



©2024 BioMedGPS, Inc

PERSPECTIVE

ISASS: Approaching 25 Years of Advancing Techniques and Technologies for Treating Spinal Disorders

ISASS's Morgan Lorio, MD, president-elect, discusses the obstacles to adopting emerging technologies in spine surgery and the importance of advocating for policy changes to support innovative treatments and improve patient outcomes in an interview with SmartTRAK.

By Kris Jacques, Analyst
May 2024

SmartTRAK recently interviewed Morgan Lorio, MD, the incoming president of the International Society for the Advancement of Spine Surgery (ISASS), to learn more about the society's commitment and goals to spine advocacy and research as it approaches its 25th anniversary as a society.

Key topics discussed include ISASS's successful efforts in addressing coding and reimbursement challenges to ensure access to innovative treatments for patients, the potential impact of artificial intelligence (AI) on reimbursement, the new ICD-10 codes for discogenic pain, regenerative spine treatments, future directions and initiatives for ISASS and fostering collaboration between industry stakeholders and surgeon societies.

KJ: Good morning, Dr. Lorio. Thank you for taking the time out of your busy schedule to do this interview with SmartTRAK, especially as the ISSAS meeting gets underway in Miami. For those who don't know you, please give us a quick background on where you're from, where you trained and how long you've been a member of the ISASS society.

Dr Lorio (ML): I am an orthopedic spinal and hand surgeon with over thirty years of experience. I've been actively engaged with ISASS since its inception, and as we approach our 25th anniversary, I'm proud to have contributed to our journey during our 24th year. My involvement with the Coding and Reimbursement Task Force dates back to 2012. Over the years, I was also assimilated within the ISASS Executive Board, and I am honored to be assuming the role of president this year (2024-2025) following Dr. Mike Wang's tenure. My contributions extend to various areas, including CPT, RUC, NCCI edits, CMS, OMB, and MACRA*. I look forward to continuing ISASS's collective efforts to advance our spine field and serve our spine community.

**Current Procedural Terminology (CPT); Relative Value Scale Update Committee (RUC); Medicare National Correct Coding Initiative (NCCI) Edits; Office of Budget and Management (OMB); Medicare Access & CHIP Reauthorization Act of 20125 (MACRA).*

Your recent article in the *International Journal of Spine Surgery*, "Navigating the Future of Spine Surgery: A Surgeon's Reflection on Coding, Reimbursement and Emerging Technologies," is a summation of your passion for the last at least 12 years since you've been heading up the Reimbursement and Coding Task Force. From your perspective, in what areas has ISASS been the most successful in advancing patient care, especially regarding access to new and maybe more disruptive technologies?

ML: I believe the most impactful technological disruption ISASS has effectively managed has been in sacroiliac joint (SIJ) fusion. Addressing the CMS mis-valuation of CPT code 27279 for the legacy lateral device was a significant hurdle. Through persistent efforts, including engagement with a refinement panel and direct presentations to OMB, we increased the Relative Value Units (RVUs) for that code by 27%. This achievement stands as a testament to our dedication.

To preserve the legacy approach for surgeons, ISASS recently collaborated to introduce a new code for the 'dorsal' intra-articular space for the SIJ, expanding options for addressing complex SIJ issues. This innovation allows for salvage opportunities and addresses cases with abnormal anatomy, osteomyelitis, trauma-related bone defects, tumors and retained implants. Moreover, it facilitates the hybrid use of transfixing 'lateral' legacy and intra-articular devices.

Another proud accomplishment is establishing the bone resection requirement for a transforaminal lumbar interbody fusion (TLIF). By successfully unbundling codes 22630 and 22633, we clarified that the additional decompression required for decompression at the TLIF index level should be reimbursed separately, distinct from TLIF itself. With support from the American Association of Neurological Surgeons (AANS), ISASS defined TLIF in its original scope, ensuring fair reimbursement practices.

This endeavor—fixing TLIF—was particularly significant for me, as it fueled my commitment to serving as the chair for coding and reimbursement in ISASS since 2012.

Fantastic. In the article, you also discussed the intralaminar and interspinous process stabilization distraction and the flatlining of this procedure, CPT code 22867, due to the RVUs assigned versus the open laminectomy code 63876. You're passionate about revaluing this procedure and others. What do you see as the next steps here?

ML: Regrettably, the trajectory of [Coflex](#) has plateaued. Nonetheless, it continues to be utilized by surgeons driven by patient-centric motives rather than financial motives. On a brighter note, another product in this domain, [Empirical Spine's LimiFlex](#), is awaiting FDA approval. Notably, data from LimiFlex indicates a procedure time of approximately 120 minutes, contrasting with the RUC methodology survey's reported time of approximately 90 minutes. This discrepancy has influenced the placement of RVUs, underscoring the significance of procedure duration in RUC assessments. While intensity is purportedly considered, its impact remains limited. The stagnant valuation of Coflex reflects this disparity. Given these circumstances, advocating for a re-RUC or an emerging technology assessment for this code, coupled with LimiFlex's FDA approval, presents avenues for resolution. Engaging with the Centers for Medicare & Medicaid Services (CMS) or OMB could expedite this process, addressing the undervaluation evident in this domain.

Do you see the migration of spine procedures to the outpatient side of care and cost savings positively impacting payer policies? Can we reverse some of the experimental investigational policies for these new, disruptive technologies with a strong place in the outpatient side of service?

ML: Kris, your question is quite perceptive and mirrors our industry's unfolding dynamics. Currently, the proposed rule to reassess and re-categorize Diagnosis-Related Groups (DRGs) is under scrutiny. While it's not yet finalized, its potential impact on traditional hospital systems is significant. Without establishing a spine workgroup or similar initiatives, patient migration to Ambulatory Surgery Centers (ASCs) is possible. However, it's essential to note that not all codes are covered in the ASC setting. During the COVID era, the concept of "hospitals without walls" emerged, facilitating the transition of procedures from traditional hospital settings to ASCs for eligible patients. This shift has demonstrated tangible patient benefits, as highlighted in a paper I co-authored showcasing the feasibility of performing TLIFs in Medicare patients with careful selection criteria. Moving in this direction is crucial for our collective progress and societal advancement in the US.

You also mentioned the need for stronger collaboration between industry, regulatory agencies and surgeon societies to improve patient care. Do you have any ideas about how we can improve this multimodal collaboration?

ML: Absolutely. I believe there's potential for collaboration between the Medical Device Manufacturers Association (MDMA) and various societies to identify a societal leader who could serve as a pivotal figure in the next presidential cycle, thereby instigating significant transformations in spine healthcare and medicine at large. While this may or may not materialize, another effective avenue is for industry to recognize the value of societies holding positions in the American Medical Association (AMA) House of Delegates and for industry to support that advocacy. Through the CPT process, these societies play a crucial role in defining procedural standards post-FDA approval, enabling companies to progress toward reimbursement with carriers. By providing financial support to these relevant societies, we can shape procedural definitions, achieve reasonable reimbursement rates and address policy coverage, ultimately facilitating the advancement of these procedures. This approach represents a pragmatic path forward for our industry.

Do ISASS and other societies receive adequate support from industry today? Is support similar from larger, medium-sized and smaller companies?

ML: As with many other societies, we're facing challenges securing adequate support while appreciating the industry's contributions. While our society remains financially stable, the landscape has shifted due to the impacts of COVID-19. Larger companies, which may focus on something other than emerging technologies, seem less inclined to maintain their support for achievements they've already made, resulting in decreased sponsorship. This trend has been particularly noticeable this year across all societies. However, we've been fortunate to receive assistance from smaller companies, who have stepped up to support our society and others in pursuing our objectives. We're immensely grateful for their contributions, as they shoulder a significant burden akin to Atlas holding up the world. ISASS increasingly values the partnership with smaller companies and their vital role in our endeavors. Nevertheless, we remain open to collaboration with larger companies and welcome their support.

As the next president, what are your top focus areas?

ML: As president, I will focus primarily on leveraging Rasch's methodology to gather psychometric data. This data will enable us to amalgamate surgeons' experience, intuition and levels of evidence, as originally intended for levels of evidence, to formulate guidelines and pathways for emerging technologies promptly. Instead of waiting for randomized controlled trials (RCTs) and registries to catch up, which insurance carriers may ultimately disregard, we aim to swiftly gather and define this data in a dynamic document that reflects the current landscape. Rasch's methodology will help shape surgeons' activities, guiding their decisions and efforts.

It sounds like a heavy lift. Do you see that happening in the one year or continuing across new leadership?

ML: I'm confident that we can kickstart this process within the year by further establishing Rasch guidelines in peer-reviewed journals. This will allow us to create a template for navigating emerging technologies in the future. Collaborating with Dr. Kal-Uwe Lewandrowski, we've conducted international webinars, particularly focusing on endoscopy, to address challenging questions often overlooked in the US context. By tapping into global expertise, we've collected responses from over 4,000 participants, surpassing the data yield of cherry-picked RCTs or registries. This wealth of information will be invaluable in shaping guidelines and policies for endoscopic spine procedures moving forward. We plan to analyze and publish the data from these four webinars, culminating in creating a comprehensive guideline—a practical roadmap for the year ahead.

That's exciting. You recently co-authored an RVU survey published in the 2023 *Journal of Personalized Medicine* to assign RVU values to CPT code 62380. Are there any next steps in valuing the RVUs with the RUC committee?

ML: Well, as you know, we have gathered and published data in this space, and the code you specify defined 'discectomy' and what many people have overlooked is that it also includes stenosis compromising the neural elements within the foramen. Endoscopic lumbar decompression has evolved past soft-disc herniation, past foraminal compromise, and now we conquer bilateral and/or central stenosis using either uni-portal or bi-portal techniques. So, the current CPT code for lumbar endoscopic discectomy has been marginalized. It doesn't encompass what's possible; it needs to be revisited and a family of codes created. More importantly, the intensity of the procedure needs to be recognized. RUC methodology did not sufficiently value the intensity of the procedure, so much so that CMS ignored the survey results and then smartly decided to allow surgeons to broker what their charges would be geographically/locally. This approach allows surgeons to obtain equitable remuneration for their work performed rather than receive a mis-valued reimbursement otherwise. The uptick in US utilization is sufficient to revisit the code from an RUC perspective, or it might simply be better to consider a parity option for technologies where the work is equivalent. Endoscopic results are not only equivalent, the outcomes are outstanding, payment for same may require a different reimbursement model.

Do you see any other obstacles to the endoscopic spine procedure taking off in the US, or is it really all around the coding and reimbursement?

ML: The current focus is predominantly on coding and reimbursement, yet a contingent within relevant societies is resistant to embracing new technologies. As is often the case with emerging innovations, pioneers drive progress. Still, our recent webinar series revealed that the level of engagement from Asia and South America surpassed that of the US and Europe. As discussed in Friday's session, if spine surgeons fail to embrace these advancements, interventionalists may take the lead in adopting and advancing the technology.

What was the percentage of US surgeons that attended the webinars compared to Asia and Latin America? Is it 25% US, 75% OUS?

ML: It was 90-plus percent OUS.

Wow, so changes on the reimbursement and coding side could dramatically impact this spine segment.

ML: Mis-valued reimbursements are hindering the advancement of this procedurally.

Has industry invested in technology, or would it need to catch up should reimbursement become more positive?

ML: Industry engagement has been subpar throughout COVID-19, with only recent signs of interest emerging. Frankly, without active participation from industry stakeholders, it's unclear how much further progress can be made in this area without industry collaboration with surgeons to propel advancements forward.

ISASS and other societies advocate for healthcare policies that align with the clinical best practices and preferences of patients and their surgeons. The current Aetna policy on limiting the use of synthetic cages for cervical fusion is one policy that restricts the surgeons' choice and care for their patients. What is the best way to address policies like these?

ML: Aetna's coverage policy has shifted towards favoring synthetic cages for complex procedures like tumor treatments, while denying their use in lieu of structural allografts for average patients to lower surgeon reimbursement. Despite efforts by ISASS and other societies to engage Aetna, the insurer maintains its stance, citing financial considerations over patient preference. Surgeon choice, crucial for both patient and procedural success, is sidelined in favor of cost containment.

To address this, leveraging resources from organizations like MDMA could be beneficial. Additionally, employing psychometric analysis using Rasch methodology could provide robust evidence, though payors may be hesitant due to its early adoption stage. Interestingly, some insurers prioritize cost containment by labeling certain technologies as experimental, disregarding evidence-based medicine's core principles. Surgeon intuition, a cornerstone in decision-making, remains vital, with the potential for AI augmentation looming on the horizon.

Moving to some of the other work you've been doing around advocacy and longer-term work, congratulations on the new ICD-10 diagnosis codes for degenerative disc disease associated with discogenic low back pain. I believe only a few know what goes into a new diagnosis code. Please tell us about your journey getting these new codes and the process.

ML: In pursuit of an ICD-10 code for a discogenic family following [Relievant Medsystems'](#) acquisition of a vertebrrogenic code for the lumbar space, I engaged with the Centers for Disease Control (CDC). Unlike CPT and RUC, ICD-10 lacks a clear rule or rubric, relying instead on individuals behind the scenes. I endeavored to initiate a dialogue by approaching what I'll metaphorically call a "Wizard of Oz" to gain access to this space. Through three presentations and two supporting articles advocating for recognizing discogenic pain and granularity in low back pain codes, I persisted in highlighting the need for specificity. Historically, while we acknowledged discogenic back pain, a dedicated code was absent. Despite the existence of codes for disc degeneration lumbar, low back pain, facetogenic pain, neuro-compressive lesions and psychogenic pain, the absence of a code for discogenic pain was glaring. With SIJ pain and vertebrrogenic pain recently added, the omission of a code for discogenic pain became increasingly apparent. Through relentless advocacy efforts akin to "Horton Hears a Who," involving multiple phone calls and emails, ISASS ensured our message was heard. Ultimately, sheer persistence led to our voices being acknowledged.

Others would have given up, but you didn't. Could you summarize why the new codes are important to surgeons, clinical research and patient access? Why is the granularity in the new codes so important?

ML: In healthcare, the cornerstone of effective patient care is accurately diagnosing the patient's condition. A precise diagnosis identifies the problem at hand and guides subsequent treatment decisions, whether they involve conservative, interventional or surgical approaches. However, when it comes to spinal issues, confusion in coding or diagnosis can lead patients down the wrong treatment path, resulting in suboptimal outcomes.

Poorly defined diagnoses and treatment plans can significantly compromise the validity of research findings, even in well-conducted studies. Data becomes muddled with unclear diagnostic criteria, rendering the study useless. Therefore, it's imperative to differentiate between lumbar discogenic pain and other forms of back pain to ensure accurate diagnosis and appropriate treatment selection. The ability to accurately code diagnoses is crucial for analyzing data retrospectively and refining treatment approaches. By leveraging these codes to re-evaluate patient outcomes, we can revolutionize lumbar spine care and dramatically improve patient outcomes.

I think you mentioned to me earlier that the codes will be published by CMS this summer in July and then go into effect, and physicians and coders can use the new codes in October this year.

ML: That is correct. We're looking forward to that.

Fantastic work, Dr. Lorio. I will move on to another subject. There is a renaissance now, at least from my viewpoint, with motion preservation. There is much clinical research with total disc replacement on both the cervical and lumbar side. Still, there are some newer technologies, well maybe not new, but now we are finally seeing the light of day—one being the [Premia Spine TOPS System](#) launched last year. Then, the completion of the IDE study for the [3Spine's MOTUS](#), a total joint replacement system for the lumbar spine. Can you speak to any advocacy work in this space, as these technologies will be marked as experimental and investigational right out of the gate?

ML: I plan to engage with the industry at the upcoming ISASS meeting and look forward to discussing a potential collaboration with 3Spine. ISASS has been actively preventing the under-utilization of Premia Spine's posterior arthroplasty. We achieved this by employing a Rasch methodology to determine interim values, rather than relying on a cumbersome crosswalk methodology, to establish the RVU for this procedure accurately. This approach used a building block methodology compared to, for example, the traditional TLIF procedurally and requires a comprehensive understanding of all the associated codes for a single-level TLIF—as an example paired comparator.

This meticulous process enables the company to gather valuable data and surgeon experience and sets the stage for obtaining a category-one code in the future. It's worth noting that the journey to establish FDA approval for the TOPS System from Premia Spine is remarkable, spanning many years. The familiarity with the posterior approach to surgeons will set this technology apart and contribute to its expedited progress. The posterior spine approach aligns with surgeons' anatomical training, eliminating the need for additional personnel or setup alterations. This familiarity streamlines implementation and accelerates procedural adoption, paving the way for advancements in spinal care.

That's a great point. I want to touch upon another area you've been involved in for over a decade: regenerative medicine. Are we getting close to the possibility of some of these technologies regenerating the disc? And how important is it to have these types of procedures earlier in the treatment cascade?

ML: Early interventions for disc degeneration, especially in the lumbar spine, hold significant value for patients and government healthcare systems, particularly given recent advancements in our understanding of the condition. It's crucial to differentiate between disc restoration and regeneration in the context of FDA regulations. While disc regeneration is promising, caution is warranted due to potential implications, such as cell proliferation resembling tumor growth. Despite these challenges, progress is underway. Companies like [Spine BioPharma](#) are making progress despite the rigorous study design.

Alternatively, [VIA Disc](#) by [Vivex Biologics](#) has made notable strides in disc restoration within a 361 regulatory category. The unprecedented patient interest in participating in such studies has accelerated progress and may lead to the earlier announcement of results, augmenting those of the previous VAST Trial. This accelerated pace of research has the potential to reshape our perception of biologics in the 351 category. As companies advance in disc restoration and regeneration, we anticipate significant shifts in how we approach and treat disc degeneration.

Also, [DiscGenics](#)' results are very exciting, especially because they've presented 24 months of patient data with promising pain reduction and improved function. They also showed increased disc height with their therapy maintained through 24 months. So, going back to restoration versus regenerative, how do you distinguish between those two?

ML: While I view them as synonymous, there exists a distinction in regulatory terms. While "regeneration" resonates positively with the public, it doesn't align with FDA regulations. Products that undergo minimal manipulation are categorized as restoration, whereas those with further manipulation fall under the regenerative category. This classification subjects regenerative products to stringent scrutiny within the biologic drug pathway.

How important is showing restoration in disc height?

ML: I believe height restoration or rather maintenance is crucial in disc repair procedures. A notable example is the [Barricaid](#) product, which has garnered attention for its potential in height maintenance. A recent Korean study demonstrated that maintaining disc height decelerates disc degeneration among patients who underwent the procedure, showcasing promising results. These findings underscore the significance of Barricaid in height preservation and maintenance, offering optimism for its role in disc repair.

That's interesting. With the Barricaid device, you're repairing the annulus to prevent disc reherniation after microdiscectomy. Is that right?

ML: Indeed. With Barricaid we are able to repair larger disc defects that are prone to reherniation and thus lessen a significant burden on the healthcare system and/or this patient subset.

Do you see an opportunity for better clinical research, patient selection and outcomes with the enabling technologies and diagnostics/biomarkers?

ML: In a recent comment to *Becker's*, I discussed the emerging role of genetic screening in pain management. This screening could potentially guide opioid usage, help avoid failed surgical interventions and mitigate the risk of drug abuse. AI is becoming increasingly feasible for integration into patient screening and treatment algorithms. This shift towards AI-driven healthcare will revolutionize the spine industry within the next decade, possibly prompting a re-evaluation of how physicians and surgeons are reimbursed based on their involvement versus that of machines or computers. As AI advances, its impact on current methodologies, such as those used by the RUC, is inevitable.

Is the RUC starting to discuss the impact of AI as you describe?

ML: I have not yet but implementing such changes takes time.

What can we look forward to next year's ISASS in 2025?

ML: This meeting is set to be the largest yet in ISASS surgeon attendance, surpassing all previous records. We're excited to announce that the next meeting will be held at the prestigious Fontainebleau, elevating the event to new heights. As we approach our 25th anniversary, we're planning special initiatives to commemorate this milestone, including a dedicated arthroplasty section in the *International Journal of Spine Surgery*, slated for publication later this year.

We deeply appreciate the unwavering dedication of our members and ISASS in advancing patient care, and we eagerly anticipate continued collaboration as we journey toward our 25th anniversary.

Thank you, Dr. Lorio.

Other Perspectives

[ISASS: Approaching 25 Years of Advancing Techniques and Technologies for Treating Spinal Disorders](#)

MAY 09, 2024

by [Kris Jacques](#)

ISASS's Morgan Lorio, MD, president-elect, discusses the obstacles to adopting emerging technologies in spine surgery and the importance of advocating for policy changes to support innovative treatments and improve patient outcomes in an interview with SmartTRAK.

[Vaporox Company Spotlight](#) MAY 01, 2024

by [Susan Paquette](#)

New leadership at Vaporox to launch a second generation of vaporous hyperoxia therapy at SAWC Spring 2024.

[Spine Market Movers to Watch in 2024](#) MAR 20, 2024

by [Kris Jacques](#)

SmartTRAK highlights companies to watch as they continue their double-digit growth train with multiple catalysts for expansion in 2024.

[Highlights in Sports Medicine and Arthroscopy from AAOS 2024](#) MAR 12, 2024

by [Andy Knapik](#)

SmartTRAK highlights key trends and happenings in sports medicine and arthroscopy at AAOS 2024.

[Route 92 Medical: Raising the Bar in Neurovascular Thrombectomy](#) MAR 08, 2024

by [Anne Staylor](#)

Adam Hattan, VP of marketing for Route 92 Medical, discusses the SUMMIT MAX trial and provides an update on the company and products in an interview with SmartTRAK.