WHITEPAPER:

The Future of Surgical Visibility and Navigation for Enhanced Patient Safety

Technology Makes Minimally Invasive Surgery Accessible

For over a decade, minimally invasive surgery (MIS) has progressively replaced open patient surgery for many types of procedures, and astonishingly so for some. In 2003 less than 38% of appendectomies were performed via MIS, now, the number is closer to 93%, becoming the de facto method for the procedure.[1] Patients who have undergone appendectomies using MIS can be discharged from the hospital within 24-36 hours, versus 2-5 days for open surgery, with much less recovery time.

These performance improvements, made possible through enabling technologies—namely the laparoscope—are also realized in a wider selection of surgical procedures and applications. By pairing traditional technologies with advanced machine vision algorithms, intelligent sensors, robotics and augmented reality (AR), surgeons can reduce their operational footprint and improve patient safety. Surgeons, though, are challenged by the inherent goal of the MIS task, specifically to reduce damage and shock to a patient's body by minimizing the incisions that allow access to the internal organs.

MIS techniques aim to eliminate the need for long scalpel incisions (6-12 in.), replacing them with smaller “keyhole” incisions (<2 in.) that allow laparoscopic tools to enter the patient, look inside, and perform biopsies or surgical operations. These small access points complicate visibility for surgeons. During open surgery, patient safety and visibility are in opposition. To see inside the body, a surgeon opens it to the outside environment, putting the patient at risk. This exposure is less of a concern since the advent of MIS techniques, but MIS is not a riskless surgery.

Managing risk begins by visualizing as much as of the surgical area with preoperative and intraoperative tomographic images as possible. Using image-guided surgery (IGS) techniques, surgeons can rely on the alignment of imagery and corresponding anatomical landmarks or virtual digital representations, to assist in guiding surgical tools. This allows for preoperative planning and enables real-time tools tracking. Yet, even when doctors can peer into the patient via cameras, visibility is obstructed by surgical debris. And when scopes are clear, surgeons can further reduce risks from poor-quality displays by replacing monitors with high-fidelity medical-grade 4K true color models.

Visibility Challenges in Minimally Invasive Surgery

MIS is performed routinely across many specialties with great success. Fundamentally, laparoscopic surgery follows four sequential stages: patient positioning, port insertion and insufflation, specimen retrieval, and port removal. In each of these stages, challenges to patient comfort and safety, as well as surgical visibility, are minimized through technique, technology, and planning.[2]

Preparations are taken to reduce surgical risk throughout this process. When positioning the patient, the Trendelenburg position is commonly used—declining the patient's head below the pelvis improves organ exposure during abdominal and laparoscopic surgery. Trocars inserted through keyhole incisions act as portals into the patient, sealing the outside environment from the patient's internal body cavity and allowing cameras and tools to safely pass inside. Insufflator pumps then can inflate and regulate carbon-dioxide in the body cavity (harmless CO_2 is common because it dissolves easily into the patient)[3], creating a dome of gas so organs can be visualized. Since pressure inside the patient is evenly distributed, there is less local wound trauma. Intraoperatively, surgical tools are tracked within the patient via optical or electromagnetic tracking and displayed on monitors or a surgeon's AR headset.

Though the number of fundamental steps are few, each one presents visibility challenges for surgical teams:

1. **Lack of Clear Tools Tracking** — Surgeons should be able to locate and track their surgical instruments within the patient safely. Without tools tracking, surgeons must rely only on laparoscopic cameras and eyesight to successfully complete operations.

2. **Precision Surgical Placement** — Surgeons operate within miniscule margins of error, so precision surgical placement is vital. Robot-assisted spinal surgery is one area where robotics are helping surgeons improve visibility and accuracy.

3. **Obstructed Internal Visibility** — Laparoscope lenses can fog up or become obstructed by debris inside the patient with few ways to clear the lens besides removing the device and cleaning it, both risky and inconvenient.

4. **Lack of Ultra-Realistic Image Display** — Fiber optic laparoscopy provides a view into the body, but the resolution and color gamut of OR monitors can limit picture display fidelity, possibly obscuring from the surgeon critical visual details.

Decades of experience and custom engineering efforts have led to the five technologies presented below which overcome these critical MIS challenges and enable surgeons greater visibility of the surgical field during MIS procedures.

Case Study 1: Machine Vision Tracks Surgical Tools in Real-time

A leading global surgical navigation systems developer, specializing in sophisticated 3D visualizations, has developed a stereoscopic vision tracking system in conjunction with custom machine vision engineering group JADAK, a Novanta Company. The current surgical navigation system has been reengineered from the ground up with the idea of accelerating optical object tracking to achieve 60 fps. The new system does this and is ideally suited for real-time instrument tracking across many disciplines.[4]

The use of object tracking in the common case of guided dental implant surgery presents significant improvements over traditional techniques. For instance, tooth replacement requires multiple dental visits to fully examine a patient's mouth, capture preoperative images, cast molds of the jaw, and then further revisits for installing and fitting the implant. Fabrication of the crown is completed in-between patient visits, but can take weeks or months to be received from the dental lab, during which time the patient is without one or more teeth. During placement and fitting, the dentist discovers imperfections in the implant or crown, and introduces other human

inaccuracies during installation, which results in patient discomfort and further return visits for adjustments.

Contrastingly, computer guided surgery has enabled dentists to reduce the number of patient visits needed, often to a single visit. This is achieved by using advanced 3D imaging with CAD/CAM software to model crowns for fabrication. In the final stage of placing and fitting the implant, the dentist uses surgical navigation object tracking to align surgical tools with predefined landmarks resulting in accurate installations.[5]

Technical Breakdown

The new generation of tracking technology utilizes visible light, a stereoscopic camera setup, and a machine vision algorithm to track passive marked tools. This is performed by processing standard video images, which allows engineers to use common and inexpensive component parts. Algorithms, which integrate processing, object tracking, and systems control on a single camera adjacent field programmable gate array (FPGA), do the heavy lifting of image processing without the latency resulting from relaying data back and forth from an external processing host. Performance improved by 20X.

Machine Vision System Benefits

- Stereoscopic camera setup with inexpensive USB3 component parts
- Hyper-accurate tracking with standard video images and passive marked instruments
- Pattern-based, real-time detection and tracking algorithm built on FPGA offers 60 fps visible light tracking

The design of this system provides a platform for specialized variants. An enhanced model makes capability improvements that enable robotic tracking for ultra-precise surgical tracking.

Case Study 2: Robot-assist Boosts Accuracy in Critical Surgeries

In an evolutionary step towards hyper-precise surgery, a leading global manufacturer of musculoskeletal device products has integrated its advanced computer assisted navigation capabilities with a medical-grade rigid robotic arm. This model allows surgeons to plan operations based on intraoperative, preoperative, and fluoroscopy imagery, and plot a trajectory for the robotic arm to accurately place intramedullary devices. A common application is in spinal surgery, particularly the placement of posterior screws and the fixation of rods. Robot-assisted placement of pedicle screws results in a clinical accuracy of 100%.[6]

Technical Breakdown

The main components of robot-assisted surgical systems are the surgical navigation system and the robotic arm that performs the operation. The rigidity of the arm demonstrates significant stability over a human surgeon’s grip, providing stability to accurately track without jitter. The navigation system, using auxiliary visible light cameras, tracks and registers reference markers with imagery references by using passive marked instruments. Designed and developed by JADAK, the real-time image processing capabilities are built directly onto camera adjacent FPGAs which eliminates latency normal with host processing, and improves performance by 20X. Surgeons are further able to access all available images and information from a tablet style

control interface connected to the navigation system, and make intraoperative adjustments on-the-fly.

Surgical Robot Benefits

- Preoperative, intraoperative, and fluoroscopy imaging can be used to plot surgical routes
- Rigid robotic arm provides unbeatable stability and accurate placement of surgical instruments
- Surgical navigation bar uses visible light avoiding radiation-based navigation systems

Case Study 3: Augmented Reality Headset Empowers Next Level Surgical Visibility

In collaboration with JADAK machine vision engineers, the same leading global surgical navigation OEM in the previous case studies, developed its latest surgical navigation system extending capabilities with AR. The precision navigation system uses AR coordinated with multiple external cameras to onlay 2-plane images of the internal structure of patient's bones over the surface anatomy of their body. Image overlays are displayed on a surgeon's headset offering unprecedented access to data and imaging information during procedures.

Utilizing custom engineered algorithms and Allegro USB3 component cameras, JADAK custom engineered a visible light tracking algorithm in tandem with implementing multiple Allegro USB3 camera cores into a multiple camera system. While JADAK's custom camera technology overcomes board level constraints, the OEM also needed to address the comfort of the surgeon wearing a headset and how the headset will interfere with the operating environment. JADAK streamlined cable management by installing an FPGA with tracking algorithm on the headset and reducing cabling to a single USB3.

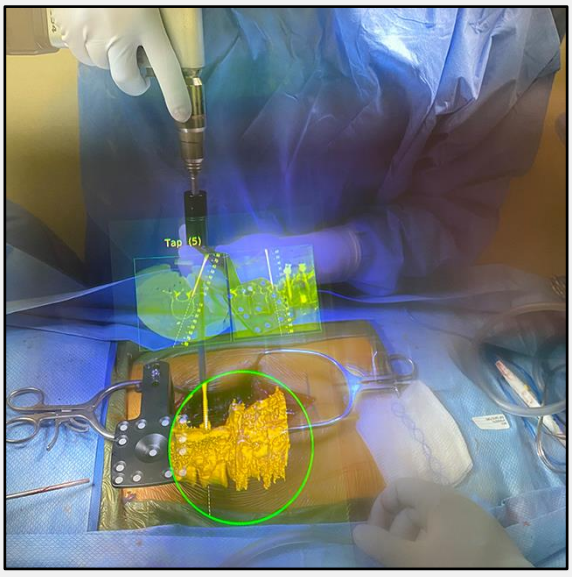

Figure 1: Operating view using augmented reality. Medical scans and relevant data can be superimposed over the surgical site. [7]

Technical Breakdown

This breakthrough navigation system is composed of three components, the headset, navigation cart, and marked surgical instruments. The headset design is streamlined and adjustable—a single 20’ USB3 cable with belt clip reduces cabling, two vision display panels synced to three headset-mounted high accuracy cameras project the AR display on a HUD reflective combiner, also designed to accommodate prescription glasses. The navigation cart with mounted navigation bar fitted with 5 cameras provides a host workstation with tablet style touch controls for surgical teams to view preoperative, and intraoperative imagery. The navigation bar coordinates object tracking with the headset and navigated instruments in the field.

Headset Component Technical Specifications

- Allegro USB3 Technology with FPGA based Region of Interest (ROI) tracking
- Integrated USB3 Hub
- 20’ USB3 w/ Active Element Connects Headset to Cart at 5 Gb/sec
- 2 Peripheral Cameras for Tools Tracking
- 1 Central Color Digital Camera, with Zoom, Acts as Loupe Camera
- 2 Programmable Strobe Lights
- Inertial Measurement Unit (IMU) Input

Navigation Bar with Auxiliary Cameras Technical Specifications

- 5 Cameras Integrated with FPGA based Region of Interest (ROI) tracking
- Designed with Multiple FPGA
- Integrated USB3 Hub
- Single USB3 Connection to Cart Host at 5 Gb/sec
- Inertial Measurement Unit (IMU) Input

Augmented Reality System Benefits

- Augmented reality overlays accurate internal imagery registered to anatomical landmarks
- Adjustable HUD provides relevant surgical data along with AR imagery

Intelligent Insufflation Clears Operating Field

AR solutions provide ground-breaking visibility into patients, still many critical procedures, especially abdominal operations, must rely on insufflation to achieve visibility within the patient. By pumping gas into the patient, a dome like bubble will form exposing the organs to laparoscopes. In that bubble, however, pressure must be regulated for patient safety and comfort. Temperature differences between the body and laparoscope can fog up the lens preventing visibility. When surgeons cut or burn organic matter inside the bubble, either debris or smoke is produced and can also obstruct laparoscopic lenses.

Over the years surgeons have devised their own solutions to visibility problems during MIS, such as warming up instruments before surgery to prevent fogging. Or, when lenses become dirty, laparoscopes can be removed and wiped clean, alternatively, special tool-cleaning trocars are also available. And a common practice is dabbing the laparoscope against the abdominal

wall to remove debris. While these methods are used, technology solutions offers options to eliminate the time and risk in these ad-hoc methods.

Technical Breakdown: Insufflation Pump

Medical device leader, World of Medicine (WOM), a Novanta Company, has produced an Intelligent Insufflation Pump to simplify MIS procedures and eliminate common visibility issues during insufflation. Two key algorithms, ISI (Intelligent Steady Insufflation™) and IPM (Intelligent Pressure Monitoring™), work together to ensure stable pressure and comfort for the patient. An integrated suction system will continuously exchange gas contaminated by any RF cutting devices inside the patient to ensure a clear surgical field from smoke and fog.

Figure 2: WOM 50L insufflator pump

Medical Grade 4K Visualization Systems Enhance Image Clarity

A final visibility constraint is the laparoscopic image displayed to surgical teams on monitors in the OR. The risk of poor-quality monitors is in overlooking or misinterpreting conditions on the screen due to lack of image detail, inaccurate image colors, and insufficient brightness. NDS Surgical Imaging develops medical-grade ultra-high-quality display monitors specifically designed to optimize 4K endoscopic applications.

Technical Breakdown: 4K Medical Display Monitors

NDS Surgical Imaging, a Novanta Company, produces several models of their medical grade monitors. However, there are common features that elevate these monitors above consumer quality displays and make them ideal for OR environments.

- **4K/UHD Monitors** display up to 4X the resolution of Full HD, with significantly higher levels of detail and sharpness.
- **Ultra Wide Gamut (UWG)** reproduces a color gamut that encompasses more of the colors the human eye can see. UWG displays can often double the visible color space over standard monitor gamut.
- **BT.2100 Color Emulation Algorithm** faithfully reproduces within the monitor's range the BT.2020 + HDR color gamut, benefiting from the wide color gamut of BT.2020

(63.37% more visible colors to the human eye over BT.709) and the contrast and brightness enhancements from HDR technology.

Figure 3: Radiance Ultra 4K 32" 3D medical grade monitor

About Novanta
Novanta is a trusted technology partner to OEMs in the medical and advanced industrial technology markets, with deep proprietary expertise in photonics, vision and precision motion technologies. For more information, visit www.novanta.com.

Novanta offers highly reliable, precise and safe solutions that enhance system performance and improve patient outcomes. Insufflators, pumps and disposable tube sets, along with medical visualization and operating room integration technologies from WOM and NDS are the preferred solutions for minimally invasive surgery applications. Barcode scanning, RFID readers and machine vision cameras from JADAK are the preferred detection and analysis solution and are deployed in the majority of healthcare facilities, worldwide.

About JADAK
JADAK, a business unit of Novanta, is a market leader in machine vision, RFID, barcode, printing, and color and light measurement products and services for original equipment manufacturers. The business designs and manufactures custom embedded detection and analysis solutions that help customers solve unique inspection, tracking, scanning and documenting challenges. JADAK is based in Syracuse, New York, with sales and technical locations across the globe. For more information, visit www.jadaktech.com.

About WOM
WOM produces cameras, insufflators, medical pumps, and tubing that simplify and facilitate diagnosis and treatment easier for everyone. These insufflators and pump systems dilate cavities in the body and turn previously complicated surgeries into minor procedures. For more information, visit www.wom.group/en/.

About NDS
As an industry pioneer over the last 25 years, NDS has been first to market with LCD surgical displays, 60 GHz wireless imaging, cordless secondary monitors, and OR integration solutions. Our mission is to deliver innovative solutions that benefit clinicians by engendering clinical confidence, improving ergonomics, increasing efficiency, and enhancing safety. For more information, visit www.ndssi.com.

[1] St. John, A., Caturegli, I., Kubicki, N. S., & Kavic, S. M. (2020). The Rise of Minimally Invasive Surgery: 16 Year Analysis of the Progressive Replacement of Open Surgery with Laparoscopy. JSLS : Journal of the Society of Laparoscopic & Robotic Surgeons, 24(4), e2020.00076. https://doi.org/10.4293/jsls.2020.00076

[2] Minimally Invasive Surgery (MIS). (2017, October 6). Basic Medical Key. https://basicmedicalkey.com/minimally-invasive-surgery-mis/

[3] Perrin, M., & Fletcher, A. (2004). Laparoscopic abdominal surgery. Continuing Education in Anaesthesia Critical Care & Pain, 4(4), 107–110. https://doi.org/10.1093/bjaceaccp/mkh032

[4] Chen, X., Lin, Y., Wu, Y., & Wang, C. (2008). Real-time motion tracking in image-guided oral implantology. The International Journal of Medical Robotics and Computer Assisted Surgery, 4(4), 339–347. https://doi.org/10.1002/rcs.215

[5] Clarnav (2018). Dynamic Navigation for Surgical Implant Placement: Overview of Technology, Key Concepts, and a Case Report. https://www.claronav.com/wp-content/uploads/2019/04/2018-Dynamic-Navigation-for-Surgical-Implant-Placement-Overview-of-Technology-Key-Concepts-and-a-Case-Report.-Mandelaris-Stefanelli-DeGroot.-Compendium.-10_2018.pdf

[6] Burström, G., Balicki, M., Patriciu, A., Kyne, S., Popovic, A., Holthuizen, R., Homan, R., Skulason, H., Persson, O., Edström, E., & Elmi-Terander, A. (2020). Feasibility and accuracy of a robotic guidance system for navigated spine surgery in a hybrid operating room: a cadaver study. Scientific Reports, 10(1). https://doi.org/10.1038/s41598-020-64462-x

[7] Johns Hopkins Performs Its First Augmented Reality Surgeries in Patients. (2021). Hopkinsmedicine.org. https://www.hopkinsmedicine.org/news/articles/johns-hopkins-performs-its-first-augmented-reality-surgeries-in-patients