Research Correspondence

Three-dimensional printing in robot-assisted radical prostatectomy - an Idea, Development, Exploration, Assessment, Long-term follow-up (IDEAL) Phase 2a study

Dear Editor,

The surgical management of prostate cancer has been shown to be determined by the anatomical location of the tumour and its associated intricate relationship to the neurovascular bundle and the prostatic capsule. Studies have shown an improvement in decision making about preservation or resection of neurovascular bundles during robot-assisted radical prostatectomy (RARP) [1,2], during which the surgeon lacks the tactile feedback of conventional open surgery. In T3 disease, ~35% positive margin rates have been reported [3], irrespective of an open or minimally invasive approach. In this context, improvement in tactile appreciation of the size, number and location of the tumour(s) during RARP may prove useful. Early reports of preoperative three- dimensional (3D)-printing technology in urological surgery have focused on proof of concept, face and content validity [4,5]. We report an Idea, Development, Exploration, Assessment, Long-term follow-up (IDEAL) Phase 2a study [6] of the use of patient-specific 3D printing in RARP.

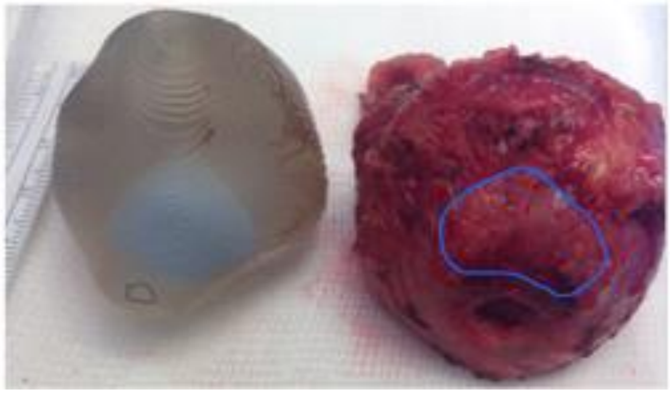
In all, 10 patients with localised T3 prostate cancer either clinically or on pre-biopsy multiparametric MRI, subsequently treated with RARP, were included in this prospective pilot study after ethics approval, patient consent, and discussion at the regional multidisciplinary team meeting.

Patient-specific geometries were segmented from MRI data. Two-dimensional, axial, T2 images were used. To account for the relatively coarse resolution (typically 3 mm) of these scans, all image segmentation was also informed by biopsy result and at least one of coronal and sagittal T2 acquisitions and diffusion-weighted imaging. Manual segmentation was performed using Mimics Medical v.18.0 (Materialise, Leuven, Belgium) with the multi-slice editing tool. Boolean subtraction of the tumour from the prostate geometry was completed using 3-Matic Medical v.10.0 (Materialise) and ensured two isolated components, which were subsequently exported in standard triangulation language (STL) file format. Patient-specific models were printed in-house using multi- material polyjet printing technology (Objet500 Connex1; Objet-Stratasys, Rehovot, Israel). Materials were assigned such that the tumour could be visualised and palpated as an opaque structure within a transparent prostate gland (VeroClear FullCure 810, UK) (Fig. 1).

All RARPs were performed by a single surgeon who inspected the 3D model before surgery and took it into the operating room during the procedure. This allowed tactile interaction with the model and incremental nerve spare or wider excision of the neurovascular bundles were performed around the palpable tumours. For anterior tumours, the fat in front of the prostate was sent for histology. The models were also shown to the patients as part of the informed consent process before the procedure and given to the patients after surgery. The final excised prostates were sent for histological examination.

The mean (range) patient age was 58 (54–68) years and the PSA level was 6.2 (3.8–14.9) ng/mL. Bilateral nerve sparing was achieved in two patients with anterior tumours, unilateral nerve spare and wider excision in five patients, and unilateral nerve spare and contralateral incremental nerve spare in the remaining three patients. There were no intraoperative complications and all patients had an unremarkable postoperative recovery.

3D print with postoperative prostate gland showing anatomical geometrical correlation between the anterior tumour on the model (blue) and the tumour localised on the prostate (blue outline). The tumour was T3 on MRI and very close to the sphincter.



The Gleason score was 3 + 4 (Grade Group 2) in four patients, 4 + 3 in (Grade Group 3) in three, 4 + 4 (Grade Group 4) in two, and Gleason 4 + 5 (Grade Group 5) in one. The final pathological stage was pT2 in three patients (down- staged), pT3a in six, and pT3b in one. One patient had a positive margin of 1 mm at the apex. There were no positive lymph nodes and the anterior fat biopsies were clear. All patients have completed ≥1-year follow-up with the pT3b patient opting for adjuvant radiotherapy. There have been no biochemical recurrences thus far. Continence (no pads) was immediate in four of the 10 patients, was reported by seven patients at 3 months, eight at 6 months, and all 10 at 12 months. For penile rehabilitation, of seven patients with preoperative Sexual Health Inventory for Men (SHIM) scores of >21, four achieved erections strong enough for intercourse at 24 months, which included the two patients with anterior tumours who had bilateral nerve sparing. All patients found 'personalised' counselling using their 3D-printed prostates useful, although this has not been compared to standard of care where a 3D print was not used.

3D printing is a cutting-edge topic and we chose to explore its potential role in RARP, adopting the IDEAL framework as a basis for this implementation, progressing from Phase 1 (idea) to Phase 2a (development) within this small cohort of patients. However, the models do not replicate normal tissue elasticity and add extra cost to the procedure (~£250). A multicentre randomised controlled trial - Touch and Image Guided Robotic Surgery (TIGERS) is being planned with positive margins as the primary outcome.

Acknowledgments

MRC Centre for Transplantation and NIHR BRC, KCL, Vattikuti Foundation. Chandak P, Byrne N, Lynch H, Allen C, Rottenberg G, Chandra A, Raison N, Kasivisvanathan V, Ahmed H, Elhage O, Dasgupta P.

Funding

King's-Vattikuti Institute of Robotic Surgery.

Conflict of Interest None.

Pankaj Chandak,* Nick Byrne,† Hugo Lynch,‡ Clare Allen,§ Giles Rottenberg,¶ Ashish Chandra,** Nicholas Raison,* Hashim Ahmed,†† Veeru Kasivisvanathan,‡‡ Oussama Elhage* and Prokar Dasgupta*

*MRC Centre for Transplantation, National Institute for Health Research (NIHR) Biomedical Research Centre (BRC), King's College London (KCL), London, UK, †Department of Medical Physics, St Thomas' Hospitals, London, UK, ‡Nuada Medical London, University College Hospital London, London, UK, §Department of Radiology, ‡‡Department of Urology, Guy's and St Thomas' NHS Foundation Trust, London, UK, Departments of ¶Radiology, **Histopathology, and ††Department of Urology, Imperial College NHS Trust, London, UK

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Correspondence: Oussama Elhage, MRC Centre for Transplantation, National Institute for Health Research (NIHR) Biomedical Research Centre (BRC), King's College London (KCL), London, UK.

e-mail: Oussama.Elhage@gstt.nhs.uk

Abbreviations: 3D, three-dimensional; IDEAL, Idea, Development, Exploration, Assessment, Long-term follow-up (study); RARP, robot-assisted radical prostatectomy.