

Experiences with Innovation

A Personal Journey through, and review of, the Landscape of Surgical Robotics in Knee Arthroplasty: My Transition from Mako® to NAVIO™ and finally to the ROSA® Knee System

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The growth of robotic capabilities in arthroplasty surgery over the past few years has mirrored the slow, almost immeasurable progress and adoption of digital technologies across various industries, in general, followed by a veritable explosion. For many years, the field of robotics in orthopaedics was met with skepticism by many of our surgical colleagues who thought that the expense, learning curve, and lack of proof rendered the class of technology unnecessary. The use of robotics for total knee arthroplasty (TKA) is now growing at an exponential rate, reminiscent of the UKA experience from a decade earlier. The purpose of this review was to describe my own personal experience with robotics in knee arthroplasty which highlights an evolution over a thirteen-year period

INTRODUCTION

Robotics was still just something of sci-fi lore in the mid 2000s. Sure, as a kid, I loved watching the Jetsons and Lost in Space, but it was hard to fathom that a robot was ever really going to be relevant in orthopaedic surgery. Robotics made sense in warehousing, auto manufacturing, and maybe even prostate and gall bladder surgery, but at the time I couldn't imagine using a robot in knee replacement surgery... until I was introduced to an orthopaedic robot in 2006. I initially perceived robotics to be an important adjunct for a relatively small, but potentially growing, niche market - unicompartmental knee arthroplasty (UKA). Now, having transitioned through three robotic "chapters," my philosophy regarding robots in arthroplasty has evolved. It turns out that each of the three robotic systems I've used provide improved accuracy and precision, but I eventually pivoted from one robot to another over the course of 13 years after accumulating substantial experience with each and what I perceived to be considerable advantages of the "next generation" system. As Gordon reflected, "it is useful to think of the innovative process as a series of discrete

inventions followed by incremental improvements, which ultimately tap the full potential of the initial invention" (Gordon 2012). I believe that comment closely embodies my experience as I transitioned from the Mako® to NAVIO™ to ROSA® Knee systems. Herewithin, I elaborate on my experiences with each system, the contemporaneous experiences of robotics in the larger orthopaedic community, and the rationale for my shift from one robot to another. For transparency, I have several potential conflicts to disclose, including consulting services for Smith & Nephew as well as Zimmer Biomet. I had also consulted with Mako Surgical in its early years. My full list of disclosures can be found on the AAOS website: <https://disclosure.aaos.org/search>. Despite this, I've attempted to discuss my experience with robotics in a fair and objective fashion.

"GRADUALLY AND THEN SUDDENLY" (HEMINGWAY 1926)

While this paper highlights my personal journey through the field of robotics, I think it's worth reflecting on its trajectory in arthroplasty on a broader scale. In a nutshell, the

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growth of robotic capabilities in arthroplasty surgery over the past few years has mirrored the slow, almost immeasurable progress and adoption of digital technologies across various industries, in general, followed by a veritable explosion (Lonner and Fraser 2019). It just was delayed in orthopaedics compared to those other industries. For many years, the field of robotics in orthopaedics was met with skepticism by many of our surgical colleagues who thought that the expense, learning curve, and lack of proof rendered the class of technology unnecessary. Ironically, many of those who held a healthy reservation about the role of robotics are now among its greatest advocates and highest volume users. Between 2006 and 2012, there were relatively few users of robotic technology for knee and hip replacement surgery worldwide. That has changed in the last five to ten years. While many see legitimate value of robotics for improving accuracy and potentially for improving functional outcomes and durability, others have a more practical rationalization, as they simply have adopted the technology to capture or maintain (or not lose) market share, noting the pressures from competing hospitals and practices that are offering robotic surgery. A recent survey by the American Association of Hip and Knee Surgeons notes that 54.7% of the captured membership believe robotics are used for marketing purposes (Sherman and Wu 2020). This is further supported by the work of Pagani et al. who used online crowdsourcing to understand the public's perception of robotics (Pagani et al. 2021). Though they report that the public is often misinformed about the outcomes with robotic assistance, the authors assert that the availability of a robot may be used as a powerful marketing tool. It should also be noted that I have personally heard from a number of colleagues around the country that they will sporadically use a robot in arthroplasty not necessarily for its benefit of improving accuracy (and potentially outcomes), but rather for the explicit purpose of not losing patients interested in having a knee replaced robotically. In fact, the adoption pattern of robots in orthopaedic practice has followed the traditional pattern of the Technology Adoption Life Cycle, whereby innovators and early adopters lead the pack, and then, after a substantial gap in time and experience, others begin to buy-in to the technology at varying times...or not (Moore 2014). Ultimately, it is often those who fail to embrace the technology at some point that lose out. In the case of arthroplasty, the biggest loser is the hapless patient who may never be offered the option of this innovative technology. The emergence of robotics in the realm of arthroplasty was fueled first by a commitment of a small group of innovative surgeons (Bargar 2007; Conditt et al. 2013; Conditt and Roche 2009; Lonner 2009a), and then further advanced mostly due to the interest of a generation of more digitally inclined (read, younger) orthopaedic surgeons (as well as a number of our experienced colleagues who have taken on the mission of robotics more recently).

The greatest credit of course is due to Bill Bargar, who developed Robodoc in the late 1980s and early 1990s. Despite his taking decades of criticism from the arthroplasty "elite," and although it was slow to commercialize in the United States, that system finds itself in rarified display at

the Smithsonian Institution in Washington D.C. (Smithsonian 2016). Later, early innovators and enthusiasts of another robotic technology eased into the field. In 2006, Martin Roche performed 13 robotic uni's using Mako. In 2007, he and a few other surgeons combined for 165 cases. My first case was in 2008, and that year there were 601 unicompartmental robotic cases performed in the United States. In 2009, 2010 and 2011, the U.S. saw robotic volumes of 1,602, 3,485 and 6,932, respectively. It wasn't until 2013 that 15% of uni's performed in the U.S. were done with robotic assistance (Orthopedic_Network_News 2013).

The use of robotics for total knee arthroplasty (TKA) is now also growing at an exponential rate, reminiscent of the UKA experience from a decade earlier. Nationwide, the prevalence of robotic assistance in TKA in the U.S. increased from 0.1% in 2008 to 4.3% in 2018 (Emara et al. 2021), and one statewide database reported that the utilization of robotics in joint arthroplasty increased from 16.2% to 29.2% of hospitals and 6.2 to 16.7% of surgeons between 2008 and 2015 (Boylan et al. 2018). That same state experienced a 500% increase in the utilization of robotic assistance in all knee replacements performed between 2009 and 2013 (Naziri et al. 2019). A survey of the American Association of Hip and Knee Surgeons (AAHKS) between November 2019 and January 2020 found that 33% of the membership were using robotic assistance for TKA (Sherman and Wu 2020). Analysts suggest that once robotic penetration in the joint arthroplasty market achieves a 35% level, orthopaedic surgeons and hospitals will routinely demand access to robotic technologies (ResearchMoz 2016) – that threshold is quickly approaching.

Academic activities related to robotic-assisted arthroplasty are also growing tremendously. Peer-reviewed publications on the topic have gone from a trickle in 2008 to a deluge in 2021. For many years I was the token presenter on robotics in knee arthroplasty at various meetings. Now I'm happy to note that in 2021, robotic-related studies and presentations have occupied between 5-8% of the curricula at the Members' Meeting of the Knee Society, Annual Meeting of the American Association of Hip and Knee Surgeons (AAHKS 2021) and Current Concepts in Joint Replacement (CCJR 2021). It is now common for an entire session or symposium to be dedicated to robotics in arthroplasty. Patent activity in robotics is greater than most other areas of arthroplasty-related technology development at this time, highlighting the tremendous interest in, and resource allocation toward, the field of robotics (Dalton et al. 2016). The field is picking up momentum and I don't believe it'll turn back at this point.

My own personal experience with robotics in knee arthroplasty highlights an evolution over a thirteen-year period through three chapters: 1) the CT based/haptic robotic arm period (Mako); 2) the CT-free handheld robotic period (NAVIO); and 3) the CT-free robotic surgical assistant period (ROSA Knee System).

CHAPTER 1: FIRST FORAY INTO ROBOTICS (2006-2013)

The robotics industry today is where the PC industry was 30 years ago.

—Bill Gates (Gates 2007)

It was 2006, nine years into practice, and I had a growing body of experience performing unicompartamental knee arthroplasties. I was extremely selective and my results were pretty good, but not perfect. The data on UKA at that time were mixed. Depending on what series you read, the results in the hands of high volume UKA surgeons, some of whom were developers of various UKA implants, were remarkably good, with 10-year survivorship hovering around $\pm 90\%$ (Berger et al. 2005; Keblish and Briard 2004; Kozinn and Scott 1989; Naudie et al. 2004; Pennington et al. 2003), but the International Registries circa 2005/2006 and insurance databases were showing (and still do today) that failure rates in UKAs were considerably higher than the failure rates of TKAs at all time intervals in the hands of the masses (AOANJRR 2006; Hansen et al. 2019; NJR-UK 2007; SKAR 2006). Sure, some of the designs at that time had crude aspect ratios and polyethylene inserts that were prone to wear, oxidation or both, but there were some tremendous designs available at that time that were doing extremely well, but not well enough in the hands of many surgeons (including me). It turns out that aseptic failures were due to even small errors of as little as 2° in the alignment of the components, and the problem was exacerbated by our enthusiasm to shift from extensile approaches to minimally invasive incisions (Cobb et al. 2006; Collier et al. 2006; Hamilton et al. 2006; Hernigou and Deschamps 2004a, 2004b). Unfortunately, component positioning beyond 2° of the desired alignment may occur in as many as 40% to 60% of cases with conventional techniques, even in the hands of talented surgeons (Cobb et al. 2006; Collier et al. 2006; Keene, Simpson, and Kalairajah 2006). Further, soft tissue imbalance between flexion and extension was a prominent failure mode then, and it remains a problem today (Chatellard et al. 2013; Epinette et al. 2012). I was teaching UKA courses for Zimmer and would often observe that many surgeons were struggling to accurately align the components using conventional instruments and manual techniques; they were having difficulty balancing the flexion and extension gaps; and there were often significant rotational errors of tibial components because landmarks were either not well visualized through the small incisions or the surgeons were using landmarks that were more appropriate for TKA, but not necessarily appropriate for UKA.

In 2006, I had the good fortune of being introduced to the engineer-inventor behind the Mako technology. His team developed a CT-based, haptically-guided robotic arm in the heat of south Florida for use in UKA to help improve accuracy of bone preparation and quantify soft tissue balance. The goal was to eliminate error and with it the expectation that it would enhance function, improve durability, and optimize surgical efficiency. Soon thereafter, I tried out the Mako® robot in a cadaver lab in Newark, NJ,

and was immediately hooked on the potential of the surgical tool. The registration process at that time was a little bit time consuming, and the early generation product was admittedly crude by today's standards, but immediately I was drawn to the precision with which bone could be removed and prepared with a five or six mm spherical bur, and was confident that Mako would improve and modernize the early features. That moment began my interest in robotics for UKA. I wanted one, and I believed immediately that it would make me a better UKA surgeon.

Of course, convincing our hospital that this was a worthy investment took some time. As one would expect, when I presented this technology to the hospital administrators where I was practicing at the time, there were big roadblocks. The capital expense was tremendous, over \$1.2 million, not to mention the high cost of disposables and concern about an adequate surgical volume given that I was really the only one in Philadelphia, and certainly at the hospital, doing any significant volume of UKAs at that time. And this was a niche tool... only for UKA. In those days, capital cost was capital cost. There were no reasonable considerations at the time to offset the system costs, such as volume-based incentives. The premise was that the prospect of incremental volume growth of UKA and TKA would allow the system to "pay for itself" after roughly 100 cases/year. Ultimately it was approved by the hospital administration and proved to be a good investment for our patients and certainly for the hospital that achieved unique status as being one of the few hospitals in the U.S. to offer robotics for UKA. Of course, with all technologies, there was a learning curve to optimize efficiencies, but we saw precision and accuracy immediately with my first robotic-assisted UKA performed in 2008.

With Mako, the system rep would do the initial limb segmentation from a 3D CT scan, defining and determining the limb axes, including rotational indices. Occasionally, segmentation errors would be noted, leaving the surgeon to have to double check these steps. At times, changes would be made pre-operatively or occasionally during surgery if the virtual images didn't make sense. This could be a five to ten minute exercise. Prior to all cases and before "scrubbing in," the virtual sizing and implant positioning would be manipulated and determined by the surgeon, based on the 3D model and segmentation. This was a necessary and critical component of the procedure, which would take another 5 to 10 minutes. Granted, it could often be done in parallel, while the surgical tech, nurses, and assistants were setting up the table and prepping the patient. Finally, with Mako Partial Knee, intra-operative surface mapping and landmark registration would require acquisition of 66 points (32 from the femur, 32 from the tibia, and 2 checkpoints; the total knee platform would ultimately require acquisition of 94 registration points, including the 2 checkpoints). This didn't take long, but it consumed roughly another five to ten minutes of time.

While we weren't yet doing these surgeries at an ASC, I was impressed by the notion of requiring far fewer instruments than conventional UKAs (Lonner 2008). Fewer trays and quicker OR table set up were small incremental steps to

help offset the capital costs and regain some time for a robot that otherwise consumed additional surgical time (Lonner 2009b; Swank et al. 2009). Striving to be time neutral was a challenge and ultimately became a holy grail of sorts, but it was my belief that in time, with this robot - or, more likely, some other down the road - we could simplify steps, enhance efficiencies and save time (Lonner 2009c).

With experience, data on the Mako robot began to emerge with studies primarily focused on radiographic analyses of alignment (S. W. Bell et al. 2016; Dunbar et al. 2012; Karia et al. 2013; Lonner, John, and Conditt 2010) and ability to quantify soft tissue balance (Plate et al. 2013). In 2010, we reported on a comparison of the post-operative radiographic alignment of the tibial component with the pre-operatively planned position in 31 knees in 31 consecutive patients undergoing UKA using robotic arm-assisted bone preparation and in 27 consecutive patients who underwent unilateral UKA using conventional manual instrumentation with particular emphasis on the error of bone preparation and variance with each technique (Lonner, John, and Conditt 2010). Radiographically, the root mean square error (RMSE) of the posterior tibial slope was 3.1° when using manual techniques compared with 1.9° when using robotic arm assistance. In addition, the variance using manual instruments was 2.6 times greater than the robotically guided procedures. In the coronal plane, the average error was $2.7^\circ \pm 2.1^\circ$ more varus of the tibial component relative to the mechanical axis of the tibia using manual instruments compared with $0.2^\circ \pm 1.8^\circ$ with robotic technology ($p < 0.001$), and the varus/valgus RMSE was 3.4° manually compared with 1.8° robotically (Lonner, John, and Conditt 2010). But these were merely surrogate measures of success.

It wasn't until years later that some improvements in clinical outcomes were being measured with this robotic device. One prospective study compared the early clinical outcomes in 139 patients undergoing medial UKA randomized to using either manual traditional surgical cutting jigs or Mako robotic arm-assisted technology (Blyth et al. 2017). From the first post-operative day through to week eight post-operatively, the median pain scores for the robotic arm-assisted group were 55.4% lower than those observed in the manual surgery group ($p = 0.040$), and at three months post-operatively, the robotic arm-assisted group had better Knee Society Scores (KSS), although no difference was noted with the Oxford Knee Scores. At one year post-operatively, there were no longer differences in the KSS; however, a greater proportion of patients receiving robotic arm-assisted surgery improved their UCLA activity scores (69% versus 52% [$p = 0.06$]) (Blyth et al. 2017). Further two-year follow-up on that study cohort found that patients in the robotic group had significantly less stiffness ($p = 0.019$) and continued to have better Forgotten Joint Scores ($p = 0.017$) compared to the conventional group. In a highly active subset of patients, Oxford Knee Scores were significantly better ($p = 0.04$). Additionally, while no revisions were necessary in the robotic-assisted group, there were two revisions (2.8%) in the manual group (Gilmour et al. 2018).

My years using the haptic system were marked by excellent results, few failures, and a great degree of patient satisfaction. Nonetheless, I became increasingly concerned about the fact that the system required pre-operative mapping with a CT scan to plan out the case. The CT scan itself was costly and insurers were frequently refusing to cover the expense of the scans, often times leaving patients stuck having to pay out of pocket for the scans, or the hospitals having to absorb the cost of the scans, hoping to offset that expense with the revenue generated by the surgery itself. The scans required a specialized protocol, that only a small select group of certified centers could accommodate. That created an inconvenience for patients who occasionally had to drive for hours or fly in from afar to get the scans. At times, the scans were done errantly and needed to be repeated, which was even more of a problem.

I became particularly troubled by the under-acknowledged risk of exposing patients to radiation from CT scans used for pre-operative surgical planning. In our analysis of 211 of my own patients who underwent pre-operative CT scans for pre-surgical mapping and planning before Mako-assisted UKAs, we found that the mean effective dose of radiation from these CT scans was 4.8 ± 3.0 mSv (millisieverts), approximately equivalent to 48 chest radiographs (Ponzio and Lonner 2015). To make matters worse, 25% of patients in that study had undergone one or more additional CT scans, typically on other body regions with a maximum cumulative effective dose of 103mSv. The U.S. Food and Drug Administration (FDA) has stated that an effective CT radiation dose of 10mSv may be associated with the possibility of fatal cancer in 1 in 2,000 patients, much higher than the natural incidence (FDA 2017). Therefore, the risk of radiation exposure from these and other CT scans is not negligible. I felt I needed to take steps to reduce exposing my patients to avoidable radiation. This study emboldened my resistance to the routine use of CT scans for pre-operative planning and fueled my desire to find a CT-free robotic alternative in order to lower patient risk.

CHAPTER 2: TRANSITION TO A HAND-HELD ROBOTIC SCULPTOR – DISRUPTIVE INNOVATION IN THE ROBOTICS SPACE (2011-2021)

Disruptive technologies bring to a market a very different value proposition than had been available previously...Products based on disruptive technologies are typically cheaper, simpler, smaller, and, frequently, more convenient to use.

–Clayton M. Christensen (Christensen and Stoltz 1997)

We are at a major inflection point in our history... dawn of the second Industrial Revolution.

–Erik Brynjolfsson and Andrew McAfee (Brynjolfsson and McAfee 2014)

In November 2007, I was listening to a lecture at an Innovator's Conference in Pittsburgh, PA given by the CEO of a start-up named Blue Belt Technologies. It was then that I was presented with the prospect that robotic UKA

surgery had the potential to be done without a pre-operative CT scan using a device in development that was considerably less expensive, smaller, and more portable than its predecessor. His presentation dealt primarily with funding considerations for tech start-ups, but I was intrigued by his company's pre-clinical technology - a novel handheld robotic sculpting tool developed by Dr. Tony Digioia and Branko Jaramaz for use in UKA. Afterwards, we spoke extensively about their device, a relatively crude prototype at this stage, that was barely bigger than an arthroscopic shaver. The tool provided a safety mechanism by modulating the speed or exposure of a motorized bur to avoid inadvertent bone resection beyond the plan, and all of the surface mapping was performed intra-operatively without the need for a pre-operative CT scan. It was highly portable which meant it would be more conducive to staggering cases between two operating rooms than the larger Mako unit. Its potential intrigued me.

In November 2009, I presented my experience with, and musings about, robotic technology in knee replacement surgery to the scientific advisory board of a private equity firm in New York City. While we discussed the improved accuracy of bone prep and quantified soft tissue balance with the Mako robotic arm, I also noted my concerns related to radiation, cost, and ergonomics. It was not long thereafter that Blue Belt Technologies was acquired. Development was rapid, and in short time, the NAVIO robotic sculptor, as it became known, was ready to be commercialized. Its competitive advantage was in its handheld device, portability, and far lower capital cost. As I saw it, its most impactful advantage was that it did not require a pre-operative CT scan. In early 2013, two of the hospitals where I worked at the time exchanged their Mako robots for NAVIO and within a short period of time were profitable despite still paying down debt on the earlier systems. The per-case costs were less and the capital cost for the system was low enough to allow the hospitals to become profitable quite quickly. Within a short period of time, I was using the NAVIO handheld robot at several ambulatory surgery centers (ASC), unburdened by a large capital cost that kept its predecessor out of the ASC environment.

It was imperative to determine whether NAVIO had the precision we desired from a robotic tool, particularly since it did not require a pre-operative CT scan for planning. An early cadaveric study of 25 cadaveric specimens showed precision that was basically equivalent to that of the Mako system, when comparing the "planned" and "actual" angular, translational, and rotational positions of the femoral and tibial components. The RMS angular errors were 1.42°-2.34° for the three directions for the femoral implant and 1.95°-2.60° for the three directions of the tibial implant. The RMS translational errors were 0.92-1.61 mm for the femoral implant and 0.97-1.67 mm for the tibial implant (Lonner et al. 2015). In my mind, this was highly acceptable. NAVIO would later prove accurate for TKA as well. One study compared the planned and achieved implant placement in 18 cadaveric specimens undergoing TKA by eight surgeons using the NAVIO robotic tool. The mean femoral flexion, varus/valgus, and rotational errors were

-2.0°, -0.1°, and -0.5°, respectively. The mean tibial posterior slope and varus/valgus errors were both -0.2° (Casper et al. 2018).

Subsequently, we reported that robotic assistance, with both Mako and NAVIO, resulted in more conservative tibial resections compared to conventional methods (Ponzio and Lonner 2016). In an analysis of 8,421 robot-assisted UKAs and 27,989 conventional UKAs, statistically more 8mm and 9mm polyethylene inserts, a proxy measure of bone conserving tibial resections, were used in the robotic group (93.6%) than in the conventional group (84.5%) ($P < .0001$). Additionally, larger tibial inserts of ≥ 10 mm were utilized in 6.4% of robotic-assisted cases and 15.5% of conventional cases. This has both physiological and practical implications. First, proximal tibial bone is weaker with more distal resection and thus it is biomechanically advantageous to minimize bone resection. Second, in the event of a future revision to TKA, reconstruction is more challenging and more likely to require tibial augments and stems when larger tibial resections were made at the time of UKA.

Other studies found that joint line preservation, which could optimize kinematics and reduce polyethylene stress, was more accurate in UKA performed with NAVIO robotic preparation compared to conventional methods (H. Fu et al. 2018; Herry et al. 2017). A retrospective case control study by Fu et al. compared tibial component slope and femoral joint line position in 175 matched medial UKAs performed using a conventional spacer block technique ($n=52$), image-free robotic system (NAVIO, $n=57$) or CT-based robotic system (Mako, $n=66$) by a single surgeon. The joint line was significantly distalized in the conventional group (-1.57mm \pm 1.62) when compared with NAVIO (-0.3mm \pm 1.06) ($p<0.001$) or Mako® (-0.26mm \pm 0.98) ($p<0.001$). There were no differences in joint line preservation between robotic systems in that study ($p=0.65$). Furthermore, the mean post-operative posterior slope was highest in the conventional group (8.98° \pm 2.83), followed by Mako (7.1° \pm 2.5), then NAVIO (5.56° \pm 2.18). The differences between groups were statistically significant ($p<0.001$). Importantly, while the senior surgeon attempts to restrict the posterior tibial slope to $\leq 7^\circ$, the percentage of posterior slope outliers $>7^\circ$ were 25%, 5% and 3.5% for conventional, Mako and NAVIO cases, respectively (H. Fu et al. 2018). Consistent with these findings, Fu et al. (J. Fu et al. 2018) also performed a meta-analysis and identified several randomized and quasi-randomized controlled trials supporting improved accuracy with robotic-assisted UKA.

Having amassed a reasonable clinical volume of robot-assisted UKA cases, it was time to review the safety of the two available semiautonomous robotic systems with which I had experience, particularly in light of reports of soft tissue injuries with the Robodoc autonomous robotic system that had been in use in Europe and Asia (Chun et al. 2011; Honl et al. 2003; Park and Lee 2007). In a series of 1,064 consecutive UKAs that I performed between 2008 and 2017 with either of the two commercially available semi-autonomous robotic systems (Mako [$n=492$] and NAVIO [$n=572$]), there were no soft tissue or bone injuries related to use of the robotic bone preparation method. Six

complications related to the use of standard computer navigation pins occurred (0.6%) – one pseudoaneurysm of a branch of the tibialis anterior artery, one tibial metaphyseal stress fracture, and four areas of pin site irritation/superficial infections that resolved with a short course of oral antibiotics (Lonner and Kerr 2019).

Eventually, clinical data began emerging with the NAVIO UKA system. A retrospective analysis of 89 matched consecutive patients who underwent outpatient UKA by me using either conventional instruments (n=39) or robotic methods (n=50), with otherwise identical peri-operative protocols, was performed (Crizer et al. 2021). The robotic-assisted UKA resulted in more rapid recovery and less early post-operative pain than conventional UKA. Patients in the robotic cohort had superior early functional outcomes, with greater lower extremity function scores (LEFS) at one-week post-operative (p=0.015) and KOOS JR at up to six months post-operative (p=0.037), although functional differences equilibrated by one-year post-operatively. At one-year post-operative, despite comparable function, expectations were more likely to be met in those who received robotic assistance (p=0.006).

Two-year UKA implant survivorship in cases performed with NAVIO by five novice surgeons, who had no prior experience with the robotic system, was found to exceed the survivorship of conventional UKA's reported in international registries (Battenberg, Netravali, and Lonner 2019). Overall survivorship of the knee implant in these robotic-assisted cases at two years was 99.2% (95% confidence interval: 94.6 to 99.9%), which was non-inferior when compared to the reference survival rate of 95.7% in UKAs from the Australian registry (AOANJRR 2015), 96.3% in the New Zealand registry (NZOA 2013), and 96% in the Swedish registry (SKAR 2013). Additionally, several cohort studies have also reported two- to three-year UKA survivorship ranging from 94.7% to 98.0%, which are lower than the reported durability found in our NAVIO study (Battenberg, Netravali, and Lonner 2019; Eickmann et al. 2006; Hamilton, Ammeen, and Hopper 2014; Liebs and Herzberg 2013; Lim et al. 2012; Pandit et al. 2011; Vorlat et al. 2006; Yoshida et al. 2013).

NAVIO was clearly a “disruptive innovation” with its lower capital costs, portability, and image-free platform compared to its bulkier, costlier, and less efficient predecessor. Compared to Mako, the system setup time was an improvement, but still not great. Surface mapping, limb registration, and femoral bone preparation were quicker than Mako, but not enough to offset the inefficiencies of the tibial bone prep. Often, tibial cuts needed to be refined, including smoothing the surfaces with a rasp, and manual removal of sections of un-resected tibial cortex, with a combination of rongeur, rasp or bur off constraint. Then, there were ergonomic challenges for me as the surgeon user, like persistent anteromedial knee pain from having to stand on a foot pedal to control the burring process; thenar cramping and hand fatigue that would routinely occur from gripping the hand-held device; low back pain and strain from standing in a lumbar-flexed position; and shoulder pain from extensive shoulder elevation and abduction. After a few years of this, I began to feel the impact.

In fact, paradoxically, we found increased energy expenditure, physiologic stress and ergonomic strain of the lumbar spine and shoulders while using the NAVIO robot for UKA compared to conventional UKA's (Haffar et al. 2022b).

Up until somewhere around 2016, I had thought of robotics for the knee as mostly a niche procedure, useful for UKA, but generally unnecessary for TKA (Lonner and Fillingham 2018). The data regarding TKA's suggested that a range of limb and implant alignment could be accommodated without compromising function or implant durability, as long as the knees were balanced (Bonner et al. 2011; Howell et al. 2013; Parratte et al. 2010; Ritter et al. 2011). And the Robodoc data seemed to corroborate that. Namely, equivalent functional outcomes and durability despite improved alignment in a robotic system that did not quantify soft tissue balance (Agarwal et al. 2020; Karunaratne et al. 2019; Kim, Yoon, and Park 2020; Yang et al. 2017). Then I read an article about a man named Abraham Wald and I had a major epiphany that completely changed the way I thought about the potential role of robotics in TKA (Mangel and Samaniego 1984).

During World War II, concerned about the state of fighter planes that were returning from combat missions with their fuselage and tails riddled with bullet holes, the U.S. military leadership sought counsel from Wald, a prominent mathematician, to develop a solution to reinforce those sections without weighing the planes down and impairing their ability to fly. After contemplating the issue, Wald advised the group that their perception of the problem was misguided. The planes that had been struck with bullets in the tails or fuselage were making it back safely -- they were not the problem, he noted. Rather, it was the planes struck in their noses and engines that were not returning, and thus it was the engines and noses of the planes that needed reinforcement and due consideration (Mangel and Samaniego 1984). So, with that kind of logic in mind, even if equivalent functional outcomes are achievable with robot assistance, I now believe that it is very important to consider what I refer to as “the Wald principles” when contemplating a role for robotics in TKA. There are additional potential benefits of robotics to consider in the TKA space other than alignment and whether or not that impacts outcomes: reduced inventory and sterilization costs; surgical efficiency; improved surgeon ergonomics; quantified soft tissue balancing; reduced opioid needs; and incorporating artificial intelligence (AI) and analytics to influence intra-operative and peri-operative decisions (Lonner and Goh 2022). These considerations were front and center as I began giving serious consideration to using a robot for TKAs and expanding my robotic footprint beyond the small “niche market” of UKA.

In 2016, at the Open Meeting of the Knee Society, I mentioned that in my opinion, the real potential value of the robot for TKA was not necessarily in the precision of bone preparation, but rather in the ability of the robot to quantify soft tissue balance and guide subtle alterations in bone resection angles, specific for each patient (Lonner 2016). The added bonus is that since then, compelling data has been emerging that shows that in robots that prioritize

both bone resection precision and soft tissue balance, functional outcomes may be improved (Bhimani et al. 2020; Blum et al. 2021; Lee et al. 2021; Smith et al. 2019; Wakelin et al. 2021; Zhang et al. 2021).

As my interest in expanding the role of robotics into TKA in my personal practice grew, I knew the systems with which I've had experience would not work for me, even though they were both accurate and quantified soft tissue balancing. The time was right to look around again. As Thomas Edison said, if "there's a way to do it better – find it".

CHAPTER 3: TRANSITION TO ROSA KNEE AND A PARADIGM SHIFT TO A BROADER APPLICATION OF ROBOTICS FOR TKA AND THE EXPANDING DIGITAL PLATFORM – TRANSFORMATIVE PHASE OF ROBOTICS (2021-)

...we are, in all likelihood, at the leading edge of an explosive wave of innovation that will ultimately produce robots geared toward nearly every conceivable commercial, industrial, and consumer task.

–Martin Ford (Ford 2015)

...innovate to change the rules of the game.

–David O. Adeife (Greer 2013)

All truth passes through three stages. First, it is ridiculed; second it is violently opposed; third, it is accepted as self-evident.

–Arthur Schopenhauer (1788-1860)

In July 2016 Zimmer Biomet (ZB) acquired Medtech (the previous developer of an early robot called Brigit, which never fully commercialized). Of course, at this point the ROSA Knee System was still an unpublicized project somewhere between Montpellier, France and Montreal, Canada. The ROSA Knee System was presented to me at the ZB booth at AAOS in March 2017. Unlike Mako and NAVIO, the ROSA Knee System came to the plate attacking the primary volume procedure – TKA – rather than pursuing the smaller niche UKA market first. Why not? They had the potential to pair advanced technology with their top performing portfolio of total knee implants, refine the procedure, enhance its efficiencies, prove its precision and value, and then pursue other applications like UKA and total hip arthroplasty.

In January 2019, ZB received FDA clearance for its ROSA Knee System, and its coming out party at AAOS in March 2019 was exhilarating. I was thrilled that the development team chose to robotize the cutting guides – in my mind this would provide the optimal blend of surgical efficiency, precision, and ergonomics. The fact that the positioning of cutting guides are robotized, but the surgeon has unconstrained use of the saw, allows for a more normal and familiar feel for many surgeons who desire to keep control of the cutting device. Additionally, using a saw for tibial and femoral preparation is certainly more efficient than using a motorized bur. I remember thinking at the time that it was extremely impressive, but predicted that the Mako® camp

would try to claim that since the end effector robotized the positioning of the cutting blocks but not the saw blade itself, it was somehow "less robotic." In reality, what I knew then was that many surgeons were feeling that the forced haptics with the Mako system in the saw were bothersome. I had also heard from several surgeons using Mako for TKA, that the haptic constraint of the saw caused shoulder strain and pain, and the system's periodic stalling at the interfaces of bone resection (often seen during chamfer preparation) had been frustrating.

In my opinion, one of the notable features of the ROSA Knee System is the ability of its software to seamlessly and efficiently determine femoral component rotation and flexion gap balance based on rapid intra-operative assessment of the medial and lateral extension gap characteristics (Batailler et al. 2021). This simplifies the complexities of managing numerous interrelated and constantly changing variables and data points (e.g. soft tissue balancing, resection depth, alignment etc.) and accelerates the surgical procedure. Also impressive was ZB's ongoing commitment to thinking outside the "conventional" robotics realm to advance their platform that integrates a vast digital ecosystem spanning the entire care experience. The system can leverage the passive collection of pre-, intra-, and post-operative data points using the intrinsic capabilities of the ROSA Knee System and objective post-operative functional outcomes using a smartphone-based care management platform (mymobility®). That data can then be synthesized using an analytics platform that is unique to the field (ZBEdge™ and the OrthoIntel Orthopedic Intelligence platform) to ultimately better understand how patient specific personalized adjustments in alignment and soft tissue balance may optimize care efficiencies and improve clinical outcomes. With the information thus derived, it is our hope that AI algorithms will eventually be refined to guide patient-specific surgical decisions to drive efficiencies and ultimately influence joint kinematics and outcomes. These applications may prove to be even more advantageous compared to the obvious benefits of improved alignment accuracy currently offered by the robotic system itself.

As with each of the predecessor robots, studying alignment of the components and limb was the first necessary measure of ROSA Knee's value in TKA. In a preliminary cadaveric study of 30 knees in which TKA was performed using ROSA, the mean differences between the planned angles and the measured values were below 1° and the standard deviations were less than 1°. Furthermore, the mean differences (and standard deviations) between the target resections and the measured resection depths were below 1.1 mm (Parratte et al. 2019).

Another cadaveric study comparing 14 ROSA Knee-assisted TKAs and 20 conventional TKAs performed by four board-certified high volume arthroplasty surgeons with no (or limited) prior experience with robotics reported significantly more accurate results ($p < 0.05$) and fewer outliers ($p < 0.05$) in TKAs performed with ROSA Knee than conventional instrumentation (Seidenstein et al. 2021). Aiming for neutral alignment in all cases, final limb alignment (hip-knee-ankle angle) with ROSA Knee's assistance was $0.8^\circ \pm$

0.6° vs 2.0° ± 1.6°, with 100% vs 75% of cases within 3° and 93% vs 60% within 2° of the plan. For the ROSA Knee-assisted knees, the accuracy of bone resection angles was below 0.6° with standard deviations below 0.4°, except for the femur flexion (1.3° ± 1.0°), and below 0.7 mm with standard deviations below 0.7 mm for bone resection levels.

Early clinical limb and component alignment data on the initial TKAs performed in 30 patients with ROSA Knee are on par with competitive systems. Compared to historical controls using conventional manual techniques or standard computer navigation in TKA, ROSA Knee had fewer outliers. When using ROSA Knee for TKA, 99.9% of hip-knee-ankle (HKA) angle and 99% of coronal, sagittal, and rotational alignment parameters were within 3° of the plan, which was far superior to that observed in historical controls when using conventional computer navigation or manual instrumentation (Hetaimish et al. 2012; Klein, James, and Lonner 2019).

More recently, Rossi et al. reported on the in vivo accuracy of the ROSA Knee System and noted that the average difference in femoral flexion, the tibial coronal axis, and resection depths for medial and lateral cuts were <1 degree (SD<1) or 1mm (SD<1) from the planned measure, respectively (Rossi et al. 2022). Additionally, Vanlommel et al. reported that when evaluating outliers, considered as >3 degrees from planned, for the HKA angle in robotic (ROSA Knee) vs. conventional instruments the robotic group had significantly fewer outliers (5.2% vs. 24.1%, p=0.003) (Vanlommel et al. 2021). They also noted an absolute mean difference of <1 degree for validated vs. planned angles.

Early on, ROSA Knee has proved to be efficient in my practice. For instance, the process of registration in its TKA application requires 17 points (unlike Mako which requires 94) and pre-operative virtual planning was a non-issue with this system. A recent retrospective study of 90 ROSA-assisted TKA's found an initial learning curve of between 6 and 11 cases for operative times, suggesting rapid integration of the ROSA Knee System into a surgeon's workflow (Vanlommel et al. 2021). This is on par with the learning curves reported with other robotic systems, which have been reported to be between 7 and 43 cases (C. Bell et al. 2021; Kayani et al. 2019; Mahure et al. 2021; Sodhi et al. 2018).

Given the ergonomic and physiologic struggles I experienced with one of its predecessors (Haffar et al. 2022b), I wanted to study the ergonomics of ROSA Knee for TKA to make sure it did not cause more energy exertion, and didn't strain the lumbar spine, hands, or shoulders. For me, that could make or break my decision to even bother with a robot for TKA, since poor surgical ergonomics could predispose to strain, musculoskeletal pain and injury in surgeons performing arthroplasty surgery. Thus, on the first day that we rolled this robotic system into our operating room, we began a study comparing surgeon physiologic stress and ergonomic strain during robotic-assisted TKA using either ROSA Knee or conventional instruments (Haffar et al. 2022a). We measured continuous cardiorespiratory and ergonomic data during 40 consecutive unilateral primary TKA surgeries (20 ROSA Knees, 20 conventionals) us-

ing a smart garment and wearable sensors. Heart rate (HR), HR variability, respiratory rate (RR), minute ventilation and calorie expenditure were used as surrogate measures of physiological stress. Intra-operative ergonomics and postural strain were assessed by measuring cervical and lumbar flexion, extension and rotation, and shoulder abduction/adduction. Our findings were compelling and favored ROSA Knee despite being in a learning curve with the system. In our study, mean operative time was predictably longer with ROSA Knee (48.2±9 vs. 31.8±7 min, p<0.001), but surgical times were significantly shorter in the second 10 robotic cases than the first 10 robotic cases (43 minutes vs 53 minutes). Calories expended per minute were lower with ROSA Knee (2.53 vs. 3.50, p<0.001). Total calorie expenditure in ROSA Knee cases 11-20 was significantly lower than the first 10 ROSA Knee cases (107.1±27 vs 137.6±24, p=0.015), and lower even than the conventional group (112.3 ±37). Mean HR was lower with ROSA Knee (81.5±4 vs. 90.1±5, p<0.001). Minute ventilation was also lower with ROSA Knee (14.9±1 vs. 17.0±1.0 L/min, p<0.001). Mean lumbar flexion (13.1°±6° vs. 22.3°±5°), as well as the percentage of time spent in a demanding lumbar flexion position >20° (23% vs 55%) were significantly lower with ROSA Knee (p<0.001). And there was significantly less neck rotation with ROSA Knee (-0.1°±65° vs -41.6°±54°, p= 0.034). ROSA Knee resulted in less surgeon physiologic stress, energy expenditure per minute, and postural strain than conventional methods, with which I had decades of experience. I was hooked. Now, by the way, my surgical times from tracker pin insertion, through skin incision, limb and surface landmark registration, ligament stressing, surface preparation and completion of trialing is routinely between 25 and 30 minutes.

If extremely early registry data bode well for the future of TKAs done with ROSA Knee assistance, then the future is bright. According to an Industry Report from the Australian arthroplasty registry, the cumulative percent revision (CPR) for Persona® Knee CR and PS bearings was 1.9 (95% CI, 1.6 – 2.2) at five years, compared to a CPR of 3.4 (95% CI, 3.4- 3.5) for the same follow-up time with all other total knee products. The revisions/100 observation years was 0.39 (95% CI, 0.14 – 0.86) for robotic-assisted TKA using the Persona TKA and ROSA Knee compared to 0.60 (95% CI, 0.52– 0.68) without robotic assistance for the same implants. This demonstrates a relative reduction in revisions of 35% with the ROSA Knee System (Anderson and Hueller 2021), though this is not statistically significant. However, the most recent report from the Australian registry reports reduced revision risks for both UKA and TKA when robotic assistance was used (AOANJRR 2021). The report demonstrates a 4.5% (3.7, 5.4) cumulative percent revision rate at five years for robotic UKA compared to 5.6% (5.1 , 6.1) for non-robotic UKA. For TKA, the three-year cumulative percent revision rate for robotics was 1.9% (1.5, 2.3) compared to 2.3% (2.2 , 2.3) for non-robotic TKA. These data support the promising trend noted in the ROSA industry report.

Finally, it's been important to study both the feasibility of peri-operative passive data collection afforded by the ROSA Knee System and mymobility®, given the "promise"

of the ZBEdge digital ecosystem. One pilot study of a cohort of 131 patients who underwent TKA with ROSA Knee and who used the mymobility care management platform peri-operatively were analyzed using the ZBEdge™/OrthoIntel Orthopedic Intelligence platform (Anderson et al. 2021). First, the study demonstrated that passive data collection across the episode of care is indeed feasible using these platforms. Secondly, the study began to tease out associations between intra-operative measures of laxity and post-operative outcomes.

Of course, further study on a broader scale will be needed to better show the impact of component alignment and soft tissue balance on function, inform decisions on optimal balance, and ultimately improve our understanding of individual recovery patterns, guide individualized care and surgical decisions, and ultimately inform AI algorithms.

Despite the available and emerging literature demonstrating the improved accuracy and reliability of robotics in arthroplasty, without question further high quality clinical studies, including randomized controlled trials, are needed to further explore the value add of robotics in joint reconstruction. Only with these additional clinical studies will we be able to gain further insight into whether the use of robotic technology might continue to expand in the future or alternatively fall prey to the to the same fate as a number of prior iterations of non-robotic computer navigation technologies – which were gradually abandoned because there was little, if any, high-quality evidence to show that their improved accuracy led to improved outcomes (Lei et al. 2022; Shah 2021).

CONCLUSION

My evolution through the robotics field in arthroplasty has been a most exciting one. Watching the space transition from its niche application in a small percentage of UKAs to one more broadly embraced and now utilized by roughly one-third of surgeons performing TKAs, by some measures, is validating. One might even suggest that robots are on the verge of being accepted as “self-evident.” With this, my third “chapter” of robotics using the ROSA Knee System, I have observed equivalent accuracy in TKA compared to what’s been reported with the predecessor systems. I’ve also seen considerable improvements in setup time, surgical efficiency, and ergonomics. Perhaps most importantly, our patients are better off with a device that does not subject them to the unnecessary burden of radiation, expense, and inconvenience of a CT scan. The potential of the confluence of the ROSA Knee System and analytics platforms to simplify the surgical procedure, improve accuracy, and provide a vehicle for mass customization and individualization of care for each patient is a noteworthy advance. In my opinion, we are just beginning to tap into the overwhelm-

ing possibilities of this technology, particularly when we consider the prospects of further advancing AI and analytics to inform the surgical process and peri-operative care to optimize clinical results. In fact, the majesty of contemporary knee robotics may not yet be fully appreciated. To paraphrase the author Yuval Noah Harari (Harari 2018), many emerging technologies are advancing faster than our understanding of them – this may very well be the case with robotics in TKA. My transition from Mako to NAVIO and finally to the ROSA Knee System has made tremendous sense, stemming from a combination of years of personal experience and clinical data. Indeed, there is a better way to do TKA in 2021 and beyond, and I believe robotics is changing the paradigm of knee replacement surgery.

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