

cnsq IS THE OFFICIAL NEWSMAGAZINE OF THE CONGRESS OF NEUROLOGICAL SURGEONS

CongressQuarterly

SPRING 2024

Profiles in Innovation

CNS MEMBERS across the spectrum of practice to share their personal stories of innovation in their practices and careers



Congress of
Neurological
Surgeons

4 Upcoming Events by the CNS
Innovation Committee

16 Adding Insight to Injury: An
Innovation Story

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EDITOR'S NOTE



Ellen L. Air
Co-Editor



Clemens M. Schirmer
Co-Editor

Innovation. From the days of Harvey Cushing, innovation has been core to Neurosurgery. New devices, approaches, and technology are brought into the field constantly. In this Issue of *Congress Quarterly*, we focus on the individuals who have innovated and persevered to bring their ideas to fruition. Looking beyond the end product, there is much to learn about the inspirations, processes, and hurdles these innovators tackled.

A common theme prompting innovation is frustration with the status quo. Michael Sughrue shares how daily patient interactions, in which he did not have answers to patients' questions, led him from processing brain network maps on his own to a practical tool available broadly.

For Nadan Lad, it was the need to engage patients in their care and make the path more efficient that led to a digital platform to support patients on their healthcare journey.

Another theme is the drive to solve a nagging problem. R. Loch MacDonald aimed to tackle post SAH vasospasm while Carl Heilman and Adel Malek were frustrated by the current state of hydrocephalus treatment.

Doug Kondiolka provides insights into the long, and still ongoing, process of developing cell-based therapy for stroke recovery. Learning from each stage and iterating for the next continues to bring us closer to the final goal. As Nicholas Theodore discusses, taking an idea to end-product is a journey that requires communication skills, including the ability to convince others to invest. Costas Hadjipanayis and Steve Kalkanis walk us through the regulatory process. In particular, the FDA is a complex agency that requires patience and perseverance to navigate. Uzma Samadani shares how the final step, getting CMS approval for a payment code, is yet another hurdle to bringing ideas to the bedside.

Sometimes the hardest part is getting started. While many of these profiles share a moment in which a colleague says "do it already" as the impetus to really dig in, beginning is no easy task. Katrina Firlirk provides great advice to get started on your own innovation.

Innovation takes many forms. Kathryn Ko is well known for her talent as both a Neurosurgeon and an Artist. She has merged these loves into the Ko Iki Museum, which brings art to the University of Hawaii Medical School Campus. All are invited to contribute.

We hope their insights on the process, challenges and rewards inspire the innovative drive in you!

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PRESIDENT'S MESSAGE



Alexander A. Khalessi, MD, MBA
President, Congress of Neurological Surgeons

Dear Colleagues,

For more than 70 years, the Congress of Neurological Surgeons (CNS) has been a vital driving force of innovation in neurosurgery. From our very first CNS Annual Meeting to our recent “Data Science Models for Neurosurgeons” virtual course, the CNS has provided a platform for neurosurgeon thought leaders to share their research and ideas, leading to groundbreaking advancements in the field. Likewise, our commitment to staying at the forefront of neurosurgical research and technology has enabled the CNS to bring those innovations and advancements to our members through world-class educational programs and industry-leading publications.

This relentless focus on innovation is central to CNS’ mission to enhance health and improve lives. There is no doubt that our patients have benefited greatly from our efforts. This year, the CNS Innovation Committee is working to bring the 2024 Annual Meeting theme *Neurosurgery Origins* to life. Offerings will include the “Digital Fluency in Neurosurgery Symposium” and the “Transforming Neurosurgery through Technology: Innovation Symposium.”

We will also be bringing our popular Innovator of the Year submissions to the main stage on Wednesday, October 2—giving the top three finalists a broader platform to share their projects with their colleagues. Attendees will vote for the winner in real time and the winner will be announced during Wednesday’s General Scientific Session. Submissions for the 2024 Innovator of the Year Award are now open at cns.org/annualmeeting/awards/innovator-of-the-year

While the CNS strives to be a catalyst for innovation in our specialty, it is truly our members who drive that innovation day in and day out. That is why our editors, Drs. Ellen Air and Clemens Schirmer have dedicated this issue of *Congress Quarterly* to spotlighting just a



CNS Innovator of the Year competition is getting an update in 2024 with the top three finalists bringing their presentations to the main stage on Wednesday, October 2 for our entire audience to hear about their innovations and vote on the winner.



Transforming Neurosurgery through Technology: Innovation Symposium” at the CNS Annual Meeting brings together neurosurgeon-entrepreneurs, engineers, industry partners, and investment professionals to discuss unique approaches to innovation that can lead to return on investment.

few of your stories. From bringing life-saving technologies to market, to empowering patients to take control of their treatment plans, the authors in this issue share their personal stories of innovation within—and beyond—the field of neurosurgery. I hope you find their stories as inspiring as I did.

For the many CNS members not featured in this issue, I also hope you also find the CNS a welcoming and nurturing place to connect with your colleagues and share your big ideas. We are working hard this year to create space for the collaborations and synergies that drive scientific and clinical innovation in our field. You’ll see it in the committee initiatives above and in the innovation track at the 2024 CNS Annual Meeting in Houston. I look forward to seeing you there. 🇺🇸

Sincerely,

Alexander A. Khalessi, MD, MBA
President, Congress of Neurological Surgeons

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Mohamad Bydon, MD



Eric K. Oermann, MD


Profiles in Neurosurgical Innovation:

Upcoming Events in 2024 by the CNS Innovation Committee

As we are moving into the era of advanced data analytics and artificial intelligence, the world seems to be moving faster than ever. It is important for everyone in the neurosurgical field to be exposed to the latest technological advancements and innovations and learn ways to incorporate those advancements into their clinical practice. More importantly, it is crucial to encourage leveraging current innovations within neurosurgery to develop further innovative research and to ensure that the progress being made is sustainable and is setting the ground for further progress in the future.

Having a deep understanding of data science is crucial in that regard, as it allows for critically appraising findings reported in the published literature, leveraging existing neurosurgical datasets to develop or use data science models, as well as for contributing to the implementation of data-driven practices in the neurosurgery department. A data-driven approach is considered the cornerstone of evidence-based practice and could not be more relevant to modern neurosurgical patient care and research. In the last few years, the CNS has invited members to delve deeper into the world of neurosurgical innovation and advanced data analytics through several events occurring both as part of the CNS Annual Meeting, such as the “Transforming Neurosurgery through Technology (TNT) Symposium” and in the form of courses hosted throughout the year, including the Data Science for Neurosurgeons Virtual Course last year. Following successful completion of these events in previous years, our Innovation Committee is excited to announce that neurosurgical innovation will be a central theme of the 2024 CNS Annual Meeting, with the inaugural “Digital Fluency in Neurosurgery Symposium”, as well as

with the “Transforming Neurosurgery through Technology: Innovation Symposium” further contributing to the inspiring and motivating nature of this meeting’s content. While you are waiting for the CNS Annual Meeting, the 2024 Data Science for Neurosurgeons Virtual Course offers a unique opportunity for participants to dig deeper into the foundation knowledge of data science as it relates to the neurosurgical field, and to understand how they can benefit from incorporating data science in their everyday neurosurgical practice and patient care. The course will take place on June 8, 2024, and will provide participating neurosurgeons, junior faculty, and residents with a valuable tool to deepen their understanding of data science models, critically appraise their reliability and validity, as well as learn about ways to incorporate these models into every day neurosurgical practice in a way that is both feasible and practical.

It is today more important than ever to realize the role that technological advances and neurosurgical innovation play in neurosurgical practice, and it is even more important to identify ways to get involved and become part of this process. Per this year’s message at the CNS Annual Meeting, acknowledging how progress has been made to date can impact the way we view current achievements in the field, as well as our perception of relevant future directions for research and development. Promoting neurosurgical innovation is an integral part of the mission of the CNS and the CNS Innovation Committee, and we invite all of you to partake in appreciating, nurturing, and strengthening neurosurgical innovation efforts in 2024! 



Michael Sughrue MD

How and Why We Built Quicktome

Physicians often view entrepreneurship as an idyllic path to make a bit of money and quickly bring a good idea into the market. Having actually done this, I can assert that there is only one valid reason for pursuing entrepreneurship as a physician: frustration that you don't have what you need to do your best work. Entrepreneurship is too painful to take on for any other reason, and there is no way you will persist through the many months of endless travel and raising capital for any other reason less than a conviction that you are doing the lord's work.

About 15 years ago, I got tired of having to blow off patient and family complaints in follow-up visits after removing brain tumors. It's not that I didn't care about all the cognitive problems or depression or personality changes they had, it's that I had no idea what I could do to avoid these issues, and lacked any test or way to address this. I started attending meetings about connectomics, which is a method for using artificial intelligence (AI)/machine learning (ML) to understand brain connectivity data. I was shocked how much they knew about brain networks and the mechanisms of cognition and emotions in the brain that clinicians were entirely ignorant of—and that no one was doing anything to help us utilize this information. To be blunt, it angered me that I was forced to work without the best possible information, and no one seemed particularly bothered by this.

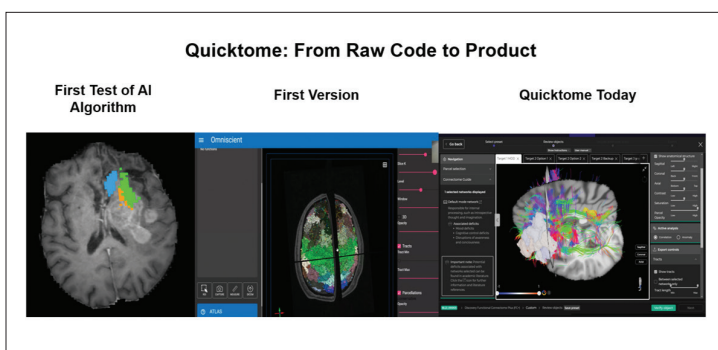
One day, while I was typing my own code to process network maps for my surgeries, it dawned on me that having the fate of people's lives based on the coding ability of non-computer engineers was absurd and unacceptable, and since no one else was doing anything, I decided I would. After running the idea for the algorithm for Quicktome by close to 100 people who did nothing with it, I met my co-founder, Stephane Doyen, who produced a working prototype in eight weeks. When it



dawned on us that we had built a scalable tool with impacts far beyond the operating room—such as mental health and other neurologic problems—we decided to raise money to bring this into the real world.

Just when you think you have completed something great, think again. This is the point where the real innovation starts: How to make a technology into a product? There is a big difference between technology and product. Products are technology that have been refined to be usable in the real world by the intended user, and to function in the socioeconomic landscape in which it is used. As a neurosurgeon, I knew it was unlikely those in the field would widely attend three days of training to gain the significant new knowledge required to use the tool correctly. We had a hard question: how would we make a tool that's easy to use yet still powerful? How do we show 144,000+ pieces of data and leverage thousands of carefully annotated neuroanatomic and neurophysiologic facts into a tool that actually provides a useful answer to a question without requiring heroic efforts from the user? Making a good product involves balancing user experience, regulatory, scientific, educational, and clinical considerations and solving problems in unique ways. Great design is always an evolving process, with a lot of mistakes, but I think we have made Quicktome into the Rolls Royce of Brain anatomic tools. Many people eventually note the extreme attention to detail put into this tool the more they drive the car.

I will clarify my previous discouragement about entrepreneurship by noting that neurosurgeons must be involved in designing the next wave of technological advances. If we do not take ownership of addressing the problems we see with practical solutions that scale outside our own institutions, we should not expect industry to do this on their own. We understand the problems best and are best positioned to ensure the solutions created actually solve these problems. It is always lower business risk for established companies to release Version 4.0 of things we already have. True progress in our field has always been made by those willing to struggle to put out Version 1.0 of products that matter. 📌





Nandan Lad, MD, PhD

Navigating the Future: Higgs Boson Health and the Digital Surgery Revolution

As Vice Chair of Innovation at Duke Neurosurgery, my vision for a more patient-centric health care system has been the driving force behind Higgs Boson Health, a Duke spinout company. Our digital platform, which now supports over 125,000+ patients across diverse procedural journeys, continues to redefine surgical care navigation. We've stayed true to our core mission: to unravel complex health care journeys, making them more accessible and understandable. We're not just building tools; we're crafting experiences that empower patients and streamline provider workflows, all while tracking clinical outcomes that matter. The success of our platform is reflected not only in numbers but also in the stories of lives changed—a testament to the power of engaged patients and personalized care.

Our journey began with a simple belief: more engaged patients do better. Leveraging big data and analytics, we've worked tirelessly to refine surgical processes, making complex procedures more transparent and manageable. As a neurosurgeon, it has been gratifying to amplify my impact on many more patients than I could from operating alone—empowering patients, providers, and medtech companies with more personalized, data-driven care.

Our partnerships—such as those with Medtronic, Clearpoint, Insightec, and others, as their preferred digital partner for key product lines nationally—are central to the widespread distribution and milestones that highlight the broad impact and industry-wide acceptance of our digital innovations. These collaborations have been pivotal in advancing digital health in surgery, underscoring the

importance of seamlessly integrating digital tools into health care workflows.

Just as the Higgs Boson particle is fundamental to atomic theory, and won Higgs and Englert the Nobel Prize in Physics around the time we were starting the company, health is also central to life. So, Higgs Boson Health came together and is more than a narrative of success—it's about the relentless pursuit of innovation and excellence in the face of health care's complexities. We've shown that technology can drive significant advancements in patient care and operational efficiency, across a wide variety of interventional and surgical verticals. We're paving the way for a future of health care that's more accessible, personalized, and effective.

I am deeply humbled by the recognition our work has received and remain committed to enhancing the surgical journey through technological innovation. As we continue to share our experiences across the interventional and surgical communities, I am reminded of the tremendous opportunities to make a scalable impact at the intersection of healthcare and technology. Our story is a testament to the power of innovation in transforming lives, serving as a blueprint for future endeavors in the rapidly evolving technology landscape. ■



“JUST AS THE HIGGS BOSON PARTICLE IS FUNDAMENTAL TO ATOMIC THEORY, HEALTH IS ALSO CENTRAL TO LIFE... SO, HIGGS BOSON HEALTH CAME TOGETHER.”

- NANDAN LAD, MD, PHD



R. Loch Macdonald, MD,
PhD

A Brief History of Edge Therapeutics: Ideas and Execution

I started my first neurosurgery job at the University of Chicago in 1993. My mentor was Bryce Weir. The University of Chicago was culturally like the University of Toronto; the only reason to work there was if you wanted to create new knowledge. I did that through a combination of hard work, great mentorship, luck, lots of ideas, and being able to execute on the ideas. I had some outstanding students working in my laboratory and by 2006 we had characterized the ion channels in cerebral conducting arteries and found that L-type voltage gated calcium channels played a major role in their constriction. Nimodipine antagonizes those channels so it should prevent vasospasm after subarachnoid hemorrhage (SAH) but that does not seem to be true in humans. Maybe that is because you can't get high enough concentrations in the head without causing systemic hypotension. What about injecting nimodipine directly into the cerebrospinal fluid (CSF)? Not a new idea. But few are.

That was the idea. The execution came from the chance apposition of several events. I gave a lecture in Toronto explaining that vasospasm should be preventable by high concentrations of nimodipine in the cerebral arteries. Michael Fehlings asked why someone didn't do that; try local CSF delivery of nimodipine in humans. Back in Chicago a few months later, I met Brian Leuthner, a pharmaceutical representative who was hawking clevidipine and was thinking about other uses for the drug. I said maybe make a sustained release formulation of clevidipine to put in the subarachnoid space after SAH. Brian wrote a business proposal for this. He presented it to his boss at the Medicines Company and was promptly fired. He called me five minutes later and said he had no job so we had to start a company and develop intrathecal calcium channel blockers for SAH.

We incorporated the company, Edge Therapeutics, in 2009 and got started in a biotech incubator in New Jersey with a bit of money from a state grant and from friends and family. We cobbled money together mostly from rich people and plowed ahead. At one point we owed at least \$1,000,000 to the chemical manufacturing and the animal contract research organizations we worked with. We applied for grants and pitched to at least 125 investing opportunities. The National Institutes of Health rejected all our grants. They said our timelines were too short and that this would not work. We met our



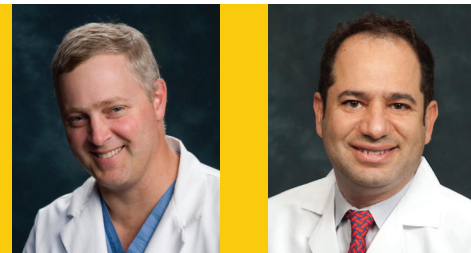
timelines. We were not able to predict the future like the esteemed grant reviewers.

By 2012, we were injecting humans with a sustained-release microparticle nimodipine formulation and by 2016 we were a public company traded on the NASDAQ. Our NEWTON studies were published in 2017 and 2020. It does work, just not as well as some wanted it to. With those "negative" studies, Edge was subsumed by PDS Biotechnology.

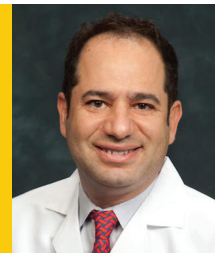
I had always planned to go back to clinical neurosurgery. Mike Lawton at the Barrow hired me and I signed a contract to work at one of their hospitals. After I moved to Arizona, bought a house and before I even got my Arizona license, some Barrow administrator sent me a letter saying they were canceling my contract unilaterally without cause. I suspect Mike's colleagues were pissed about having another cranial neurosurgeon competing for cases in that saturated market.

Edge and my foray into industry were not planned but I wouldn't change much if I could live those years again. We decisively answered a clinical question in perfectly designed studies. I learned a lot and I know more about nimodipine than anyone on earth and about intrathecal drug delivery, drug development, and starting a biotech company than most neurosurgeons. There were many good times.

I ended up in Fresno, which turned out to be the best thing I ever did. What did I learn from all this? Well, that's another chapter. ❏



Carl Heilman MD



Adel Malek MD PhD

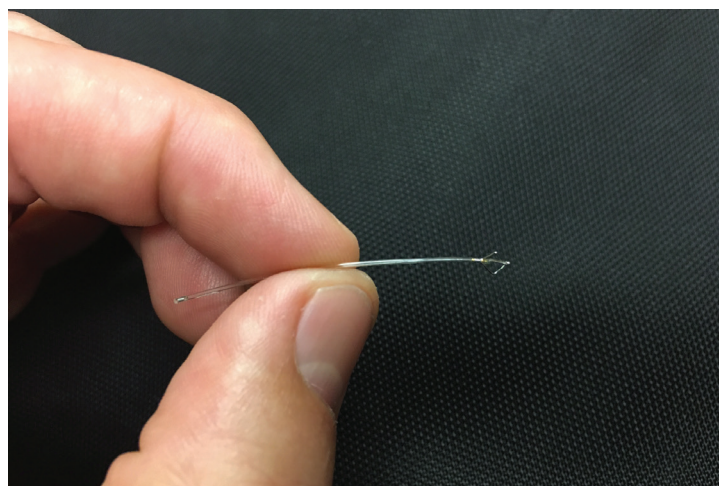
Development of a CSF Shunt Inserted by an Endovascular Technique

In December of 1993, I completed my formal training in neurosurgery under Dr. William Shucart at Tufts followed by a skull base fellowship with Dr. Jon Robertson in Memphis. I then returned to Tufts to build a skull base practice. Shortly thereafter, I was asked if I could also cover pediatric neurosurgery within the department. In addition to performing skull base surgery, I served as the Chief of Pediatric Neurosurgery at the Tufts Floating Hospital in Boston for the next 10 years. During this time, I experienced firsthand the frustration associated with the use of VP shunts for the treatment of patients with hydrocephalus. The simultaneous evolution in the endovascular treatment of cerebrovascular disease, made me start to think. There had to be a better way to treat hydrocephalus. Specifically, there had to be a means to insert the equivalent of an arachnoid granulation into the head, by an endovascular approach.

In 2009, Dr. Adel Malek and I submitted our first patent application for an endovascularly inserted shunt device which could drain CSF from the cisterns into an adjacent venous sinus. My knowledge of skull base anatomy and hydrocephalus, together with Dr. Malek's knowledge of endovascular techniques, was a perfect fit for innovation. We set out to try to completely change how communicating hydrocephalus is treated. Dr. Malek and I now have numerous patents together through our work at Tufts Medical Center and a company called Cerevasc Inc., which we co-founded with Aton Partners (Dan Levangie and Patrick Sullivan).

Dan Levangie has served as Cerevasc's CEO. His experience and skill have led us through many rounds of financing, personnel recruitment, device development, additional patents, and along the road toward FDA approval. The first eShunt was placed into a human on February 8, 2021. This eShunt was placed into a patient with post subarachnoid hemorrhage hydrocephalus by Dr. Pedro Lylyk at the Clinica La Sagrada Familia in Buenos Aires, Argentina. The Cerevasc eShunt has since been placed into a total of 38 patients in the First In Human pilot study. eShunt devices have now been placed by Drs. Pedro Lylyk, Charles Matouk (Yale), Adnan Siddiqui (Buffalo) and Howard Riina (NYU). We are currently in discussion with the FDA on the details of a Pivotal Trial in the USA for FDA approval.

The first step in the innovation process is to recognize a "pain point" in health care delivery. The second step is to decide to do



"THE SPARK FOR THE BIOLOGICALLY INSPIRED ESHUNT DEVICE CAME FROM THE CHALLENGES FACED WITH SURGICAL VP SHUNTS AND DECIDING IT WAS TIME TO TACKLE THESE HEAD-ON."

something about it. Then, study the problem and think. As ideas come, apply for patent protection of novel device designs and treatment methods. Teams often produce better solutions than individuals. Start a company, hire engineers, and work through prototypes. Seek advice from experts in medical device development. If you are convinced your idea is good and will help patients, then decide to "do something about it" and start working. ■



Nicholas Theodore, MS,
MD, FACS

Robot Dreams

As a resident at Barrow Neurological Institute in the 1990s, there was never a shortage of cases. Operating daily and performing hundreds of procedures was how neurosurgeons got their “reps”—whether by clipping aneurysms or placing pedicle screws. During that era, there was a sea change in the field of neurosurgery. The ability to touch the brain and see where you were on an imaging screen would forever change the way that neurosurgeons, well, *operated*. The technology reached the field of spine surgery shortly thereafter. Although a bit cumbersome at first, image-guided spine surgery offered tremendous advantages, including increased accuracy and decreased radiation exposure for surgeons and operating room personnel.

It was during this time that one of the first surgical robots became widely available: the da Vinci robot (Intuitive Surgical) allowed surgeons to operate through small incisions with excellent accuracy. At that time, I dreamed about the possibility of combining the accuracy of real-time image guidance with robotics, wondering whether that technology could allow surgeons to automate common neurosurgical procedures with high accuracy.


As my residency wound down, I began collaborating with my best friend Neil Crawford, who ran the Spinal Biomechanics Lab at Barrow. On countless afternoons, evenings, and weekends (and always over coffee), Neil and I began to sketch out what a neurosurgical robot would look like. We filed patents but it quickly became apparent that unlike Hewlett and Packard, we were not going to be able to assemble this device in our garage. As we moved forward with design concepts, we realized the tremendous expense of building a robotic platform. I presented the nascent project to the Barrow Foundation, which passed in favor of funding more traditional basic science research. After that presentation, the CEO of the hospital called me and asked if the device could be commercialized. “Absolutely,” I said. Through a licensing agreement, she funded the project with an investment of \$600,000—an influx that changed everything.

The coffee maker worked overtime as we developed a working prototype now affectionately known as “Big Blue.” Once the world’s first real-time image-guided robot was functioning, we hit the road, pitching to several major medical device manufacturers. One after another, they applauded the idea but harbored serious concerns

about the likelihood of FDA clearance and the amount of money it would take to commercialize Big Blue. After an exhaustive lecture on why the device would never work, one CEO called it “a great science fair project.” After that meeting, Mitch Foster—who worked for one of those companies—approached me and said, “That isn’t a project. That’s a company.” I told Mitch to quit his job and come build a company with me, and Excelsius Surgical was born within a month. Over the next several years we worked tirelessly to hone our design, file new intellectual property patents, and raise capital.

We tested the robot in the cadaver lab at Barrow. After planning the trajectory for and robotically placing multiple screws, we anxiously awaited the postoperative CT scan, which demonstrated that we hit the mark every time. **Eureka!**

Emboldened by this success and realizing that most of the big companies would not take a risk on this project, we pounded the pavement with renewed enthusiasm. We raised \$5M in short order to hire key personnel and attracted the attention of David Paul, the visionary engineer and founder of Globus Medical, who was impressed by the technology. Within several months of his visit to Phoenix, we had a purchase agreement in place and Excelsius Surgical was sold to Globus Medical.¹ On October 4, 2017, the first case using the ExcelsiusGPST[™]—our vision come to life—was performed at Johns Hopkins Hospital.² Since then, the platform has flourished, with hundreds of systems placed worldwide. The hospital prospered as our first investor, and now has a better understanding of the power of entrepreneurship in medicine.

Working with a small, trustworthy group, maintaining focus, and working hard toward a common goal paid off. I have seen firsthand that dreams can come true—so I’m dreaming big! 

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Shahaan S. Razak, MSEd



Aparna Nair-Kanneganti, MD



Alfredo Quiñones-Hinojosa, MD

Mission Brain Hackathon

Technology, information, and knowledge continue to expand our horizons and possibilities for a better world. At the same time globalization has erased boundaries that existed in the past between cultures, countries, and economies and has built bridges that ultimately has lead to “shrinking” our world. Nonetheless, disparities in income and access to resources such as healthcare have continued. According to the Lancet Commission for Global Surgery, 5 billion people worldwide do not have access to safe, timely, and affordable surgical care. This imbalance is particularly evident in the field of neurosurgery, where cutting-edge treatments and knowledge often do not reach low-resource settings.

The COVID-19 pandemic catalyzed a transition towards widespread use of digital platforms for remote collaboration. Primed by this cultural shift, our organization, Mission Brain (www.missionbrain.org), saw an opportunity to launch a global forum for neurosurgical innovation. We established the Mission Brain Hackathon, which harnesses the collective intelligence of Mission Brain’s network of student chapters (over 90 chapters in over 25 countries as of 2024), as well as medical students and professionals worldwide, to solve open problems in global neurosurgical delivery.

Our inaugural event in 2022 laid the groundwork, drawing participants from 25 different countries. By forming multinational teams, we fostered a cooperative virtual environment that transcended geographical and socioeconomic barriers. We presented teams with modified versions of real patient cases from under-resourced settings. Teams

were then asked to identify the cases’ failure modes and propose feasible solutions, thereby responding directly to critical global health needs through an experiential learning process.

In 2023, the hackathon grew and evolved to focus more intensely on innovation and resource-sharing between high and low/middle income countries. We grew our impact, doubling the number of hackathon participants and recruiting from 52 countries. The results were inspiring. We observed statistically significant changes in participants’ attitudes around the importance of innovation, equitable resource allocation, and professional development in neurosurgery. The hackathon is far more than an academic exercise; it has become an instrument for transforming participant perspectives and seeding collaboration between diverse professional communities. Teams came together incorporating engineering, business, STEM, socioeconomics and many other disciplines and created a fusion of ideas and innovative solutions.

Looking ahead to our third annual global hackathon, slated for June 28-31, 2024, we aim to further expand our reach and deepen our impact. The upcoming hackathon will incorporate more extensive preparatory workshops, more robust mentorship opportunities, and a broader scope of challenges for teams to tackle. Our goal is to innovate not just within the confines of neurosurgery, but across disciplines and borders, in a manner befitting the interconnected world of today and ultimately benefiting patients. With the Mission Brain Hackathon, we hope to turn barriers into



Figure 1: Hackathon Programming: Schedule of Events from the 2023 Hackathon Weekend, which incorporated multiple stakeholders, advisors, and other organizations that supported participants and culminated with presentations and judging.

bridges, connecting minds and hearts in the pursuit of a more equitable global neurosurgical landscape and ultimately a better world. ❏

To learn more about this event, check out this [video](#)

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Katrina S. Firlik, MD

Starting a Company: My Top 5 Pieces of Advice

Being a neurosurgeon is the best job in the world. So why do anything else, even on the side? The answers are as diverse as the people who ask themselves the question: to bring a brilliant idea to fruition, to develop a product around a new device patent, to fulfill outside interests, to improve patient care, to diversify income streams.

In my case, starting digital health company HealthPrize, it was a combination of catching the entrepreneurial bug and wanting to bring some creativity to a major problem in healthcare. Then, what started off as a part-time endeavor ended up becoming full-time, prompting a career change. Why? As I tend to joke: Who wants a part-time brain surgeon?

This line always gets a laugh but it's not quite accurate. In reality, I didn't feel adept at parallel processing, and worried I wouldn't be able to do both well, despite my passion for neurosurgery. Plus, I didn't want to attempt both at the expense of family. Some neurosurgeons are adept at achieving success in a side hustle without compromising their primary career. It can be done. (After all, part-time research has been around forever.)

But how to start? For any neurosurgeon with an inkling that they might want to found—or join—a start-up, I offer my top five pieces of advice, learned equally through failure and success.

Embrace a beginner's mind

"Knowing what you don't know is more useful than being brilliant." - Charlie Munger

If you don't have an MBA and have never been in a business outside of medicine, you're likely to have a ton of new lingo and skills to learn. Don't be embarrassed. Act like a medical student: ask a lot of questions, seek out experienced mentors, be humble. And best of all, embrace the thrill of being on the steep part of the learning curve again.

Advocate for yourself

"I learned a long time ago the wisest thing I can do is be on my own side, be an advocate for myself and others like me." - Maya Angelou

Compensation is often in the form of both salary and equity, with equity typically the more significant driver. Learn how equity is structured and, again, familiarize yourself with the lingo pertaining to

what your stake might be worth: pre-money/post-money valuation, cap table, liquidation preferences, dilution. Befriend a lawyer in the startup space, or a venture capital or angel investor. How are deals structured? What might your role be worth? And remember: a small piece of a successful company is worth more than a larger piece of one likely to fail. Negotiating over even a fraction of a percentage point can be meaningful.

Determine your ideal position on the team

"It's amazing what you can accomplish when you do not care who gets the credit." - Harry Truman

Although your first instinct might be to assume the CEO role, joining forces with a seasoned serial start-up CEO might be the more efficient and fruitful path. Chief medical officer can be an excellent alternative depending on the company. Don't let pride get in the way.

Learn from failure

"My dad encouraged us to fail growing up. He would ask us what we failed at that week. If we didn't have something, he would be disappointed." - Sara Blakely

Expect plenty of failure. Apply the spirit of an M&M conference to learn from it so that no failure goes wasted. Refreshingly, unlike in surgery, failure is not typically accompanied by the threat of death or disability, making it an easier pill to swallow.

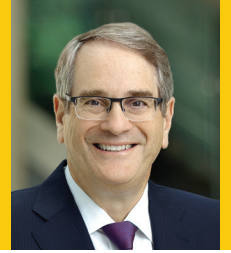
Strengthen communication skills

"The most important investment you can make is in yourself. One easy way to become worth 50 percent more than you are now, at least, is to hone your communication skills—both written and verbal." - Warren Buffett

I can't stress this point enough. Learning how to communicate complicated things in a simple way is very powerful. It will help you win investors, attract talent, and sell a product or a vision. In most cases, first drafts are too long. Keep editing, simplifying. ❏

Feel free to reach out if any of this advice speaks to you. I wish you the best of luck!

Dr. Katrina Firlik is co-founder and chief medical officer of HealthPrize, a digital health company with an innovative approach to medication nonadherence, combining education, incentives and gamification. Prior to founding [HealthPrize](#) she practiced neurosurgery in Greenwich, Connecticut. She is also the author of [Another Day in the Frontal Lobe: A Brain Surgeon Exposes Life on the Inside](#), published by Random House. See her author website here: www.KatrinaFirlik.com



Henry Brem, MD

Discovery of Brain Tumor Therapies

I have always been intrigued about the origins and treatments for cancer. After my freshman year in college, I had the opportunity to work with Professor Herbert Rosenkranz in the microbiology laboratories of Columbia. We discovered that a common gasoline additive was in fact mutagenic and carcinogenic. That summer I also began working in the Columbia operating rooms and was fascinated both by the simplicity of surgically removing a tumor as well as the limitations in doing so.

I was fortunate to be exposed to the brilliant and innovative thinking of Judah Folkman, professor and chairman of surgery at Children's Hospital Medical Center at Harvard. Dr. Folkman had demonstrated the biologic beauty of angiogenesis as a critical control point in cancer development. While studying embryology as a premedical student at NYU, I learned that fetal cartilage is vascularized, but neonatal cartilage is avascular and remains so for the lifetime of the animal. I therefore proposed to Dr. Folkman that we explore whether embryonic cartilage has a chemical substance that causes vessels to regress. Working in his laboratory as a graduate student, we discovered the first known angiogenesis inhibitor. The purification of this inhibitor was quite challenging. We were joined in this effort by Bob Langer, who joined Dr. Folkman's laboratory as a postdoctoral fellow. Bob Langer completed the purification of the cartilage derived inhibitor. To efficiently carry out the purification he and Dr. Folkman developed a polymer system for direct delivery of purified stimulants and inhibitors to their targeted site.

I completed medical school at Harvard, internship at the Peter Bent Brigham Hospital, and neurosurgery residency at Columbia. During my residency, I spent a year at Johns Hopkins, in the laboratory, exploring whether CSF contained markers of angiogenesis. This was a forerunner for later work on liquid biopsies for brain tumors.

As I started on my academic career at Johns Hopkins in 1984, I felt strongly that we needed to improve our understanding in treatment of brain tumors. Computerized tomography and magnetic resonance imaging were revolutionizing neurosurgical localization of brain and spine lesions. I was fortunate at Hopkins to work with outstanding radiologists and engineers and companies that brought the preoperative imaging technology into the operating room by utilizing navigation. We carried out the pivotal FDA clinical trials demonstrating its accuracy and safety so that navigation became a standard tool in the operating room. While this transformed the safety and efficiency of surgery, it did not change the biology or the ultimate outcomes for patients.

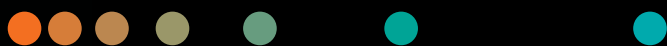
Many new therapies had been tried for malignant gliomas and not one had succeeded in changing the clinical outcome. So many of these therapies looked promising in the laboratory but when tested in people failed to improve survival. I began to question whether in fact we were delivering these potentially therapeutic agents into the brain to their target site. I therefore reached out to my colleague at MIT, Bob Langer, to explore whether the polymers he and Dr. Folkman had developed for purifying angiogenesis inhibitors could be utilized to deliver chemotherapeutic agents directly to a brain tumor in people. In fact, Bob Langer had just discovered that polyanhydrides were biodegradable and ideally suited for controlled drug delivery in the brain. We therefore began a series of collaborative experiments to show that the biodegradable polymer was biocompatible in the brains of rats, rabbits, and monkeys in that it could release locally and effectively the then-standard chemotherapeutic drug, carmustine. We worked closely with Avi Domb in Bob Langer's lab and with Rafael Tamargo and Betty Tyler in our laboratory as well as Michael Colvin, professor of pharmacology at Hopkins, Kam Leong and Mark Saltzman in Engineering. We developed the pharmacology, drug distribution models and efficacy of Gliadel. Three years after I joined the faculty at Hopkins, in 1987, we initiated a five institution, safety study for the Gliadel chemotherapy wafer. We met regularly with experts at the FDA and worked closely with a Hopkins startup company, Nova Pharmaceuticals, and designed a randomized prospective placebo-controlled study for recurrent malignant gliomas, carried out at 27 medical centers throughout the United States and Canada. We also initiated two randomized prospective placebo control studies in Europe and Israel demonstrating the safety and efficacy of this new treatment as the initial therapy for malignant brain tumors. Based on these three studies and our preclinical laboratory work, the FDA approved Gliadel as a safe and effective therapy for brain tumors. This was the first time in 23 years that the FDA approved a new therapy for malignant gliomas. 30 years later this therapy is still utilized throughout the world to help patients.

Along the way, we have discovered many other drugs, immunotherapy agents, angiogenesis inhibitors and targeted therapies that are in different stages of development and hopefully will contribute to better understanding and treatments for neurosurgical diseases. Funding came from the NIH, foundations, industry and philanthropy. As clinical neurosurgeons, we have the unique opportunity to observe nature and develop insights into better treatments. These advances come from collaborating outside of our own silos and by inspiring our colleagues in basic science and engineering and industry to work with us to improve our patients' outcomes. ■

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Kathryn Ko, MD, MFA

Ko Iki Museum

Art can perforate your skull rendering you unable to move, awestruck by its power. It's that wild companion who leads you away from the textbooks to embark on unfamiliar journeys. Like a canary in the depths of the mind, art diagnoses the atmosphere. Joseph Beuys said, "Every human being is an artist." At the very least, every human being needs the artist. Art is medicine.

Medical practice itself, too, is an art form. I'm a surgeon even while holding a brush. Every painting is an operation, a poem that may ease a neurosurgical heartbreak. An artist needs to create to live, while a surgeon lives to save lives. A neurosurgeon painstakingly reconstructs a fractured skull whereas an artist takes those shattered bits, adds a hinge and transforms it into something new. It is a reciprocal relationship; artists divine possibilities and ideas, and we physicians assess their feasibility. We need each other to innovate. To heal.

During my time in medical school, my mother pursued a master of fine arts in painting at the same university. I found relief from my textbooks by visiting the student studios, where the creative atmosphere was fire. Two and a half decades later, to my amazement, I became an art student. I am fortunate. Many in the medical field don't have this opportunity or time to engage with the arts, missing out on the deep impact it can have on their lives. The arts can lighten the intense weight of a medical career.

Inspired by the innovative "Little Free Libraries" movement, the Ko Iki Museum integrates art within the medical school campus. After visiting the Museum of Contemporary Art in Patchogue where a "mini" museum stood outside in the sculpture garden, I was determined to have one installed at my medical school. I then directed the construction of the Ko Iki Museum (pencil drawing by Dr. Ko). The Ko Iki embarked on a 5,000-mile journey from New York across the US and Pacific Ocean, changing hands seven times, before finally arriving at the John A. Burns School of Medicine (JABSOM) at the University of Hawaii. The word "Iki," meaning "tiny" in Hawaiian, captures the spirit of this project to bring art to medical schools, JABSOM being the first. Individuals are invited to contribute mini artworks, unleashing their imagination on blank canvas, and returning the piece to be showcased in the museum. At



Ko Iki Museum, drawing Kathryn Ko.

the heart of the Ko Iki Museum is the idea that art, in all its diverse forms, is necessary for well-being.

Long after I depart the operating room, neurosurgery remains my chosen medium. When lost and unsure, I listen for the birdsong, my reminder to keep art close. Art, tiny or grand, can ignite our minds so we are inspired to move a museum across a continent and an ocean. ■



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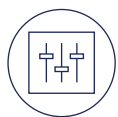
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Uzma Samadani, MD,
PhD

Adding Insight to Injury: An Innovation Story

Having finished my residency at the University of Pennsylvania in June 2006, I set off for Germany to do a VanWagenen fellowship. I arrived the first week of July. My fellowship involved research on animals, and due to the complexities of the German research approval system (the American equivalent of IACUC), there wasn't much for me to do in July and August. It seemed that at least half of the Germans were on vacation and my protocol wasn't approved yet. I settled down to catch up on tasks I hadn't finished in residency, which included writing a book chapter on vagus nerve stimulation. As the chapter came together, I decided to turn it into a grant, investigating whether one might improve outcomes from severe traumatic brain injury using vagus nerve stimulation.

By the time the grant was written, I knew I would be taking a job at the New York Harbor Healthcare System (Manhattan VA), so I submitted to the DOD. The grant scored right at the edge of the funding range, Congress set the budget, and I didn't make the cut.

No worries. By then, I had finished my fellowship and moved to New York City. I resubmitted as a VA merit award and was finally funded, after revision, in 2010. I submitted an IDE to the FDA, and they balked at the idea of putting brain injured patients with a vagus nerve stimulator into an MRI scanner. I had intended to use functional MRI as my outcome measure, and now I needed to find something else.

David Heeger and Marisa Carrasco, computational neuroscientists at NYU, suggested I try eye tracking. David recommended hiring a post doc from his lab to work on the project and in May 2011 we set up the first eye tracker at the Manhattan VA and started eye tracking ourselves and patients to see if we could collect meaningful data that correlated with levels of consciousness.

In February 2012, I realized that eye tracking correlated with the nature of neurologic deficit. The first finding was that supratentorial mass effect appeared to impact the function of cranial nerve three, manifested as reduced movement of the superior and inferior rectus. Infratentorial mass effect appeared to impact the function of cranial nerve six, manifested as reduced movement of the lateral rectus.¹ Elevated intracranial pressure appeared to impact cranial nerve six more than three, but showed effects on both to some extent.²

At that point, I realized the technology was a highly sensitive physiologic assessor of central nervous system function. In August of 2012 an awake trauma patient with a skull fracture came to the VA, and I recognized the value of the technology for brain injury. October 2012 brought Hurricane Sandy, and my lab at the VA was shut down.

In May 2013, I reopened my lab in a storage closet borrowed from Dr. Theodore Smith in the Department of Ophthalmology at Bellevue Hospital. Over the next two years, we eye tracked more than 2,000 patients and controls and started to develop the algorithms that detect concussion³, distinguish it from alcohol or methadone abuse, and characterize the nature of injury.

In July of 2015, I left New York and moved my lab to Minneapolis. It was at this point that I stopped major work on eye tracking in my own lab, and instead focused on developing collaborations with others to further the work.

Commercialization

Once I had realized that eye tracking was a sensitive marker for central nervous system physiological function, I wanted to be able to share the technology with others. My goal was to change the way brain injury is diagnosed and defined. My first thought was to make the software open access and freely available on the web for anyone who wished to use it to evaluate neurologic function in any scenario. The tech transfer personnel at New York University discouraged this idea, as they understood the technology would not be utilized if hospitals or clinics could not make a profit.

I then considered licensing the intellectual property. Unfortunately, no one was interested in licensing a technology that was not easily usable, FDA cleared, and reimbursable. We were told it "looked like a science experiment." The tech transfer office advised me to apply for a commercialization grant. I partnered with an MBA student from the Stern school, and a NuVasive employee who was a Stern alum. We won second place and a check for \$50,000 in May of 2013. The fine print specified that in order to collect the money we actually had to have a company. So we started Oculogica that summer, opened a bank account and cashed our first check.



The EyeBox device

It took us until December 2013 to negotiate a license agreement with NYU and the VA so that we could have rights to commercialize the technology. We won another couple of grants, including \$250,000 from the National Space Biomedical Research Institute (NSBRI).

We then raised a round of friends and family money totaling \$600,000 and we hired a California company to turn our software into a commercial product. The first version was an absolute disaster. It crashed every second time you turned on the computer. Or maybe it was every time.

In July 2015 I was able to convince my sister, Rosina Samadani, who had her PhD in biomedical engineering and had already successfully sold her first two startups, to become our CEO. She hired

“ONCE I HAD REALIZED THAT EYE TRACKING WAS A SENSITIVE MARKER FOR CENTRAL NERVOUS SYSTEM PHYSIOLOGICAL FUNCTION, I WANTED TO BE ABLE TO SHARE THE TECHNOLOGY WITH OTHERS. MY GOAL WAS TO CHANGE THE WAY BRAIN INJURY IS DIAGNOSED AND DEFINED. ”

a programmer and he fixed our software. She collected more data and we submitted to the FDA for a de novo marketing authorization, as there was no precedent for our technology. In December 2018, Oculogica became the first company to have a technology that was FDA cleared for the diagnosis of concussion.

In 2019, we got a CPT code and in 2020 we were approved by Centers for Medicare & Medicaid Services (CMS). In January of that year, we closed an \$8 million round led by Titledown Tech, the investment partner of the Green Bay Packers. In 2021 we won our first major DOD contract worth \$3 million.

We launched a streamlined version of our original device in 2022 and our market share began to rise. The new device and print out made it clear that the test was a digital neurologic examination of



Receiving a check for \$50,000 from the NYU Entrepreneur's Challenge to start Oculogica

cranial nerves two through seven, assessing pupillometry, motility and blink. My goal for the technology is that it will be the gold-standard diagnostic for concussion, and also be useful for other conditions affecting central nervous system function (hydrocephalus, headache, dementia, intoxications etc.).

In 2023, we launched a second device, Ocu-Pro, that detects cannabis impairment. Also in 2023, we achieved a milestone that only 4% of startups ever reach—over \$1 million in revenue.⁴ And by the fourth quarter of 2023 we began seeing months where our profits exceeded our expenses.

We still have hurdles to overcome. Most of our users are neurologists and a lot of their patients are either on workers comp or personal injury/liability. We are focused on expanding our coverage by insurance providers, most of which already reimburse for eye tracking.

Lessons I Learned In This Process

- I was able to do this because I had time, and was able to get money, with a lot of persistence. During my VanWagenen Fellowship I wrote a grant that was ultimately funded on the third try, four years later. At the Manhattan VA I had two academic days per week. I didn't start the company until after I was board certified in 2010. Starting a company as a resident or early-career clinician might be more challenging. I currently operate three to four days a week and might have trouble starting another

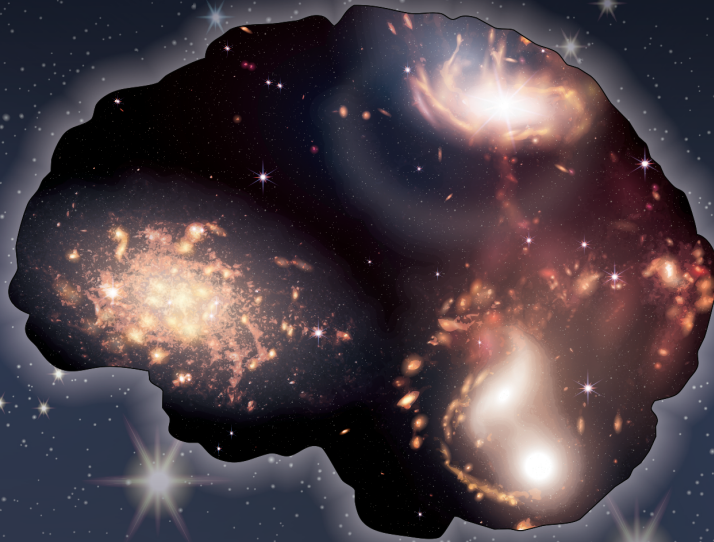
company with my current schedule. Grant funding is the best way to start a new company, in my opinion, and it takes way more time than you might think.

- Collaborations were key. David Heeger and Marisa Carrasco were the initial innovation drivers. Floyd Warren was my first ophthalmology collaborator at the VA. When my lab shut down due to Hurricane Sandy, I was able to move in with Ted Smith in ophthalmology at Bellevue. He housed my entire lab. I had support from Paul Huang who was the Chief Neurosurgeon at Bellevue and from Steve Wall, an ER physician. Without those connections, we never would have obtained trauma center data. Charlie Marmar, Jeff Wisoff, Howard Weiner, David Harter and Doug Kondziolka were also collaborators at NYU.
- The single biggest enabler of Oculogica's success was the fact that I was able to recruit a highly qualified, previously successful CEO to get the company through FDA and enable reimbursement. Critically, she was able to raise capital. These processes require a skill-set completely distinct from practicing neurosurgery. They never would have happened without the right person.
- Having a great idea that improves patient care—no matter how brilliant it is—does not enable integration into the health care system, unless the new tech enables its user to make money. The American health care system favors the success of innovation that is not particularly innovative. It is easier to get a 510K (predicate approval) than a *de novo* FDA clearance. It is easier to get insurance and government reimbursement for a tech that is marginally different from current tech rather than something that requires an entirely new process. Sadly, the commercial value of a technology is not in how much it helps people, but rather in how much money it earns the person using it. A technology that only helps people is thus less likely to succeed in a capitalist system. ❏

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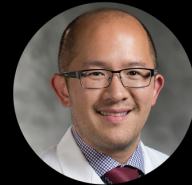
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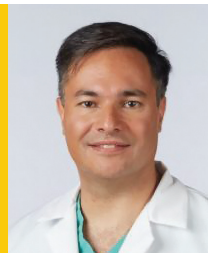


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Costas Hadjipanayis,
MD, PhD



Steve Kalkanis, MD

Lighting the Path to FDA Approval of 5-ALA

The date was May 10, 2017, and a group of neurosurgeons (including Steve and myself), industry partners, brain tumor patients and their families, and brain tumor advocacy leaders all came together for an important meeting with the FDA in Silver Springs, Maryland. This meeting, known as the Medical Imaging Drugs Advisory Committee (MIDAC) meeting, was the last hurdle to gain FDA approval for an oral drug, 5-aminolevulinic acid (known as Gleolan), we now routinely employ for the intraoperative visualization and fluorescence-guided surgery (FGS) of high-grade gliomas. Prior to FDA approval of any agent, advisory committees comprised of outside expert individuals are appointed by the FDA to review the unmet need, safety, efficacy, and risk-benefit data in support of the drug agent. At the medical advisory committee meeting, industry and physician experts present the data to the group. A majority approval in the form of a vote by the advisory committee is necessary for FDA approval to proceed. Our day was finally here and represented years of work convincing the FDA how important this agent was for our neurosurgeons and brain tumor patients. We were all gathered in a large, daunting room filled with key experts assembled for the MIDAC panel.



Fig. 1: Dr. Hadjipanayis presenting to the MIDAC at the FDA on May 10, 2017.

Why was it so difficult to get to this point?

Why could we not get FDA approval earlier, as Europe had over 10 years prior in 2006?

Emotions ran high that day at the MIDAC meeting since there was a real chance MIDAC would not vote in favor for FDA approval of 5-ALA. Much of the reason for this concern was the fact that we needed to convince the FDA that their established paradigm of improved overall survival (OS) for brain tumor patients, as the primary outcome measure for approval of a drug, did not apply to

5-ALA. We all knew that 5-ALA was not a typical therapeutic drug that treats malignant brain tumors. 5-ALA is an oral drug used to improve the visualization of malignant brain tissue and was felt to be more of an intraoperative imaging diagnostic agent.

In 2011, a group of medical experts (including myself and Dr. Walter Stummer, University of Muenster, Germany) and industry approached the FDA to discuss the approval process of 5-ALA in the US. The European clinical experience, including the landmark Phase III randomized study, led by Walter Stummer, was provided to the FDA. That trial not only confirmed safety of using 5-ALA during surgery but also, for the first time ever, established more complete tumor resections could be performed with use of 5-ALA FGS and better patient outcomes with improvement in progression-free survival (PFS). Unfortunately, the Stummer study did not provide a treatment specific OS benefit to patients and more importantly, the trial was not powered for this type of OS study. At that time, an FDA Advisory Group, which included members of the FDA Division of Medical Imaging Products and the Oncologic Drugs Advisory Committee (ODAC) felt further clinical benefit in the form of OS was needed in addition to PFS for consideration of 5-ALA approval. We had a real disconnect since no one, including our industry partners, had any appetite for any large randomized 5-ALA clinical trial in the US that would require large patient numbers, lengthy patient enrollment, and high costs. We had to go back to the drawing board and decide on a new strategy!

How do we convince the FDA that 5-ALA is not a therapeutic but an intraoperative imaging agent?

At that time, multiple studies in Europe and a new multicenter study in the US were underway to focus on the intraoperative diagnostic accuracy of 5-ALA. These biopsy-driven histopathology studies confirmed what was known by surgeons all along: 5-ALA and its intracellular tumor metabolite, protoporphyrin IX (PPIX), had unprecedented intraoperative diagnostic accuracy. 5-ALA was highly sensitive at detecting malignant tumor tissue and the probability that fluorescent tissue representing malignant tissue, or the positive-predictive value (PPV) of 5-ALA, was close to 100 in almost all studies. We quickly learned; however, the specificity and negative-predictive value (NPV) were not as high in those same studies. We had to make sure the FDA understood that due to the infiltrative biology of high-grade gliomas, tumor cells are present with surrounding cells in the infiltrative margin that weakens the fluorescent signal given by PPIX, lowering specificity and NPV. Nevertheless, we felt a new pathway for FDA approval of optical imaging agents could be developed that focused on clinical benefit associated with high intraoperative diagnostic accuracy. If a neurosurgeon could visualize fluorescent tissue after 5-ALA administration, they could confidently assume this was tumor tissue and could make the decision to remove.

In 2013, FDA granted orphan drug designation of 5-ALA for visualization of malignant tissue during surgery for high-grade gliomas (WHO grades III and IV). This was a very significant positive development in our quest for FDA approval of 5-ALA. More subsequent meetings with the FDA in 2014 permitted the submission of a new drug application (NDA) to the FDA in December of 2016. The NDA consisted of the Stummer phase III European study results (greater overall tumor resection and PFS with 5-ALA FGS) and biopsy-driven studies

completed showing high sensitivity and PPV to support 5-ALA as an intraoperative imaging agent. The NDA submission could not have been possible without our industry support and Dr. Walter Stummer.

After receipt of the NDA and release of key discussion points by the FDA, the MIDAC meeting was set. May 10, 2017, was truly a glorious day for neurosurgery and brain tumor patients. We had a magnificent showing of neurosurgeons (both academic and community-based), industry, brain tumor patient advocacy leaders, and a surviving glioma patient and her son who presented to the FDA the need for 5-ALA. The MIDAC voted unanimously (11 votes in favor and 0 votes against) for the approval of 5-ALA (Gleolan). The official FDA approval of 5-ALA shortly followed on June 6, 2017, and the rest is history.



Fig. 2: *It takes a village: academia, industry, and the community representing brain tumor patients after the successful MIDAC meeting.*



The road to 5-ALA approval in the US was a bumpy ride over years that uncovered difficulties associated with regulatory requirements for a nontherapeutic agent used in brain tumor patients. The path now developed with the FDA may permit other optical imaging agents used in the operating room to move forward toward approval for the benefit of our patients.

Fig. 3: *Dr. Hadjipanayis and Kalkanis celebrating triumph after unanimous MIDAC approval of 5-ALA for glioma surgery.)*

We acknowledge the great effort provided by so many individuals in academia, industry, patients, families, and the community who provided their strong support for lighting the path towards 5-ALA approval in the US. ❖

Reference:

1. Hadjipanayis CG and Stummer W. 5-ALA and FDA approval for glioma surgery (2019). *J Neurooncol* 141(3):477-478.



Douglas Kondziolka, MD
Editor-in-Chief, Neurosurgery Publications

Journal Spotlight: Editor-in-Chief Profile in Innovation

A neurosurgical career involves innovation on a continuous basis. New clinical challenges, solving problems in different ways, incorporating new technologies into practice, and evaluating results. We all do this. I was asked to comment on an element of innovation in my own practice that was particularly unique. For me, the story of some of the “firsts” in cerebral cell transplantation fits the bill. Although cellular transplantation had been performed in a number of different ways (perhaps adrenal medullary transplantation for Parkinson’s Disease (PD) got the most attention), we did the first human work in stroke. It represented the first use of cryopreserved cells rather than fresh tissue, the first use of a laboratory-created cell line, the first use for the indication of stroke, and the first use of cells not developed on site.

Peter Jannetta was the Chair of Neurosurgery at the University of Pittsburgh. His brother Tony was an entrepreneur helping to fund and develop neuroscience research at the University of Pennsylvania. Scientists John Trojanowski and Virginia Lee with their colleagues had developed the hNT neuronal cell line from a teratocarcinoma source. Tested in vitro and in vivo with promise, it was time to consider human clinical applications. The group (Layton BioScience Inc.) came to Pittsburgh to discuss the possibilities. As a neurosurgeon trained in stereotactic surgical techniques, I was comfortable with the delivery of probes to brain targets, and the care of patients with neurodegenerative problems. About seven of our faculty met with them and we discussed the usual list of disorders for whom a brain repair concept might pertain, but afterwards, I was the only one who gave them a vision – a vision for repair of lacunar or subcortical stroke. So when they came back to Pittsburgh, the next set of meetings were focused on this area. Why stroke? Animal studies of ischemia had shown some recovery, we could see the stroke on brain imaging (unlike PD where the target was still in debate), the target volume was not large, the patients had a major fixed deficit and would be desire improvement, and we thought the United States Food and Drug Administration (FDA) would be amenable to the idea. And so, after discussions with the funding source, a group of advisers, and the FDA, which took months, we got approval to go ahead with our own institutional review board. We also filed an invention disclosure

and patent application for cell therapy for stroke. Interestingly we were granted the patent in the European Union, Japan and Australia but not in the United States—because a reporter from Lancet had done an interview with me and published a short news statement that we did the surgery (but not how), before we filed. They considered this information in the public domain. If you have an innovative idea worthy of protection, file early.

But how many cells to implant and how to deliver them? We had to decide on inclusion and exclusion criteria, and on a cellular dose and volume to evaluate in a safety study. We had to create a new stereotactic cannula with a small internal dead space for accurate delivery that would also not damage the cells. We needed to define the outcome measures to evaluate response. We needed a laboratory under good manufacturing practice (GMP) guidelines to take frozen cells, thaw them, count them and check viability, and bring them to an operating room. We had to learn how long cells could remain viable which determined the maximum length of surgical time. All of these questions led to additional research. We used FDG-PET to evaluate the implants and the regional brain response. Tom Freeman at the University of South Florida and I had many discussions on these topics. Did we need immunosuppression? Dr. Paul Sanberg, also from the University of South Florida led the preclinical work. And so in 1999 we implanted the first patient. Our phase 1 study included 12 patients and was published in *Neurology*.¹ I went on Good Morning America the next week and suddenly we were inundated with requests for a “cell transplant”. Based on what we learned in trial design with biologics, I was asked to lecture at the FDA to their staff.


That first study showed an excellent safety profile and some elements of clinical benefit. A second trial was planned and begun, and I wanted another site, on the west coast for more diverse patient access. I recruited Gary Steinberg from Stanford University as my new surgical investigator and he put his team together. We safely completed a second trial, published in the *Journal of Neurosurgery* in 2005, which also included neuropsychological testing and post-implantation rehabilitation therapy.² But this work was expensive and was industry-funded. NIH funding was sought for the goal of

additional trials with higher numbers of cells. But FDA requested that this be tested in an animal primate model of chronic stroke, which really did not exist. We were to create an entirely new stroke model. Preliminary work in this direction was so expensive, that the company ran out of funding and the license to the cell product was sold to another firm. But they were never able to continue the work using this cell line.

At the same time, a new neuronal line developed from bone marrow progenitor cells at Kyoto University showed promise in preclinical work. Since our group had the most experience in this area of translational neuroscience, we were approached to design and implement a new clinical trial. But each new cell line required work to go “back to the beginning” to test suitability for surgical delivery. Unlike the initial cells that persisted in brain tissue, this new line was found to be lost over time in the xenograft models it was tested in. The mechanism of action was believed to be through the release of neurotrophins that helped recovery, but it was well understood that any mechanisms were likely multiple and theorized. This cell line was developed by a company called San Bio. Our trial, again conducted at the University of Pittsburgh and Stanford, was published in *Stroke* in 2016 and was honored as one of the top papers of the year in that journal.³ Following this a pivotal randomized trial, with a sham surgery control group including simulating surgery with a partial burr hole but not a brain implant was performed. Despite safety and some efficacy, the primary outcome was not reached. A separate trial was conducted to study cellular repair in focal traumatic brain injury⁴

The last decade has seen other trials in cell repair for stroke using different cell lines, both using direct brain implantation or endovascular delivery. One important element of the studies we conducted, was the finding of good safety and tolerability, which kept the door open for other studies to follow. We made numerous assumptions in trial design for which little information existed. However, decisions had to be made. It is a fact that future studies often incorporate these assumptions and decisions in trial design because “that is what was done before”, rightly or wrongly. Innovation in translation neuroscience is time-consuming, expensive, and requires the input and oversight of many key individuals and agencies, as well

as a long-term commitment. The work was performed in parallel with my regular clinical practice and other research. Trials were separated by years. Although 25 years later there is not an established cell-based therapy for stroke, much was learned, and new concepts for neurorepair and functional augmentation have been developed. I remain so thankful to the many people involved in this innovative work, including the neuroscientists who trusted us with using their research in real people, and particularly to Dr. Gary Steinberg who was willing to add this line of work to his busy clinical practice and other research interests.

Innovation is what we do, whether in an academic or community practice. We are all translational science neurosurgeons in one respect or another. Think big, involve excellent and committed people to help address your vision, and work with industry, regulatory agencies, and other groups to meet your goals. The public depends on us to innovate. 

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FOUNDATION UPDATE



OUR MISSION:

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“Every dollar is a catalyst for change, and it is through the unwavering generosity of you—our donors and corporate partners—that we can achieve the Foundation’s goals through our array of initiatives.”



Martina Stippler, MD
CNS Foundation Chair
CNS Secretary

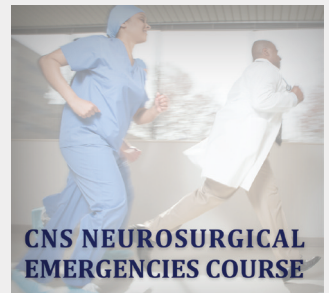
FEATURED PROGRAM

INTERNATIONAL OBSERVERSHIP PROGRAM

The Foundation observership and visitorship program invites neurosurgeons—often from low- and middle-income nations—to observe first-hand practices they can use to improve patient care in their home countries. Mentors from the observership institutions graciously dedicate time and unwavering support to provide rich experiences for a growing body of neurosurgeons from around the world.

INTERNATIONAL IMPACT

In addition to supporting numerous observerships, your donations supported 25 neurosurgeons from developing nations Uganda and Ethiopia to attend the Neurosurgical Emergencies Course.



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“Thanks to your support, the students were able to rotate in the OR/clinic/cadaver lab, dissect a sheep brain, remove a clot on thrombectomy model and coil an aneurysm, and had multiple workshops and lectures focused on academic preparation, college applications, financial aid, and immediate next steps.”

– Alexandra Giantini Larsen, MD / Pilot Program

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INSIDE THE CNS



Washington Committee Report



Russell R. Lonser, MD
Chair, Washington
Committee

Congress Passes Legislation Partially Reversing 3.37% Medicare Pay Cut

Congress passed the Consolidated Appropriations Act, 2024 (H.R.4366), partially reversing the 3.37% Medicare physician payment cut that went into effect on Jan. 1. President **Joseph R. Biden** signed the bill into law. The legislation reduces the cut by half, providing a 1.68% increase in current payment levels. The new payment rate took effect on March 9 and will continue through the remainder of 2024.

The legislation also extended incentive payments for physicians participating in certain advanced alternative payment models, providing eligible participants with an additional 1.88% bonus payment. In a statement to [MedPage Today](#), **Katie O. Orrico**, Esq., Senior Vice President for Health Policy and Advocacy in the Washington Office, stated:

When coupled with medical inflation and ongoing sequestration cuts, physicians are now experiencing a staggering 10% Medicare payment cut in 2024. While we appreciate the additional resources Congress is providing, it is a drop in the ocean of need. This discrepancy highlights the unique and untenable position of physicians, who are the only Medicare providers without an inflationary-based payment update, emphasizing the critical necessity for long-term payment reform that genuinely reflects the economic realities faced by physicians who are the foundation of patient care in our health care system.

Neurosurgeons are encouraged to go to the Washington Committee Advocacy Action Center and urge your representatives to co-sponsor [H.R. 2474](#), the Strengthening Medicare for Patients and Providers Act. This legislation would provide physicians with an annual Medicare physician payment update based on the Medicare economic index.

Click [here](#) to send a letter to your elected officials.

CMS Finalizes Prior Authorization Reform

The Centers for Medicare & Medicaid Services (CMS) [finalized rules](#) streamlining prior authorization in Medicare Advantage, state Medicaid and Children's Health Insurance Program (CHIP) fee-for-service, Medicaid managed care, CHIP managed care and Qualified Health Plans on the federal exchange. The final rule requires, among other things, covered plans to:

- Implement an electronic prior authorization process;
- Reduce care delays by responding to prior authorization requests within 72 hours for urgent requests and seven days for standard requests; and
- Report the use of prior authorization, including specific reasons for denials and other prior authorization metrics.



CMS projects this rule could save providers more than \$15 billion by reducing administrative burdens associated with prior authorization.

Following the rule's publication, the Regulatory Relief Coalition, of which the CNS and the AANS are leaders, issued a [press release](#) lauding CMS for its finalized landmark rule. "This is a watershed moment for patients' access to care," said **Russell R. Lonser, MD**, chair of the department of neurosurgery at The Ohio State University and chair of the Washington Committee. He added, "The rampant overuse of prior authorization, particularly in Medicare Advantage, continues to cause inappropriate delays and denials of medical treatments that our seniors need."

Click [here](#) for a CMS fact sheet on the rule and [here](#) for the agency's press release.

In addition, on Jan. 5, the CNS and the AANS joined the Regulatory Relief Coalition in commenting on the Centers for Medicare & Medicaid Services (CMS) 2025 Medicare Advantage proposed rule. The comment letter offers several reforms to prior authorization in the Medicare Advantage program, including improvements to ensure health equity and prior authorization reporting requirements.

Click [here](#) to read the letter.

CNS and AANS Support Prior Authorization Legislation

The CNS and the AANS recently joined the Regulatory Relief Coalition in sending a [letter](#) supporting [H.R. 5213](#), the Reducing Medically Unnecessary Delays in Care Act. Sponsored by Rep. **Mark Green, MD**, (R-Tenn.), this legislation would reform prior authorization in Medicare by requiring that all prior authorizations and adverse determinations must be made by a licensed physician who is board certified in the specialty relevant to the health care item or service requested.

CNS and AANS Urge CMS to Address Network Adequacy Standards

On Jan. 8, the CNS and the AANS joined the Alliance of Specialty Medicine in submitting [comments](#) to the Centers for Medicare & Medicaid Services (CMS) regarding the 2025 Notice of Benefit and Payment Parameters, urging the agency to address network adequacy concerns. Physician network adequacy is an ongoing issue, particularly for consumers who require specialty and subspecialty care. The comment letter urges CMS to take necessary steps to ensure robust access to specialty medicine.

CMS Provides Guidance on Reporting of New G2211 Complexity Add-on Code

On Jan. 18, the Centers for Medicare & Medicaid Services (CMS) posted guidance for using the new G2211 complexity add-on code. Effective Jan. 1, the new code may be reported with new and established patient office/outpatient evaluation and management services. The CMS guidance provides instructions and examples for using this new code.

Click [here](#) for the guidance document.

Neurosurgery Expresses Concerns about EHR Information Blocking

On Jan. 2, the CNS and the AANS joined the Physician Clinical Registry Coalition in sending a [comment](#) letter to the Centers for Medicare & Medicaid Services (CMS) and the U.S. Department of Health and Human Services Office of the National Coordinator for Health Information Technology (ONC) expressing concerns about the proposed rule to enforce the information blocking provisions of the 21st Century Cures Act ([Public Law 114-255](#)). The letter applauds ONC's and CMS' commitment to addressing information blocking by electronic health record (EHR) vendors and hospitals. The letter stresses that for clinical data registries to accomplish their missions, they must be able to collect data from providers and EHR vendors.

Neurosurgery Comments on FDA Off-Label Guidance

On Dec. 21, 2023, the CNS and the AANS joined the Alliance of Specialty Medicine in sending a [letter](#) commenting on a Food and Drug Administration (FDA) [notice](#) regarding a revised draft industry guidance titled "Communications From Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers." The revised draft guidance, when finalized, will provide the FDA's current thinking on common questions regarding communications by industry to healthcare providers of scientific information on the off-label use of approved/cleared medical products. The revised guidance replaces the 2014 FDA document on the topic. In the letter to the FDA, the specialty societies commend the agency for a concerted effort to support health care providers' interest in access to scientific information about unapproved uses of approved/cleared medical products.



Neurosurgery Issues Position Statement on Firearms

In 2023, the Washington Committee Firearms Task Force conducted a survey of CNS and AANS members regarding their views and experience with firearms and opinions regarding the involvement of organized neurosurgery in advocacy efforts to reduce firearm injury and death and to make firearm ownership as safe as possible. On Jan. 2, the CNS and the AANS also published an updated position statement on firearms, reflecting the views expressed by neurosurgeons nationwide.

Click [here](#) for the survey results, published in the *Journal of Neurosurgery*, and [here](#) for the position statement.

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IMAGES IN NEUROSURGERY

Halo Gravity Traction Followed by Anterior-Posterior Cervical Fusion to Correct Post-Laminectomy Cervical Kyphotic Deformity

CASE PRESENTATION:

A 39-year-old female with previous C1-6 laminectomy for a large intramedullary ependymoma resection in 2010 during which a gross total resection was achieved, but neuromonitoring signals were lost towards the end of the resection, and the decision was made to not instrument in favor of not prolonging the case. After 11 years of living independently and raising her son, she

presented in the spring of 2022 with neck pain and worsening left sided weakness for 6-months, accelerated over the last three weeks, worse in the left upper compared to the left lower extremity.

Preoperative x-ray showed C3/4 grade III anterolisthesis and C4/5 grade II anterolisthesis, prior laminectomies from C1-6, as well as a significant cervical kyphosis (Figure 1). Serial MRI scans demonstrate her progression from 2010 to 2022 with severe spinal cord compression at C3-C5 caused by narrowing of the spinal canal by the significant anterolisthesis at C3/4 (Figure 2).

Due to the flexible nature of the deformity on flexion-extension x-rays, the operative

plan was to provide halo gravity traction for 1 week, followed by anterior-posterior fusion to restore proper alignment, thereby opening the spinal canal. Halo gravity traction was performed for one week, with a progressive increase in weight from 10 lbs, 20 lbs, and 25 lbs (Figure 3). A staged anterior-posterior cervical fusion was planned with ACDF from C3-C6 and posterior cervical instrumentation and fusion from C2-T2. X-rays at 3-months showed a significantly improved alignment of the cervical spine and reduction of the C3/4 and C4/5 subluxation (Figure 4). At most recent follow up, the patient was eating and transferring independently, and her neck pain improved. ■



Figure 1: Preoperative PA and lateral neutral, flexion and extension cervical x-rays showed C3/4 grade III anterolisthesis, C4/5 grade II anterolisthesis and significant cervical kyphosis.

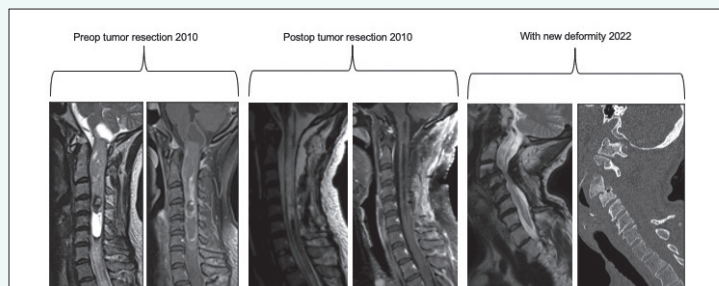


Figure 2: Pre- and postop MRI scans from 2010 showing tumor resection compared to MRI and CT in 2022 demonstrating progression with severe spinal cord compression at C3-C5 caused by narrowing of the spinal canal by the significant anterolisthesis at C3/4.

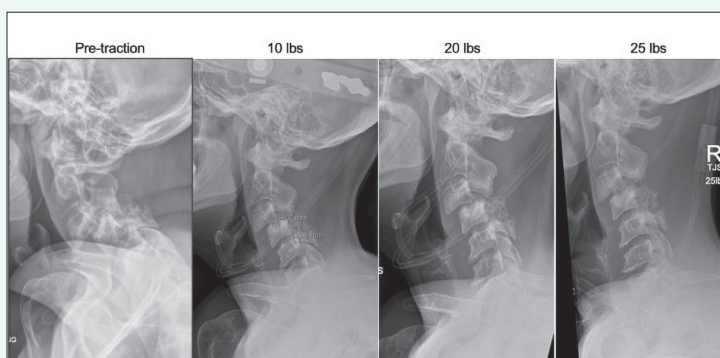


Figure 3: Serial lateral cervical x-rays showing results of halo gravity traction applied with a progressive increase in weight from 10 lbs, 20 lbs, and 25 lbs with improvement of cervical kyphosis. Traction was stopped at 25 lbs due to numbness/tingling in lower extremities.

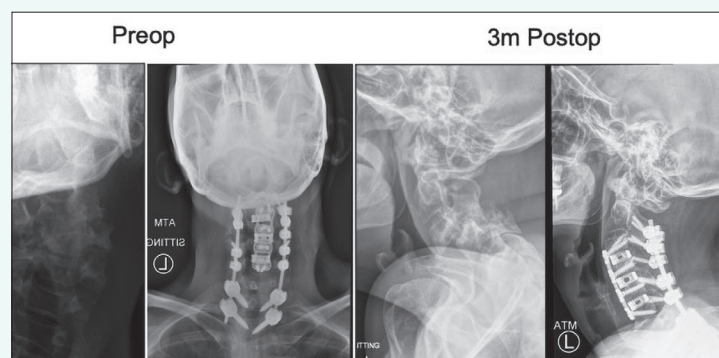


Figure 4: Three-month post-op PA and lateral cervical x-rays showed C3-C6 ACDF and C2-T2 posterior cervical instrumentation and fusion with significantly improved alignment of the cervical spine and reduction of the C3/4 and C4/5 subluxation.

Submitted by: Iyan Younus, MD¹, Hani Chanbour, MD¹, Aaron M Yengo-Kahn, MD¹, Allen K. Sills, MD¹, Scott L. Zuckerman, MD, MPH^{1,3}

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NEUROSURGERY ORIGINS



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