The Evolution of Image-Free Robotic Assistance in Unicompartmental Knee Arthroplasty

Jess H. Lonner, MD, and Vincent M. Moretti, MD

Abstract

Semiautonomous robotic technology has been introduced to optimize accuracy of bone preparation, implant positioning, and soft tissue balance in unicompartmental knee arthroplasty (UKA), with the expectation that there will be a resultant improvement in implant durability and survivorship. Currently, roughly one-fifth of UKAs in the US are being performed with robotic assistance, and it is anticipated that there will be substantial growth in market penetration of robotics over the next decade. First-generation robotic technology improved substantially implant position compared to conventional methods; however, high capital costs, uncertainty regarding the value of advanced technologies, and the need for preoperative computed tomography (CT) scans were barriers to broader adoption. Newer image-free semiautonomous robotic technology optimizes both implant position and soft tissue balance, without the need for preoperative CT scans and with pricing and portability that make it suitable for use in an ambulatory surgery center setting, where approximately 40% of these systems are currently being utilized. This article will review the robotic experience for UKA, including rationale, system descriptions, and outcomes.

The concept of robotics is relatively new in medical practice. The term "robot" itself is less than 100 years old, having been first introduced to popular culture in 1917 by Joseph Capek in the science fiction story *Opilec*.[1,2] Robots eventually transitioned from this initial fictional literary setting to reality in 1958, when General Motors began adding automated machines to its assembly lines.[1] However, it was not until the 1980s that robotics and their exacting efficiencies would be introduced in the medical field, and it would take another decade before they would enter the specialty of orthopedics.[1-4]

The first robotic-assisted orthopedic surgery was reportedly performed in 1992, when the Robodoc autonomous system was utilized for total hip arthroplasty.[2-4] A robotic system for total knee arthroplasty (TKA) was first described in 1993, but it would take several more years until a system for unicompartmental knee arthroplasty (UKA) would be commercialized and used clinically.[5,6] The rationale for advancement of robotic technology for isolated medial or lateral knee arthritis stems from the recognition that while UKA is effective and durable when components and limb are well aligned and soft tissues appropriately balanced, they are less forgiving of even slight component malalignment of as little as 2° to 3° and prone to premature loosening or wear in those circumstances.[7-13,14] In the mid 2000s, Cobb and colleagues[6] reported using a semiautonomous robot for UKA. Since then, emergence of other semiautonomous robotic systems has led to greater market penetration and technology utilization.[15]

Currently, an estimated 15% to 20% of UKA surgeries are being performed with robotic assistance.[16] Further, patent activity and peer-reviewed publications related to robotic technology in UKA (which can be considered surrogate measures of interest and evolving development and experience with robotic technologies) have increased dramatically over the past few years.[2,6,14,17,18-34] To

Authors' Disclosure Statement: Dr. Lonner reports he is a paid consultant to and received royalties from Smith & Nephew and Zimmer Biomet. Dr. Moretti reports no actual or potential conflict of interest in relation to this article.

date, while the most dramatic growth of robotic utilization and case volumes has occurred in the subspecialty of UKA, semiautonomous robotic systems have been used with increasing frequency for patellofemoral and bicompartmental knee arthroplasty.[35,36] Robotics have been used sparingly for TKA, and limited to autonomous systems;[37,38] however, it is anticipated that emergence of semiautonomous platforms for TKA will further expand the role of robotics over the next decade, particularly as our focus shifts beyond component and limb alignment in TKA and more towards the role of robotics in soft tissue balancing, reduction in instrumentation and inventory and its attendant cost savings, and surgical efficiencies. One semiautonomous robotic technology first used in 2006 (Mako, Stryker) reported a 130% increase in robotic volume from 2011 to 2012; another, first used in 2013, reported growth of 480% between 2013 and 2014, due to its improved cost structure, ease of use, smaller footprint, image-free platform and applicability in ambulatory surgery centers (Navio, Smith & Nephew; data supplied by manufacturer), demonstrating the growing popularity of robotic technology.[17,39] Further, a recent analysis of potential market penetration over the next decade published by Medical Device and Diagnostic Industry (http://www.mddionline.com) projected that nearly 37% of UKAs and 23% of TKAs will be performed with robotics in 10 years.

Figure 1. Intraoperative photograph of handheld robotic system (Navio) in use.

Figure 2. Screenshot demonstrating graph of planned ligament balance through a range of motion after an algorithm that includes surface mapping, ligament tensioning, and virtual component sizing and positioning before starting surface preparation. Adjustments in component position and orientation can be made to modify the graph before surface preparation begins. In this case, 2 mm of medial laxity is anticipated between the components through a full range of motion.

Distinction Between Robotic-Assisted Technologies

Autonomous systems involve pre-programming the system with parameters that define the amount and orientation of bone to be removed, after which the system prepares the surfaces independent of surgeon control, other than having access to a "shutdown" switch. There are currently no autonomous robotic tools approved by the US Food and Drug Administration (FDA) for knee arthroplasty.

Semiautonomous systems involve the mapping of condylar landmarks and determination of alignment indices, which also defines the volume and orientation of bone to be removed. While the systems remove bone and cartilage within the pre-established parameters, the robotic tools are controlled and manipulated by the surgeon (**Figure 1**). The predetermined safe zones modulate and safeguard the surgical actions. These systems also provide real-time quantification of soft tissue balancing, which may contribute to the reported successful clinical and functional outcomes with semiautonomous systems (**Figure 2**).[2,4,19,22] There are several semiautonomous robotic systems that are approved for use by the FDA.

Each robotic-assisted surgery (RAS) system utilizes some sort of 3-dimensional digital map of the surgical surfaces after a process of surface mapping and landmark registration.[2] In the case of Mako, this planning process also requires a preoperative computed tomography (CT) scan. Over the past few years, the requirement of a CT scan has proven problematic and costly, as increasingly third-party payers and insurers are denying coverage for additional studies used for preoperative planning, leaving the burden of cost on the patients and/or hospitals. Additionally, in an era in which bundled payment arrangements are commonplace or in which providers are held accountable for costly care, the use of costly preoperative imaging is untenable. Furthermore, there is a growing concern regarding the risk of radiation exposure from CT scans that makes image-free technologies, such as Navio, an alternative for stakeholders.[40]

At this time, the 2 semiautonomous systems in use for UKA employ different methods to safeguard against inadvertent bone preparation: one by providing haptic constraint beyond which movement of the bur is limited (Mako); the other by modulating the exposure or speed of the handheld robotic bur (Navio) (**Figure 3**).

Outcomes of RAS in UKA

Compared to conventional UKA, robotic assistance has consistently demonstrated improved surgical accuracy, even through minimally invasive incisions (**Figures 4, 5**).[6,20-28] Several studies have found substantial reduction in variability and error of component positioning with use of semiautonomous robotic tools.[6,21,25] In fact, precision appears to be comparable regardless of whether an image-free system or one requiring a preoperative CT scan is used (**Table**). Further, in addition to improving component and limb alignment, Plate and colleagues[22] demonstrated that RAS-based UKA systems can help the surgeon precisely reproduce plans for soft-tissue balancing. The authors reported ligament balancing to be accurate up to .53 mm compared to the preoperative plan, with approximately 83% of cases balanced within 1 mm of the plan through a full range of flexion.[22]

When evaluating advanced and novel technologies, there is undoubtedly concern that there will be increased operative time and a substantial learning curve with those technologies. Karia and colleagues[30] found that when inexperienced surgeons performed UKA on synthetic bone models using robotics, the mean compound rotational and translational errors were lower than when conventional techniques were used. Among those using conventional techniques, although surgical times improved during the learning period, positional inaccuracies persisted. On the other hand, robotic

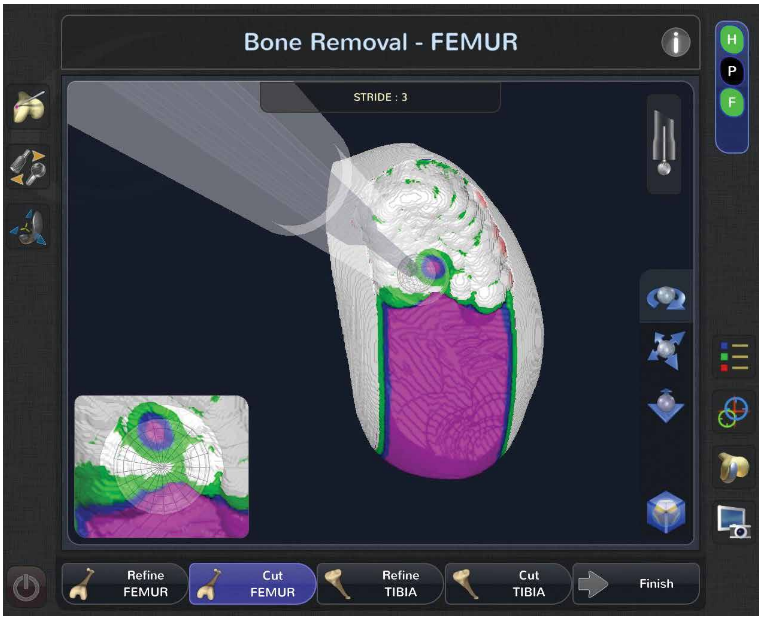

Figure 3. Screenshot showing virtual image of femoral surface preparation.

Table. **Positioning Error—Robotic Techniques vs Conventional**

RMS Error	Acrobot[6]	Mako[21]	Navio[25]	Conventional[21]
Flexion/Extension (°)	2.1	2.1	1.8	6.0
Varus/Valgus (°)	1.7	2.1	2.5	4.1
Interior/Exterior(°)	3.1	3.0	1.7	6.3
Proximal/Distal (mm)	1.0	1.0	1.3	2.8
Anterior/Posterior (mm)	1.8	1.6	1.3	2.4
Medial/Lateral (mm)	0.6	1.0	1.0	1.6

Abbreviation: RMS, root mean square.

assistance enabled surgeons to achieve precision and accuracy when positioning UKA components irrespective of their learning experience.[30] Another study, by Coon,[31] similarly suggested a shorter learning curve and greater accuracy with RAS using the Mako system compared to conventional techniques. A prospective, multicenter, observational study evaluated the operative times of 11 surgeons during their initial clinical cases using Navio robotic technology for medial UKA after a period of training using cadaver knees and sawbones.[41] The learning curve for total surgical time (tracker placement to implant trial phase) indicates that it takes 8 cases to achieve 95% of total learning and maintain a steady state surgical time.

Potential Disadvantages of RAS in UKA

RAS for UKA has several potential disadvantages that must be weighed against their potential benefits. One major barrier to broader use of RAS is the increased cost associated with the technologies.[17,19,27,32] Capital and maintenance costs for these systems can be high, and those that require additional advanced imaging, such as CT scans, further challenge the return on investment.[17,19,32] In a Markov analysis of one robotic system (Mako), Moschetti and colleagues[17] found that if one assumes a system cost of $1.362 million, value can be attained due to slightly better outcomes despite being more expensive than traditional methods. Nonetheless, their analysis of the Mako system estimated that each robot-assisted UKA case cost $19,219, compared to $16,476 with traditional UKA, and was associated with an incremental cost of $47,180 per quality-adjusted life-year. Their analysis further demonstrated that the cost-effectiveness was very sensitive to case volume, with lower costs realized once volumes surpassed 94 cases per year. On the other hand, costs (and thus value) will also obviously vary depending on the capital costs, annual service charges, and avoidance of unnecessary preoperative scans.[19] For instance, assuming a cost of $500,000 for the image-free Navio robotic system, return on investment is achievable within 25 cases annually, roughly one-quarter of the cases necessary with the image-based system.

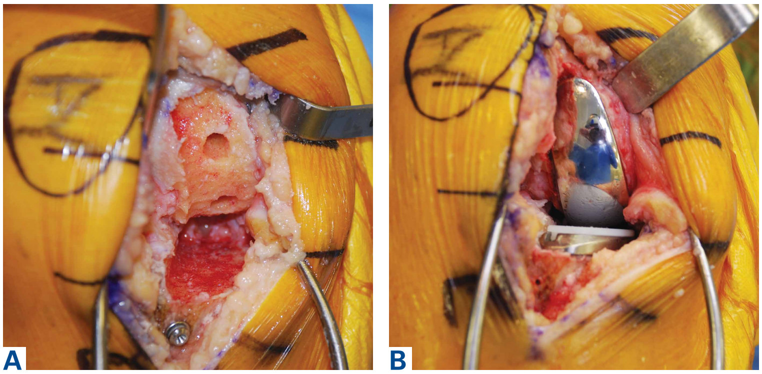

Figure 4. (A) Clinical view of the condylar surfaces after bone preparation and (B) with the implants in place.

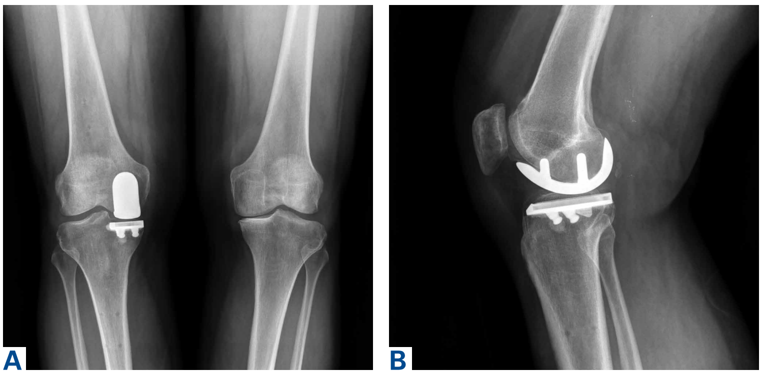

Figure 5. Postoperative (A) anteroposterior and (B) lateral radiographs after UKA with Navio robotic system.

Another disadvantage of RAS systems in UKA is the unique complications associated with their use. Both RAS and conventional UKA can be complicated by similar problems such as component loosening, polyethylene wear, progressive arthritis, infection, stiffness, instability, and thromboembolism. RAS systems, however, carry the additional risk of specific robot-related issues.[19,27] Perhaps most notably, the pin tracts for the required optical tracking arrays can create a stress riser in the cortical bone,[19,27,33,42] highlighting the importance of inserting these pins in metaphyseal, and not diaphyseal, bone. Soft tissue complications have been reported during bone preparation with autonomous systems in total knee and hip arthroplasty;[37,38] however, the senior author (JHL) has not observed that in 1000 consecutive cases with either semiautonomous surgeon-driven robotic tool.[19]

Finally, systems that require a preoperative CT scan pose an increased radiation risk.[40] Ponzio and Lonner[40] recently reported that each preoperative CT scan for robotic-assisted knee arthroplasty (using a Mako protocol) is associated with a mean effective dose of radiation of 4.8 mSv, which is approximately equivalent to 48 chest radiographs.[34] Further, in that study, at least 25% of patients had been subjected to multiple scans, with some being exposed to cumulative effective doses of up to 103 mSv. This risk should not be considered completely negligible given that 10 mSv may be associated with an increase in the possibility of fatal cancer, and an estimated 29,000 excess cancer cases in the United States annually are reportedly caused by CT scans.[40,43,44] However, this increased radiation risk is not inherent to all RAS systems. Image-free systems, such as Navio, do not require CT scans and are thus not associated with this potential disadvantage.

Conclusion

Robotics has come a long way from its humble conceptual beginnings nearly a century ago. Rapid advances in medical technology over the past 10 years have led to the development and growing popularity of RAS in orthopedic surgery, particularly during UKA. Component placement, quantified soft tissue balance, and radiographic alignment appear to be improved and the incidence of outliers reduced with the use of RAS during UKA. Further assessment is needed to determine whether the improved alignment and balance will impact clinical function and/or durability. Early results are very promising, though, creating optimism that the full benefits of RAS in UKA will be further confirmed with additional time and research.

Dr. Lonner is an Orthopedic Surgeon, Adult Reconstruction, and Dr. Moretti is an Adult Reconstruction Fellow, Rothman Institute, Sidney Kimmel Medical College at Thomas Jefferson University, Philadelphia, Pennsylvania.

Address correspondence to: Jess H. Lonner, MD, Rothman Institute, 825 Old Lancaster Ave, 2nd Floor, Bryn Mawr, PA 19010 (tel, 610-672-1151; email, jess.lonner@rothmaninstitute.com).

Am J Orthop. 2016;45(4):249-254.

References

1. Hockstein NG, Gourin CG, Faust RA, Terris DJ. A history of robots: from science fiction to surgical robotics. *J Robot Surg.* 2007;1(2):113-118.
2. Tamam C, Poehling GG. Robotic-assisted unicompartmental knee arthroplasty. *Sports Med Arthrosc.* 2014;22(4):219-222.
3. Beasley RA. Medical robots: current systems and research directions. *Journal of Robotics.* 2012. doi:10.1155/2012/401613.
4. Bargar WL. Robots in orthopaedic surgery: past, present, and future. *Clin Orthop Relat Res.* 2007;463:31-36.
5. Matsen FA 3rd, Garbini JL, Sidles JA, Pratt B, Baumgarten D, Kaiura R. Robotic assistance in orthopaedic surgery. A proof of principle using distal femoral arthroplasty. *Clin Orthop Relat Res.* 1993;(296):178-186.
6. Cobb J, Henckel J, Gomes P, et al. Hands-on robotic unicompartmental knee replacement: a prospective, randomised controlled study of the acrobot system. *J Bone Joint Surg Br.* 2006;88(2):188-197.
7. Borus T, Thornhill T. Unicompartmental knee arthroplasty. *J Am Acad Orthop Surg.* 2008;16(1):9-18.
8. Berger RA, Meneghini RM, Jacobs JJ, et al. Results of unicompartmental knee arthroplasty at a minimum of ten years of follow-up. *J Bone Joint Surg Am.* 2005;87(5):999-1006.
9. Price AJ, Waite JC, Svard U. Long-term clinical results of the medial Oxford unicompartmental knee arthroplasty. *Clin Orthop Relat Res.* 2005;(435):171-180.
10. Collier MB, Eickmann TH, Sukezaki F, McAuley JP, Engh GA. Patient, implant, and alignment factors associated with revision of medial compartment unicondylar arthroplasty. *J Arthroplasty.* 2006;21(6 Suppl 2):108-115.
11. Hamilton WG, Collier MB, Tarabee E, McAuley JP, Engh CA Jr, Engh GA. Incidence and reasons for reoperation after minimally invasive unicompartmental knee arthroplasty. *J Arthroplasty.* 2006;21(6 Suppl 2):98-107.
12. Hernigou P, Deschamps G. Alignment influences wear in the knee after medial unicompartmental arthroplasty. *Clin Orthop Relat Res.* 2004;(423):161-165.
13. Hernigou P, Deschamps G. Posterior slope of the tibial implant and the outcome of unicompartmental knee arthroplasty. *J Bone Joint Surg Am.* 2004;86-A(3):506-511.
14. Lonner JH. Indications for unicompartmental knee arthroplasty and rationale for robotic arm-assisted technology. *Am J Orthop.* 2009;38(2 Suppl):3-6.
15. Lonner JH. Robotically-assisted unicompartmental knee arthroplasty with a hand-held image-free sculpting tool. *Orthop Clin North Am.* 2016;47(1):29-40.
16. Orthopedic Network News. 2013 Hip and Knee Implant Review. http://www.OrthopedicNetworkNews.com. Published July 2013. Accessed March 7, 2016.
17. Moschetti WE, Konopka JF, Rubash HE, Genuario JW. Can robot-assisted unicompartmental knee arthroplasty be cost-effective? A Markov decision analysis. *J Arthroplasty.* 2016;31(4):759-765.
18. Roche M. Robotic-assisted unicompartmental knee arthroplasty: the MAKO experience. *Orthop Clin North Am.* 2015;46(1):125-131.
19. Lonner JH. Robotically assisted unicompartmental knee arthroplasty with a handheld image-free sculpting tool. *Oper Tech Orthop.* 2015;25:104-113.
20. Mofidi A, Plate JF, Lu B, et al. Assessment of accuracy of robotically assisted unicompartmental arthroplasty. *Knee Surg Sports Traumatol Arthrosc.* 2014;22(8):1918-1925.
21. Dunbar NJ, Roche MW, Park BH, Branch SH, Conditt MA, Banks SA. Accuracy of dynamic tactile-guided unicompartmental knee arthroplasty. *J Arthroplasty.* 2012;27(5):803-808.e1.
22. Plate JF, Mofidi A, Mannava S, et al. Achieving accurate ligament balancing using robotic-assisted unicompartmental knee arthroplasty. *Adv Orthop.* 2013;2013:837167.
23. Smith JR, Riches PE, Rowe PJ. Accuracy of a freehand sculpting tool for unicondylar knee replacement. *Int J Med Robot.* 2014;10(2):162-169.
24. Smith JR, Picard F, Lonner J, et al. The accuracy of a robotically-controlled freehand sculpting tool for unicondylar knee arthroplasty. *J Bone Joint Surg Br.* 2014;96-B(Suppl 16):12.
25. Lonner JH, Smith JR, Picard F, Hamlin B, Rowe PJ, Riches PE. High degree of accuracy of a novel image-free handheld robot for unicondylar knee arthroplasty in a cadaveric study. *Clin Orthop Relat Res.* 2015;473(1):206-212.
26. Lonner JH, John TK, Conditt MA. Robotic arm-assisted UKA improves tibial component alignment: a pilot study. *Clin Orthop Relat Res.* 2010;468(1):141-146.
27. Sinha RK. Outcomes of robotic arm-assisted unicompartmental knee arthroplasty. *Am J Orthop.* 2009;38(2 Suppl):20-22.
28. Pearle AD, O'Loughlin PF, Kendoff DO. Robot-assisted unicompartmental knee arthroplasty. *J Arthroplasty.* 2010;25(2):230-237.
29. Mozes A, Chang TC, Arata L, Zhao W. Three-dimensional A-mode ultrasound calibration and registration for robotic orthopaedic knee surgery. *Int J Med Robot.* 2010;6(1):91-101.

30. Karia M, Masjedi M, Andrews B, Jaffry Z, Cobb J. Robotic assistance enables inexperienced surgeons to perform unicompartmental knee arthroplasties on dry bone models with accuracy superior to conventional methods. *Adv Orthop.* 2013;2013:481039.
31. Coon TM. Integrating robotic technology into the operating room. *Am J Orthop.* 2009;38(2 Suppl):7-9.
32. Swank ML, Alkire M, Conditt M, Lonner JH. Technology and cost-effectiveness in knee arthroplasty: computer navigation and robotics. *Am J Orthop.* 2009;38(2 Suppl): 32-36.
33. Roche M, Augustin D, Conditt M. One year outcomes of robotically guided UKA. In: Proceedings of the 21st Annual Congress of the International Society of Technology in Arthroplasty. Sacramento, CA: International Society for Technology in Arthroplasty; 2008:175.
34. Dalton DM, Burke TP, Kelly EG, Curtin PD. Quantitative analysis of technological innovation in knee arthroplasty: using patent and publication metrics to identify developments and trends. *J Arthroplasty.* 2015. [Epub ahead of print]
35. Lonner JH. Modular bicompartmental knee arthroplasty with robotic arm assistance. *Am J Orthop.* 2009;38(2 Suppl):28-31.
36. Kamath AF, Levack A, John T, Thomas BS, Lonner JH. Minimum two-year outcomes of modular bicompartmental knee arthroplasty. *J Arthroplasty.* 2014;29(1):75-79.
37. Song EK, Seon JK, Yim JH, Netravali NA, Bargar WL. Robotic-assisted TKA reduces postoperative alignment outliers and improves gap balance compared to conventional TKA. *Clin Orthop Relat Res.* 2013;471(1):118-126.
38. Chun YS, Kim KI, Cho YJ, Kim YH, Yoo MC, Rhyu KH. Causes and patterns of aborting a robot-assisted arthroplasty. *J Arthroplasty.* 2011;26(4):621-625.
39. MAKO Surgical Corp. Fact Sheet. http://www.makosurgical.com/assets/files/Company/newsroom/Corporate_Fact_Sheet_208578r00.pdf. Published 2013. Accessed March 7, 2016.
40. Ponzio DY, Lonner JH. Preoperative mapping in unicompartmental knee arthroplasty using computed tomography scans is associated with radiation exposure and carries high cost. *J Arthroplasty.* 2015;30(6):964-967.
41. Wallace D, Gregori A, Picard F, et al. The learning curve of a novel handheld robotic system for unicondylar knee arthroplasty. Paper presented at: 14th Annual Meeting of the International Society for Computer Assisted Orthopaedic Surgery. June 18-21, 2014; Milan, Italy.
42. Wysocki RW, Sheinkop MB, Virkus WW, Della Valle CJ. Femoral fracture through a previous pin site after computer-assisted total knee arthroplasty. *J Arthroplasty.* 2008;23(3): 462-465.
43. Costello JE, Cecava ND, Tucker JE, Bau JL. CT radiation dose: current controversies and dose reduction strategies. *AJR Am J Roentgenol.* 2013;201(6):1283-1290.
44. Berrington de González A, Mahesh M, Kim KP, et al. Projected cancer risks from computed tomographic scans performed in the United States in 2007. *Arch Intern Med.* 2009;169(22):2071-2077.