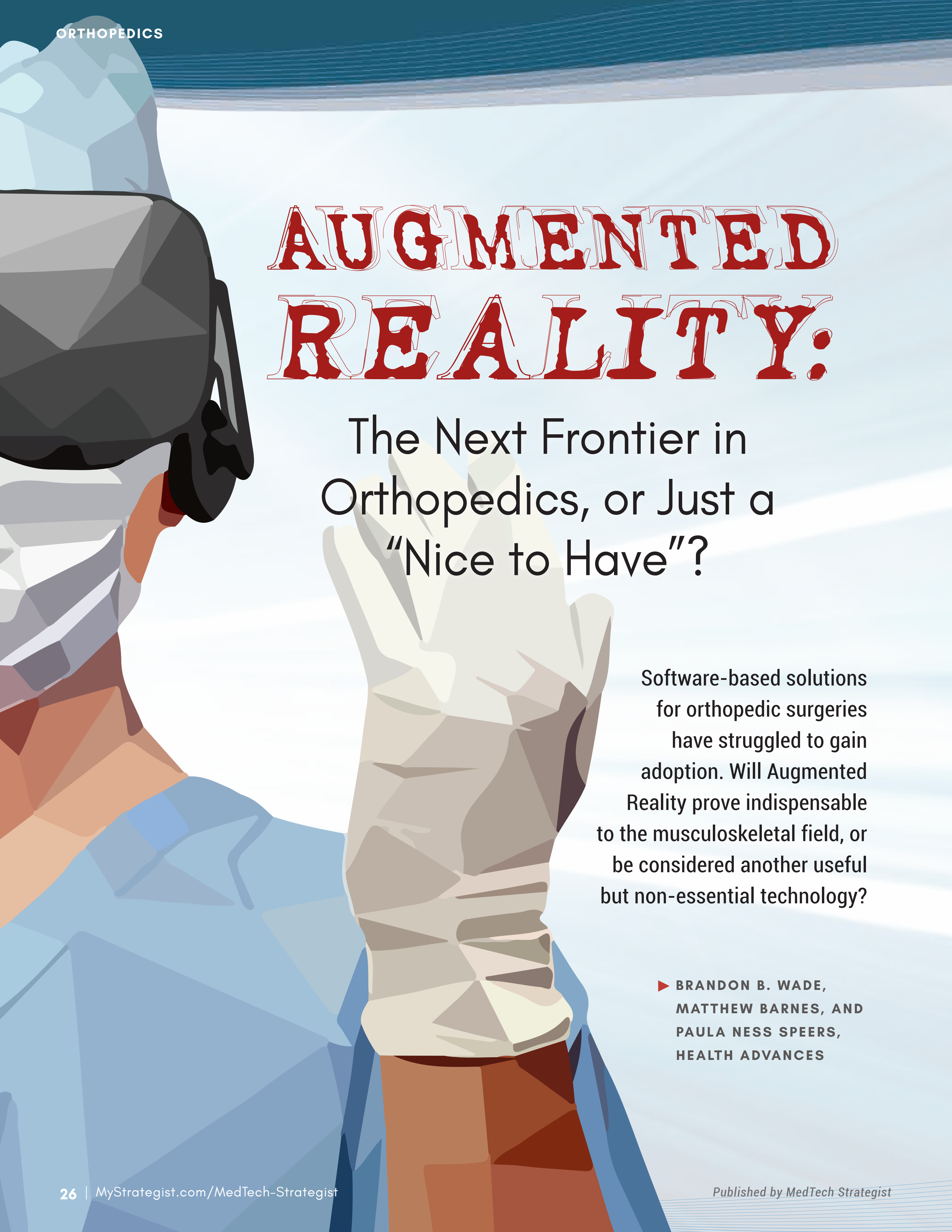

AUGMENTED REALITY:

The Next Frontier in Orthopedics, or Just a "Nice to Have"?

Software-based solutions for orthopedic surgeries have struggled to gain adoption. Will Augmented Reality prove indispensable to the musculoskeletal field, or be considered another useful but non-essential technology?

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A s the orthopedics industry continuously seeks to improve outcomes in the treatment and management of musculoskeletal diseases, much of the focus has been on modifications to implants and instrumentation, the lifeblood of the industry to date. In recent years, however, some companies have started to explore other areas of innovation outside of hardware—specifically software-based solutions. In this article, we focus on an innovative technology beginning to generate more enthusiasm in the orthopedics sector: Augmented Reality (AR). Following AR's first approval for intraoperative use in December, 2019 (**Augmedics**' *xvision spine system*), we sought to address a key question: *Will AR overcome the operational challenges that have constrained the full penetration of other software-based surgical solutions (e.g. surgical navigation) and be more broadly adopted as the "next frontier" of orthopedic surgery? Or is it just another "nice to have" technology?*

The History of CAOS Technologies

Software-based solutions in various surgical applications are starting to gain greater traction and produce compelling data that show a material impact on ease and accuracy of surgical planning, procedural accuracy, and even improvements in patient outcomes. Computer-Assisted Orthopedic Surgery (CAOS), for example, is increasingly used across musculoskeletal sub-specialties. Since the first CAOS technologies were developed in the mid-1990s, significant technological progress has been made utilizing the most advanced imaging modalities, navigation software, image analytics, and instrument tracking technologies. These provide surgeons with improved planning and procedural accuracy, as well as better visualization tools during orthopedic procedures. As an example, recent studies have demonstrated use of navigation systems results in superior accuracy in the placement of pedicle screws. A 2015 systematic review of over 40,000 pedicle screw placements showed 97.3% of navigated screws were safely placed (within a 2mm increment grading) compared to just 91.4% of screws placed freehand (see *Figure 1*).

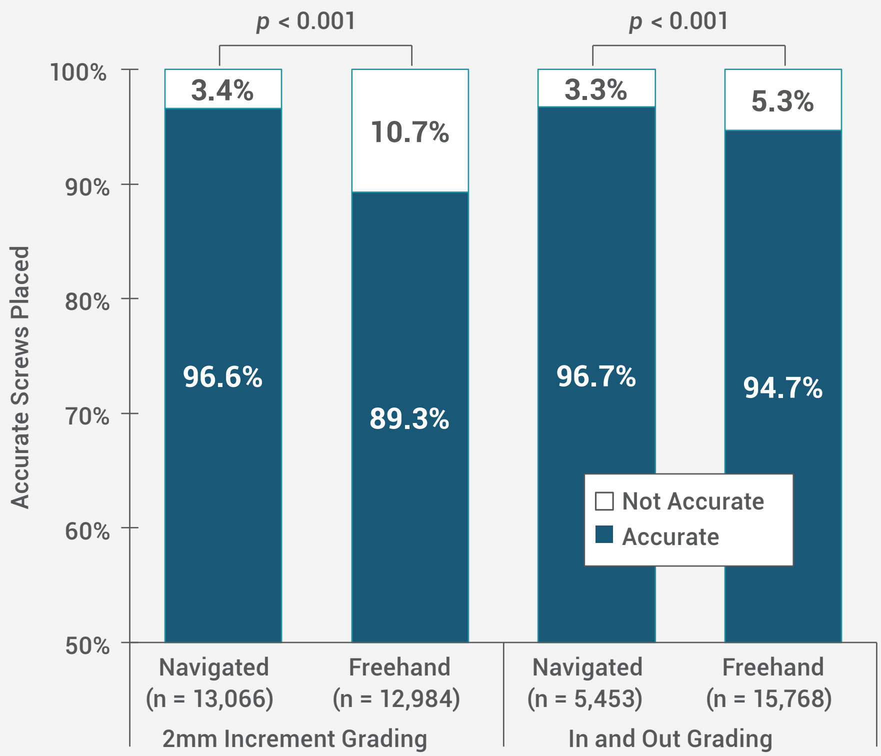
The orthopedic community has long recognized that software-based technologies can assist with and even improve the accuracy of surgical procedures, but documentation of their true clinical and/or economic value has been limited. Initially, hospitals and health systems adopted CAOS technologies and equipment—such as navigation and robotics—as much for their "halo effect" as powerful marketing levers to attract both patients and top clinical talent to their institutions as for their promise of clinical value. While more compelling data is starting to accumulate (i.e. clinical outcomes and cost-effectiveness literature supporting the value of CAOS technology-assisted surgery over traditional/manual surgery), available CAOS technologies have yet to gain utilization in more than a fraction of orthopedic surgeries. So, what is holding back adoption?

A Spotlight on Surgical Navigation's Slow and Limited Uptake

One of the first CAOS technologies introduced into the surgical setting was navigation for spine surgery pedicle screw placement. While this technology has now been available for spine surgery for nearly 25 years, its use in the operating room remains surprisingly low. Survey data from the American Hospital Association estimates that less than 25% of US hospitals performing spine or general orthopedic surgeries had navigation equipment as of 2017, and only an estimated 15% of surgeons at those facilities regularly used this equipment. (see *Figure 2*).

Figure 1

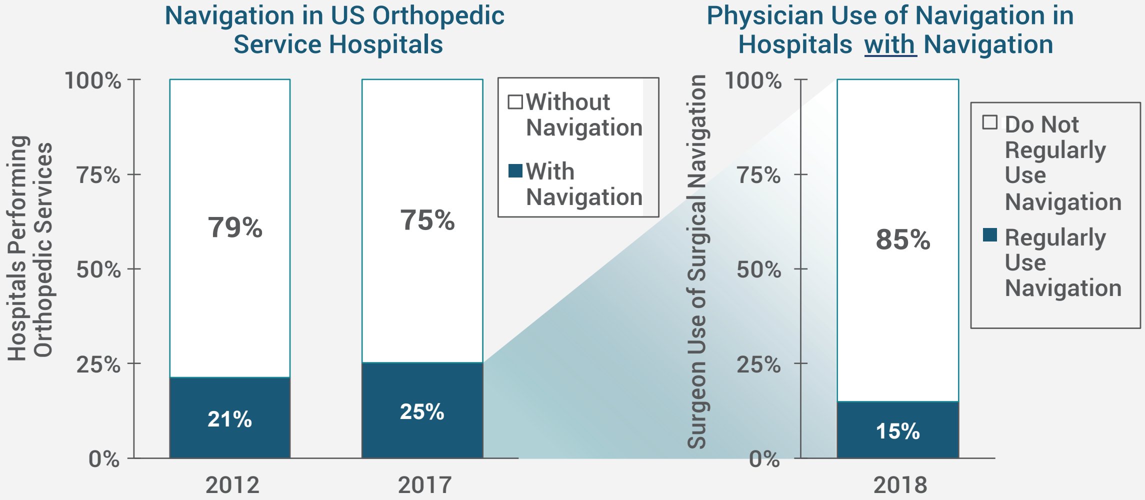
Accuracy of Navigated vs. Freehand Pedicle Screw Placement



Sources: Health Advances; Aoude 2015 Eur. Spine

Figure 2

Adoption and Physician Use of Navigation in US Orthopedic Service Hospitals



Sources: Health Advances; AHA Annual Survey Database; *MedTech Strategist*

The reasons for this slow adoption of surgical navigation tools are multifaceted. Cost has certainly been a deterrent to some centers, however cost alone does not explain the low penetration (~25%) and utilization (~15% of the ~25%) of these technologies. Orthopedic surgeons view navigation as cumbersome, time-consuming, and simply not needed by experienced surgeons who already achieve positive outcomes. Standalone navigation can also be cumbersome, unintuitive and time consuming to use. Surgeons must first spend costly OR time registering the patient's anatomy to align with digitized images. Then, they must reference these images displayed outside the surgical field of view on a monitor and translate what they are seeing on the two-dimensional screen to their manual manipulation of surgical instruments within the surgical field. These steps typically lead to longer OR times, causing many surgeons who are comfortable with standard manual procedures to opt out of using navigational systems altogether. Even newer robotic surgery systems rely on the same navigation and visualization of spatial data outside the surgical field. Furthermore, and most notably, compelling clinical evidence that using navigation has positive impacts on long-term patient outcomes is lacking, as is evidence that navigation can be cost-effective for facilities adopting the technology. Finally, most payors do not reward surgeons with significant additional professional fees to utilize navigation (The 2020 Medicare National Physician Fee for the use of Navigation is set at $243.97.)

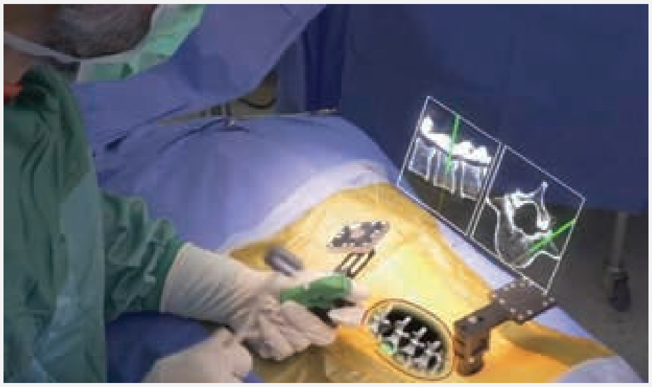
The Introduction of Virtual and Augmented Reality

One of the newest trends in the world of CAOS has been the development of Virtual Reality (VR) and Augmented Reality for use in training (both VR and AR) and during orthopedic and other surgical procedures (AR only). (*See "How Virtual Reality is Changing Healthcare,"* MedTech Strategist, *March 17, 2020.*)

Virtual Reality enables physicians to view and manipulate computer-generated images within a headset-based virtual environment. VR is meant to be used for educational and training purposes, but not in real-time surgical applications. Augmented Reality, on the other hand, is an intra-operative solution comprised of a combination of hardware and software that superimposes 3D computer-generated digital images of the patient's anatomy directly onto the patient's procedural site, thereby enabling physicians to visualize spatial details of a patient's underlying anatomy in relation to their surgical tools in real time. (*see Figure 3*). While AR, like VR, can be used for

Figure 3

Augmented Reality Overlay from Augmedics



Source: Augmedics

educational and training purposes, surgeons are most excited about the intra-operative use of AR to "view" the patient's underlying anatomy even before an incision is made.

Although AR technology has been around for several years, only recently has its application been showcased broadly at major orthopedic and spine conferences. Prior to 2019, talk of AR revolved around stealth projects inside larger companies or early prototypes from smaller start-ups being demoed in a few small booths at the large orthopedics and spine conferences (i.e. American Academy of Orthopaedic Surgeons (AAOS), North American Spine Society (NASS). The 2019 NASS conference in Chicago in September 2019 signified a palpable change, however, as several manufacturers, such as Augmedics, **Holo Surgical Inc.**, and **Novarad**, showcased their AR solutions. The floor also buzzed with anticipation as attendees watched the big countdown clock at the **BrainLab AG** booth leading to its announcement of its "Mixed Reality" VR system. While its first product in this arena is focused on its VR technology applications, BrainLab clearly has plans for expanding into intra-operative AR applications in the near future. Shortly following NASS, in December 2019, Augmedics' *xvision* became the first AR product to receive FDA approval for intraoperative use in spine procedures and the company is starting to roll out the product. A summary of some of the other companies pursuing their AR technologies—both within orthopedics and spine, as well as in other clinical areas—can be seen in *Figure 4*.

AR is no longer a technology found just in science fiction movies. Yet, although they are undoubtably watching the space, only a few of the largest medtech players—namely **Stryker Corp.** and **Philips NV**—have ventured into it to date. Stryker entered into the world of 3D surgical planning and AR overlays for ENT endoscopic procedures through its 2017 acquisition of Scopis (the *Target Guided Surgery Navigation System* is currently approved for sinus surgery), but it is not yet publicizing development of this technology for orthopedic or spine applications.

Other major orthopedic hardware manufacturers may be focused instead on incorporating AR into their existing robotics and navigation platforms versus developing free-standing units. This approach enables these players to upgrade current equipment with AR software and headsets, while also differentiating their robotic and navigation platforms from competitors without AR. This is similar to the nature of much of technology evolution within orthopedic and spine robotics. Innovation generally comes from smaller, private companies and once it is proven, the large OEMs quickly jump in and acquire those innovators. So, the question remains: *will AR systems deliver the same or greater value as robotics to drive investment by the largest public companies? And if so, what will it take for them to make that leap?*

Figure 4

Augmented Reality Competitive Landscape

Company	Display	Current Navigation Player	AR Development Status for Intraoperative Use		
			Spine	Other Orthopedics	Other Specialties
Augmedics	Headset		Launched in 2020	Plans to develop for other ortho procedures	ENT, Neurosurgery, Trauma
Holo Surgical	Transparent Screen		Ongoing Study, Expected 510(k) Submission in 2020	Plans to develop for other ortho procedures	Neurosurgery, General Surgery
Brainlab	Headset	✓	AR scheduled for launch in 2022	*No development reported*	*No development reported*
Philips	Headset		Clinical data on 20 patients already collected	*No development reported*	Neurosurgery, Trauma
Surgical Theater	Headset		VR capabilities only	*No development reported*	Neurosurgery, Cardiac
Novarad	Headset		AR for surgical planning only	*No development reported*	*No development reported*
Stryker Scopis	Transparent Screen	✓	*No development reported*	*No development reported*	Launched in 2017 for FESS*
Medivis	Headset		*No development reported*		AR for surgical planning only

* FESS = Functional Endoscopic Sinus Surgery

Sources: Health Advances; Company reports

Farther from Surgical Launch ⟷ Launched

What Value Does AR Bring to Orthopedic Surgery?

While AR may seem to have limitless potential, its value across the range of musculoskeletal procedures is still unclear. It could be viewed as simply an extension of current navigation and robotic systems, instead of a completely novel and disruptive technology. Many of the core capabilities are similar, if not exactly the same. All three technologies use many of the same components, including a core guidance software used to track instruments to the patient's anatomy intraoperatively, allowing all CAOS technologies to enable safe instrument alignment and implant placement (see *Figure 5*).

AR has two key differences however (see *Figure 6*).

1. ***The way in which the surgeon visualizes data in the operating room.*** In contrast to traditional navigation, where surgeons view anatomical structures on a flat-screen monitor outside of the surgical field, AR generates 3D anatomical representations and superimposes them onto the patient as surgeons look through a headset, or transparent screen placed between the surgeon and patient. This allows the surgeon to interact with both the real and virtual objects at the same time, all while looking directly at the surgical site. The surgeon thus has a far more intuitive and ergonomically comfortable method for performing a navigated procedure because he or she can maintain eye contact on the patient rather than looking at a separate screen.
2. ***AR's software creates a 3D-image rendering and superimposes it on the patient.*** AR software takes 2D imaging slices (e.g. pre-surgical CT or MRI) and creates a complete 3D computer-generated model of the anatomy. The software then utilizes patient registration to overlay those images onto the patient's planned surgical site, providing surgeons with real-time visualization of the underlying anatomy. Most AR platforms are also able to segment which anatomical landmarks are displayed at a given time – such as bony structures versus various soft tissues, giving surgeons the ability to obtain 'X-ray vision' of sensitive anatomical structures while never looking up from the patient. In sharp contrast, navigation, while using all the same inputs, typically displays that information to physicians in 2D profiles on monitors mounted outside of the surgical field of view.

A skeptic's view of these differences could be that AR is almost the same as navigation today and just presents the same information to the surgeon in a more convenient way to prevent them from looking at a distant screen and not at the patient. It's a "nice to have."

A more optimistic view, however, is that AR truly is the "next frontier" and has the potential to become standard of care for all orthopedic procedures. By providing a real-time virtual overlay of anatomical structures prior to incision and throughout the procedure, as well as navigation guidance, AR can enable more consistent and accurate surgical technique across an array of procedure types and surgeon experience levels, which translates to better patient outcomes. Good surgeons could become great,

Figure 5

Traditional Navigation vs. Robotics vs. AR

Traditional Navigation

Traditional navigation systems include a TV screen, camera tower, and navigated surgical tools. The TV screen is typically outside the surgical field that the surgeon must turn to during surgery.

Robotics

Robot systems utilize many of the same components of traditional navigation, though they replace hand-help navigated surgical tools with a navigated robotic arm. Surgeons still must rely on a TV screen for visualization outside the surgical field.

Augmented Reality

With AR, the TV screen is replaced with goggles that superimpose relevant patient images directly onto patient anatomy. The camera tower and navigated tools are still necessary, but the surgeon no longer has to pivot to look at a distant screen.

Source: Health Advances

and even great surgeons could become better by having all the information needed to perform the procedure visible in their line of sight at all times. By using AR, surgeons may also be able to perform safer and more accurate procedures more efficiently (faster) due to better visualization and localization, which could save time in the OR – vital for patients and staff. From a surgeon's perspective, AR technology is not prescriptive nor constraining, as is the case with some of the pre-programmed robotic software. Instead, AR "*allows surgeons to be surgeons,*" enabling them to follow their pre-surgical plan by displaying information directly onto the patient's surgical site. When coupled with navigation or with robotic surgery, AR can deliver enhanced visualization to the surgeon throughout the procedure. Regardless of operating the tools by hand or guiding a robotic arm, AR may allow physicians to more confidently and more intuitively operate on their patients.

While intraoperative utilization of AR has unique potential value propositions, its earliest applications (as is also true with VR) have been outside of the OR. Both technologies have near-term value and are gaining traction in the training setting.

Students and surgeons working at medical schools and teaching hospitals, as well as companies training surgeons and sales reps on their products and associated procedural techniques, can already see the amazing benefits for training via VR or AR. Some have even postulated that AR could eliminate the need for many of the costly cadaver labs and the associated time and travel costs when attending those labs.

For example, Brainlab launched its new anatomy viewer in partnership with **Magic Leap Inc.** this past November for surgical plan review, medical student training, and patient consultation using the latest in 3D virtual reality. Instructors have never before been able to show medical school students, residents, and even experienced surgeons, 3D anatomical structures with such accuracy, high resolution, and incredible functionality. Being able to isolate an anatomical structure and zoom-in, enlarge, and rotate it to visualize the targeted area from infinite perspectives, is an incredibly powerful tool.

AR and VR tools also enable surgeons to walk a patient through a procedure in advance, enabling clearer communication about the surgical procedure. The patient can thus gain more confidence in the surgeon and have a better understanding of the upcoming procedure, improving cooperation and compliance. In addition, surgeons interviewed by Health Advances mentioned the undeniable "cool factor," which can go a long way towards driving both patient and surgeon demand for using a new technology.

The growing use of VR to train young surgeons presents an opportunity for a natural shift to using AR in actual surgery as more surgeons become comfortable with the technology and concept. Younger surgeons, having grown up in an era of gaming software, may even feel more comfortable using this type of visualization than they do in traditional surgery with no CAOS component.

Figure 6

Comparison of AR Solution Components to Other Surgical Techniques

			Surgical Techniques			
			TRADITIONAL	NAVIGATION	ROBOTICS	AR
REQUIRED STEPS	Pre-Op	Imaging (e.g. CT)	Not required	Required	Required	Required
		Surgical Planning	Not required	Required	Required	Required
	Intra-Op	Patient Registration	Not required	Required	Required	Required
		Imaging (e.g. X-Ray)	Significant	Minimal	Minimal	Minimal
PRODUCT COMPONENTS	Software	Guidance System	-	✓	✓	✓
		Image Rendering / Representation	-	2D (on screen)	2D (on screen)	3D (in headset)
	Hardware	Navigation Camera	-	✓	✓	✓
		Navigated Instruments	-	✓	✓	✓
		Visualization Equipment	-	Monitor	Monitor	Headset / Transparent Screen

☐ Key differentiator

Source: Health Advances

Where Does AR Go from Here? Recommended Next Steps for Industry

While AR started to generate a higher level of buzz and excitement in the past year, it still needs technical improvements and key questions answered before it becomes mainstream in musculoskeletal surgeries. Companies developing AR technologies should learn from standalone surgical navigation equipment's slow and limited adoption into musculoskeletal procedures. AR companies must ensure that they understand and are focused on 1) investing further in their technology platforms to improve current performance and accuracy, 2) addressing some of the shortfalls of navigated surgery, and 3) most importantly, gathering and documenting robust clinical outcomes and economic data.

1. Improve Performance and Accuracy of the Technology

Recently we spoke with several surgeons who have trialed various AR systems. Their sentiment was that most systems are not quite ready for seamless transition into the OR for real-time surgical applications. Some of the systems demonstrated at NASS experienced noticeable deviations between the virtual images and the mannequins or Sawbone models used for the demonstrations, as well as noticeable time lags in image rendering. These surgeons commented that, for a system to be acceptable for intra-operative use, an error range on the order of 1 millimeter or less is required. Upon trial of existing platforms however, surgeons believed that the current window of error is as much as 1-centimeter, 10x greater than what is needed. Obviously, for surgeons to trust and operate confidently with reliance on the digitally rendered 3D images, that gap is too large.

In addition to improved accuracy, surgeons commented that the digitally rendered 3D images should be further refined to reduce visual clutter and remove unnecessary, distracting graphics. Some surgeons mentioned that continuous visualization of all anatomical elements or visualization of multiple computer-generated "displays" projected over the patient can be burdensome on the eyes during a long procedure. Images should be crisp, clean and - above all - not distracting to the surgeons spending significant time interacting with them in the OR. We certainly expect future generations of the technology to address these issues. However, many surgeons will not have the patience in the OR to deal with cluttered or imperfect visuals and could lose confidence in the technology overall, if these products are launched prematurely.

2. Address the Key Shortfalls of Navigated Surgery

AR does not yet address some of the problems that have slowed adoption of navigation, such as time-consuming patient registration, lack of compelling clinical outcomes data, and lack of robust cost-effectiveness data. While registration steps are continually being shortened and improved, they still remain, and likely will continue to be, a requirement in the near future. The solution / product that provides navigation without the burden of manual patient registration is certainly expected to be a winner. AR companies should continue to pursue registration improvements on top of visualization enhancements. For instance, some surgeons have postulated that integrating a technology like **7D Surgical**'s *Flash Registration*, as just one example, could go a long way to reducing the time and registration requirements.

3. Demonstrate Tangible Clinical and/or Economic Value

While the benefits of AR in enabling the visualization of the surgical plan directly in the line of sight of the patient's anatomy may be conceptually clear, industry players should continue to work to document the actual clinical and/or economic value of these AR capabilities to help drive faster and greater adoption of the technology. As an example, some data on the accuracy of pedicle screw placements using AR exists, yet it remains limited, and the linkage from accuracy of screw placement to tangible clinical and/or economic benefit has not been established. Accuracy alone will not sell systems. If it did, we would see more than the current low penetration and sparse utilization of standalone navigation systems in orthopedic surgeries. Demonstrating superior clinical outcomes versus traditional or navigated surgery will make for a much more compelling value proposition and sell more systems than selling purely on the "cool factor" of the technology.

Other outcomes, like cost-effectiveness from shorter OR times or reduced radiation exposure for patients and clinicians, could also help drive demand. Regardless of the outcome though, industry must commit to invest in well-run studies with sufficient patient numbers and multiple surgeons and sites participating. To prove these key clinical outcomes and other benefits, industry will have to invest in AR clinical trials and/or gather retrospective real-world data over time, to compel an increasingly skeptical group of surgeon, facility, and health system stakeholders who are demanding more evidence to support large capital outlays on new products or software.

AR Has Staying Potential, but is Still in its Infancy

Despite the hurdles outlined above, with the current air of excitement surrounding this technology, AR has a chance to become more than a "nice to have" commonplace technology in orthopedic surgery. In addition to improving the accuracy, ease of use, and documentation of clinical value, other work must be done to ensure the optimal adoption of AR into the MSK sector.

The economic implications of AR must also be worked through before we see large investment from orthopedics' top players. AR systems today are being sold as standalone units, complete with their own navigation towers and equipment. Therefore, hospitals and ASCs must absorb a large upfront capital outlay, without promise of much, or any, incremental reimbursement dollars being generated. Adding more cost to procedures which have—or are likely to have in the future—capitated reimbursement requires a strong and compelling financial story to hospital and ASC financial decision makers. AR companies must document the economic value of their technologies in specific procedures.

Attractive business models that reduce upfront capital costs through creative financing terms, such as offering leases or per-click models instead of out-right sales, for example, can help lower the risk of a poor ROI. Some companies with large robotics platforms have addressed the added cost issues by offering discounts on their implants to customers using their robotic systems. Eventually, if VR/AR technology gains traction among the top orthopedic companies, they could offer the software and minimal hardware (i.e. headsets) as add-on products to their current navigation and/or robotic platforms, drastically reducing the cost for facilities that have already invested in their equipment, while also being a differentiator to help sell their navigation and/or robotic platforms + AR to new facilities.

VR and AR systems are starting to make commercial headway, with the first applications in training and education. They are then expected to expand into selected intraoperative applications that have the best opportunity to leverage the incremental benefits of improved accuracy and surgical speed. If manufacturers gather data along the way to demonstrate robust, tangible and reproducible clinical and economic benefits then, and only then, will AR truly be the "next frontier" of orthopedic surgery. MTS

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