karen Lusky, and Bruce Wicks.

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