Developing neonatal minimally invasive surgery: Innovation, techniques, and helping an industry to change

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**A R T I C L E  I N F O**

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**A B S T R A C T**

The field of minimally invasive surgery (MIS) in neonates and infants is a relatively new field, evolving over the last 20 years. This has required the development of not only new techniques but new instruments. The process has resulted in a unique partnership between pediatric minimally invasive surgeons and industry, as both groups have struggled to find the right mix of need, technical viability, and economic sustainability. The results have spawned a new generation of MIS instrumentation that not only enables the neonatal MIS surgeon but also leads the way in the field of mini-laparoscopy in children and adults.

It is truly a great honor for me to be here addressing this joint congress today, on the state of the development of neonatal minimally invasive surgery (MIS). There are a number of reasons for this.

Firstly, IPEG has meant a great deal to me over the last 20 years. It is the place I have come for inspiration, to exchange ideas, to learn, and perhaps most importantly to be with great friends and colleagues. IPEG and its members, more than anything else, have been the guiding light and influence in my career. The fact that we meet this week with BAPS is an added bonus and not without historical and personal significance for me. BAPS was the first international meeting I ever attended as a resident. That encounter showed me the importance and the strength of the global pediatric surgery community and the impact it could and would have on the treatment of children, something that has been strongly embraced in IPEG. It also opened the door to many great friendships and collaborations.

Secondly, my career as a thoracic surgeon really started in England during a one year fellowship at Broadgreen Hospital in Liverpool, now known as the Cardiothoracic Center for Northern England. It was here that I honed my skills as a non-cardiac thoracic surgeon and learned the beauty and elegance of chest surgery. It was also where I had my first exposure to thoracoscopic, which was quite primitive at the time. The combination of the vast open experience and the introduction of thoracoscopy allowed me to dream about possible applications for the future and build on the pioneering work of others.

Thirdly, this lecture is named after, and honors the Karl Storz family. They have long been committed to the care of children around the world, and are true pioneers in the development of pediatric MIS equipment. I first met Mrs. Storz in 1999 at her factory in Tuttligen, Germany with the then Vice-President of US marketing, John Davis, and Dr Keith Georgeson, on the way to the Berlin IPEG meeting. This started a personal relationship for me with the Storz family, and they have been incredibly supportive of my efforts to improve the care of children through MIS techniques. We would not be discussing many of the advances we have seen at this joint congress were it not for their unyielding support.

The story of neonatal MIS really started for me in 1992 after I had completed my fellowship in Houston and started in practice in Denver. I joined a practice that had a large high-risk maternal and neonatal service as its referral base. I wanted to apply minimally invasive techniques in the treatment of these infants. However, I quickly realized that none of the instruments available were appropriate for the treatment of these patients. They all broke the cardinal rule that I had adopted, which was never to use an instrument that was bigger than the patient! The instruments were too long, too wide, just too big, and made no ergonomic sense when trying to operate on a patient < 10 kg. This realization put me on a course to try and find the right tools to perform neonatal MIS.

I knew the key was convincing industry that they needed to build these tools, and the key to that was convincing them there was an adequate market so that it made financial sense.

One of my mentors, Dr Greg Stiegmann, had introduced me to SAGES (Society of Gastrointestinal Endoscopic Surgeons) as a resident. This was the place that the thought leaders of adult MIS and industry came together and were changing the future of surgery as never before. The exhibit hall was a place of energy, innovation, and ideas, but at that time pediatric surgery was not a part of it. To most of industry we did not exist. I convinced Dr Stiegmann, then president of SAGES, that they should put on a panel about pediatric MIS at the SAGES meeting in Nashville in 1994. I thought this would attract pediatric surgeons to

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the meeting. My hope was to get pediatric surgeons and industry excited about what was being done, and push for new advances and miniaturization. He put that panel on and asked Dr. Greg (Whit) Holcomb to run it. Whit was a few years ahead of me and had already written a book on laparoscopic cholecystectomy in children. I didn’t really know Whit, but I think he was forced to put me on the panel by Greg because I had suggested it. Whit asked me to talk about laparoscopic fundoplication because he had seen a video of a Laparoscopic Nissen procedure I had presented at APSA the previous spring. I had somehow managed to condense my first Laparoscopic Nissen and G-tube case, which took me almost 4 hours to accomplish, into a beautiful 10-minute video. That panel changed my life. It was there that I met the current thought leaders in pediatric MIS, Whit, Thom Lobe, and Keith Georgeson. These men became not only mentors and friends, but were comrades in arms in trying to get companies to build what we needed. At that meeting, Keith Georgeson, who immediately disliked me because I had taken what he thought should be his talk, as he had done more pediatric fundoplications than anyone else at that time, became one of my best friends. He asked me to help him run what would become the first American IPEG meeting the next spring just prior to that year’s APSA meeting in Orlando, FL. This meeting had a huge impact on my career and development as a surgeon and innovator. It was the first IPEG meeting in the USA. It was my first exposure to IPEG and it was the first IPEG hands-on animal lab, and the first lab that I was in charge of running. It was the first time that I had to ask for industry support, and the first time I ever had to help coordinate an exhibit hall. All of this helped clarify for me the unique relationship between IPEG and industry, and how that relationship was key to our success in developing pediatric and neonatal MIS.

I was also exposed to my first set of smaller laparoscopic instruments, made by a company then called Jarit. They were 3.5 to 4 mm in diameter and shorter shafted, 20 cm rather than 35 cm in length. These had not been designed for pediatric surgeons, but rather for gynecologists. I immediately got a set and spent the next 2 years working with their engineers to refine and develop new instruments. I was convinced that these instruments needed certain properties. They needed to have tensile strength and withstand the rigors of sterile processing. They needed to be durable, rotate, insulated for cautery, and the working heads needed to resemble real surgical instruments. And whenever possible they needed to be smaller than the patients we were operating on.

I also became convinced that surgeon training was the best way to influence product development, as industry would see the needs and hear from more pediatric surgeons. At that time Ethicon and US Surgical were running training courses for every general surgeon in the country but very few were geared towards pediatric surgeons. Thom Lobe, and then Raleigh Thompson organized the initial pediatric surgery training courses, but we were forced to operate on large animals with large instruments. However these courses gave us visibility and industry began to hear our voices and understand our needs. A yearly fellows course, courses at APSA and IPEG helped push this agenda, but for me the most important course was the one run at University of California, San Francisco (UCSF) by Dr. Michael Harrison and Craig Albanese. Craig had an interest in developing pediatric MIS, and he and Mike decided the best way to get good at it was to run courses and invite experts to help teach it. So over a 3 year period Dr. Georgeson and I would travel to San Francisco every 4–6 months to help teach an intensive 3 day course. This occurred during a time when techniques in pediatric MIS were evolving rapidly. The environment at UCSF, one that had developed fetal surgery, was the perfect place to foster further development. It not only allowed us to exchange ideas and techniques during a period when we were all rapidly changing our approaches and techniques but it gave us access to engineers and marketing people who were interested in what we had to say about the pediatric market. We all fed off of each other, and each time we met new ideas, techniques, procedures, and instruments were born.

One of the most significant developments was adoption of a radically expanding trocar system called STEP. This was a less traumatic and safer system than the cutting trocars, which were currently available. During this time period we worked with the company to downszie the trocars, and created a 3 mm reducer cap that allowed us to use 3 mm instruments without a massive air leak, something that had been a huge problem for all of us. This product dramatically changed our ability to safely and efficiently operate in small infants [1].

During this time we were also able to work with Storz and Stryker, to develop insufflators that were more sensitive to the small body cavities we worked in, and would accommodate lower flows and pressures, something that was often a significant problem during these cases. Both companies also began to seriously focus more on 3 mm instrumentation.

A major breakthrough occurred in the late 1990’s when Storz introduced their Clickline™ instruments. This concept separated the handles from the shafts, meaning that one instrument set could hold both 5 and 3 mm instrument shafts and a single set of handles. This enabled us to use a single instrument pan from which we could custom make a set to operate on a 2 kg premie to a 100 kg teenager. This dramatically changed how we set up and stocked instruments, allowing us to create multiple reproducible sets, as opposed to many different specialty pans. This greatly cut down on the cost, as well as the loss and breakage of expensive specialty items, and we were able to create multiple sets of the same instruments so that a sterile set was always available no matter what case we were doing.

This initial push by these few companies and the evolution of the field over the last decade has encouraged other companies to produce 3 mm instruments, many of which are in our exhibit hall today. But many needs are still not met, and many ideas, which were production ready over 10 years ago, remain un-produced because many in industry are not convinced that a significant market exists. One example is the evolution of an endoscopic clip applier. The initial devices were 10 mm. In the late 1990’s many of us were asking for a 5 mm device. This became increasingly important to me as I began to perform thoracoscopic patent ductus arteriosus (PDA) ligations. I performed my first MIS PDA ligation early in 1998 using 3 mm laparoscopic instruments but an open clip applier [2]. Labrador, a cardiac surgeon in Paris and Burke a cardiac surgeon in Boston had also performed a number of these procedures, but had to use a combination of open and endoscopic instruments, making the procedure less than optimal. Apparently the engineering required in the development of a 5 mm endoscopic clip was quite daunting. Finally, 2 years later the first generation of the 5 mm clip applier became available. Within 2 years after that both Ethicon and USCSS came out with versions similar to what we have today. This was a major breakthrough for both adult and pediatric MIS. Yet the PDA ligation and some other neonatal procedures really called for a 3 mm endoscopic clip. In 2005 I found the drawings for such a clip at one of the industry booths at SAGES, yet the device has never been developed because the company did not believe an adequate market existed.

It was clear that industry needed to be convinced that an adequate market did exist and the way to do this was by defining and performing new procedures, and getting the data in peer reviewed literature. A major breakthrough occurred in 1999 when Tom Lobe and I performed the first thoracoscopic esophageal atresia repair during a live surgery demonstration at the Berlin IPEG meeting. Another significant milestone followed the next year when I was the President of IPEG and arranged for a joint meeting of IPEG and SAGES in Atlanta, GA. This meeting was a critical turning point in many ways. It was the first time that a large number of pediatric surgeons were exposed to SAGES and the energy, ideas, and techniques that were rapidly evolving in adult MIS. We were also able to expose general surgeons to pediatric MIS, and perhaps most importantly we were able to expose pediatric surgeons to industry and industry to pediatric MIS. That year I also presented a surprise video of the first thoracoscopic TEF repair at the meeting, a procedure I had done just 3 days earlier [3]. These events showed
that even the most complex and delicate neonatal procedures could be done safely using MIS techniques.

I was also asked to give a keynote lecture at SAGES on “mini-laparoscopy”, a concept crucial to pediatric surgeons, but something which is only now being embraced by other surgical specialties. This was also the year that the Rocky Mountain Hospital for Children partnered with Storz Endoscopy to create the first fully integrated minimally invasive surgical suite for children. This would go on to be the prototype for MIS suites for children all over the world. Following the meeting the seed was planted and pediatric surgeons around the world would push the frontiers and continue to look for industry to change.

In 2001 the first report of a laparoscopic repair of duodenal atresia in Europe by Bax et al. [4] was published. Shortly after we published the first series of this procedure [5]. The first large series of MIS procedures in neonates was published in 2004 [6], and the first multi-institutional study of TEF repair was published by Holcomb et al. [7] in 2005. These publications began to give credibility to the concept of neonatal MIS and mini-laparoscopy. Those pediatric surgeons who had been resistant or skeptical began to take notice, and so did industry. At this point more and more pediatric surgeons began to sit on industry advisory boards and ask for smaller more ergonomic instruments. We needed energy devices that would work for our smallest patients, we needed smaller staplers and vessel sealers, and we wanted to be able to do an anastomosis without needing to suture. Our industry colleagues would listen earnestly but when it came time to develop them they could not find a viable business plan because they felt the market was just too small.

Then in 2004, an event, which would forever change the landscape of MIS occurred in India [8]. Two surgeons, Rao and Reddy performed a transgastric appendectomy using a flexible endoscope and natural orifice translumenal endoscopic surgery (NOTES) was born. This event was followed by the first NSCOS meeting (Natural Orifice Surgery Consortium for Assessment and Research) in Phoenix, AZ in 2005. Suddenly, the need to miniaturize on a mass scale was born. And some of us attending the meeting felt that perhaps the umbilicus was a natural orifice and it would be easier to operate with a rigid scope through there than using a long flexible scope through the mouth, anus, or vagina. The end result was that now every surgeon was interested in smaller instrumentation, and many pediatric surgeons were pioneering single-site procedures as well as mini-laparoscopy.

The next significant milestone was in 2009 when the federal government recognized the lack of pediatric specific instrument development because the market share and profit margin was not significant enough to warrant adequate investment from large corporations. So the FDA started the Pediatric Device Consortia Grant Program to award grants of millions of dollars to aid in the development of badly needed devices. A number of our pediatric surgeon leaders and innovators started consortia and applied for, and received grants, and have been working to develop badly needed instruments. These included the Mistral Pediatric Device consortia by Sanjeev Dutta at Stanford University, the Pediatric Device Consortium led by Michael Harrison at UCSF, the National Capitol Consortium Pediatric Device Innovation (NCC-PDI) run by Dr Peter Kim, and The Sheikh Zayed Institute for Surgical Innovation in Washington, DC. These groups and others have led the drive for pediatric device innovation, and have come up with ideas that have the potential to make great advances in pediatric MIS.

The grant program also prompted another movement. In the spring of 2009 I received an email that would have a dramatic effect on pediatrics. For years they had heard me talk at their advisory meetings about how they needed to downsize their instruments for neonatal and pediatric use. Prior to contacting me they did some market research and decided a reasonable business case could be made to pursue pediatric devices. They felt it was a worthwhile and important project, and they wanted to be involved in improving the health care of children around the world. With that, 6 of us, 2 past-presidents, 2 engineers, a head of marketing, and myself became the founders of a medical device company committed to creating badly needed pediatric MIS device, and JustRight Surgical™ was born.

The initial device was something that many minimally invasive pediatric surgeons had wanted for years, a 3 mm vessel and tissue sealer (Fig. 1). The other was something I was told couldn’t be done, a 5 mm endoscopic stapler (Fig. 2). As we did the initial feasibility studies we held advisory meetings at IPEG and APSA with the world’s top pediatric MIS surgeons to see what they thought were the top priorities for

![Fig. 1.](image1.png) (a) Early schematic drawing of 3 mm tissue sealing device. The device resembles a 3 mm Maryland dissector and has a working head just over 1 cm. (b) Final production model of 3 mm sealer.

![Fig. 2.](image2.png) (a) Schematic drawing of 5 mm endoscopic linear stapler. The shaft length is approximately 18 cm and fits down a 5 mm trocar. (b) Working head of stapler. It is 2.5 cm long, lays 4 rows of staples and cuts between them.
instrument development. Almost all agreed that these were the two top needs.

Three and a half years after the initial studies, the products were brought to market and already have made a significant impact. More importantly, a pediatric device company now exists which is committed to meeting the needs of pediatric surgeons around the world.

I believe the future holds great promise for pediatric surgical device innovation, and for maybe the first time in our history pediatric surgeons are leading the charge. Companies, consortia, and the government recognize the need and are jumping in like never before; and most importantly they are being guided and led by pediatric surgeons, to ensure the right devices are being investigated and made. I believe this will lead even greater innovation and advancement in neonatal MIS in the next decade.

For me personally this has been an incredible journey and one full of unexpected turns, great friendships, and unique opportunities. The list of people I need and want to thank for supporting me, advising me, and encouraging me are simply too many to list, but without all of you I could not have accomplished any of this. I must again thank Mrs. Storz and the Storz family for all of their support and their commitment to the health care of children around the world. I need to thank all of my partners past and present, as well as Keith, Whit, Thom, and all of the IPEG leadership who have given me support, guidance, and friendship for the last 20 years. I need to thank the founders of JRS for enabling us to build what we all knew we needed but no one would give us. And lastly I need to thank my family, but most importantly my wife Susan, for their unending support, encouragement, sacrifice, and love, as none of this would have been possible without them.

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