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Safe Technical Innovation

Development and Implementation of a Robotic Breast Operation Program

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INTRODUCTION

In 2016, Sarfati et al[1] described the feasibility of robotic-assisted nipple-sparing mastectomy (RNSM) in a cohort of 4 cadaveric breasts. During the ensuing years, surgeons, predominately in Europe and Asia, have developed innovative techniques to explore the utility of RNSM. Early adopters of RNSM cite superior visualization, greater stability with tremor elimination, enhanced precise movement with more degrees of freedom, better access to small or difficult to reach spaces, and improved ergonomics compared with traditional nipple sparing mastectomy (NSM).[2–4] However, these benefits come with a prolonged operative time, uncertainty surrounding its oncologic safety, and potentially increased costs. Recently, Toesca et al[5] reported outcomes from the first randomized controlled trial comparing RNSM to open NSM. Among 80 women with breast cancer or a BRCA mutation, RNSM took significantly longer but produced better quality of life for patients after surgery as determined by the Breast-Q and Body Image Scale instruments. Overall, postoperative complications were equivalent between study arms, but no skin or nipple necrosis was observed for the 40 patients that underwent RNSM compared with 12.5% of patients after open NSM. Long-term follow-up with comparisons of oncologic outcomes is expected in a future report.

While RNSM may relieve some of the technical challenges to traditional NSM and provide superior cosmetic outcomes, concerns over safety and effectiveness remain due to lack of long-term data on local disease recurrence, disease-free survival, and overall survival. As a response to the rising number of RNSMs performed in community hospitals and outside of a clinical trial setting, the U.S. Food and Drug Administration (FDA) issued a safety communication in early 2019 directed towards patients with or at high risk of developing breast cancer and health care providers that were performing RNSM.[6]

As the first step to addressing these concerns, we opened the first US investigator-initiated clinical trial assessing the safety, efficacy, and potential risks of RNSM with the daVinci Xi surgical system.[7] While the technical details of performing RNSM has been reported previously, prior studies did not discuss the logistics of implementing a successful new Robotic Breast Operation (RoBO) program. In this article, we discuss the development and implementation of a RoBO program (Table 1).

REGULATORY CONCERNS

Persistent concerns about the performance of off-labeled use of robotic-assisted mastectomy led to an updated FDA safety communication.[8] Clinical trials conducted to investigate a new intended use of an already approved device requires FDA oversight. Study sponsors are expected to obtain FDA approval of investigator device exemption (IDE) if a study involves the use of a "significant risk device." Thus, while the da Vinci robotic Si and Xi platforms do have 510(k) clearance by the FDA, for trials evaluating its role for mastectomy procedures, an IDE is required since this procedure is considered a new indication. Investigators can obtain an IDE by following the process outlined on the FDA website: https://www.fda.gov/medical-devices/how-study-and-market-your-device/investigational-device-exemption-ide. Once IDE approval has been granted by the FDA, investigators can apply for local institutional review board approval for the study.

ENGAGE STAKEHOLDERS

To develop, launch, and maintain a successful RoBO program, it is important to engage stakeholders early. Identifying and engaging team members at various levels will help address issues before they become significant barriers. Aside from the breast and plastic surgeons, stakeholders should include administrative leaders from the operating room, surgical department, or division. Given the potential additional operative time and cost associated with performing RNSMs, engaging administrative leaders early and often in the process may help mitigate these concerns that arise while establishing a RoBO program. Additional stakeholders may include operative personnel such as surgical technologists and circulating nurses, surgical scheduling team members, private or industry personnel (ie, Intuitive representative), research team members, or patient advocates.

SURGEON TRAINING

For surgeons not familiar with the basic principles of NSM, they should start out with training in open NSM. For example, there are opportunities for training in open NSM through the American Society of Breast Surgeons oncoplastic course. If the breast surgeon has not trained previously in robotic surgery, the surgeon should start by obtaining additional basic training in operating a robotic device. Surgeons not already performing

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TABLE 1.

Process for Implementation of a Robotic Breast Operation Program

Task
1. Apply for investigator device exemption approval from the FDA
2. Engage multiple stakeholders throughout the institution
3. Develop technical expertise required to perform robotic-assisted breast surgery in a safe and timely fashion
a. Obtain foundational robotic skills via modules and bedside assisting other robotic procedures
b. Perform breast surgery on cadaver models
i. Include key intraoperative personnel in the exercise to perform all aspects of the procedure including positioning, robotic device docking, port placement, instrument exchanges, robotic device undocking, and specimen removal
4. Establish team members and responsibilities
a. Involve the same operative personnel whenever possible to establish familiarity with roles and responsibilities
5. Schedule the first case
a. Optimal patient selection is important
b. Transparent discussion with the patient regarding equipoise and experiemental nature of the procedure in addition to the risks/benefits with study participation
6. Monitor outcomes and provide feedback to team members for performance improvement
a. Provide feedback to patients and team members
7. Communicate with oversight—FDA and IRB—especially regarding adverse events
8. Publish and disseminate the data for peer review and critique

FDA indicates U.S. Food and Drug Administration; IRB, Institutional Review Board.

robotic surgery for other indications should consult their hospital credentialing committee for clarification on robotic credentialing. This can help guide the training and proctoring needed to obtain credentialing to independently performing the operation. To the novice robotic surgeon, we suggest that, at minimum, the training should entail online didactics, virtual reality simulation, dry lab simulation, and, ultimately, the Intuitive certification course, which includes an animal lab. The local Intuitive representative can often help coordinate these training sessions. After obtaining sufficient proficiency in the general use of the robotic device, the surgeon should observe a live RNSM procedure then perform at least 1 RNSM on a female cadaver.[9] If the breast surgeon is not experienced with robotic surgery, a trained robotic surgeon should be recruited to proctor at the console while the breast surgeon gains experience during the early portion of the learning curve. The proctor does not need to be trained in the specifics of RNSM as the main role for proctoring is to assure safe handling of the robotic device. A trained robotic proctor can be especially helpful in troubleshooting issues such as instrument clashes as the robotic arms will be confined to a tight space during certain portions of the operation.

A hospital wide curriculum is in place at The Ohio State Wexner Medical Center to obtain a training certificate in robotic surgery. The curriculum includes general and specialty-specific online training modules, bedside assisting, as well as dry and wet lab experience. The qualifications for robotic-assisted surgery privileges at our institution includes completion of an accredited residency or fellowship training program in a surgical specialty or obstetrics/gynecology, documentation of completion of formal robotic training, and completion of at least 5 proctored cases with satisfactory outcomes.

BUILDING A RoBO TEAM

A seasoned surgical team with robotic experience provides invaluable assistance during the early portion of the surgeon's learning curve. Coordination, cooperation, and communication between the robotic first assist, circulator, scrub tech, and anesthesia team are critical for safe robotic surgery. Basic principles in docking, undocking, and proper use of robotic instruments must be adhered to by the surgical team to assure a safe operation. A bedside assistant with breast surgery experience (eg, another breast surgeon or plastic surgeon) is critical to optimize intraoperative communication during the dissection until the operating surgeon has achieved sufficient experience performing RNSM. For reconstruction post RNSM, the team should include an experienced plastic surgeon comfortable with implant or tissue expander placement through axillary incision. When possible, team members should perform in a wet lab together to better understand crucial aspects of a successful operation that optimizes patient safety and outcomes including room set up, patient positioning, console docking/undocking, and challenging technical aspects of the procedure. Prior to our first live case, 5 cadaveric RNSM were performed by the same breast surgeon, plastic surgeon, and registered nurse first assist.[10] Prior to the first patient, our RoBO team met to simulate a "dry run" of the case to discuss patient positioning, room set up, instrument set up, and the anticipated operative course.

PATIENT SELECTION AND ELIGIBILITY CRITERIA

As with all operations, much of the overall success can be attributed to appropriate patient selection. The ideal candidate does not smoke, has a normal body mass index, small to moderate breasts without ptosis, an early-stage breast cancer without nodal involvement, or the patient requires the procedure for risk reduction.[11] Finally, surgeons need to be transparent with patients during the informed consent process regarding the current state of robotic-assisted surgery for mastectomy as well as their own robotic experience with clear discussion of the experimental nature of the procedure.

SCHEDULING A ROBOTIC CASE

After the patient has been appropriately consented, surgery scheduling challenges may arise depending on the institutional policy regarding access to robotic devices. If the robotic device availability and operating room availability are coordinated separately (eg, having a robot available does not necessarily mean an available operating room), additional organizational efforts may be required. Having an available robot, operating room, breast surgeon, and reconstructive surgeon on the same day may pose scheduling challenges such that the time from the decision to perform robotic-assisted surgery to the actual operation may be unacceptable for a patient with an active cancer diagnosis.

CONCLUSIONS

Breast surgeons continue to evolve the mastectomy from the debilitating and disfiguring radical approach performed by Halsted at the turn of the 20th century to the more cosmetically appealing mastectomies of today without compromising oncologic principles. RNSM offers an exciting next step in this evolution with promising benefits to both patient and surgeon. Surgical technical innovation is inevitable and necessary to ultimately provide the best patient outcomes. However, adherence

to rigorous safety guidelines, transparency, and independent oversight are foundational to assure the highest level of excellence and safety for our patients.

REFERENCES

1. Sarfati B, Honart JF, Leymarie N, et al. Robotic-assisted nipple sparing mastectomy: a feasibility study on cadaveric models. J Plast Reconstr Aesthet Surg. 2016;69:1571–1572.
2. Sarfati B, Struk S, Leymarie N, et al. Robotic prophylactic nipple-sparing mastectomy with immediate prosthetic breast reconstruction: a prospective study. Ann Surg Oncol. 2018;25:2579–2586.
3. Toesca A, Invento A, Massari G, et al. Update on the feasibility and progress on robotic breast surgery. Ann Surg Oncol. 2019;26:3046–3051.
4. Houvenaeghel G, Bannier M, Rua S, et al. Robotic breast and reconstructive surgery: 100 procedures in 2-years for 80 patients. Surg Oncol. 2019;31:38–45.
5. Toesca A, Sangalli C, Maisonneuve P, et al. A randomized trial of robotic mastectomy versus open surgery in women with breast cancer or BRCA mutation [published online ahead of print June 9, 2021]. Ann Surg. doi: 10.1097/SLA.0000000000004969.
6. U.S. Food and Drug Administration. Caution When Using Robotically-Assisted Surgical Devices in Women's Health including Mastectomy and Other Cancer-Related Surgeries: FDA Safety Communication. 2019. Available at: https://www.fda.gov/medical-devices/safety-communications/caution-when-using-robotically-assisted-surgical-devices-womens-health-including-mastectomy-and. Accessed June 12, 2022.
7. Park KU, Lee S, Sarna A, et al. Prospective pilot study protocol evaluating the safety and feasibility of robot-assisted nipple-sparing mastectomy (RNSM). BMJ Open. 2021;11:e050173.
8. U.S. Food and Drug Administration. UPDATE: Caution With Robotically-Assisted Surgical Devices in Mastectomy: FDA Safety Communication. 2021. Available at: https://www.fda.gov/medical-devices/safety-communications/update-caution-robotically-assisted-surgical-devices-mastectomy-fda-safety-communication. Accessed June 12, 2022
9. Lee J, Park HS, Lee DW, et al. From cadaveric and animal studies to the clinical reality of robotic mastectomy: a feasibility report of training program. Sci Rep. 2021;11:21032.
10. Park KU, Tozbikian GH, Ferry D, et al. Residual breast tissue after robot-assisted nipple sparing mastectomy. Breast. 2021;55:25–29.
11. Lai HW, Toesca A, Sarfati B, et al. Consensus statement on robotic mastectomy-expert panel from International Endoscopic and Robotic Breast Surgery Symposium (IERBS) 2019. Ann Surg. 2020;271:1005–1012.