ROUNDTABLE DISCUSSION

The Interaction Between Industry, Orthopaedic Surgical Practice, and Residency Education

Among medical specialties, orthopaedic surgery has a particularly strong relationship with the medical device industry given the use of implants in many orthopaedic procedures. The choice of implants used in any given surgery involves many factors, including cost, regional availability, and patient-specific and anatomic considerations but may also be subject to surgeon bias. There is an inherent conflict in orthopaedic education between learning orthopaedic procedures with specific implants as they are used clinically and avoiding potential biases that come with interaction with these medical device companies. In this roundtable, we discuss the interaction between industry, orthopaedic practice, and residency education and how potential biases can be minimized.

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Thank you all very much for giving your time tonight. The goal of this roundtable is to discuss the relationship between industry and orthopedic residency education. First question, what role should industry representatives play in regard to education both inside and outside of the operating room?

DR. KANG: The primary role of industry representatives ("reps") in the operating room is to help the OR staff manage specialized equipment, as it is usually burdensome and difficult for the surgical technicians to know all of the intricate details and nuances of the many implant and instrumentation sets. By handling these specifics, reps can help a case progress more smoothly. I do not believe that industry representatives are responsible in any way for directly educating residents. If the resident has an earnest desire to learn, the representative can educate on various parts of the implant tray and assembly of instrumentation. However, it is not expected that the rep should be teaching the resident, as this is the role of the faculty.

DR. WRIGHT: The industry representative is in the operating room to ensure the safe and efficacious use of the product, to facilitate the inventory by making sure that it is ready and available, and to train the operating room staff in the correct use of the instrumentation. They are certainly not present for any promotional purpose, nor are they present to influence clinical or medical decision making in the operating room.

Regarding their role with trainees in the operating room, it is perfectly reasonable to supply surgical technique manuals to the trainees to familiarize them with the technique associated with the implant. However, this technique manual should not be promotional but more like a recipe that explains "here's how you use the equipment" rather than "here's why the implant is good."

DR. DYER: I am going to start by telling a story that occurred to me prior to starting medical school. I was visiting a friend who was in medical school in a distant city at a general hospital far from here. There were few rules at this time. While visiting, he asked if I would like to visit him in surgery and I agreed. It happened to be an orthopedic surgery, and—in retrospect—a sliding hip screw surgery. There were many people in the operating room and I had no orientation at all to the operation, as I had never been to the hospital in this capacity. I looked around the room, and I could tell the role of the anesthesiologist and the role of the surgeons. However, there was this one person who was clearly in charge of the whole room. He was explaining and instructing the surgical technician and instructing the surgeons on how to do this operation. At the end of the case, I inquired my friend about the identity of this person and he explained that it was the industry representative. In this case, all eyes were to him regardless of what the rules were. Now, this was a bunch of residents doing an evening case in a city hospital 25 years ago, but I think it is helpful for context. In this day, at this hospital, with the level of expertise of the physicians and staff, you don't realize how big of a role that a knowledgeable rep can play at times, but you have to be careful when you set up a situation where the person who knows the most about the operation works for a company. This creates an inherently risky scenario, but it happens.

DR. KANG: I do not disagree that this scenario occurs, but times have changed. You cannot have residents independently performing the case anymore unless the chief resident has attending privileges. However, it is important to note that the role of the representative is different geographically. For example, in Egypt or some developing countries, the implant representative is an orthopedic surgeon who scrubs in with the surgeon and instructs during the case. There are variations to this relationship, but this is not the case in the United States. We have hospital-based policies on the role of industry representatives in the operating room, and these are pretty rigorous.

DR. WRIGHT: We would expect our sales representative to interject if they thought someone was going to use the equipment in a way that would harm a patient, as they have a duty to notify the clinician of that. However, if the C-arm is ready but the operator had to leave the room, and you request the sales rep to take a picture, the answer is "no." Our policy is that representatives are unable to do anything that touches a patient or handle equipment that touches a patient. That is a hard and fast rule. We have many rules about behavior in the operating room and also expect that the rules of the institution are followed. There are instances where company policies are more stringent than the hospital guidelines. For example, in Australia it is a community standard that the orthopedic sales rep works the OR table for the surgeon while performing anterior total hip arthroplasty. However, our sales representative is not allowed to perform this duty due to our own company policy. Some would suggest that this is disadvantageous in that marketplace.

DR. KANG: When you have a skilled and trusted representative who has been working at one hospital and serving the needs of three or four experienced surgeons for years, you naturally develop a relationship. The representative may have seen 15,000 or 20,000 hip operations or knee operations, and they may know every step of these operations and feel fully capable of educating a resident in some form. However, this is still not their role.

On the topic of experienced and knowledgeable representatives, what are your thoughts when an industry representative offers techniques or tips in the operating room based on past experiences with other surgeons?

DR. DYER: I find that those suggestions are usually solicited by the surgeon. Often the exchange is, "I have trouble with this step. Who does this better and what do they do?"

DR. WRIGHT: The sales force is allowed to offer advice regarding the procedure if it is consistent with the published and FDA-approved surgical technique and the published instructions for implant use. This pertains to on-label usage. Representatives are not allowed to give any commentary in any way about off-label use. Now, surgeons are allowed to use products off-label as part of their own clinical decision-making, and the Medical Affairs department can discuss specific questions pertaining to off-label use with clinicians as needed. However, the sales force is not allowed to give any advice on this.

There are tight constraints about what the sales team can discuss. Certainly, conveying technical information - such as answering the millimeter step in size between implants or if certain augments are compatible, is allowed. This is product information. However, as an example, it would be inappropriate to recommend utilization of a cemented stem in an uncemented fashion.

DR. KANG: Representatives may have seen twenty surgeons do the same operation differently. They know who can perform certain steps quickly and efficiently. As a surgeon, it is almost human nature to want to discuss this collection of experiences with the industry representatives. Part of the educational process is trying to learn the best methods and best practice, and I do not have a problem with learning from everybody. However, the representatives do not usually offer this advice unless prompted. It would not be appropriate to volunteer information to sway a surgeon to employ a certain technique, but if asked by the surgeon, I have no issue with the representative rendering an opinion. It is up to the surgeon to determine if this advice is valid or not.

DR. WRIGHT: If the sales representative is asked about an off-label use, they cannot answer but can refer the surgeon to submit a medical information request to the company. This request would come to a physician in the Medical Affairs department and could be answered as long as it was a specific, unsolicited question.

Some hospitals and surgery centers are trying to move towards "rep-less" operating rooms. What are the possible negative effects of having an industry representative in the OR?

DR. DYER: One thing to realize is how many reps are present in the hospital. I remember when hospital policy was changed to have reps wear scrubs of a different color. One week afterward, it was striking to see how many people were present in black scrubs.

DR. WRIGHT: It would be negative if the sales force were present for promotional purposes. As a surgeon, I did not want a salesman in the operating room trying to sell me a product. The operating room is not the place for that. It is important to differentiate the activity of a promotional visit where you are informing about a product versus a service requirement in the operating room.

Another interesting point—hospitals essentially increase their headcount and manpower in the operating rooms by using the salesforce for inventory control, running to obtain implants, etc. Many hospitals believe that moving to a rep-less model would decrease the cost of obtaining implants from companies, but then they often find that the internal staff does not have the technical expertise regarding the products or are unable to effectively manage inventory. This either prompts the return of representatives to the operating room to alleviate this issue or the specialized training of a single staff member in the ORs to fulfill this role.

DR. DYER: It seems that we are saying positive things. It is hard to stay on the question, as I have not seen many negatives from the relationship.

DR. WRIGHT: It is having another person in the operating room which increases the infection risk. If the representatives are not professional and are engaging in idle discussion with members of the staff or the surgeon, it can be distracting. A focused, professional environment should be maintained.

DR. KANG: It only becomes a negative if that individual displays unethical behavior or performs promotional activities in the operating room. I am very tolerant, but I can recall an interaction with a single individual who was not compatible with what I was looking for in the operating room. That was just individual behavior.

There have been past instances where 2-3 reps were in the room simultaneously and this created an element of tension, but now the hospital has policies that prevent multiple reps from being present simultaneously.

Industry often sponsors courses and cadaver labs for surgical trainees. What are the benefits of these offerings and what are the risks in potentially biasing residents?

DR. KANG: I'll give my perspective from 26+ years in orthopedic education. I think there is a role for this relationship, but again there is a fine line between education and promotion. It is a constant struggle. For resident education, when learning a Gamma nail, Stryker nail, J&J nail, or any other nail, a nail is a nail but with specific nuances. However, if you go to a course and they are only specifically teaching a single type of nail, you are getting educated but also promoted on the product. The likelihood of using the implant is much higher and companies know this, but we still value this educational experience.

The fine balance occurs when traveling to a course. Most institutions have rigid policies regarding attendance at a course where a single company pays for your room and board or travel specifically to learn their technique. Attending a course about femoral neck fractures that is sponsored by a company but does not discuss certain implants is acceptable. It's a fine line though. Is it promotion or is it education? From a resident standpoint, there is often much to be learned even at a promotional event. From an institutional standpoint, Harvard and HMS won't allow for companies to pay for trainees to attend a meeting without a formal review and educational grant process.

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DR. WRIGHT: Companies differentiate between healthcare providers who have completed training and those who are still in training. We can cover costs of residents to attend educational programs. For healthcare providers who have completed training, we differentiate between promotional meetings and product training. For example, if you were to attend a knee replacement program about a specific implant, its characteristics and outcomes, we cannot pay for the travel expenses or course costs. But a training program on the use of the device and how to properly and safely implant it can be funded.

There are other things that we can do for trainees. We can provide textbooks if it is part of a formal program, but I could not walk in here and freely pass out books. It would have to take place as part of a formal textbook program with a value less than $350 and a limit of one book per year.

DR. DYER: Our residency is very generously supported by multiple industry grants. It really is a partnership, but there are certainly areas where we need to be careful. As the cost of obtaining cadavers and performing direct, hands-on training has become extraordinarily high, we begin to depend on this support. We solicit about $500,000 in direct and indirect educational support in the form of grants each year, which doubles our educational budget. These grants are both in-kind and cash grants, allowing access to cadavers and labs.

DR. KANG: These are education grants. Companies are not doing this for the purposes to showcase their specific product in a femoral nail lab, for example.

DR. DYER: Well, it may be their implant. Whichever company that is providing the lab is also providing the implant. But the companies are scrupulously careful to not market a product. They "un-brand" and speak generically in their descriptions, but anyone can see the brand during the "unbranded" training experience. I think it is the best that we can do. The alternative is no such training. For my part, I am willing to endure the moral hazard of making sure that this educational experience is done correctly in order to let it be done at all.

DR. WRIGHT: What companies cannot do is provide an item of value to induce someone to use a certain product. There can be no contingency. If there is, it is a violation of the Anti-Kickback Statute and would lead to claims under the False Claims Act also.[1,2] There is significant legal jeopardy if a company were to do so.

When we discuss matters of value—one penny has value. When a surgeon has a baby, the reason that you do not receive a congratulations card or flowers from the sales rep is that a card has value and this can be misconstrued as attempting to induce someone to use a product.

This is different from consulting. Consulting is an exchange of value. Companies are paying someone for their knowledge and their services—an entirely different arrangement.

DR. DYER: I will not discuss names, but there was a company who basically set a price for my personal use of certain implants in order to support residency education. As a result, I no longer use those implants at all, and the residency is not educated or supported in any way by this company. I refuse to do it. Again, that is the moral hazard that I am willing to navigate in this situation.

"It is not blinded, but the marketing and sales teams are not part of research funding discussions at all."

DR. KANG: There must be ethical behavior without quid pro quo associated. However, there may be some gray areas. A company's sponsorship of research can be perceived as some inducement. I have received grants through companies for my basic research, but it is made very clear that the money is not transferred through the sales committee but the scientific committee, and this is established through a contractual grant. However, there can be some appearance of conflict even if you are using the funds altruistically.

DR. WRIGHT: Take, for example, an investigator-initiated study where someone applies to a company for research funding unsolicited. If it's not contingent and the topic is of interest to the company, we may fund the study but will not write the protocol. We may offer advice like "we don't think that study is all that useful. Why don't you measure the outcomes with a KOOS[3] or a WOMAC[4]?" That would be advice that an investigator could utilize or not, but these grants are unrestricted in order to support the research. This is allowable. But if the grant is provided to induce an investigator to use a product, that's not acceptable. If, in a meeting to discuss approval of investigator-initiated studies, somebody says something along the lines of, "Well this is a very important customer." I would say, "Time out. We're done here and we're not going to support this study." As soon as the hint of contingency is introduced, we are not able to participate anymore. I have turned down multiple studies in the past because of this exact scenario.

Can't this still be an issue when the comment is not explicitly made? Is this process blinded? If the name up on the screen has a big influence in the orthopedic community, the name may carry enough weight that would make them "an important customer" without it being explicitly said in a meeting.

DR. WRIGHT: We would have to demonstrate that we had a strategic interest in the outcome of the study, document that it was an unsolicited study with complete investigator control of the protocol, and the investigators would have rights to publishing. We would not control the output in any way. You are right though. It is not blinded, but the marketing and sales teams are not part of research funding discussions at all.

What are the steps for an attending surgeon who is interested in developing new equipment? Does this process start independently or is there an industry partnership at the onset?

DR. WRIGHT: There are multiple routes to initiate the process. A surgeon may develop intellectual property and approach a company to license or sell the rights to the product. Also, companies may approach individuals because they have a unique knowledge or experience that would be useful in product design. This relationship may be as a consultant or developer and the compensation may be fee-for-service or a royalty arrangement. Oftentimes,

the acquisition of knowledge is paid in a consulting arrangement but intellectual property is compensated in royalties or licensing.

DR. KANG: This interaction is appropriate but ethical behavior regarding disclosures must be maintained. Every institution has a transparency and disclosure policy to manage these relationships. If I develop a pedicle screw and make royalties on that product, it is difficult as the chairman of a program to manage my conflicts and negotiate contracts with vendors. This occurs at the institutional level as well, as institutions may be making large royalties on faculty-created products. The way to mitigate this conflict is to recuse yourself from these types of negotiations. Ethical behavior is paramount.

The Memorial Sloan Kettering incident serves as an example.[5] All of the policies were in place but the study investigator, who was making significant royalties, did not declare his conflicts when publishing or speaking.

DR. WRIGHT: If companies engage a surgeon as a consultant, they need to establish a clear business need for the service and a fair market value. Companies need to establish that they are the appropriate person to deliver what is needed. This cannot be an inducement to use the product. In 2006-2009, there was extensive legal action around the idea that surgeons were brought on as consultants to encourage use of a company's products. In fact, Chris Christie brought legal suits against the major orthopedic companies to address this. There were a number of consent decrees to change the way that behavior occurred.

DR. HARRIS: This led to the $500/hour Department of Justice limit for what a surgeon's market value is--a number that is quite surprising when compared to the hourly charges of other professionals.[6]

Prior to these events, it was very common for junior faculty members to be enlisted as consultants to give feedback to industry on how a product was functioning. However, they immediately became indebted to that particular company. That was the trend for many years until the public response in 2006.

DR. DYER: Those relationships started very early on, even as resident. There were a lot of dinners for inducement purposes.

We still receive occasional dinner invitations by email.

DR. WRIGHT: There are federal, state, institutional, and company rules about those dinners. Within Massachusetts, a dinner must have an educational purpose with a formal educational program. There has to be a reasonableness of the type of place and limits on the amount that can be spent per person. These details have to be recorded as well as which practitioners were present. The amount that was spent is then reported to the Sunshine Reporting process.[7]

Although there are more difficulties and limitations today, the relationship between industry and clinicians remains really valuable. In order to make forward progress, companies rely on the expertise of clinicians. New products are reality-tested with clinicians. We do not want to lose this relationship, but we must remain ethical and abide by the rules.

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DR. HARRIS: The dinner spending may be reported as $250 when you did not eat $250 worth of food. It depends on company spending and how it is reported. Massachusetts is particularly strict, and it captures the public's attention.

I'd like to discuss another important aspect of product design--intellectual property. If you work at an institution, you are never free from the influence of your institution. Years ago, a surgeon at MGH invented a product that was outside of his specialty and line of practice. It was very unique and in a completely different area. However, a legal ruling supported that MGH owned the intellectual property. This is a different relationship than if one were in private practice, and surgeons have left academics for the private sector in order to pursue ideas without the secondary conflict of IP ownership.

DR. KANG: The institution, by contract, owns the invention. If I invented a cure for rheumatoid arthritis, the company that develops it owns the product and pays out royalties. Typically, 50% of the royalties may go to the institution, 25% to the individual, and the 25% to the individual's department. The majority of royalties stay within the institution. Even with dated and signed documents and associated patents, it is very difficult to demonstrate that the development of a product was completely independent from an institution.

DR. DYER: There is additional conflict when inventors prescribe use of their product to patients, as it can be seen as a self-referral. However, you can imagine that an inventor may believe—with the highest moral integrity—that their product is the best option for the patient.

DR. KANG: Neither you nor your institution may collect royalties on the utilization of your own invention. You can use it but not make money by doing so.

DR. WRIGHT: For example, I once received a radiology report from a radiologist who was a principle inventor for an implant company. In the impression, it stated that the patient would be an ideal candidate for a specific device. That is crossing the line. It was a very interesting radiology report, to say the least.

DR. HARRIS: You should disclose to the patient that you have been involved in designing the product but that you do not receive royalties by utilizing it. Your royalties must come from the utilization at outside institutions.

Also, you often need approval to obtain certain products at larger institutions. Interestingly, the vitamin E polyethylene, a product that was invented in the Partners system, was not approved by Partners for clinical use due to its high cost.[8] At meetings and lectures, the inventors had to discuss registry data because they could not describe their own clinical experiences with the polyethylene.

DR. WRIGHT: The Value and Technology (VAT) and Perioperative Products Committee at Partners reviews price and clinical efficacy data before approving product selection.

DR. HARRIS: Does the need for efficacy data drive companies to perform trials elsewhere in order to speed up the process before bringing technology to the US?

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DR. WRIGHT: The FDA usually approves products years before Europe. Generally, the clinical information is generated in the US. There are some other places, such as New Zealand and Israel, where regulatory requirements are different and FDA approval is usually sufficient and can generate data. European approval, however, is very burdensome and requires a long time.

Can you explain how you proceed with the evaluation of new technology for introduction into your practice?

DR. DYER: I never try a new technology simply because it is new. It has to solve a clinical problem that I have, and I often don't want to be the first or last to adopt something. Actually, I'm willing to be the last, but I do not typically want to be the first. Also, my first use of something is not with a patient. Superior capsular reconstruction is an example of new procedure and technology that I introduced into my practice a few years ago.[9] It was a hot, new procedure that solved a problem that almost every shoulder surgeon had encountered. "What do I do with someone who has an irreparable rotator cuff tear but is far too young for arthroplasty and their joint is still okay?" There was no good answer before SCR. I read about the procedure and spoke to friends who had performed it. I approached a company with a device and asked for them to set up a cadaver lab so that I could practice the procedure before attempting it on a patient. I practiced until I was convinced that I could perform it safely in a patient. This isn't the only way to introduce a new technique or technology, but it's a reasonable process.

DR. KANG: In orthopedics, we are inundated with a multitude of new implants that debut each year. The real question is "how do you evaluate the data and information? Is this a reinvention of old technology or techniques or is it a paradigm shift?" If you are a new practitioner trying to evaluate a new technology, I think you must progress through a couple of checkpoints. When new implants come out, I advise not to immediately jump on. If you're the one to do the first 1000 cases and something goes wrong, you are going to be in big trouble--metal on metal arthroplasty for example. I hate to say it, but the first wave is often driven by conflicted surgeons. Another example: the use of BMP in spine. The first series of articles were written by heavily conflicted surgeons making millions of dollars with a company. Then there was a wave of data by non-conflicted surgeons that highlighted complications that were not reported initially. This was a better picture of the truth--that BMP can help, but it does have complications. If you were a young surgeon who just jumped aboard and was using BMP in the cervical spine, you would be in trouble. You have to evaluate literature on new technology by looking at the authors and evaluating conflicts of interest. I'm not accusing people of lying, but omissions seem to happen when people are conflicted.

There is a principle called Scott's parabola which describes the introduction of new technology that is prematurely introduced and not backed up with rigorous data.[10] Enthusiasm by conflicted surgeons leads to wider use, and then there is the realization of complications once the technology gets into the hands of non-conflicted practicing surgeons. Finally, there is legal involvement and the eventual death of this new technology. There are many examples of this in orthopedics.

DR. WRIGHT: There are a number of pathways through which we introduce new products. If a product or technique is uncommon and difficult, we may require training before we will sell it. That is not typical, however. In order to prevent the safety issues that were previously discussed, we sometimes perform an early performance program where we limit the utilization to 25 surgeons for 2 years. This exerts a sizeable economic load and may affect the commercial viability of a product, but it allows us to ensure safety before a wide release. There are other approaches though.

Another example of enthusiastically hyped new approaches is two-incision hip surgery.[11] Nobody does it anymore, but it was an incredibly powerful market driver for community hospitals at one point. It rose to prominence by surgeons attending a manufacturer-subsidized course to learn the procedure with specific devices and instruments. It was a training program to sell instrumentation based on a technique. By teaching the technique, companies gained influence over the devices that were used because special retractors and instruments were needed.

DR. DYER: As a resident during that time, I saw conflicts everywhere. I had heard of studies being performed by surgeons who would scold the overnight resident for transfusing a two-incision hip patient--regardless of hematocrit or symptoms. The data just had to be better. It was awful. The procedure sometimes had higher blood loss and was not necessarily better, and residents were reportedly pressured by conflicted attendings to not transfuse patients who might have needed it.

DR. WRIGHT: There were surgeons who built their entire practice on two-incision hip surgery, and it was an invalid procedure from the start.

DR. KANG: Some of the early data showed these amazing results of patients walking down the hallway and going home the next day. Previously, these patients would stay in the hospital for a week. This was a paradigm shift with having patients walking the same day.

DR. WRIGHT: What we really learned from two-incision technique are the improvements in post-operative protocols and perioperative pain management. Setting expectations and selecting your patients determined the outcomes as opposed to just the technique.

DR. DYER: It's fascinating. A failed innovation that made us think out of the box actually improved arthroplasty.

What about robots and industry?

DR. WRIGHT: Robots are interesting. If you accept the value proposition that new products and techniques should do one of two things: either:

1. *Improve the patients' outcome or*
2. *Reduce the cost of care and delivering that outcome*

Does the current generation of robots do that? No, not really. In orthopedics currently, robots earn market share. Patients like robots, and surgeons like patients. That drives a lot of business toward people with robots, but it has not yet been demonstrated that robots lower costs, increase efficiency, or improve outcomes.

Maybe this is part of an evolutionary cycle, and we will develop robots that become necessary for surgery in order to deliver personalized surgeries for patients with precision. However, I think a robot should really be a way of gathering data to figure out precisely what was done in an operating room and feeding data back into an algorithm to determine what the procedure should be for the next patient. That's not happening yet, but it's probably the future.

"By teaching the technique, companies gained influence over the devices that were used because special retractors and instruments were needed."

DR. DYER: For several years, robotic surgery made the outcomes for prostatectomy worse. Oncologic control and complications were worse compared to skillful, open prostatectomy. This was even true for the specifically targeted patients for whom it was thought to be optimal. As learning curves were surpassed, this may have balanced out. I think that the robot's initial adoption was really driven by marketing because just as you said - patients like robots.

What are your thoughts on marketing directed toward patients? It seems that robots are actively being targeted toward the general public. How are institutions adapting?

DR. WRIGHT: The missing aspect of this marketing is the transparency of value—costs versus outcome—to patients. Reasonable change needs to be driven by transparency of value and outcomes.

DR. KANG: We are leasing a robot for specific reasons. Some of this is marketing but mainly it is to augment younger surgeons who may not be as adept as senior surgeons at making blind cuts. There is no data to support this, but it may help early surgeons in their first hundred or so operations make more precise cuts and removing the variation from the equation. Since the robot is controlling the cut, it should add to safety by preventing the ability to encounter the popliteal artery, for example. I didn't know much about the robot, so I went and tested it myself since I've obviously done a TKA before. It takes a little bit longer, but there is a level of safety to it especially when working with a trainee.

DR. WRIGHT: To put that into context, I'm unaware of a popliteal artery injury at this hospital in the last 30 years.

DR. DYER: However, we have had some expert surgeons in this hospital for a long time. I've always thought that the value of the robot is in the hands of younger, less experienced, or low-volume surgeons.

DR. KANG: In terms of how an institution decides to adopt robots, there's no question that some of this is marketing. This is America. If there's a demand, someone is going to supply it. Every competing institution wants a competitive advantage. I'm not a fool, however. I needed compelling reasons to spend the money on a robot. My reasons were for education and research. To have a

device that can make and record precise cuts and then you track outcomes with exceptional researchers like Antonia Chen—it can really be a valuable tool. There is also a tremendous demand by residents going into arthroplasty because there is an appearance of "outdated training" if you never had the opportunity to learn how to use robots. Even if none of the existing senior faculty want to use it, younger surgeons, fellows, and residents are asking for it. It may be right or wrong, but this kind of educational experience is important.

DR. WRIGHT: I agree that there is a role for robots in the future, but it would have to be a robot that helps me do an operation faster and with better outcomes. People used to ask me why I didn't use a robot to navigate a total knee. I maybe had an error of 1-2 degree in alignment, but it is not clear what that error means for the patient's outcome. I cannot justify the time and expense on navigation for precision when I do not yet know what the true target is.

DR. DYER: Precise but potentially inaccurate.

DR. WRIGHT: Yes. Once we know what the solutions are and gather the data to make predictive algorithms, then precision becomes really important. Navigation alone is not sufficient because you are still making hand cuts which we know have a significant error in them. A robot making a precise and correct cut in order to optimize outcomes—that is the difference maker. Then the recording of what was done in the procedure will also be very important.

I was at a Chinese Orthopaedic Association meeting in November, and every single Chinese manufacturer had a spine robot on their stand. The Chinese market is interesting because it used to be made up of start-ups and me-too devices, but gradually they are developing an oligopoly on robots. It is starting to look more like American device companies. Some of the products are truly impressive.

DR. HARRIS: I feel that the industry is shifting. Instead of simply the sale of an implant, it will become the package of robot and technology. That will be the shift. A robotic system will perform a certain procedure better, but it will only fit a certain screw or apparatus. The implants will become the commodity while the robot is the real technology.

DR. WRIGHT: As we become more accountable for outcomes and study them more, it is clear that the implant often doesn't determine the outcome. It likely will not be the robot, either. It will be the control of the entire episode of care by patient characterization and optimization so you are operating on the right patient, at the right time, with the right tools and devices to improve efficiency and precision, and following the right rehabilitation program. As we move to that system, determining the factors that matter will be really important. In order to do this, we need access to the data that clinicians provide. That's why a partnership is so important.

DR. KANG: You can't just separate clinicians from industry. Partnership and ethical behavior is important to bring new technology into the market. We'll just have to sort through the data and judge its value.

"You can't just separate clinicians from industry."

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