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Robotic mastectomy: the next major advance in breast cancer surgery?

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In the past three decades, remarkable advances in de-escalating breast cancer surgery have occurred, with breast-conserving surgery replacing radical mastectomy, sentinel lymph node biopsy replacing axillary dissection, and neoadjuvant chemotherapy used to downstage both the axilla and the breast, allowing smaller operations with less morbidity. These advances were incorporated into practice after high-quality scientific evidence demonstrated equivalent survival and local control compared with standard surgical approaches.

The use of robotic-assisted surgery in urological, gynaecological, and general surgery has increased more than three-fold in the past decade[1], so it is not surprising that it is now being proposed as the next major advance in breast cancer surgery. Since the initial case report of robotically assisted nipple-sparing mastectomy (R-NSM)[2], case series have emerged from Europe and Asia describing experiences with R-NSM for breast cancer treatment and risk reduction[3–6]. The primary benefit of R-NSM is improved cosmetic outcomes, owing to incision placement in the mid-axillary line, although it has also been suggested that this incision location and avoidance of traction injuries from retractors improve viability of the nipple–areolar complex[5–7].

What has been learned from these initial reports, the majority of which are retrospective single-institution studies, is that, in small-breasted women (cup size C or less, majority A and B), rates of R-NSM complications were low, conversion to an open approach was infrequent, and blood loss was acceptable[3–7]. Somewhat surprisingly for a procedure performed for cosmetic reasons, almost no information on patient-reported cosmetic outcomes is available. Lai and colleagues[8] administered a 10-item questionnaire 1–3 months after surgery to 23 patients undergoing R-NSM with implant reconstruction; only 11 of the 23 indicated that they were very satisfied with their breast appearance—not overwhelming evidence of a cosmetic advantage.

Multiple questions regarding robotic mastectomy remain unanswered, foremost among them the oncological safety of the procedure. The published reports lack sufficient numbers of patients and adequate follow-up to provide information on this critical question. Those concerned about oncological outcomes of R-NSM should not be dismissed as ageing Luddites; experience with robotic and laparoscopic radical hysterectomy is instructive in this regard. Minimally invasive radical hysterectomy was endorsed in the National Comprehensive Cancer Network and European Society of Gynaecological Oncology guidelines on the basis of retrospective studies showing oncological safety[9], and was widely adopted in practice until a multicentre phase III trial[10] comparing the minimally invasive approaches with open surgery was stopped early after the finding of statistically significantly improved disease-free and overall survival in the open surgery arm. The enthusiasm for robotic mastectomy in the absence of oncological outcome data prompted the US Food and Drug Administration[11] to issue a safety communication to patients, surgeons, and hospital systems in February 2019 stating that the safety and effectiveness of robotically assisted surgery for mastectomy for the treatment or prevention of breast cancer has not been established.

Although oncological safety is the primary concern regarding R-NSM, other important issues remaining to be addressed include the learning curve and the cost-effectiveness of the procedure. Learning curves in robotic surgery have been measured by procedure duration and conversion to open approaches, both of which have been shown to decrease with experience, but at a highly variable rate[4–6,12]. Previous experience with minimally invasive surgery, something many specialist breast surgeons lack, has been shown to be a factor in the learning curve[13], as has procedure volume[14]. Experience in gastrointestinal cancer suggests that a formal robotic training programme incorporating virtual reality simulation, skill development on inanimate biotissue, use of a video library, operative evaluation, and ongoing quality assurance can reduce complications and decrease the number of operative procedures needed to acquire proficiency[15]. All of this raises questions about the feasibility of R-NSM for the majority of breast surgeons. Even this rigorous approach to training, however, lacks metrics to assess completeness of breast tissue removal, which are far more relevant to oncological outcomes than procedure time.

Cost-effectiveness is the other important aspect of R-NSM. The costs of robotic surgery include the cost of the robotic console, the service contract, and disposable instrumentation, as well as the cost of increased operating time. In one large study[16] comparing laparoscopic and robotically assisted radical nephrectomy, 90-day direct hospital costs were almost US $3000 (€2484; exchange rate 16 January 2021) higher for the robotic procedures. For more complex procedures in which robotic surgery may shorten hospital stay or reduce complication rates, these excess

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costs may be offset by downstream cost savings, but this is unlikely to be the case for nipple-sparing mastectomy, for which 23-h hospital stays are the norm and complications of open procedures requiring hospitalization are infrequent[17].

In spite of the lack of evidence supporting substantially improved cosmetic outcomes, oncologic safety, or cost-effectiveness of R-NSM, an expert panel of 10 general and plastic surgeons published a consensus statement[18] that included indications for R-NSM, technical considerations, and preoperative counselling of patients. Although the patient counselling section suggests discussion of complications, indications and contraindications, and possible conversion to skin-sparing mastectomy for a positive subnipple biopsy, there is no mention of the need to discuss the lack of any oncological outcome data at all, no less the level 1 evidence that has been demanded for other paradigm changes in breast cancer surgery. A review of ongoing clinical trials listed on ClinicalTrials.gov suggests that this evidence drought will not be resolved in the near future. An 82-patient study of robotic *versus* open nipple-sparing mastectomy performed at the European Institute of Oncology has completed enrolment, but the primary endpoint is patient satisfaction, and the sample size is insufficient for meaningful assessment of oncological outcomes. Prospective studies with primary oncological outcomes are not currently listed.

In evaluating the current state of R-NSM, the evidence shows that the procedure can be performed safely, when safety is defined in terms of perioperative morbidity and mortality, by a select group of surgeons. There is no convincing evidence of superior cosmetic outcomes from the patient perspective, no meaningful data on oncological outcomes, and the procedure is highly unlikely to be cost-effective. The only conclusion that can be drawn at this time is that there is no role for R-NSM outside of a clinical trial; the technical capability of performing a procedure is not a justification for its use.

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References

1. Childers CP, Maggard-Gibbons M. Estimation of the acquisition and operating costs for robotic surgery. *JAMA* 2018;**320**:835–836
2. Toesca A, Peradze N, Galimberti V, Manconi A, Intra M, Gentilini O *et al.* Robotic nipple-sparing mastectomy and immediate breast reconstruction with implant: first report of surgical technique. *Ann Surg* 2017;**266**:e28–e30
3. Houvenaeghel G, Bannier M, Rua S, Barrou J, Heinemann M, Knight S *et al.* Robotic breast and reconstructive surgery: 100 procedures in 2-years for 80 patients. *Surg Oncol* 2019;**31**:38–45
4. Lai HW, Wang CC, Lai YC, Chen CJ, Lin SL, Chen ST *et al.* The learning curve of robotic nipple sparing mastectomy for breast cancer: an analysis of consecutive 39 procedures with cumulative sum plot. *Eur J Surg Oncol* 2019;**45**:125–133
5. Sarfati B, Struk S, Leymarie N, Honart JF, Alkhashnam H, Tran de Fremicourt K *et al.* Robotic prophylactic nipple-sparing mastectomy with immediate prosthetic breast reconstruction: a prospective study. *Ann Surg Oncol* 2018;**25**:2579–2586
6. Toesca A, Invento A, Massari G, Girardi A, Peradze N, Lissidini G *et al.* Update on the feasibility and progress on robotic breast surgery. *Ann Surg Oncol* 2019;**26**:3046–3051
7. Angarita FA, Castelo M, Englesakis M, McCready DR, Cil TD. Robot-assisted nipple-sparing mastectomy: systematic review. *Br J Surg* 2020;**107**:1580–1594
8. Lai HW, Chen ST, Lin SL, Chen CJ, Lin YL, Pai SH *et al.* Robotic nipple-sparing mastectomy and immediate breast reconstruction with gel implant: technique, preliminary results and patient-reported cosmetic outcome. *Ann Surg Oncol* 2019;**26**:42–52
9. Cao T, Feng Y, Huang Q, Wan T, Liu J. Prognostic and safety roles in laparoscopic *versus* abdominal radical hysterectomy in cervical cancer: a meta-analysis. *J Laparoendosc Adv Surg Tech A* 2015;**25**:990–998
10. Ramirez PT, Frumovitz M, Pareja R, Lopez A, Vieira M, Ribeiro R *et al.* Minimally invasive *versus* abdominal radical hysterectomy for cervical cancer. *N Engl J Med* 2018;**379**:1895–1904
11. US 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*. https://www.fda.gov/medical-devices/safety-communications/caution-when-using-robotically-assisted-surgical-devices-womens-health-including-mastectomy-and (accessed 18 November 2020)
12. Pernar LIM, Robertson FC, Tavakkoli A, Sheu EG, Brooks DC, Smink DS. An appraisal of the learning curve in robotic general surgery. *Surg Endosc* 2017;**31**:4583–4596
13. Park SS, Kim MC, Park MS, Hyung WJ. Rapid adaptation of robotic gastrectomy for gastric cancer by experienced laparoscopic surgeons. *Surg Endosc* 2012;**26**:60–67
14. Boone BA, Zenati M, Hogg ME, Steve J, Moser AJ, Bartlett DL *et al.* Assessment of quality outcomes for robotic pancreaticoduodenectomy: identification of the learning curve. *JAMA Surg* 2015;**150**:416–422
15. Knab LM, Zureikat AH, Zeh HJ III, Hogg ME. Towards standardized robotic surgery in gastrointestinal oncology. *Langenbecks Arch Surg* 2017;**402**:1003–1014
16. Jeong IG, Khandwala YS, Kim JH, Han DH, Li S, Wang Y *et al.* Association of robotic-assisted *vs* laparoscopic radical nephrectomy with perioperative outcomes and health care costs, 2003 to 2015. *JAMA* 2017;**318**:1561–1568
17. Matsen CB, Mehrara B, Eaton A, Capko D, Berg A, Stempel M *et al.* Skin flap necrosis after mastectomy with reconstruction: a prospective study. *Ann Surg Oncol* 2016;**23**:257–264
18. Lai HW, Toesca A, Sarfati B, Park HS, Houvenaeghel G, Selber JC *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