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## **Robotic Reboot: New Study Shows Minimally Invasive Robotic Surgeries Effective for Nipple Sparing Mastectomies**

**Delivers Significant Potential Advantages for Patients and Surgeons**

***Abstract: A Prospective, Multi-Center Randomized Controlled Trial (RCT) of the da Vinci SP® Surgical System vs Open Surgery in Nipple Sparing Mastectomy (NSM) Procedures for Patients with Breast Cancer***

**Seattle, WA, May 1, 2026**—Nipple sparing mastectomies (NSM)—surgeries that remove all breast tissue while preserving the nipple-areolar complex (NAC) and most breast skin—performed with minimally invasive robotic technology can be as safe and effective for early-stage breast cancer as conventional open surgeries, according to a prospective, multi-center randomized trial presented this week at The American Society of Breast Surgeons (ASBrS) Annual Meeting in Seattle. Researchers anticipate that going forward robotic nipple sparing mastectomy (rNSM) will deliver significant advantages for both patients and surgeons.

“While for eligible women, nipple sparing surgeries typically provide multiple benefits,” says lead researcher Katherine Kopkash, M.D., Director of Oncoplastic Breast Surgery at Endeavor Health and Clinical Professor of Surgery at University of Chicago Pritzker School of Medicine, “in our study, surgeries performed with the da Vinci Single Port robotic system demonstrated improved patient satisfaction on BREAST-Q assessment compared to conventional procedures.” The BREAST-Q tool measures patient perceptions of surgical outcomes.

Notably, for surgeons, robotic technology also improves the considerable ergonomic issues inherent in open NSM procedures that cause fatigue and discomfort, while enhancing surgical visualization. “Painful posture is a major issue for physicians performing frequent open NSM procedures and may also hamper their ability to manage a full surgical schedule,” she explains.

Dr. Kopkash explains that robotic systems operate from an ergonomically designed console with hand controls and pedals. The high-tech platform, which is specially outfitted for a specific application, translates physician movements into precise robotic actions to perform surgery.

Minimally invasive robotic procedures also potentially enhance patient outcomes. They reduce surgical incisions to three to four centimeters in length that are typically hidden under a woman's bra line. Open procedures require a 10-to-15-centimeter surgical cut in the inframammary fold under the breast, resulting in a more visible scar on some women.

Smaller incisions and elimination of the surgical retractors required for open procedure also support improved blood supply to the skin, decreasing the possibility of flap necrosis and potentially improving nipple sensation by minimizing damage to peripheral nerves.

"Robotic breast surgery may have real benefits for both the patients and surgeons," she says.

The study was conducted under the US Food and Drug Administration (FDA) Investigational Device Exemption (IDE) G220319 from August 2023 to December 2025. It involved 23 participating surgeons at 14 U.S. sites who had specific training in the use of the da Vinci system.

All 74 study participants met accepted criteria for nipple sparing mastectomies. Contralateral prophylactic NSM was permitted. Patients were randomized into the two groups with similar cancer characteristics and included 65 robotic procedures (38 therapeutic, 27 prophylactic) and 66 open surgeries (38 therapeutic, 28 prophylactic).

Researchers examined event rates at 42 days post-operatively, positive surgical margin (PSM) rates, duration of surgery, final pathology results, blood loss, length of hospital stay, SKIN score assessment of the mastectomy flap and NAC viability. The study found no statistically significant differences between rNSM and open NSM on any of these measures except blood loss, which was less for robotic NSM, and duration of surgery, which was longer for robotic NSM. Researchers attribute the latter to a system learning curve.

Patient-reported outcomes were measured through BREAST-Q scores. All results were analyzed using Fisher's exact tests. rNSM ergonomics were measured through electromyogram to assess physician neuromuscular activity and questionnaires. These results are currently being analyzed.

Surgical duration was longer for rNSM at 141.6 minutes compared to open NSM at 83.9 minutes. At 42 days, serious adverse events (SAEs) were reported in three robotic patients and eight open patients. NAC preservation and PSM rates were similar in both groups. No rNSM patients were converted to open surgery, and no device-related SAEs were reported.

At six months post-surgery, there were more favorable changes in the BREAST-Q scores for rNSM compared to open surgeries for sexual well-being, satisfaction with breasts and physical well-being chest. However, these differences did not reach statistical significance.

The study concluded prior to planned enrollment when the device was granted FDA 510(k) clearance for rNSM. da Vinci SP is the first robotic platform cleared by the FDA for use in NSM surgery in the U.S. Participants will be followed for the full five-year study protocol.

“A more comfortable position with enhanced visualization enables better surgeries,” comments Dr. Kopkash. “Potential patient benefits may be significant. We eagerly await long-term data from these promising clinical trials.”

## **A Prospective, Multi-Center Randomized Controlled Trial (RCT) of the da Vinci SP® Surgical System vs Open Surgery in Nipple Sparing Mastectomy (NSM) Procedures for Patients with Breast Cancer**

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**Background/Objective:** Robotic nipple-sparing mastectomies (rNSM) are being performed at increasing rates worldwide, yet clinical outcomes data on the U.S. experience are lacking. This trial evaluated the safety and effectiveness of rNSM performed using the da Vinci Single Port (SP)® vs. open NSM in women in the United States (US) with early-stage breast cancer.

**Methods:** This study was a prospective, two-arm, multi-center randomized controlled trial (RCT) performed under the US Food and Drug Administration (FDA) Investigational Device Exemption (IDE) G220319. Surgeries were performed at 14 US sites after IRB approval by 23 surgeons who had undergone specific training in the use of the SP system, the study protocol, and the study procedures. Study patients were women with early-stage breast cancer (clinical Tis-T2 and N0), BMI <30, tumor-skin distance ≥5mm, tumors located ≥10 mm from the nipple-areolar complex (NAC), calcifications ≤5 cm for DCIS, breast size C cup or smaller, breast ptosis ≤grade 2, and candidates for unilateral or bilateral NSM procedure(s). Contralateral prophylactic NSM and neoadjuvant treatment were allowed. Immediate reconstruction was performed as one- or two-stage implant-based procedures. Patients were randomized 1:1 to rNSM or open NSM. The primary outcomes of interest were conversion from rNSM to open NSM, adverse event rates at 42 days post-operatively, and positive surgical margin (PSM) rates. The PSM was defined as ≤2mm for DCIS and "ink on tumor" for invasive cancer. Additional data was collected on operative times, final pathology results, blood loss, hospital stay, SKIN score assessment of mastectomy flap, NAC viability and patient-reported outcomes (PRO) including BREAST-Q data. Results were analyzed using Fisher's exact tests. The study concluded prior to completion of planned enrollment due to 510(k) clearance being granted by the FDA.

**Results:** A total of 74 patients were consented, enrolled, randomized, and had the surgery completed per protocol (37 rNSM, 37 open NSM) between 8/11/23 and 12/31/25. Many of these patients had bilateral NSM and the final number of NSM was 65 rNSM (38 therapeutic, 27 prophylactic) and 66 open NSM (38 therapeutic, 28 prophylactic). Patient and tumor characteristics were similar between the two groups (Table 1). The average time for the NSM procedure for rNSM vs. open NSM was 141.6 minutes (min) vs. 83.9 min ( $p < 0.001$ ), and the average time for reconstruction was 79.7 min for rNSM vs. 62.5 min for open NSM ( $p = 0.008$ ). No patients in the rNSM arm required a conversion to an open procedure. Serious adverse events (SAEs) at 42 days occurred in 3 rNSM pt (8.1%) and 8 open NSM patients (21.6%). Per the Data Safety Monitor (DSM), there were no device-related SAEs in the rNSM

group. NAC preservation at 42 days was 100% in the rNSM patients vs. 98.5% in the open NSM group. There were 2 unplanned reoperations in the rNSM patients (5.4%) vs. 8 in the open NSM group (21.6%). The PSM rate was the same between the rNSM (6 patients, 16.2%) and open NSM groups (6 patients, 16.2%;  $p > 0.9$ ). There was no statistical difference in the rate of "ink on tumor" (0 in the rNSM group, 0.0%, vs. 1 in the open NSM group, 2.7%,  $p > 0.9$ ) or DCIS  $\leq 2$ mm from the margin (6 patients in rNSM group, 16.2%, and 5 patients in NSM group, 13.5%,  $p > 0.9$ ). There were no local or distant recurrences of cancer in any trial patients. There were more favorable baseline to 6-month changes in BREAST-Q scores in the rNSM group compared to open NSM in the domains of sexual well-being (-7.2 vs. -11.6,  $p = 0.2$ ), satisfaction with breasts (-0.6 vs. -6.3,  $p = 0.3$ ), and physical well-being chest (-9.1 vs. -16.6,  $p = 0.1$ ), although none of these were statistically significant.

**Conclusion:** These results demonstrate that da Vinci SP® rNSM is safe and effective for patients with early-stage breast cancer with comparable outcomes to open NSM. The operative times were longer for rNSM and rNSM reconstruction, which likely reflects the early learning period for this technique. The PSM rate was similar between the groups. BREAST-Q scores suggest favorable trends in the rNSM group compared to the open NSM group. These investigators eagerly await additional long-term data from robust clinical trials to help determine the role of rNSM for breast cancer patients.

Table 1 Patient characteristics, Tumor information, and Clinical Outcomes

Characteristic	SP RCT	Open RCT	p-value
	Patients N = 26 Breasts N = 46	Patients N = 27 Breasts N = 48	
Age (years)			0.2
Mean (SD)	49.3 (9.19)	45.6 (11.45)	
Body Mass Index (BMI)			0.093
Mean (SD)	21.7 (2.48)	22.9 (2.95)	
Breast Cup Size			0.5
A	5/26 (19.2%)	4/27 (14.8%)	
B	17/26 (65.4%)	17/27 (62.9%)	
C	4/26 (15.4%)	8/27 (29.6%)	
Therapeutic Breast Cancer Type*, n (%)			
Ductal Carcinoma In-Situ	10 (37.0%)	16 (59.3%)	0.2
Invasive Ductal Carcinoma	18 (66.7%)	18 (66.7%)	0.9
Invasive Lobular Carcinoma	5 (18.5%)	1 (3.7%)	0.11
Other	3 (11.1%)	2 (7.4%)	0.7
Tumor Size* (cm)			
Mean (SD)	1.8 (1.06)	1.6 (1.22)	0.7
Closest Distance of Tumor to Skin* (mm)			0.3
Mean (SD)	13.8 (8.65)	16.5 (12.37)	
Closest Distance of Tumor to Nipple Areolar Complex (NAC)* (mm)			0.5
Mean (SD)	35.2 (19.99)	31.8 (15.57)	
History of Chemotherapy or other neoadjuvant therapies	4/26 (15.4%)	7/27 (25.9%)	0.3
Estimate Blood Loss (EBL)			0.076
Mean (SD)	55.6 (29.15)	90.6 (91.01)	
Cancer Recurrence (at 6 months)	0	0	

\*Only applicable for therapeutic breasts, analysis performed at breast level.