COMMERCIAL INTERVIEW

The Pransky interview: Professor Jacob Rosen, Co-Founder of Applied Dexterity and ExoSense

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Abstract

Purpose – The following article is a "Q&A interview" conducted by Joanne Pransky of *Industrial Robot* journal as a method to impart the combined technological, business and personal experience of a prominent, robotic industry engineer-turned-entrepreneur regarding the evolution, commercialization and challenges of bringing a technological invention to market. The paper aims to discuss these issues.

Design/methodology/approach – The interviewee is Jacob Rosen, a Professor of Medical Robotics at the Department of Mechanical and Aerospace Engineering, University of California, Los Angeles (UCLA), where he directs the Bionics Lab. Professor Rosen is also the Director of Surgical Robotics Engineering at the UCLA School of Medicine's Center for Advanced Surgical and Interventional Technology and has joint appointments at UCLA's Department of Surgery and UCLA's Department of Bioengineering. Professor Rosen is the co-founder of the companies Applied Dexterity, ExoSense and SPI. As a pioneer in medical robotics devices and technologies, Professor Rosen describes his unique approaches and philosophies.

Findings – Dr Rosen received his BSc degree in Mechanical Engineering, MSc and PhD degrees in Biomedical Engineering from Tel-Aviv University in 1987, 1993 and 1997, respectively. From 1987 to 1992, he served as an officer in the Israeli Defense Forces studying human–machine interfaces. From 1993 to 1997, he was a research associate at Tel-Aviv University, as well as held a position at a startup company developing innovative orthopedic spine/pelvis implants. From 2001-2013, he held faculty positions at the University of Washington and at University of California, Santa Cruz.

Originality/value – Dr Rosen developed several key systems in the field of medical robotics, such as the Blue and the Red Dragon, for minimally invasive surgical skill evaluation; RAVEN, a surgical robotic system for telesurgery; and several generations of upper and lower limb exoskeletons including the Exo-UL7 – a dual arm wearable robotic system. He is a co-author of 100 manuscripts in the field of medical robotics and a co-author and co-editor of two books entitled "Surgical Robotics – Systems, Applications, and Visions" and "Redundancy in Robot Manipulators and Multi-robot systems" published by Springer. Professor Rosen has filed eight different patent applications and also works as an expert witness and consultant on design, patent protection & litigation and malpractice regarding surgical robotics.

Keywords Teleoperation, Exoskeletons, Medical robots, Rehabilitation robots, Surgical robots, Man machine interface (MMI)

Paper type Case study

Pransky: Your philosophy seems to be very much one of collaboration between research groups in the development of the RAVEN and also the end goal of collaboration between surgeons working together on a single patient. Is this an accurate summary? And where did this drive towards collaboration originate? (Figure 1)

Rosen: I did my undergraduate study in mechanical engineering which gave me a solid foundation in science and engineering. My graduate studies were in biomedical engineering, a field that attracted me given its multidisciplinary and collaborative nature. Medicine is a problem rich environment and engineering is a solution rich environment. When you marry the two, you establish a fruitful ground for innovative research and development. This is exactly the space that I wanted to operate in – full of new problems with an altruistic social impact. In surgery, collaboration is the *modus operandi*. Surgeons collaborate in the operating room in part because the cognitive load and the motor control load are too high for a single surgeon to cope with. As a result, there are typically two surgeons interacting with the surgical site. When surgical robotics were first introduced into the operating room, these dynamics changed completely and this collaboration was broken by putting in a single surgeon who was physically

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Figure 1 Professor Jacob Rosen, Co-Founder of Applied Dexterity and ExoSense

removed from the patient and now teleoperating from a surgical console. We developed the RAVEN surgical robotic system, in part, to foster collaboration by reproducing the original dynamics of two surgeons in two remote locations interacting with the surgical site, using one four-arm robotic system with two cameras (Figure 2).

From the engineering research perspective in developing the RAVEN, we took an open and collaborative approach right from the beginning by developing a resource many labs could benefit from. Not every lab can develop a surgical robot, although many labs focus on algorithm development for surgical robotics. With a grant from the National Science Foundation, we produced seven identical copies of the RAVEN system as an open source/open platform and gave the RAVEN systems away essentially for free to major universities in the USA, thereby creating a network of researchers for collaboration, sharing of results and the facilitation of more rapid progress. Later on Applied Dexterity *applieddexterity.com* evolved as a spinoff company to address unmet needs by research labs across the globe for an open platform. Currently, there are 18 sites

Figure 2 Two surgeons collaboratively teleoperate the RAVEN IV robot system located 900 miles away

using RAVEN on three continents with a total of more than 20 RAVEN robots (Figure 3).

Pransky: How did you first come up with the concept of the RAVEN?

Rosen: When I started my post-doctoral studies at the University of Washington in 1997, along with my mentors Professors Blake Hannaford and Surgeon Mika Sinanan, we studied algorithms that could objectively assess surgical skills in minimally invasive surgery (MIS). We used, in part, Hidden Markov Models, a method that was previously applied in speech recognition. This unexpected association of the modeling approach led me to the conclusion that MIS is essentially a spoken language with various words and different pronunciations used by all surgeons trying to tell the same story as they operate, regardless of their skill level. The research challenge was to identify the words, pronunciation and the rules of grammar of surgery and use this framework to assess surgical skills objectively.

By analyzing hundreds of hours of surgical procedures, we managed to develop a model of specific surgical tasks for each skill level representing the training or expert levels. A byproduct of this massive data collection of quantitative data that was recorded from instrumented surgical tools allowed us to gather the engineering specifications of a new surgical robot. The

Figure 3 Rosen and team members distributed seven RAVEN II surgical robotic systems to other labs

Source: Carolyn Lagattuta

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RAVEN was later developed based on this unique data with the help of an award by the USA Army.

Pransky: What significant developments in the RAVEN have originated from one of the developers?

Rosen: The vast majority of the robotics labs in the USA are focused on algorithm developments, a situation that is unique to the USA. Current and future research with the RAVEN by the Bionics Lab, a lab that I direct at UCLA, along with other colleagues worldwide is focused on automation in surgery, as well as different modes of collaborations between surgeons and autonomous agents who share the common surgical site. The philosophy behind this is that we want to move the surgeon from someone who is holding, manipulating and controlling the tools to someone who is making decisions as to when and how to proceed in a surgical procedure. The research efforts are not trying to automate the entire surgery from beginning to end but, at this point, only to focus on repetitive subtasks in surgery. The human is making decisions and can intervene at any point, but the robot is an automatic agent that can suture and manipulate tools, tissue and make dissections.

Pransky: What are the technical risks of collaboration?

Rosen: Technical risks depend if a human surgeon is collaborating with another human being versus collaborating with an autonomous agent/machine. There are no risks *per se* when the two surgeons are humans because their roles are well-defined. There is a primary surgeon who is responsible for making all the decisions and for making all the critical steps of the operation. And there is an assistant who is aiding in different retracting, suctioning and irrigation functions and positioning the anatomy in different ways.

The risk in automation is obviously when the algorithm behaves in an unpredictable way. There is a high problematic expectation by humans, expressed as a zero tolerance toward errors, once the task is handed to an autonomous machine. For example, if a human is driving a car and gets into an accident, it is totally acceptable because that is just the nature of a human making the wrong decision. However, if you are trying to automate the driving, the expectation is that the automation will be flawless, meaning if the algorithm controlling the car makes a mistake which leads to an accident, this would be unacceptable. The expectations from autonomous systems are much higher than what is expected from humans and that is a very high bar to meet for those of us who are developing automation in a complex environment such as surgery. Therefore, we have to be very careful in what we deliver, and we cannot really take the same risks as a human who will take risks in some circumstances and may be excused if the risk ends up with some trauma or some unexpected result.

Pransky: What modification does the RAVEN IV have that differ from the previous RAVEN version?

Rosen: Our goal from the redesign of RAVEN I to the RAVEN II was to try to create a detailed optimization of the surgical manipulators that minimizes the footprint of the system in the operational field while maximizing the manipulability of the arms in their shared workspace. Thus, we changed the design to four arms above the patient without compromising operational performance and while avoiding collisions and facilitating the collaboration of two surgeons each holding a pair of tools. RAVEN IV was essentially two sets of RAVEN II (Figures 4 and 5).

Pransky: Do you have any plans for clinical trials?

Rosen: Applied Dexterity is seeking funding for the commercialization of the RAVEN as a clinically approved system. All the clinical trials, which are necessary for commercialization in the USA, will be part of this effort.

It's also interesting to look at how the Food and Drug Administration is viewing surgical robotic technology given the experience accumulated in the past two decades. Back in 2001, the FDA approved Intuitive Surgical's Da Vinci system through their 510(k) premarket notification program www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K002489%20 with the FDA classifying it essentially as a system that is not significantly different than minimally invasive surgical tools already on the market. However, each surgical procedure had to be approved individually.

In the summer of 2015, the FDA held a Workshop on Robotically-Assisted Surgical (RAS) Devices www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm435255.htm. They invited experts in the field to better understand what should be included in approving or disapproving robotic surgical systems since this process can affect in part, the price point of such systems.

The FDA approval of medical devices and drugs philosophically reflects the conservative field of medicine since human lives are at stake. The FDA process for a RAS

Figure 4 RAVEN I system overview

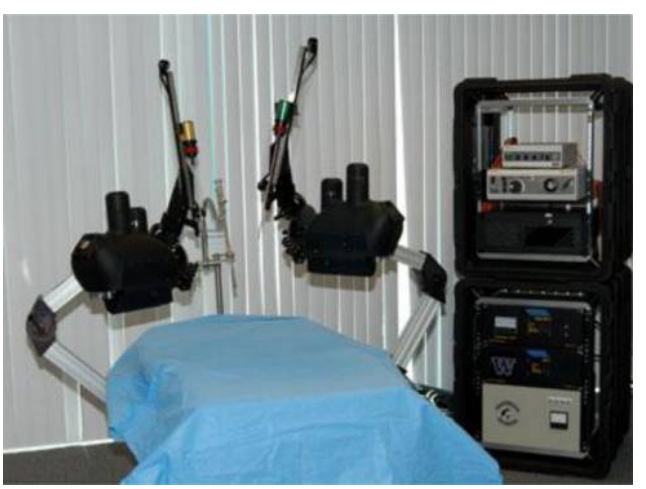


Figure 5 (a) RAVEN IV and its (b) Surgical Cockpit featured in the NBC TV show Heartbeat (image credit NBC)

(a) (b)

device is exorbitant, costing approximately $100,000,000. RAS manufacturing companies are going elsewhere around the world where regulations are less stringent. Historically, the USA market was considered the primary, the biggest and the most prominent but now is not as strong as it used to be. The Asian market is emerging, where China, for instance, is three times the USA market or even more. The implications are that technology which is developed in the USA in part by taxpayer money eventually ends up in other countries because other countries are more receptive to it and willing to approve it at a lower cost. The cost of running clinical trials in the USA is about $100,000 per trial on a single subject. In China, for example, it's $5,000. Since Asia is such a large market with 5 per cent of the cost for essentially gaining the same approval, why should a company insist on operating and trying to get products through such an expensive and highly rated system as the USA? The USA public should be the first to benefit from the technology that was funded in part by its own tax money. The FDA is receptive to having discussions on these issues.

Pransky: Are electromyography (EMG) and the electrochemical mechanical delay the key to developing natural-feeling exoskeletons?

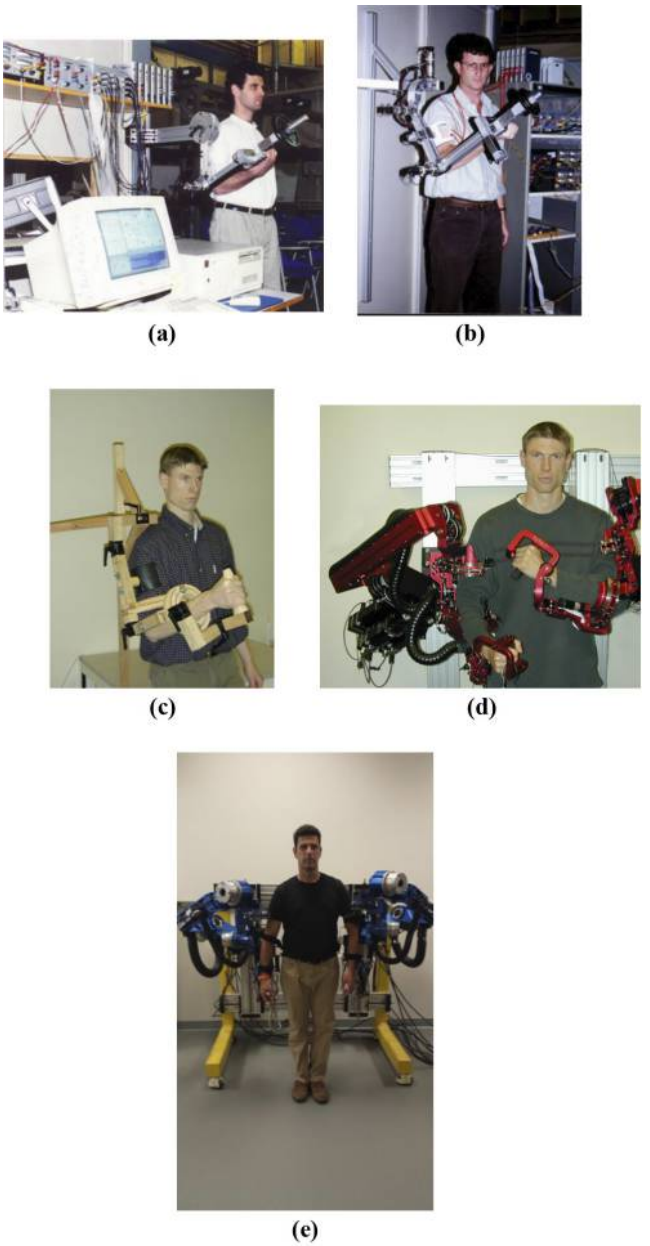
Rosen: In my early work in this field, I set the human machine interface at the neural level to assess neural activity using the EMG signal and to feed this information into a muscle model that takes into account the current muscle length and velocity and predicts the muscle force. Integrating multiple muscles into the correct human anatomy may allow the prediction of the joint torque since there is a delay between the point in time when the EMG can record and the point in time where the actual joint moment is developed. The prediction can be performed in this timeframe and fed into the exoskeleton system. By the time the human body moves, the exoskeleton moves with it without any delay.

Since this early work, my research shifted into how the physical interaction and manipulation of the human arms may generate new neural connections in the brain. This problem is studied in the context of stroke recovery and rehabilitation, in the learning of both cognitive and motor control tasks. My research interests are in part based on neuroscience theory, claiming that mirror image symmetric motions are our fundamental way of moving. Since only half of the body is paralyzed in stroke cases, we study how the exoskeleton operating in a local mirror image teleoperation can lead to the brain recovery – a mode of operation in which the healthy side of the body drives the disabled part of the body through the exoskeleton system (Figure 6).

Pransky: Can you talk about the funding and intellectual property of your other companies: Exosense and SPI and about the greatest challenges you faced with each of these companies?

Rosen: They are essentially all startups but each one is evolving in a different direction driven by different market forces. The challenge – and all have IP and potential for commercial products – is to find investors, which is certainly not unique. Investment in medical devices is particularly problematic for two reasons: the time to market is typically longer than other products and the FDA approval is a costly process. Products developed by Applied Dexterity and SPI are classified by the FDA as Class II devices (devices that penetrate through the skin and removed at the end of the procedure) which are subject to premarketing approval; however, Exosense, which is trying to commercialize the exoskeleton, is not, because the exoskeleton is classified by the FDA as a Class I (devices that do not penetrate the skin), similar to say, gym equipment that is used for rehabilitation, which means they can be sold even without FDA approval as long as no claims are made for any therapeutic qualities to it. As a result, the

Figure 6 Evolution of the various generations of the exoskeleton system



Notes: (a) EXO-UL1; (b) EXO-UL3; (c) Wooden mockup of EXO-UL7; (d) EXO-UL7; (e) EXO-UL8

regulatory barriers for the exoskeleton to get into the market are much lower than surgical robotic systems.

The business dynamics in surgical robotics is currently under rapid change given the significant commercial success of these systems. Well-established companies in the field of surgical tools with an existing presence in hospitals are getting into the market with new surgical robotic platforms. They view the surgical robot platform as an incentive to sell more surgical tools and to rely more on yearly contracts of supplying tools than the current model in which the initial sale of the surgical robotic system itself is the source of about half of the revenue.

Pransky: What is the greatest mistake or the greatest lesson that you have learned?

Rosen: Early in my graduate studies, I was involved in designing orthopedic implants. I worked with an orthopedic surgeon on a new approach for a spine fusion system of a broken sacrum (aka the tail bone) with a single implant that applied to a very wide spectrum of human anatomies to allow the fracture in the sacrum to heal. The mistake that we made in an attempt to meet the design requirements was putting too many features into a single implant instead of designing multiple implants for various anatomical dimensions. The take-home message from this experience is that incorporating many features that the user will never use is a result of a bad design process. I learned this lesson the hard way, but, since then, minimalism in design is the mantra that I teach my students.

Pransky: Let's assume that your life is only 50 per cent complete. What groundbreaking challenges do you think you'll be working on 25 and 50 years from now?

Rosen: Communicating directly with our brains is likely to be a long-term major challenge for humankind. The brain's anatomy, unlike any other organ in our body, does not in most cases teach us about its function. Although we understand how a single neuron works to some extent, we are far from understanding the function of the brain's network as a whole and in particular the effects of brain damage.

From the human machine interface perspective, it is critical to create a reliable neural interface somewhere along the neural system that the body will not reject over time and yet will also allow access of both downstream and upstream flows of information. With downstream information, peripheral devices in our environment may be able to be controlled such as orthotic or prosthetic devices; when tapping into upstream information, learning processes that bypass our senses may be able to be imposed, including for example, uploading a book or acquiring a motor skill directly to the brain or communicating and processing information between humans or a computer in a nonverbal way. I don't know if these capabilities are feasible in the next decades but they will certainly upgrade us beyond our Homo sapiens nature.

Pransky: What do you think is the single most important thing we can be doing for our PhDs to prepare them for the commercial world?

Rosen: I would like them all to experience the rare moment in which they analyze data or develop a new body of knowledge that no one before them has understood or known. The byproduct of every trained student, whether it's an undergraduate or a graduate, is teaching them how to think. We can teach them how to think indirectly by teaching math, science and engineering, but, eventually, we want them to apply this knowledge and to be able to think creatively and critically. I don't know if there is a way to teach it directly but indirectly that's what I want to accomplish.

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About the author

Joanne Pransky has been an Associate Editor for *Industrial Robot* journal since 1995. Joanne was also one of the co-founders and the Director of Marketing of the world's first medical robotics journal, *The International Journal of Medical Robotics and Computer Assisted Surgery*. Joanne served as the Senior Sales and Marketing Executive for Sankyo Robotics, a world-leading manufacturer of industrial robot systems, for more than a decade. Joanne has also consulted for some of the industry's top robotic and entertainment organizations including Robotic Industries Association, Motoman, Staubli, KUKA Robotics, STRobotics, DreamWorks, Warner Bros., as well as for Summit Entertainment's film "Ender's Game" in which she brought never-seen-before medical robots to the big screen. Joanne Pransky can be contacted at: drjoanne@robot.md