# I Did It My Way:
# On Law And Operator Signatures for Teleoperated Robots

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## Abstract

Teleoperated robotic systems are those where a human operator controls a remote robot through a communication network. In surgery, bomb disposal, underwater exploration, and other applications, institutions such as courts, agencies, and firms will want to determine and verify the identity, skill level, and other traits of the remote operator. The concept of an *operator signature* represents a new approach to monitor, analyze, and validate operators' performance. This approach is based on the assumption that each operator interacts with a remote robot in a unique way, thus generating a unique biometric (signature), which can be extracted and used for further validation.

This paper discusses preliminary legal and policy applications of operator signatures for teleoperated robotic surgical procedures. We first provide a background of teleoperated robotic systems, and introduce the concept of operator signatures. We then discuss some cyber-security risks that may arise during teleoperated procedures, and describe the three main task operator signatures seek to address—identification, authentication, and evaluation. Third, we discuss legal benefits from operator signatures. In particular, we discuss how operator signatures can refine the standard of care for robotic surgical procedures. We discuss how operator signatures may—possibly for the first time—provide objective empirical evidence of an individual operator's actions *during* robotic surgery. Fourth, we consider various scenarios where operator signatures may be applicable. Finally, we provide preliminary guidance on how to balance the need to mitigate cyber-security risks with the desire to enable adoption of teleoperation.

## 1. Introduction

In teleoperated robotic systems, one or more human operators control a remote robot through a communication network, which may combine the existing publicly available networks with temporary *ad-hoc* and satellite networks. In recent years, such systems have experienced growth in a variety of applications, including medical procedures, underwater, ground and aerial exploration, near-orbit inspection and repair, teleoperated mining, minefield detection, battlefield operation, as well as search and rescue missions.

Teleoperated robotic surgery is a particularly important application of teleoperation. By enabling expert surgery to be performed remotely and without direct human presence, it is expected to have a huge impact on the quality of medical care that can be delivered in isolated regions, battlefields, or disaster areas. Yet, even in these areas, where operating conditions may be too harsh or downright dangerous for human experts, certain expectations on the minimum level of care delivered during teleoperated surgical procedures exist. Those may, for example, include: establishing and maintaining physical safety of a patient and of medical personnel in the vicinity of the robot, maintaining and establishing patient's privacy, and making sure no unnecessary steps, which would potentially prolong the procedure or subsequent recovery, are executed.

However, verifying that these requirements are established and maintained during a teleoperated procedure is hard. There exist three possible sources of difficulty: (i) a robot may mechanically fail, (ii) an operator may commit an error, or (iii) the communication link between an operator and a robot may fail, or it may get compromised.

As surgical robots become more commonly used, it will be increasingly important to understand how operators make use of these networked cyberphysical systems. To that end, robots are being equipped with sophisticated sensors, and data-driven processing techniques are becoming sufficiently advanced that it will be possible to examine how *individuals* use surgical robots. Similar to how signatures and handwritings can be uniquely attributed to individuals, operators have a unique way of interacting with remote robots.

### *1.1. Operators Signatures*

Based on the assumption that each operator interacts with a remote robot in a unique way, thus generating a unique biometric, we introduce the concept of *operator signatures* as a way of minimizing the risk that possible sources of failure may have on teleoperated surgical procedures. We expect these operator signatures to be useful for three main purposes. First, they will be used in *operator identification*. The signatures will provide basic identification, which can be used to actively ensure a particular operator is performing the operation. Second, operator signatures will be used to *authenticate the operator*. Third, operator signatures will be used for *real-time monitoring,* for evaluation, as well as for anomalous activity detection.

The use of operator signatures for identification, authentication and real-time monitoring (evaluation) is expected to be especially helpful against a number of cyber-security threats, which may be mounted against teleoperated systems. Those may include man-in-the-middle attacks, message modification, replay attacks, delay attacks, as well as spoofing. In addition, operator signatures provide an efficient and reliable logging, forensic and training method. The properties that make operator signatures a viable tool for securing systems against cyber-security threats also can become a strong evidentiary tool with legal implications in the realms of liability and medical malpractice.

### *1.2. Our Contributions*

In this paper, we consider the ways in which operator signatures can help resolve difficult legal problems of accountability. In particular, we consider how operator signatures can refine the standard of care for surgical robotics. We do this by discussing various benefits of operator signatures according to its main features—Identification, Authentication, and Evaluation. Then we discuss a series of practical scenarios where operator signatures may be useful. In each scenario, we discuss whether, in certain scenarios, the liability may fall on the operator, the facility providing a teleoperated procedure (such as a hospital), the robotics manufacturer, or a potential intervening operator.

Through these contributions we demonstrate that operator signatures can be used to help mitigate cyber-security risks, and that implementing operator signatures for teleoperations can aid in solving legal issues. In doing so, we hope to encourage innovation and adoption of teleoperations in a manner that realistically helps mitigate cyber-security risks, and provides better legal predictability for involved actors.

## 2. Background

In teleoperated robotic systems, one or more human operators control a remote robot (often referred to as a manipulator or end-effector) through a communication network that may combine private, publicly available, as well as temporary *ad-hoc* and satellite networks. In recent years, teleoperated robotics has experienced a rapid growth in medical and underwater applications, ground and aerial exploration, near-orbit inspection and repair, teleoperated mining, minefield clean up, battlefields, as well as in search and rescue missions.

Teleoperated robotic systems have had an especially profound effect on the field of surgery. Surgical manipulators have enhanced surgeons' capabilities in both open and minimally invasive surgeries,[1] and it has been shown that robot-assisted procedures result in less injuries and faster patient recovery[2].

### *2.1. A Brief History of Robotic Surgery*

The first use of robots in surgery dates to 1985, when a *Puma 560* industrial robot was used for needle placement in brain biopsy[3]. In 1988, the *Probot* (developed by Imperial College) was used to perform prostate surgery[4]. The first teleoperated surgical manipulator, where the surgeon indirectly controls the robot manipulator through a computer, was the *M7*, developed by Stanford

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[1] R. Satava, *Future directions in robotic surgery, in* Surgical Robotics: Systems Applications, Systems Applications and Visions, pages 3–11. (2010).

[2] S. Marecik, V. Chaudhry, A. Jan, R. Pearl, J. Park, & L. Prasad, *A comparison of robotic, laparoscopic, and hand-sewn intestinal sutured anastomoses performed by residents*, 193 *American Journal of Surgery*, no. 3, 349–355 (2007). J. Hu, X. Gu, S. Lipsitz, M. Barry, A. D'Amico, A. Weinberg, and N. Keating, "Comparative effectiveness of minimally invasive vs. open radical prostatectomy," 302 *The Journal of the American Medical Association*,, no. 14,. 1557–1564, (2009).

[3] S. Kalan, S. Chauhan, R. Coelho, M. Orvieto, I. Camacho, K. Palmer, and V. Patel, "History of robotic surgery," 4 *Journal of Robotic Surgery*, no. 3,. 141–147, (2010).

[4] *Id.*

Research Institute (SRI) in the 1990s[5]. The development of robotic surgery procedures was further enabled by the advent of three commercial systems: the *Aesop* and *Zeus* (Computer Motion) and the *da Vinci* (Intuitive Surgical)[6]. The *da Vinci* system is currently the only commercially available and FDA approved system. It has been installed in over 3000 hospitals worldwide, and more than 570 000 procedures performed in 2014[7].

Given that the surgeon operates a surgical robot through a computer interface and video display, telesurgery across a network was an obvious extension. The first transatlantic telesurgery, over a dedicated Asynchronous Transfer Mode (ATM) network, was performed in September 2001. Doctors Marescaux and Gagner used the *Zeus* system to operate from New York City on a patient in Strasbourg[8].

### *2.2. The Next Generation of Telerobotic Surgery Systems*

There are currently several active research efforts developing new surgical manipulators and surgeon control stations (consoles). One example is the *Ibis IV*, pneumatically actuated minimally invasive surgical manipulator[9], and a master system based on a delta motion platform[10] (Tokyo Institute of Technology). Another example is an upper-limb exoskeleton master station that allows for whole-arm motion to be scaled down for surgical tasks (UC Santa Cruz)[11].

In some of the future applications, such systems may have to operate lacking basic infrastructure, and with limited power resources[12]. Restrictive operating conditions, which may include high

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5 A. Yoo, G. Gilbert, and T. Broderick, "Military robotic combat casualty extraction and care," in *Surgical Robotics: Systems Applications and Visions*. 13–31, (2010).

6 Marecik, Chaudry, et. al., *supra*, n. 3.

7 Intuitive Surgical. "The Intuitive Surgical Investor FAQ," Available at http://phx.corporate-ir.net/phoenix.zhtml?c=122359&p=irol-faq#22324

8 J. Marescaux, J. Leroy, M. Gagner, F. Rubino, D. Mutter, M. Vix, S. Butner, and M. Smith, "Transatlantic robot-assisted telesurgery," 413 *Nature*, , no. 6854, 379–380, (2001).

9 K. Tadano and K. Kawashima, "Development of a pneumatically driven forceps manipulator Ibis iv," in the *Proceedings of the IEEE International Joint Conference ICCAS-SICE*, 3815–3818, (2009).

10 K. Tadano and K. Kawashima, "Development of a master-slave system with force sensing using pneumatic servo system for laparoscopic surgery," in the *Proceedings of the IEEE International Conference on Robotics and Automation*, 947–952, (2007).

11 J. Perry and J. Rosen, "Design of a 7 degree-of-freedom upper-limb powered exoskeleton," in the *Proceedings of the 1st IEEE/RAS-EMBS International Conference on Biomedical Robotics and Biomechatronics*, . 805–810 (2006).

12 R. Satava, *supra*, n. 1.

temperatures, humidity or pressure, may significantly increase the probabilities of mechanical errors on the remote robot's side. Moreover, harsh conditions may negatively impact operator's performance, by potentially increasing the fatigue level or causing procedural anomalies. In both cases, a teleoperated robotic system may perform sub-optimally.

### *2.3. Extreme Environments Experiments*

In recent years, several non-clinical teleoperation experiments were conducted in extreme environments, using the *Raven* and the *M7* system[13]. In the Hap/SMRT field experiment[14], the *Raven surgical robotic system* was deployed in the Mojave Desert. It was controlled across the Internet, with the final link being a UAV-enabled wireless network, where the UAV flew in a pattern around a MASH tent. In NEEMO 12 (mission 16), remote telesurgery was tested in an underwater habitation module in Florida[15]. In these experiments, the following network factors were recognized as critical to system's performance: (i) communication latency, (ii) jitter, (iii) packet delays and out-of-order arrivals, (iv) packet losses, and (v) devices failures[16].

In addition to system failures, caused by *benign* mechanical errors or operator anomalies, operator-robot interaction through a communication network exposes teleoperated procedures to a novel set of problems, *maliciously and intentionally* caused by attackers. The open and often uncontrollable nature of communication networks may allow potential attackers to jam, disrupt or even take over the communication link between robots and operators, in order to disrupt or prevent the remote procedure.

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[13] B. Harnett, C. Doarn, J. Rosen, B. Hannaford, and T. Broderick, "Evaluation of unmanned airborne vehicles and mobile robotic telesurgery in an extreme environment," 14 *Telemedicine and e-Health*, no. 6,. 539–544, (2008). H. King, B. Hannaford, K. Kwok, G. Yang, P. Griffiths, A. Okamura, I. Farkhatdinov, J. Ryu, G. Sankaranarayanan, V. Arikatla, K. Tadano, K. Kawashima, A. Peer, T. Schauss, M. Buss, L. Miller, D. Glozman, J. Rosen, and T. Low, "Plugfest 2009: Global interoperability in telerobotics and telemedicine," in the *Proceedings of the IEEE International Conference on Robotics and Automation*, . 1733–1738, (2010). M. Lum, D. Friedman, H. King, T. Broderick, M. Sinanan, J. Rosen, and B. Hannaford, "Field operation of a surgical robot via airborne wireless radio link," in the *Proceedings of the IEEE International Conference on Field and Service Robotics*, (2007). H. King, B. Hannaford, J. Kammerl, and E. Steinbach, "Establishing multimodal telepresence sessions using the session initiation protocol (SIP) and advanced haptic codecs," in the *Proceedings of the IEEE Haptics Symposium*, , 321–325, (2010).

[14] Lum, Friedman, King, et. al., *supra*, n. 13.

[15] [17] M. Lum, D. Friedman, G. Sankaranarayanan, H. King, A. Wright, M. Sinanan, T. Lendvay, J. Rosen, and B. Hannaford, "Objective assessment of telesurgical robot systems: Telerobotic FLS," 132 *Studies in Health Technology and Informatics*, ,260–263, (2008).

[16] M. Lum, J. Rosen, T. Lendvay, M. Sinanan, and B. Hannaford, "Effect of time delay on telesurgical performance," in the *Proceeding of the IEEE International Conference on Robotics and Automation*, 4246–4252, (2009).

## *2.4. An Overview of Security Methods for Teleoperated Robotic Systems*

The importance of information-security for telemedical applications has first been recognized in[17]. In these papers, however, the authors' primary concern was patient privacy, and they typically consider the confidentiality of transmitted and stored patient data. In separate research, authors consider security issues related to the delivery of medical data in multimedia form[18]. They present a simulated surgery procedure, and introduce an idea of a smart surgery room, monitoring actions of participating medical personnel.

Motivated by the Hap/SMRT experiment, several independent research projects recently recognized the importance of information security for telerobotic surgery systems[19]. For military telesurgical robot systems, the authors developed a novel, light-weight software-attestation tool. Other authors designed an information coding approach that guarantees communication privacy and reliability[20]. In "Cyberphysical Systems Security Applied to Telesurgical Robotics," the authors propose the use of the Transport Layer Security (TLS) protocol to ensure confidentiality, authentication and authorization of the Interoperability Teleoperation Protocol[21]. In discussing security threats against rescue robotic systems, two co-authors theoretically evaluated the security of a teleoperated robotic system applied in rescue mission[22]. In addition, the same group

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[17] N. Dowler and C. Hall, "Safety Issues in Telesurgery–Summary," in *IEEE Colloquium on Towards Telesurgery*. IET, 6–10, (1995). L. Makris, N. Argiriou, and M. Strintzis, "Network and Data Security Design for Telemedicine Applications," 22 *Informatics for Health and Social Care*, no. 2,. 133–142, (1997).
F. Wozak, T. Schabetsberger, and E. Ammmenwerth, "End-to-end Security in Telemedical Networks–A Practical Guideline," 76 *International Journal of Medical Informatics*, no. 5, 484–490, (2007).

[18] Y. Yang, Z. Wang, F. Bao, and R. Deng, "Secure the Image-based Simulated Telesurgery System," in the 2 *Proceedings of the International Symposium on Circuits and Systems*, (2003).

[19] *See* G. Lee and B. Thuraisingham, "Cyberphysical Systems Security Applied to Telesurgical Robotics," 34 *Computer Standards & Interfaces*, no. 1,. 225–229, (2012). M. Tozal, Y. Wang, E. Al-Shaer, K. Sarac, B. Thuraisingham, and B.-T. Chu, "Adaptive Information Coding for Secure and Reliable Wireless Telesurgery Communications," *Mobile Networks and Applications*,. 1–15, (2011). M. Tozal, Y. Wang, E. Al-Shaer, K. Sarac, B. Thuraisingham, and B.-T. Chu, "On Secure and Resilient Telesurgery Communications over Unreliable Networks," in the *Proceedings of the IEEE Conference on Computer Communications Workshops.*, 714–719, (2011). K. Coble, W. Wang, B. Chu, and Z. Li, "Secure Software Attestation for Military Telesurgical Robot Systems," in the *Proceedings of the Military Communications Conference.*,965–970, (2010). T. Bonaci and H. J. Chizeck, "On Potential Security Threats Against Rescue Robotic Systems", in the *Proceedings of the 10th IEEE International Symposium on Safety, Security, and Rescue Robotics*, (2012). T. Bonaci, J. Yan, J. Herron, T. Kohno and H. J. Chizeck, "Experimental Analysis of Denial-of-Service Attacks on Teleoperated Robotic Systems", in the *Proceedings of the 6th ACM/IEEE International Conference on Cyber-Physical Systems*, (2015).

[20] Tozal, Wang, Al-Shaer, et. al., *supra*.

[21] Lee and Thuraisingham, *supra* n. 19.

[22] Bonaci and Chizeck, *supra* n. 19.

of authors conducted an experimental security analysis of the next-generation teleoperated robotic surgery platform, Raven II, and evaluated impact of several classes of possible cyber-security attacks on teleoperators' performance[23].

### *2.5. Overview of Legal Cases Involving Robotic Surgery*

In the United States, there is only one FDA-approved surgical robotic system: the da Vinci. The da Vinci is developed, marketed, and supported by Intuitive Surgical[24]. Intuitive Surgical has been a party in a number of actions by surgical robotics patients, as have operators and hospitals.

Overall, Intuitive Surgical has been party to actions involving strict product liability[25], strict malfunction liability[26], negligence[27], breach of warranty[28], misrepresentation[29], medical malpractice[30], Fraud Claims Act[31], as well as others[32].

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23 T. Bonaci, J. Yan, J. Herron, T. Kohno and H. J. Chizeck, *supra* n. 19. T. Bonaci, J. Yan, J. Herron and H. J. Chizeck, "*supra* n. 19.

24 *See* "Intuitive Surgical" available at http://www.intuitivesurgical.com/

25 *Mracek v. Bryn Mawr Hosp.*, 363 F. App'x 925 (3d Cir. 2010). (unprecedential; affirming district court's order granting summary judgement for Intuitive Surgical and the hospital), *O'Brien v. Intuitive Surgical, Inc.*, 2011 U.S., U.S. Dist. LEXIS 80868 (N.D. Ill. July 25, 2011).

26 *Mracek,* 363 F. App'x 925 (3d Cir. 2010). (unprecedential)

27 *Id Taylor v. Intuitive Surgical Inc.*, No. 09-2-03136-5 (Kitsap County, Wash., Super. Ct. May 23, 2013) (alleging Intuitive failed to provide adequate warning or training to a surgeon who used the device during prostate surgery. A jury found Intuitive not liable).

28 *Mracek,* 363 F. App'x 925 (3d Cir. 2010). (unprecedential)

29 *O'Brien v. Intuitive Surgical, Inc.*, 2011 U.S. Dist. LEXIS 80868 (N.D. Ill. July 25, 2011).

30 *Silvestrini v. Intuitive Surgical, Inc.*, 2012 U.S. Dist. LEXIS 13801 (E.D. La. Feb. 6, 2012) (patient alleging Intuitive "manufactured, assembled, distributed, serviced and/or maintained the surgical robot, … was responsible for training [hospital] staff members to use the surgical robot and that such training was 'totally lacking or woefully inept or inadequate.' [Plaintiff] further asserts that Intuitive, by either agreement or contract, was to provide service personnel who could quickly 'troubleshoot' any problems with the robot by telephone"). *Dulski v. Intuitive Surgical, Inc.*, 2011 U.S. Dist. LEXIS 12651 (W.D.N.Y. Jan. 19, 2011) (holding that plaintiff improperly added Intuitive and its field engineer to the suit where plaintiff alleged that Intuitive "negligently, carelessly and recklessly designed, manufactured planned, maintained, repaired, sold and/or distributed" the da Vinci. "During the course of discovery…, plaintiffs learned that approximately 21 service calls costing $199,295 were made on the DaVinci robotic surgical device prior to [plaintiff's] surgery and that defendant [Intuitive field engineer] worked on the device 18 times and as recently as six days prior to plaintiff's surgery").

31 *United States ex rel. Antoon v. Cleveland Clinic Found.*, 978 F. Supp. 2d 880, 884 (S.D. Ohio 2013) (alleging "Intuitive knowingly and willfully paid remuneration directly or indirectly, overtly or covertly, in cash or in kind to Jihad Kaouk to induce Jihad Kaouk to recommend robotic surgery over other forms of surgery or treatment for which payment was made in part under TRICARE, a Federal health care program [and] induced Jihad Kaouk to provide falsely

In two suits where Intuitive Surgical was a party, the plaintiff patient alleged Intuitive Surgical was liable as manufacturer when the robot was *not* used[33]. For example, in *Mracek v. Bryn Mawr Hospital*, a patient underwent prostate surgery that was intended to be conducted using a robot[34]. But the "robot malfunctioned during the surgery and displayed 'error' messages"[35]. Instead, the surgeon manually used laparoscopic equipment, and the patient later suffered a gross hematuria. The patient brought strict product liability, strict malfunction liability, negligence, and breach of warranty actions against Intuitive Surgical and the hospital[36]. In an unprecedential opinion, the Third Circuit rejected the patient's argument, saying specifically there was "no record evidence that would permit a jury to infer [patient's injuries] were caused by the robot's alleged malfunction"[37].

Related to robotic surgeons, many claims discussed the lack of training Intuitive or the hospital provided to the operators[38]. For example, in *Silvestrini v. Intuitive Surgical, Inc.*, the plaintiff alleged that Intuitive was "responsible for training [hospital] staff members to use the surgical robot and that such training was 'totally lacking or woefully inept or inadequate'"[39]. In the same suit, the plaintiff also alleged that the hospital was responsible for "training its staff to use the robot"[40].

The contours of these robotic surgery cases *show that there is not yet a consistent legal response to when something goes wrong during a robotic surgical procedure*. Some cases—even without

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inflated positive outcomes to patients to encourage consent for such surgery with their product, the da Vinci robotic device").

32 There are a number of pending cases against Intuitive Surgical. One pending case against Intuitive involves claims of negligent training, negligent proctoring, negligent certification; fraud; breach of express warranty; unjust enrichment; and loss of consortium. *Reece v. Intuitive Surgical, Inc.*, 2014 U.S. Dist. LEXIS 164129 (N.D. Ala. Nov. 24, 2014) (alleging Intuitive's liability for injuries sustained "by the use of the da Vinci surgical robot" during surgery doctors converted to an open laparotomy surgery to repair lacerations and tears on plaintiff's intestines and small bowels).

33 *Mracek,* 363 F. App'x 925 (3d Cir. 2010). (unprecedential), *O'Brien v. Intuitive Surgical, Inc.*, 2011 U.S. Dist. LEXIS 80868 (N.D. Ill. July 25, 2011).

34 *Mracek v. Bryn Mawr Hosp.*, 363 F. App'x 925 (3d Cir. 2010). (unprecedential).

35 *Id.* at 926.

36 *Id.*

37 *Id.* at 927.

38 *See e.g. Silvestrini v. Intuitive Surgical, Inc.*, 2012 U.S. Dist. LEXIS 13801 (E.D. La. Feb. 6, 2012).

39 *Id.*

40 *Id.*

evidence—have sought legal recourse against the manufacturer[41]. Other cases have focused on the sufficiency of training or certification of the operator[42].

## 3. Operator Signatures

The use of communication networks in teleoperated robotic systems allows us to abstract teleoperated procedures to information exchange between operators and remote robots, as depicted in Figure 1.

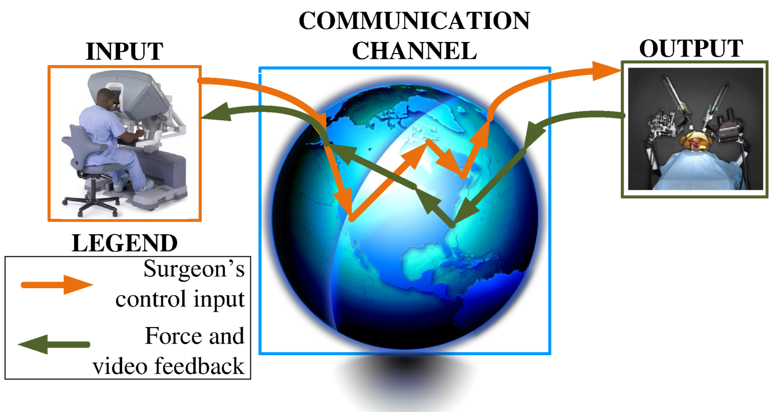


**Figure 1 Teleoperated robotic system as an information exchange system, where an operator can be seen as an input, and a robot as an output of the system.**

In such a systems, an operator typically has a good understanding of a remote robot's expected "behavior" (under normal operating conditions). Surgical robots respond to an operator's commands with predictable behavior due to an underlying mathematical model of the robot implemented in the system's code and design. These mathematical models can exist in a variety of forms and often are used to represent and analyze robot's dynamics and actions. More elaborate models may also take into account the dynamics of the communication network, in order to better predict delays, anomalies or communication failures. The development of these models is a critical component of the engineering of teleoperated cyber-physical systems. The models are not only used by engineers to test and validate system design, but are often also used in real-time to protect the robot from colliding with itself.

The same depth of understanding is, however, rarely available for the operator. It is typically assumed that teleoperators are trained and authorized to control the robot, and that they are executing a remote procedure at their highest level of performance and attention. That

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41 *See e.g. Mracek,* 363 F. App'x 925 (3d Cir. 2010). (unprecedential), *O'Brien v. Intuitive Surgical, Inc.*, 2011 U.S. Dist. LEXIS 80868 (N.D. Ill. July 25, 2011).

42 *See Silvestrini v. Intuitive Surgical, Inc.*, 2012 U.S. Dist. LEXIS 13801 (E.D. La. Feb. 6, 2012), *United States ex rel. Antoon v. Cleveland Clinic Found.*, 978 F. Supp. 2d 880, 884 (S.D. Ohio 2013), *Taylor v. Intuitive Surgical Inc.*, No. 09-2-03136-5 (Kitsap County, Wash., Super. Ct. May 23, 2013), i. Greenway v. St. Joseph's Hosp., No. 03-CA-011667 (Fla. Cir. Ct. 2003) (alleging that the hospital was negligent based on "the surgeon's lack of training and experience in operating the system").

assumption, however, many not hold valid due to a variety of reasons, many of which may be out of the operator's control. At the moment, however, neither the robot, nor any other part of a teleoperated system has a systematic way to analyze and/or validate operator's actions.

**We have developed a novel way to enable analysis and validation of a teleoperator's actions. Our approach is based on the hypothesis that every operator has a *unique* way of communicating with, and controlling a remote robot, which we refer to as *operator signature.*** More specifically, we record features of an operator's interaction with a remote robot, and to use those features to learn parameters of a model representing a unique operator signature. Once such a model is available, it can be used in hard real-time (online), in soft real-time, or offline to help with detection of possible discrepancies between an operator's expected and executed behavior.

Access to a unique operator signature during a teleoperation procedure will help us with three tasks:

1. **Identification**, i.e., identifying **who** the operator ***is***;
2. **Authentication**, i.e., identifying **how** the operator ***is***;
3. **Evaluation**, i.e., identifying **how** the operator ***does***.

Furthermore, being able to perform the enumerated three tasks will allow for:

- Easier detection of benign anomalies on the operator side of the system
- Enhanced security of teleoperated robotic systems
- Improved way teleoperation control skills are being taught, trained and evaluated.

### *3.1. History of Operator Signatures in Teleoperated Robotic Surgery*

The idea to record forces and torques applied by a surgeon during a robotic surgical procedure, and to combine these data with robotic tool/tissue interaction data, collected on the manipulator data, is not new. A number of authors have shown how such data can been used *to assess the level of surgical skill,* and distinguish between novice and expert surgeons.[43]

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[43] *See* J. Rosen, C. Richards, B. Hannaford, and M. Sinanan, "Hidden Markov Models of Minimally Invasive Surgery," Studies in Health Technology and Informatics,. 279–285, (2000). C. Richards, J. Rosen, B. Hannaford, C. Pellegrini, and M. Sinanan, "Skills Evaluation in Minimally Invasive Surgery Using Force/Torque Signatures," 14 Surgical Endoscopy, 14, no. 9, 791–798, (2000). J. Rosen, M. Solazzo, B. Hannaford, and M. Sinanan, "Objective Laparoscopic Skills Assessments of Surgical Residents using Hidden Markov Models Based on Haptic Information and Tool/Tissue Inter- actions," Studies in Health Technology and Informatics,. 417–423, (2001). J. Rosen, B. Hannaford, C. Richards, and M. Sinanan, "Markov Modeling of Minimally Invasive Surgery Based on Tool/Tissue Interaction and Force/Torque Signatures for Evaluating Surgical Skills," 48 *IEEE Transactions on Biomedical Engineering*, no. 5,. 579–591, (2001).
J. Rosen, M. Solazzo, B. Hannaford, and M. Sinanan, "Task Decomposition of Laparoscopic Surgery for Objective Evaluation of Surgical Residents' Learning Curve using Hidden Markov Model," 7 Computer Aided Surgery, , no. 1, 49–61, (2002). J. Rosen, L. Chang, J. Brown, B. Hannaford, M. Sinanan, and R. Satava, "Minimally Invasive Surgery Task Decomposition– Etymology of Endoscopic Suturing," Studies in Health Technology and Informatics,. 295–301,

These authors have defined 14 types of tool/tissue interactions and associated each interaction type with a unique surgeon's force/torque signature. Using the experimental data from 10 surgeons who performed laporoscopic cholecystomy, the authors trained a Hidden Markov Model (HMM) for each subject and each step of the procedure. The obtained HMMs where used to analyze discrepancies between expert and novice surgeons, and a statistically significant difference between two groups of surgeons was observed. Moreover, the authors observed the major differences between skill level were observed in: (a) force/torque amplitudes, (b) types of tool/tissue interactions used, and transitions between them, (c) time spent in each tool/tissue interactions, and (d) the overall procedure time.

### *3.2. Technical Details of Generation and Use of Surgical Signatures*

In defining models of operator signatures, our goal is to focus on features defining an operator state. Those may include:

1. The position and velocity of an operator's instruments, such as haptic devices,
2. The forces and torques that an operator applies to the instruments,
3. The position and velocity of a remote robot's end effectors, and
4. The exchanged messages between a surgeon and a manipulator.

When thinking about a teleoperated robotic surgical procedure, however, there are several components that may introduce variability into an operator signature we are trying to build. Those can broadly be classified as:

1. **Features specific to the medical condition/disease being treated.** These parameters are expected to determine the specific of the procedure.
2. **Features defining a patient's state**, such as the patient's age, gender, weight, height, blood pressure, overall well-being, the severity of the treated medical conditions, as well as other medical indications that may affect the conducted procedure.
3. **Features defining robot and network state.**
4. **Features defining an operator state.**

We acknowledge that in specific cases it may not be possible to de-correlate operator features from other sets of features. At the minimum, we recognize that some operator's features will be **task/procedure independent**, while other will be **task dependent**. Regardless of task dependence/independence, the observed operator's features will be used to learn/infer parameters of a *mathematical model*, representing an operator's unique surgical signature.

As already shown in the work distinguishing between expert and novice surgeons[44], the operators differ in: (a) the amount of force they apply on operator's tools, (b) the amount of time they spend at a specific step of a teleoperated procedure, and (c) the overall length of the procedure.

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(2003). J. Rosen, J. Brown, L. Chang, M. Sinanan, and B. Hannaford, "Generalized Approach for Modeling Minimally Invasive Surgery as a Stochastic Process Using a Discrete Markov Model," 53 IEEE Transactions on Biomedical Engineering, , no. 3,. 399–413, (2006).

[44] *See Id.*

Based on these observations, we use the following steps in building an operator signature:

1. Choose and develop a mathematical model of an operator.
2. At the beginning of a teleoperated procedure, record the first batch of measurable data on the operator and the manipulator sides, as well as messages exchanged between the operator and the manipulator.
3. Use the recorded data to learn the parameters of the mathematical model describing the unique operator signature.
4. Based on the developed mathematical model and the extracted set of features, identify the operator.
5. At each time interval, where the length of the time interval is determined based on the type of remote procedure:
    a. Predict the expected output of the operator's mathematical model. The predicted output will typically consist of the measurable data on the operator side and the messages sent by the operator.
    b. Monitor measurable data on the operator and the manipulator side, as well as the exchanged messages.
    c. Compare the observed (measured) data with the predicted data.
    d. If the observed and the measured data align (within the given threshold), declare that the operator is valid.
    e. If there is a discrepancy between the observed and the measured data, announce there is anomaly in the remote procedure.

Some details regarding this very general approach to telerobotic security are discussed below.

*3.2.1. Choosing a Set of Measurable Data:*

Similar to persons' handwritings, many people may write a single letter in an identical way. Simply looking at a single letter (in our case, at a single feature) may not be enough to extract an operator's unique signature. Yet, just as an individual's handwriting can be identified given a large enough sample of their writing, an operator's signature will likely also require a sufficiently sized set of recorded data. There is a large number of measurable parameters that may contain information that could be considered part of an operator's signature: (a) position, velocity, acceleration and orientation of the operator's tools, (b) position, velocity, acceleration and orientation of the remote device's end effectors, (c) forces and torques applied by the operator, (d) forces and torques applied by the remote device on the surrounding environment, (f) time differences between two consecutive control messages, (g) time differences between two consecutive feedback messages, and (h) the overall procedure time. Just as an individual's handwriting contains identifying information in the exact way they shape their letters, differences in the above data sources contain information that may be used to identify a surgeon.

In order to interpret this data, there exist a variety of mathematical models that can be used to model operator's actions. Those may include: (i) linear and nonlinear dynamical models, (ii) statistical models, such as single- and multiple-step Markov models, Hidden Markov models, Bayesian networks, and Gaussian models (iii) algorithmic models, and (iv) graphical models. Regardless of the exact method used, the models would combine data from the various measured parameters in such a way to represent the way an operator interacts with a remote device. This will enable us to extract the operator's unique features and define his/her unique signature.

*3.2.2. Choosing an Appropriate Feature Extraction, Model Training Method and Validation Time Interval:*

A variety of feature extraction and model training methods can be used to develop an operator's signature, including system identification, statistical and machine learning methods. The appropriate choice of a method will depend on: (1) the type of a remote procedure, (2) the type of a chosen mathematical model, and (3) the available measured data.

Any chosen method must be reliable, with ***low false positive and false negative results***. In other words, any chosen method should guarantee the following:

- (R1) A single set of measured parameters should never correspond to more than one operator's signature.
- (R2) Multiple different sets of measured parameters should never correspond to the same operator's signature.
- (R3) It should not be the case that any set of measured parameters does not match to one and only one operator's signature.

Considering this operator analysis and validation approach, it is obvious that a shorter validation time interval enables a quicker detection of possible benign and malicious anomalies in a remote procedure. On the other hand, a short time interval requires a faster data collection, and faster data analysis, which may impact validation reliability. There is an inherent tradeoff between the length of the validation time interval and the reliability of validation. Choosing an appropriate validation time interval will therefore depend on the type of remote procedure and the perceived risk that the procedure may get compromised.

Similar to feature extraction and model training methods, choosing an appropriate validation technique will depend on a variety of parameters, such as the type of remote procedure, the type of the chosen mathematical model and the available measured data. In addition to the reliability of a chosen validation method, we will also be interested in its computational overhead and efficiency.

## 4. Legal Benefits of Operator Signatures

Despite the great potential for surgical robotics, there are still aspects that need to be ironed out. The ECRI Institute listed both robotic surgery and cybersecurity in its 2015 Top 10 Health Technology Hazards report[45]. ECRI listed robotic surgery as a threat because of "complications due to insufficient training," and listed cybersecurity as a threat because of "insufficient protections for medical devices and systems"[46]. Operator signatures have the potential to address these hazards, and to offer a new prospective into an operator's actions *during* a surgery.

[45] *2015 Top 10 Health Technology Hazards*, ECRI, https://www.ecri.org/Pages/2015-Hazards.aspx.

[46] *Id.*

Operator signatures, an avenue for new available data, could be one of the first forms of empirical evidence for an operator's actions during surgery.

*We suggest that having available evidence of the operator's techniques and movements during a robotic procedure can lead to a growth in medical research on proper techniques (Evaluation); a clarified standard of care for sufficient surgical training (Authentication and Evaluation); and can help more clearly delineate liability (Identification and Evaluation).*

### *4.1. Background: Operator Signature's Legal Applicability to the Current Medical Legal Landscape*

Operator signatures may be beneficial to the medical field by addressing important gaps in a costly legal regime: medical malpractice. Medical malpractice claims have rapidly increased in numbers and cost since its recent emergence in the mid-1970's[47]. The threat of medical malpractice claims against a physician or healthcare provider has become an integral part of healthcare costs in America. A 2010 study estimated national medical malpractice costs at $55.6 billion per year[48]. Of this amount, an estimated $17-$29 billion per year is from preventable medical injuries[49].

One of medical malpractice's purposes is to improve patient safety by compensating injured patients[50]. More practically, medical malpractice claims may improve patient safety by linking liable conduct to a standard of care. For a plaintiff to prevail in a medical malpractice case, there must be some determination of the physician's (or provider's) proper standard of care. "The civil wrong in a medical malpractice case almost always involves a relationship between a health care provider and patient where there is a breach of some standard of care by a negligent act or omission which substantially leads to an injury or death"[51].

To determine the standard of care in a medical malpractice action, parties can look to a number of sources. There is no single codification of standard of care[52]. Sources that parties can use to

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47 *See* Glen O. Robinson, *The Medical Malpractice Crisis of the 1970's: A Perspective*, 49 Law & Contemporary Problems, no. 2, 5-35 (Spring 1986).

48 *Michael Mello, Amitabh Chandra, Atul Gawande, David Studdert, "National Costs of The Medical Liability System," no. 9 1569-1577, doi:10.1377/hlthaff.2009.0807.*

49 *Id.* citing L. Kohn, J. Corrigan & M. Donaldson, *To err is human: building a safer health system* (2000).

50 *See Id.*, though the authors note that whether or not medical malpractice improves patient safety is a point up for debate.

51 Medical liability tort system, 1 Am. Law Med. Malp. § 1:3. *See also Raines v. Lutz*, 341 S.E.2d 194, 197 (Va. 1986) ("The applicable standard of care and a deviation from that standard are two essential elements of a medical malpractice claim").

52 Practising Law Institute, Medical Malpractice: Discovery and Trial (7th ed. 2012).

determine standard of care include expert testimony by a qualified expert; "guidelines adopted by specialized medical societies and public institutions";[53] applicable case law; and applicable regulations[54].

At trial the standard of care is presented to the jury or judge through experts who are qualified in the particular field. Experts can make use of "learned treatises" or guidelines in order to inform their expert testimony. Yet the treatises or guidelines are not themselves used as evidence to demonstrate standard of care[55].

Since robotic surgery is a relatively new practice—compared to the storied medical profession—there is not yet an established standard of care. For instance, Peters notes that there is no standard of care for patient-selection for robotic surgeries[56]. Peters highlights the lack of published medical literature as one reason for a missing medical standard of care[57]. **Being able to quantifiably evaluate surgeons with operator signatures could provide empirical data needed to help develop a standard of care.**

### *4.2. Operator signatures to influence the standard of care by enabling medical research on more effective and individualized surgical techniques*

Scholars have argued that there is much research needed to better determine the appropriate standard of care for robotic surgery[58]. Medical research has historically been influential in determining an appropriate standard of care for particular medical situations[59]. In the light of that, operator signatures can aid and enable medical research in a few ways, which can be useful for determining new standards of care within robotic surgery.

First, operator signatures can be used to develop a new knowledge-base for supporting evidence-based medicine practices. Evidence-based medicine can be described as "the judicious use of the

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53 *Id.*

54 *See id.* at 2-11 ("The formation of the standards of care is the work of both public and private organizations. Amon public institutions... the state governments regulate the content of medical care directly through statutes and administrative regulations").

55 *Id.* at 2-15 ("[B]oth medical practitioners and expert witnesses rely on learned treatises, and, although such treatises are not admissible as such..."). Although Hubbard suggests that if regulations exist evidence of compliance or non-compliance is admissible to show negligence. *See* F. Patrick Hubbard, *"Sophisticated Robots": Balancing Liability, Regulation, and Innovation*, 66 Fla. L. Rev. 1803, n.287 (2014) (*citing, e.g.*, *D.C. Hous. Auth. v. Pinkney*, 970 A.2d 854, 864-65 (D.C. 2009)).

56 *See* Peters, *supra.*

57 *Id.*

58 *Id.*

59 *See* Maxwell Mehlman, *Professional Power and the Standard of Care in Medicine*, 44 Ariz. St. L.J. 1165 (2012).

best current evidence about the care of the individual patient"[60]. Evidence-based medicine—also known as EBM—"integrates the best external evidence with individual clinical expertise and patients' choice"[61].

Operator signatures can aid EBM by providing a means to address "important technical aspects of surgery… that are currently inadequately studied"[62]. For EBM to be useful, there must be an *accessible* knowledge-base that provides operators with external studies operators can use to evaluate their own practices[63]. Current studies on technical surgical aspects are often burdensome because they require observers to review video of an operation[64]. Operator signatures may be useful to develop a body of research that—as discussed above—develops a more refined standard of care.

Operator signatures can also aid EBM by providing the operator with her own 'playback' of her operation during a robotic surgical procedure. This may—with a standardized knowledge-base for technical aspects of surgery—provide the ability for direct comparison of an operator's actions with external studies.

In addition, the operator signatures can potentially be used to monitor and control for differences in skill in surgical robotics research. Deveraux, et. al. have identified a need to control for a surgeon's expertise in randomized control trials[65]. They contend that traditional randomized control trials for surgical interventions suffer from "expertise bias" because they typically do not account for the individual surgeon's expertise. This "expertise bias" may skew results toward less technically challenging procedures[66]. Researchers suggest creating expertise based randomized control trials may also be a more ethical approach to randomized control trials because it provides informed consent as to the surgeon's level of expertise[67].

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60 DL Sackett, WM Rosenberg, JA Gray, RB Haynes, WS Richardson, *Evidence based medicine: what it is and what it isn't*, 312 BMJ, no. 7023, 71 (Jan. 1996).

61 *Id.*

62 Mary Kwaan & Genevieve Melton, *Evidence-Based Medicine in Surgical Education*, 25 *Clin. Colon Rectal Surg* 151-155 (2012).

63 *Id.*

64 *C.f.*, John Birkmeyer, Jonathan Finks, Amanda O'Reilly, et. al., *Surgical Skill and Complication Rates after Bariatric Surgery*, 369 New Eng. J. Med. 1434-1442 (2013), http://www.nejm.org/doi/full/10.1056/NEJMsa1300625.

65 Devereaux PJ, Bhandari M, Clarke M, et al., *Need for expertise based randomised controlled trials*, 330 *BMJ* 88 (2005), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC543877/.

66 *Id.*

67 *Id.*

Third, the availability of operator signatures can enable research as to the validity of operator signatures themselves. This type of validation research will be necessary to support the use of operator signatures in legal cases[68]. This validation could aid in standard of care evaluations in medical malpractice cases. Namely, the validation of operator signatures could help evaluate whether or not the particular operator performed the procedure in question with the requisite standard of care[69].

### *4.3. Operator signatures can help determine the level of training needed to be sufficiently skilled in the particular robotic surgical procedure*

More knowledge is needed to determine what an appropriate standard of care is, and the level of training needed in order for an operator to be sufficiently skilled to be the primary operator during robotic surgeries. Operator signatures could help determine levels of sufficient training in at least three ways.

First, operator signatures can be used to conduct research testing as to the appropriate level of training needed to perform a certain surgical robotic operation. In particular, operator signatures can be logged during robotic surgical procedures currently approved and used in hospitals. These robotic procedures include hysterectomy, prostatectomy, nephrectomy, lung surgery, cardiac surgery, and more[70]. For these procedures, operator signatures could pair volume of surgeries per operator with a study of expertise relative to other operators. This approach would provide more individualized attention to an operator's learning curve compared to traditional volume-based determinations what is considered sufficient training[71].

Second, evaluation of surgeons by examining their operator signatures can be used toward credentialing of operators for certain robotic surgical procedures. This would more empirically address challenges to improper certification by hospitals or other entities. In *Mohler v. St. Luke's Medical Center*, the plaintiff Mohler sued the hospital for failing to properly credential the

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[68] *See* Section VI.

[69] Whether operator signatures are accepted as evidence in a particular legal case may turn on whether operator signatures could pass under the *Daubert* evidentiary standard. See *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579 (1993) (using a four-part standard for a judge to determine whether evidence is sufficiently reliable and valid to be admissible as evidence). Application of *Daubert*'s four-part standard is flexible. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999).

[70] *See e.g. Robotic-Assisted Surgery*, UW Medicine, http://www.uwmedicine.org/services/gynecology/robotic-assisted-surgery; *Robotic Surgery Center*, NYU Langone Medical Center, http://nyulangone.org/locations/robotic-surgery-center.

[71] *See* J. Rosen, M. Solazzo, B. Hannaford, and M. Sinanan, *Task Decomposition of Laparoscopic Surgery for Objective Evaluation of Surgical Residents' Learning Curve using Hidden Markov Model*, 7 Computer Aided Surgery, no. 1, 49–61 (2002) (using haptic and visual information to determine individualized differences in skills levels).

operator "regarding his use of the robotic equipment"[72]. Mohler alleged that the improper use of the robotic system led to his intestinal complications because the operator had perforated his small intestine during gallbladder removal surgery[73]. Credentialing while using operator signatures as an empirical measure could mitigate a hospital's risks against similar legal cases.

Third, operator signatures can be used to proactively understand and adapt a surgical procedure for use with a robot. Currently, robotic surgery is used for a limited number of operations, but the types of procedures that can be done with surgical robots will grow. For this growth to happen safely and effectively, skills training must be available for operators. Skills training informs operators of the procedure, nuances, risks, and other information needed to be sufficiently trained to perform the particular surgical procedure[74]. Operator signatures can be used in order to develop effective techniques, and train operators on such techniques[75].

Operator signatures can also go beyond current simulation tools[76] by accounting for the uniqueness of each operator. **With an understanding of the uniqueness of each operator, operator signatures can be used to more empirically determine an individual's learning curve.** In particular, the variability in an operator's signature may be an important aspect of developing individualized training. As an operator becomes more trained in a procedure, he would become less variable in the way he goes about performing it. As the operator becomes more comfortable, then he would potentially become more consistent, and his operator signature may show more consistency between operations.

For a manufacturer, operator signatures can be used in understanding what types of malfunctions or errors may arise during a surgical procedure. With this knowledge, manufacturers could provide more effective (and potentially tailored) adequate warning to the operator. The manufacturer's adequate warning to the operator would shield the manufacturer from liability[77].

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72 *Mohler v. St. Luke's Med. Ctr., LP*, No. 1 CA-CV 08-0078, 2008 WL 5384214, at 2-3 (Ariz. Ct. App. Dec. 26, 2008) (finding that issue of proper credentialing of surgeon to use robot existed and reversing summary judgment for the hospital with control of the system).

73 *Id.*

74 *See* J. Hance, R. Aggarwal, S. Undre, A. Darzi, *Skills training in telerobotic surgery*, 1 Int'l. J. Med. Robot 7–12 (2005), http://onlinelibrary.wiley.com/doi/10.1002/rcs.36/pdf.

75 *See* Irene Suh, Mukul Mukherjee, Dmitry Oleynikov, Ka-Chun Siu, *Training program for fundamental surgical skill in robotic laparoscopic surgery*, 7 Int'l J. Med. Robotics & Comput Assist Surg 327–333 (2011), http://onlinelibrary.wiley.com/doi/10.1002/rcs.402/epdf (demonstrating that a four-day robotic skills training program showed objective improvement by participants).

76 *Id.* at 10 (discussing use of simulators for laparoscopic surgery training).

77 *See e.g., Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741 (W.D. Pa. 2004) (finding instructions and a warning to the surgeon shielded the medical device manufacturer from liability).

Each of these benefits in determining more individualized and particular training may also provide for the means to authenticate a particular operator to that operator's actions. Drawing from the uniqueness of each operator, and understanding each operator's training in a more empirical manner may help authenticate that it was the particular operator who a plaintiff may have alleged it was. While these inferences likely cannot be drawn directly from operator signatures as evidence, it may be useful circumstantially as one piece of the whole picture.

### *4.4.Operator signatures can help more clearly delineate liability between actors*

New available data on an *operator's* movements can help distinguish between a robotic malfunction and an operator's error. Distinguishing between manufacturer and operator helps distribute liability to where it may be warranted, which can increase accountability for each entity.

In many cases "the most difficult burden the plaintiff has in a case against a health care provider is proving that a breach of the standard of care in fact caused the plaintiff's injuries"[78]. The plaintiff must prove a number of aspects that are typically in the defendant's favor. These aspects include demonstrating causation between an operator's departure from the standard of care and the injury suffered, even though "important scientific issues of causation are unsettled"[79].

Operator signatures can be useful in cases where the question is whether the operator departed from an established standard of care. In these evaluative instances, operator signatures can provide objective evidence of the operation in question. It can demonstrate that the operator acted in any number of ways. The operator may have acted consistently with her past procedures of the same nature. She may have deviations from her previous actions, but in ways within the asserted standard of care. Or, she may have deviated substantially from her previous actions. Additionally, the authorization properties of operator signatures could be used to track a surgeon's state, such as if they are or are not fatigued. Operator signatures could provide objective observational data that is unique to the operator[80].

Further, operator signatures may be useful to demonstrate the alleged source of the plaintiff's harm was *not* the operator. For instance, the operator may have proceeded in ways that were consistent with his past acceptable operators. Yet, the plaintiff was still injured. Here, the operator may be able to show that his actions were within the standard of care, and that some other action—such as a robotic failure—was the source of the harm. Or, the operator may have proceeded in ways completely inconsistent with the alleged operator. There, the Identification

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78 Frank M. McClellan, *Medical Malpractice: Law, Tactics, and Ethics* (Temple Univ. Press 1994), at 43.

79 Practising Law Institute, *Medical Malpractice: Discovery and Trial* at 2-26.

80 While the availability of operator signatures may suggest more fuel for more medical malpractice actions, this is not necessarily the case. Arguably, the availability of objective observational data could quell cases that are aspirational in nature, yet ungrounded in facts.

properties of operator signatures may be used to demonstrate that it was an individual other than the alleged operator who performed the harm.

"Plaintiffs who cannot adequately address problems in proving breach of standard and causation will lose their cases; this has been the fundamental approach to failure to provide evidence of breach and causation for centuries"[81]. Just as airplane black boxes provide investigators with a record of actions taken, operator signatures may also be useful as evidence of what occurred during robotic surgery. With an actual record in place, liability between actors may be more clearly delineated. A lawsuit with the manufacturer, hospital, and operator as defendants may become more straightforward as to proving causation[82].

### *4.5.Legal discussion conclusion*

We suggest that operator signatures can be a useful tool toward determining the appropriate standard of care. When an appropriate standard of care is understood, it can have many benefits for robotic surgery. In particular, understanding the appropriate standard of care can: a) provide more predictability to actors involved as to where liability may lie; and b) further innovation for robotic surgeries by expanding it to other types of surgeries (through the development of new procedures and trainings).

## 5. Legal Cases/Scenarios

Given our construction of operator signatures and its potential benefits, the next question is: **How can operator signatures help resolve difficult problems of accountability in certain scenarios?** In this section we will pose three scenarios that help illustrate the usefulness of operator signatures. For each scenario, we will discuss how operator signatures can aid accountability by helping resolve legal issues.

Our three uses cases are:

(i) a robot may mechanically fail;
(ii) an operator may commit an error; or
(iii) communication link between an operator and a robot may fail, or it may get compromised.

### *5.1. Use Case 1: Robot mechanical failure*

Imagine a scenario where the surgical robot mechanically fails, but the failure is only partial, and the failure still allows the operator to continue the procedure. The operator knows about the partial malfunction, and using the available knowledge, she takes additional actions to mitigate

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[81] F. Patrick Hubbard, *"Sophisticated Robots": Balancing Liability, Regulation, and Innovation,* 66 Fla. L. Rev. 1803, 1852 (2014).

[82] This is not to suggest that we advocate for more litigation, rather it is to demonstrate that the availability of evidence helps assign liability.

the partial malfunction. Even with the operator's mitigating actions, the patient suffers serious injury.

### *5.1.1. How operator signatures can apply & inform use case*

In this scenario, let us assume that the robot's logs correctly indicate when the error occurs and the consequences of this error. This will allow experts to later determine what impact such an error could have had on the surgery. What these logs will not provide however, is the understanding of when the operator realized that there was a robot error and how they reacted. When the operator begins to compensate for the error, we can expect that the signals used to generate the operator signature to change. This could manifest in a multitude of task independent ways such as the operator slowing down the robot, applying less pressure to the haptic interface, or limiting the orientation of the robotic arm in some way.

Knowledge of a robot error may also alter how the surgeon attempts to perform tasks during the procedure, affecting the task dependent components of an operator's signature. An example of this may be that the operator is forced to perform a riskier technique because the robot is not physically able to perform a lower-risk alternative.

Alternatively, if the operator had not realized that the robot was malfunctioning, we would expect that the commands given to the teleoperated robot to stay relatively consistent. Even if the robot was only able to function partially due to a malfunction, we could evaluate if the operator knew this by looking for changes in his/her signature. For instance, if the operator does not realize the robot isn't working properly, it would be likely that he would attempt to move the surgical tools with the same velocity and force as before the malfunction. This would result in the possibility that the operator's signature may not change significantly over the course of the procedure despite a robot malfunction during the operation.

### *5.1.2. How operator signatures can address law & policy issues related to use case*

In this robotic failure scenario, operator signatures may be used to delineate whether or not an operator had knowledge of the robotic mechanical failure. This delineation between whether or not the operator knew about a defect matters for products liability and malpractice. If an operator knew about the mechanical defect, then the manufacturer could argue that it is not liable because of the learned-intermediary doctrine. This doctrine immunizes a manufacturer from liability when the manufacturer provides adequate warnings to the sophisticated user.[83]

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[83] *See* Thomas McLean, *Cybersurgery-an Argument for Enterprise Liability*, 23 J. Legal Med. 167, 183 (2002) ("a medical device manufacturer is relieved of the 'obligation to warn a patient when the manufacturer has provided an adequate warning to the patient's doctor,'" quoting *Jeffery E. Grell, Restatement (Third) of Torts, Section 8(D): Back to the Future of the Learned Intermediary Doctrine,* 19 Hamline L. Rev. 349 (1996)).

But whether or not the operator can be considered a learned intermediary is up for debate, as the scope and applicability of the doctrine is not well defined.[84] McLean suggests that "because surgeons cannot be presumed to have expertise in engineering, in a products liability action, whether a surgeon is a learned intermediary will require an adequate foundation."[85] This foundation could benefit from empirical evidence available during a robotic surgical procedure. In particular, the operator's signature could potentially be used as evidence to support whether or not the operator knew about the partial malfunction.

Beyond whether or not the learned-intermediary doctrine applies, operator signatures could aid in legal questions of causation. As discussed earlier[86], operator signatures may be likened to the black box of an operator's actions. When used with other evidence (such as any available robot logs), the operator's signature can address fundamental causation issues. In this use case, the causation issue pits the operator against the manufacture to determine—at a basic level—who caused the harm.

### *5.2. Use Case 2: Operator commits an error*

In our second use case, the operator performs the operation while dramatically fatigued. In this case, the robotic surgical system worked with no malfunctions. During the surgery, the operator committed an error. The operator's error resulted in serious injury to the patient.

#### *5.2.1. How operator signatures can apply & inform use case*

Using the authorization properties of operator signatures to assess how an operator *is*, we expect to be able to distinguish between various surgeon states using the subtle changes in the way the operator use the robot. This may include effects from caffeine, sleep deprivation, or possibly even drug or alcohol use. In this scenario, where the operator is fatigued, there may be subtle differences in how the operator moves or reacts during the surgery that alter the operator's signature. For instance, if the operator's depth perception is a little off, perhaps they move the robot's arms away from the camera slower than when they are not fatigued. When comparing the data to other operations that the surgeon has performed, there may be many of these task-independent changes to the operator signature. While the changes due to fatigue in position and velocity commands sent to the robot may be minor and potentially operator-specific, the mismatch with previously collected operator signatures may be large enough to make assertions about a change in surgeon state due to fatigue.

Additionally, by comparing the operator's signature during the operation in which harm occurred with prior operations, it may be possible to determine the surgeon's familiarity with the procedure as a whole. This would be similar to how we previously discussed using the evaluative

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[84] *See Construction and application of learned-intermediary doctrine,* 57 A.L.R.5th 1, 15 (citing different cases that have and have not applied the learned-intermediary doctrine to medical devices).

[85] *Id.* at 185.

[86] *See* Section 4.4.

properties of an operator signature to assess surgeon training. By comparing an operator's signature with other experts, we can gain an understanding of how the surgeon deviated in or matched expected behavior.

#### *5.2.2. How operator signatures can address law & policy issues related to use case*

Fatigue for medical personnel is a clearly identified issue[87]. In a study of residents, researchers found fatigue was "prevalent, pervasive, and variable and accounted for an increased risk of medical error"[88]. Detections in an operator's own state may be useful to determining hospital policies for fatigue and other personal impairments.

In this case, the detection of measurable fatigue could indicate that the operator is unfit to perform the operation. If the operator's relevant standard of care speaks to fatigue, then accountability that such fatigue would be detectable may be a personal deterrent for tired operators. The availability of operator signatures that may detect fatigue may be enough of a deterrent to convince an individual not to perform non-critical operations.

As with other potential uses identified in Section 4.3, delineating between fatigue and non-fatigue differences to an operator's signature would benefit from medical research. Such medical research would likely be needed before operator signatures may be used in legal proceedings to support whether or not an operator was fatigued[89].

From an institutional level, the hospital may be able to use operator signatures to develop scheduling and policies on fatigue. Such procedures may help limit the hospital's liability, and—importantly—reduce fatigue. Given fatigue's link to additional risks of medical error[90], the availability of individual and correlated fatigue measures of an operator can help reduce preventable medical error.

### *5.3. Use Case 3: Communications link between operator & robot fails or is compromised*

In our third use case, the communications link between the operator and robot is compromised. An unknown attacker compromises the link and takes control of the robot. The unknown attacker is able to control the robot's manipulators, and the attacker's action seriously injures the patient before anyone can protect the patient.

#### *5.3.1. How operator signatures can apply & inform use case*

In the case of a complete takeover by an outside actor, by logging the operator signature on both sides of the network, a mismatch can be identified after the incident occurred by using the identification properties of operator signatures. This mismatch in the commands being sent by

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[87] *See* Frank McCormick, John Kadzielski, Christopher Landrigan, et. al., *Surgeon Fatigue: A Prospective Analysis of the Incidence, Risk, and Intervals of Predicted Fatigue-Related Impairment in Residents*, 147 Arch Surg., no. 5, 430-435 (2012), http://archsurg.jamanetwork.com/article.aspx?articleid=1157932.

[88] *Id.*

[89] *See supra,* n.69 (discussing potential evidentiary barriers such as overcoming a *Daubert* challenge).

[90] *Id.*

the operator and the commands received by the robot could be used to decisively show that the operator was not in control of the robot at the time of the harm.

Alternatively, it may be possible that the attacker only compromises the communication channel between robot and operator, causing unnecessary packet delays and loss of information. These are typically referred to as denial-of-service attacks, and are commonly considered as a risk for any networked system. We have shown previously that such an attack can dramatically impair an operator's ability to use a robot, and that the robot may behave erratically and unpredictably when under a severe network attack[91]. While the operator is the only source of commands, and thus has "control" of the robot, the operator signature will reveal the magnitude of the network attack that was occurring at the time of the procedure. These network attacks may result in delays between the robot and operator, and similar to the first case, the operator signature may reveal when the surgeon realizes and begins to compensate for the attack.

#### *5.3.2. How operator signatures can address law & policy issues related to use case*

It is unclear who would bear liability in the case of a compromised robotic surgery. Yet, operator signatures could be used to demonstrate that the actions taken were *not* the operator. Those actions may be shown as inconsistent with the operator's unique signature for the particular procedure, so the operator was not be the actor that took actions leading to the alleged harm.

This type of evidence stems from the identification aspect of operator signatures, where an operator signature may be used to support that there was an intervening actor that caused the alleged harm. Once established, the questions of liability would shift to other factors outside of scope such as:

- What vulnerability did the intervening actor use?
- Who was responsible for maintenance of system or network where the vulnerability was exploited?
- Is there contractual language involved in assigning liability for cyber security incidents?
- Does the FDA provide guidance or requirements for cyber security risks?
- Is there relevant state or Federal law that discusses liability for cyber security incidents?

## 6. Conclusion

In this paper, we describe a new method for identification, authentication and evaluation of operators of teleoperated surgical robotic systems, based on the assumption that every teleoperator interacts with, and control a remote robot in a *unique way*. Our method leverages a variety of observable (measurable) data on both the operators's and the remote device's side. The recorded data are used to fit (train) a unique mathematical model of the operator, referred to as operator signature. This method enables faster and more reliable identification and authentication of operators, as well as robust and reliable detection of possible anomalies during the procedure, thus significantly enhancing safety and security of teleoperated robotic surgery. In addition, the concept of operator signatures is expected to have a wide application in teaching and training phase of different teleoperated surgical procedures.

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[91] T. Bonaci, J. Yan, J. Herron, T. Kohno and H. J. Chizeck, *supra* n. 19.

We discussed legal benefits from operator signatures, and showed that operator signatures can refine the standard of care for robotic surgical procedures. Moreover, we showed that operator signatures may also provide objective empirical evidence of an individual operator's actions *during* robotic surgery.