Checklist

All details are below, it has to be ***min 20 pages, exc. images and refs***. - OK If interested can you send over a 1-page proposal via email to me by **24th November 2021**, that would be ideal giving a brief overview of the chapter.

For the full chapter the following must be adhered to:

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Title of Chapter:

The use of 3D-printing and injection moulding in the development of a low-cost, perfused renal malignancy model for training of robot-assisted laparoscopic partial nephrectomy

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Abstract

This chapter presents a research which aims to increase accessibility and availability of surgical training in robot-assisted laparoscopic partial nephrectomy (RALPN) by producing and evaluating a low-cost training model.

A methodological and technological framework is presented with a case study which uses image segmentation and 3D-modelling software to create anatomically accurate 3D-printed moulds from an abdominal CT scan of a patient who had stage T1b renal cell carcinoma. The moulds were injected with hydrogel and fitted with an artificial renal artery to allow for simulation of blood flow. The face validity (appearance and feel) of the prototype was evaluated using a 5-point Likert-style questionnaire by surgical staff ($N = 8$) who held and inspected the model. Content validity (how successfully the model simulates a RALPN) was evaluated by expert and trainee urology surgeons ($N = 4$) who performed a RALPN on the prototype using the da Vinci Robotic Surgical System. Qualitative data regarding perceptions of the usefulness of the model was also collected.

The final cost of the prototype was £1.72 for single-use materials and £4.02 in total. Within this sample population the prototype achieved face validity with both the overall appearance ($M=4.13 \pm 0.35$) and overall feel of the model scoring ($M=4.13 \pm 0.64$). The prototype also demonstrated content validity within this sample population, with an overall average of $M= 3.92$ and the highest performing measures in "needle driving" ($M= 4.75 \pm 0.5$) and "suture holding" ($M= 4.25 \pm 0.96$). Qualitative feedback suggested the potential significant benefits of such a training model to give junior surgeons exposure to robotic techniques in training.

This research demonstrates a low-cost method of producing a physical model for RALPN training. The prototype developed was considered to be an effective training tool by both experienced and trainee surgeons. Through further development of this prototype, urology surgical training programmes could have access to a cost-effective and simple means of widening access to RALPN training and implementing it at an earlier stage of training.

Keywords

RALPN (Robot-Assisted Laparoscopic partial Nephrectomy) - 3D Printing - Face Validity - Content Validity – Hydrogel - Renal Carcinoma

Introduction

Incidence rates of cancer-by-site projected to 2035 have found kidney cancer to be among the top four most rapidly increasing cancers in the UK (Smittenaar et al., 2016). Projected average annual percentage change indicates an increase of 2.75% in males and 2.17% in females (Smittenaar et al., 2016). This trend has been attributed to the increased use of radiological imaging, which is detecting low grade (T1) incidental renal tumours (Welch et al., 2010; Znaor et al., 2017).

It is widely recommended that where there are no contraindications, patients with a T1 tumour should be offered a minimally invasive nephron-sparing surgical approach for tumour resection, known as a Minimally Invasive Partial Nephrectomy (MIPN) (NIHCE, 2006; Campbell et al., 2017; Ljunberg et al., 2019). When performing a partial nephrectomy, where a segment is removed from the kidney, it is common practice to clamp the renal artery to occlude its blood supply; this is done to reduce intraoperative blood loss and improve visibility of the surgical field (Yezdani., et al. 2016). This can be achieved by placing clamps on the main renal artery at the renal hilum, or by clamping only the segmental renal arteries feeding the tumour, this is known as segmental or selective artery clamping (SAC) (Fig. 1). The SAC technique is relatively new and was developed with the aim of limiting ischaemic damage to the kidney by keeping the area of the kidney unaffected by the tumour perfused (Zhang., et al. 2018).

Ischaemic time describes the length of time the kidney is deprived of blood and thus oxygen; this can be either warm ischaemic time (WIT), where the kidney is at normal physiologic temperature or cold ischaemic time (CIT), where ice is used to cool the kidney. Both WIT and CIT are associated with increased post-operative renal complications and reduced renal function, which occurs in a time-dependent relationship (Volpe., et al. 2015, Thompson., et al. 2007).

During MIPN, it is not usually feasible to cool the kidney and consequently the kidney is subject to WIT; in order to limit WIT, surgeons must have the skillset to operate quickly within a specific time limit, this is normally <25 minutes (Volpe., et al. 2015), although this is debated among urologists and WIT limits may vary slightly across different centres. WIT is measured from when the artery is clamped to when the clamps come off; prior to the clamps coming off,

surgeons must resect the tumour then reconstruct the kidney by closing with sutures (renorrhaphy) (Fig. 1).

Fig. 1. Illustration of three key steps involved in partial nephrectomy 1. Artery Clamping; 2. Tumour Resection; 3. Renorrhapy.

Traditionally, minimally-invasive surgery would be performed with straight-angled laparoscopic instruments, however this is beginning to be superseded by robot-assisted laparoscopic instruments which can move within 7-degrees of freedom (Choi et al, 2007). This results in improved technical and ergonomic benefits to surgeons and consequential superior surgical outcomes for patients (Choi et al., 2007; Pierorazio et al., 2011).

Despite the benefits of Robot-Assisted Laparoscopic Partial Nephrectomy (RALPN), it has been often underutilised technique within the UK (HSU et al., 2018). The most recent Nephrectomy Outcomes Data published by the British Association of Urological Surgeons (BAUS) shows that only 12.5% of urology surgeons in Scotland have RALPN outcomes and 26.2% of urology surgeons have RALPN outcomes in England (BAUS, ibid). This deficit in surgical skill is likely a consequence of an underlying deficit in available and accessible training opportunities; surgical trainees within the National Health Service (NHS) have been found to be the least satisfied with their training in comparison to other specialities due to an imbalance in time prioritised for service delivery versus training opportunities (RCSE, 2015). Due to the steep learning curve associated with working from restricted visual cues, making decisions based on attenuated tactile feedback and the need for advanced hand-eye co-ordination, a significant amount of training time is required before a urology surgeon can competently perform a RALPN. Evidence suggests that after 20-30 cases RALPN can be performed safely (Pierorazio et al., 2011), however improvements in surgical outcomes continue past 300+ cases (Larcher et al., 2019), demonstrating the important correlation between surgical experience and superior patient outcomes. Training within robotics is difficult due to limitations imposed by current working-hours pattern, increased litigation and financial constraints (Maddox et al., 2018). This applies to both established specialists wishing to move into robotics and trainees with little prior experience.

With the multiple robust clinical guidelines recommending the use of MIPN for the treatment of T1 tumours and a potential shortage of these surgical skills in the UK, it is of increasing

importance for urology surgeons and surgical trainees to have access to affordable and effective renal malignancy training, to develop and practice the skills required to carry out the advanced techniques in minimally invasive surgery. While originally surgical training was essentially an apprenticeship, embodied by the mantra "*see one, do one, teach one*", this paradigm has now shifted to one of surgical simulations, which allow trainees to develop and practice skills without posing any risk to patients (Alaker., *et al*. 2016). Perhaps the most realistic surgical simulations are human cadaver and anaesthetised animal models due to anatomical accuracy or similarity, however these pose ethical concerns and are limited in their availability and accessibility to trainees by high costs (Maddox., et al. 2018). The current guidelines on robotic training published by BAUS and the Urology Foundation stress the importance of simulation-based training as a way of dealing with some of these pressures. Several Virtual Reality (VR) surgical simulators that have been validated to varying degrees, already exist, but it is likely that these simulators will need to be used in conjunction with dry lab and animal or cadaveric models (Maddox., et al. 2018). VR surgical simulators have shown to provide are highly reproducible training environments and can objectively quantify markers of surgical skill acquisition and performance, without introducing potential biases from human error (Våpenstad., et al. 2013a; Portelli et al., 2020). Despite the potential substantial benefits of VR simulations, the fidelity of a simulation can be limited by the absence or the poor quality and accuracy of the integrated haptic feedback, which includes tactile and kinaesthetic cues (Våpenstad et al., 2013b; Hagelsteen et al., 2019, Portelli et al., 2020). Thus, there are skills such as tissue handling and adjusting to attenuated tactile feedback which can be presumably best learned using wet lab/physical models (Sharma et al., 2012). The major issue with the wet lab settings is that these tend to be very expensive.

A report by the Royal College of Surgeons has recommended that to improve surgical training, surgical simulations should be "*embedded and enhanced within the surgical curricula and there should be sufficient resource to ensure availability for all trainees*." (RCSE, 2015). Due to the additional benefits offered by RALPN, its reported underutilisation and the need to widen accessibility and availably of surgical training opportunities, the aim of this research is to develop a cost-effective RALPN training model.

An analysis of the literature was carried out to highlight the methods that have been used for generating soft organ tissue surgical models, including the raw materials employed and the outcomes of validity assessment. The search engine PubMed was used as the primary literature resource. A thematic searching approach was undertaken using a combinations of

key words to find relevant papers. The themes and their associated key words were (1) Models (Model, simulation, phantom, replica); (2) Soft Tissues (Soft tissue, organ, kidney); (3) Surgical Training (Surgical training, surgical education, procedural training, medical education, medical training); and (4) Generation (Generation, creation, development, modelling) and relevant search terms. The exclusion criteria were as follows: published before 2014, non-empirical research, research not involving the generation of a physical soft organ tissue model, research focussing on models for pre-operative planning, hard tissue surgical simulations or simulations incorporating animal or cadaver components.

The final review included seven papers; five kidney models (one laparoscopic paediatric pyeloplasty model, one model to simulate urological endoscopic procedures and testing medical devices and three renal malignancy models for surgical training or surgical rehearsal of PN) and two brain and skull models for use in surgical training of endoscopic third ventriculostomy. Full details of the papers can be found in Appendix I.

The common theme arising from all seven papers is that every production method includes an element of 3-dimenional printing. Since its inception in 1980, 3-dimenional printing has commonly been used for generating complex designs through the process of layering materials (Pugliese., et al. 2018). In order to 3D-print the desired anatomy for a surgical model, a mesh model must be created and exported as STL (sterolithography) file format, which is compatible with most 3D-printer as. Of the seven papers reviewed, six used image segmentation software to isolate out the structures of interest from either CT or MRI dataset. The other paper created their own geometry using 3D-modelling software (Cheung., et al. 2014). There was justification provided to support the decision of the researchers to create their own geometry. Compare to those research seeking for anatomical accuracy by building upon medical dataset, this method may be more likely to produce inaccuracies in the anatomy of the model and potentially give a less realistic appearance.. After initial production of the anatomical geometry, it is important to assess the quality of the mesh prior to printing to ensure there are no internal defects; one paper describes in great detail the array of open source software used for this process (Garling., et al. 2018) including MeshLab, Meshmixer and Blender, which will also be considered for use in this project. Overall, image segmentation has greater potential to produce anatomically correct models, can be validated by clinicians and provides real-life patient cases for surgeons to practice on and as such appears to be the superior method of mesh generation.

Although all seven papers used 3-dimenional printing, the technology has been utilised in three different ways within five of the papers, whereas two papers do not provide sufficient level of details about of their method to allow for classification. The most common use of 3-dimenional printing was to generate moulds, which could then be used to cast the model in different materials, this was used along with other techniques in four out of five papers. The rationale behind the creation of moulds is that once they are created, they can normally be continually used to produce repeated models and therefore become increasingly cost-effective over time. Only one paper 3D-printed an entire anatomical model (kidney model) for use in surgical rehearsal. The method is not extensively described, however it appears a blend of materials were used as an ink to create a firm yet flexible 3D-printed capsule, which could then be injected with an undefined concentration of agarose gel (Maddox., et al. 2018). The paper states that surgeons described the model felt similar to a real life, which suggests this method may provide good measures of validity, however there is no description of how validity was measured or any formal results of a validity study and as such it is difficult to draw any meaningful conclusions relating to the potential accuracy and usefulness of this model for training. It is also possible to reason that this method of production would not be as cost or time effective as creating moulds, due to the need to continually 3-dimenional printing new models, although this is not mentioned in the paper.

The researchers that created the kidney model for endoscopic procedures described an interesting method of 3-dimenional printing in wax, which was used to enable the creation of a hollow space within the kidney model to mimic the anatomy of the collecting system; the inner wax model could be dissolved in ethanol after the kidney model was cast around it (Adams. et al. 2017). This method, when considered together with the silicone drip method (Cheung. et al. 2014), of painting silicone onto a model until the required thickness is achieved, may offer a potential solution to creating a low-cost 3-dimenional printing hollow artery network, which would facilitate training in both main and SAC. Other methods used to simulate the renal artery included stitched on surgical tubing (Monda. et al. 2018) and solid 3-dimenional printing arteries (Maddox. et al. 2018), although these would facilitate training in clamp placement, a possible more realistic solution is to perfuse the arteries. Perfused arteries would allow for assessment of effective clamp placement, have the potential to simulate blood loss and thus possibly improve the content validity (the ability for the model to simulate the RAPN procedure) of the model. No paper describing a renal malignancy

model with perfused artery network was found in the course of this literature review and as such would be a novel addition to this field of development, with the potential to improve markers of face and content validity.

One of the main factors which could critically impact the validity of the model is the material choice for the kidney parenchyma and the tumour, as both need to display certain important characteristics. The tumour and kidney parenchyma, for example, exhibit different physical properties due to the differences in their cellular composition; one study tested tissue resistance of two human kidneys immediately after a radical nephrectomy and found the kidney parenchyma had a significantly lower tissue resistance than the tumour when measured with a Shore 00 durometer; lateral side of kidney = 17.4 ± 2.8 and upper pole =17.1 ± 2.3, compared to the tumour which was 41.8 ± 9.2, ($p<0.01$) (Shahani., et al. 2010). Poor differentiation between kidney parenchyma and tumour was recorded as negatively affecting the face validity of one of the renal malignancy models, which used Dragon Skin 20 (Smooth-On Inc) silicone with silicone thinner for casting the model (Monda., et al. 2018). The paper did not comment on using a different ratio of silicone thinner for the parenchyma and tumour, which could potentially be an issue. The importance of having a clear differentiation between the tumour and parenchyma has been highlighted as being critically important by the consultant urological surgeon involved in this project.
Another interesting comment related to the face validity of same model, and more particularly the malleability of the parenchyma, probably due to the Shore hardness of 20A of the Dragon Skin 20 (Smooth-On, 2019), which is substantially higher than the reported Shore hardness value of the human kidney, which was about 17 on the Shore 00 scale. The model did however get received more encouraging feedback regarding its potential to support the simulation of suturing and cutting procedures. This suggests the model had realistic tear strength for holding sutures; one reported measure of tear strength for the kidney is lateral side of kidney = 242 ± 26g and upper pole = 286 ± 17g (Shahani., et al. 2010). Thus, it will be important when deciding on an appropriate material, to consider its properties of tissue resistance and tear strength to ensure realistic simulation of tumour and parenchyma differentiation, tumour resection and renorrhaphy.

Although there were identified issues with the malleability of the Dragon Skin 20 silicone, five of the seven papers utilised various different silicones for producing their models, including a brain model which received excellent face validity scores (100% either agreed or

strongly agreed the model properties resembled human brain tissue, n=15) (Garling., et al. 2018). It is also worth noting, despite the negative feedback received around the feel of the renal malignancy model, the silicone cost per unit was reported at only $3.90 (Monda., et al. 2018) and the properties of silicone are readily adjusted. With the right mixture, silicone could therefore offer a potentially cost-effective solution with good face validity.

Another material which only appeared in two of the papers reviewed, was agarose (Adam., et al. 2017), a natural polymer derived from red seaweed that has been utilised as a hydrogel in 3D-bioprinting due to its mechanical strength and its ability to gel in low temperatures (32 °C) (Jessop., et al. 2017). Hydrogels are macromolecules, made up of chains of hydrophilic polymers which are held together by cross-linking, they are able to realistically simulate human tissues due to their ability to absorb high volumes of water (Chai., et al. 2017). There is extensive research into the use of hydrogels within multiple biomedical disciplines such as, tissue engineering, 3D-bioprinting, drug delivery systems and self-healing materials (Chai., et al. 2017). It is out with the scope of this paper to review the material properties of the extensive number of hydrogels, however some of the compounds used in their production, such as gelatine, agarose, polyvinyl alcohol or alginate can be purchased at low cost.

Four papers described using face validity questionnaires, which are used to measure participant's opinions on the general appearance and feel of the model. All papers used five-point Likert scale questionnaires to measure the participant's responses to statements or questions. Three papers also measured content validity, which evaluates the ability of the model to effectively simulate the task it is intended to, using similar approach. Where possible it is always best to use a questionnaire, which itself has gone through validity and reliably testing, as this ensures the questionnaire measures both what it is supposed to (validity) and in a consistent manner across different sets of participants (reliability) (Tavakol & Dennick., 2011). This literature review has not found any validated questionnaire for face or content validation of physical surgical models used in surgical training

RALPN training models and pre-surgical rehearsal models have previously been developed using 3D-printing and silicone injection moulding (von Rundstedt et al., 2017; Maddox et al., 2018; Monda et al., 2018), however these models were not perfused through an artificial blood supply. In addition, these models were often showing, in some aspect, limited tactile accuracy or face validity (Shahani et al., 2010, Monda., et al. 2018).

This chapter describes a 3D-printing and silicone injection moulding workflow resulting in the production of a RALPN training model made of right kidney and tumour casts. This training model incorporates a hollow renal artery which can be perfused to allow for blood loss simulation and will use a hydrogel material, instead of silicone for casting. The properties of hydrogels to resemble closely to human tissue through their ability to hold large volumes of water (Chai et al., 2017), is believed to result in superior markers of validity in the context of this research. The value of the model to support trainees and trainers will be determined through validity and content validity evaluation, looking respectively at its tactile and visual accuracy, and the extent to which it can successfully contribute to simulate a RALPN procedure. Ultimately this research has the potential to impact on surgical capacity excellence through the provision of low-cost and easy–to-embed solutions to aid surgical skill acquisition and competency in performing RALPN.

Materials and Methods

Apparatus

This section presents the material that has been used throughout this research (Tables 1 & 2).

Table 1. List of software used to develop the digital model of the 3D printed negative moulds

Brands	Description/Use	Publisher/ Producers
3D Slicer V4.10.0 	Image analysis and scientific visualisation software. Used to segment kidney, tumour and renal artery from CT scan.	Free and open source from BWH and 3D Slicer contributors. Available at: http://www.slicer.org
Autodesk Meshmixer V3.5 	Software for working with triangular meshes. Inspection and auto-repair of STL files.	Free software from Autodesk Inc, New York, USA, 2017. Available at: http://www.meshmixer.com
3DS Max 2019 	3D-modelling software. Used to create the negative moulds.	Autodesk Inc, New York, USA, 2017. Available at: https://www.autodesk.co.uk/products
BCN3D Cura V2.1.5 	3D printing slicing software. Used to prepare GCODE file.	Free software from BCN3D Technologies, Barcelona, Spain, 2019. Available at: https://www.bcn3dtechnologies.com/en/3d-printer/bcn3d-cura/

Table 2 – List of hardware and material used to create the 3D printed negative moulds

Brands	Description/Use	Publisher/ Producers
BCN3D Sigma 3D Printer	Fused deposition modelling desktop 3D printer. Used to print negative moulds.	BCN3D Technologies, Barcelona, Spain.
Polymaker, 2.85mm Polysmooth filament	3D printing filament	Polymaker, Shanghai, China.
Polymaker Polysher	Desktop 3D-prints post-processing machine. Used to smooth 3D-printed moulds.	Polymaker, Shanghai, China.

Production Workflow

The workflow to produce the RALPN training model included segmenting a kidney and tumour from an abdominal CT, creating negative moulds in 3D modelling software, 3D-printing the moulds and then injecting hydrogel into the moulds using a two-step process. This workflow (Fig. 2) which led to the production of the 3D printed negative moulds of kidney and tumour consisted of:

Step 1: Upload abdominal CT with contrast DICOM data. Segment using robust statistics segmentation. Threshold segmentation, pain, erase and model maker tools. Export models as STL filer.

Step 2 Import STL files and use sculpt and inspector tools used to create smooth and manifold mesh.

Step 3: Import STL files and use boolean operator functions to create negative mould space and to create registration pegs.

Step 4: Import ST files and use inspector tool to confirm manifold mesh.

Step 5: Import STL files and check dimensions, customise infill density and build plate adhesion. Slice and export as GCODE file.

Step 6: 3D-print in Polysmooth filament.

Step 7: Smooth moulds with 99% isopropyl alcohol.

Fig. 2. Production workflow used to create the kidney and tumour moulds.

Segmentation of CT data

The medical dataset considered in this research was provided by Mr Oades, consultant urological surgeon at the Queen Elizabeth University Hospital, Glasgow, UK and West of Scotland Cancer Network lead for urological cancers. The data consisted of an anonymised abdominal CT DICOM dataset (2mm out-of-plane distance) of the abdomen of a patient who had been given an iodine bolus to enhance contrast and improve visualisation. The dataset displayed a T1b tumour on the right kidney, situated entirely below the polar lines with ≥ 50% of the tumour presenting as exophytic (protruding out); according to the RENAL nephrometry scoring system this is a low complexity tumour (Kutikov & Uzzo. 2009).

3D Slicer, a free, open source and multi-platform software package for medical visualisation was used to segment the right kidney, tumour and renal artery from the medical dataset. The DICOM files were loaded and prior to segmentation, the image was edge-sharpened and de-noised, using respectively the Laplacian edge sharpening and the median image filters to improve visual quality. Both the kidney and tumour were segmented using the robust statistics segmentation (RSS) tool, which were then further optimised using the paint and erase tools, the renal artery network was segmented using the paint tool (Fig. 3). The accuracy of the segmentation was confirmed by overlaying the segmentations at 50% transparency on the original CT image. The segmentation outcomes were then verified by Miss Flora Rodger, urological surgeon at the Queen Elizabeth University Hospital, Glasgow, UK.

Fig. 3. Images of segmentation. Left: Segmentation of kidney (segmentation 50% transparency). Right: Segmentation of tumour (segmentation 50% transparency).

Mould Generation

The major considerations for creating the 3-dimenional printing moulds were; finding a means of casting the tumour and kidney at different densities and colours within one finished

model and laying the hollow arterial system into the model without the shape deforming under the pressure of the casting material.

Building upon the guidance and advises provided by the Centre for the Cellular Microenvironment (CeMi) at the Glasgow University's Biomedical Engineering department, two separate moulds for casting the training model were devised. One would serve for casting the tumour alone and the other for casting the kidney with the tumour. This would allow for the tumour to be casted separately in a different colour and higher density than the kidney, and then transfer into the mould of the kidney with tumour to cast the kidney around it.

Once the STL files of the kidney and tumour were exported from 3D Slicer into Meshmixer, the initial step was to inspect the model and repair the mesh using the auto-repair function (Fig. 4). This was an important step as the tool highlights areas of the mesh which are not manifold and would therefore prohibit successful 3D-printing.

Figure 4. Example of using the Meshmixer inspector tool to identify non-manifold areas of the kidney mesh and auto-repair function.

The next process carried out in Meshmixer consisted of smoothing the mesh using the sculpt tool. Building upon the methodology presented by Garling et al. (2018) for creating a mould of the human brain, a Laplacian smooth filter was initially applied but failed to remove sharp protrusions and consequently an attempt to smooth the meshes with the Meshmixer sculpt tool proved more successful outcome (Fig. 5). The brush robust-smooth was then used at strength=50 and depth = 11.

Fig. 5. Mesh smoothing. Left: kidney tumour before any smoothing. Middle: kidney tumour after Laplacian smoothing filter was applied in MeshLab. Right: kidney tumour after smoothing with the Meshmixer sculpt tool (Robust-smooth brush)

The files were then exported into 3ds Max, which was used to create the moulds (Fig. 6). The Boolean operator function was used to subtract the desired volume (tumour, and kidney with

tumour) from a cube, and create a negative mould space for each structure. In addition, the Boolean operator function was also used to create the pour hold, artery inlet and the registration pegs. The registration pegs were included in the design to improve alignment and reduce movement of the mould halves during material casting. After initially creating spherical pegs for the tumour mould it was clear after 3D-printing the model, that cubes would be an easier geometry to print and subsequently the kidney with tumour mould was changed. For the tumour mould, two registration indents were made on one side of each mould half to ensure the moulds were assembled correctly. The finished mould files were exported back into Meshmixer, for the inspector tool to check the meshes were still manifold.

Fig. 6. Mould creation. Top image showing the design of the tumour mould including pour hole, registration pegs and registration indents. Top left: top view. Top right: right view. Bottom left: transparent half mould. Bottom right: complete mould. Bottom right: complete mould.

Model Generation

After the segmentation process, the STL files of the kidney and tumour models were then exported from 3D Slicer and imported into the software Meshmixer (http://www.meshmixer.com), where the mesh was smoothed using the sculpt tool and then subsequently inspected, repaired and confirmed as manifold.

Then STL files were imported in the STL format into BCN3D Cura (Fig. 7). BCN3D Cura allows customisation of print settings and then slices the model to be exported as a GCODE file, which can be read by the 3D-printer. An infill density of 10% was added every one layer to provide structural support and thus prevent warping. A brim of 8mm was added to the model to improve adhesion of the model to the print bed, this again helps to prevent warping.

Fig. 7. Slicing mesh in BCN3D Cura. Top: Solid view of kidney with tumour mould on print bed. Bottom: Layer view of kidney + tumour mould showing infill density.

Finally, the finished moulds were printed using a BCN3D printer in the CeMi. The moulds were made from a 2.85mm Polysmooth Filament. This allowed for the moulds to be smoothed post-production in a 99% isopropyl alcohol mist using the Polymaker, Polysher (Fig. 8).

Fig. 8 –Production of moulds. Top: 3D printing one half of the tumour mould. Bottom left: Polymaker Polysher in use. Middle right: Tumour mould pre-polishing. Bottom right: Tumour mould post-polishing

Kidney and Tumour Cast Production

The key properties the materials to simulate are; differentiation in tissue resistance and colour between the kidney and tumour, kidney material with a realistic tear resistance as it should hold sutures but also tear when adequate force is applied, and materials which produce an overall realistic look and feel. In addition, the artery system within the kidney cast must allow for the blood to flow and must be made of a material which will respond adequately when clamped/unclamped.

Colour

To determine an appropriate colour for the kidney material, images taken from a purchased pig kidney and online source depicting a clear cell renal cell carcinoma (http://webpathology.com/image.asp?n=7&Case=66) were opened in Adobe Illustrator and the eye dropper tool was used to determine the CMYK (cyan, magenta, yellow, black) values (C= 23%, M= 43%, Y= 44%, K= 9%). After consultation with Mr Oades, the colour was darkened and made more vibrant, in order to emphasise the differentiation between the kidney and tumour. The tumour was coloured in yellow; this was advised by Mr Oades.

Kidney and Tumour Cast

To create the renal malignancy model the moulds were cast with coloured sodium alginate (SA)/gelatin hydrogel. SA is a water-soluble gelling polysaccharide extracted from brown algae (Samp., 2017) and combining it with gelatin increases the viscosity of the mixture and results in a further increase in the strength of the gel. All materials were dyed with different mixes of food colouring, in accordance with the colours defined in the previous section. To

increase the flexibility and elasticity of the hydrogels, glycerine and sorbitol were added to act as plasticisers. The major advantages of these materials are they are low-cost, readily accessible, safe and easy to use. In addition, building upon tutorial videos from the website Smooth-On (https://www.smooth-on.com/) which show how fabrics and meshes could be used to increase the strength of silicones, cotton wool and a mesh material were added to the gel in order to improve the tear strength while maintaining a realistic soft feel.

As aforementioned, the training model was cast in a two-step process; the tumour was cast first in its individual mould and subsequently placed in the kidney with the tumour mould for the kidney to be cast around it (Fig. 9).

Fig. 9. Production of tumour. Top left: coating moulds in gel. Middle: injection of gel. Bottom left: removal of mould. Right: placement of tumour in the kidney with tumour mould.

To simulate the higher tissue resistance of the tumour compared to the kidney parenchyma, the quantities of SA and Gelatin were increased for the tumour hydrogel by 53.8% and 80%, respectively. This was decided through trial and error testing. For the model to adequately simulate renorrhaphy an artificial renal capsule was created using a superficial mesh, this increased the tear strength of the hydrogel and aimed to prevent unrealistic rupture of sutures. An artery, which could be perfused and clamped was simulated using a silicone tube (inner diameter 4mm, outer diameter 6mm) connected to a plastic Y-shaped connector which was set in the model (Fig. 10). To allow for the vessel to be closed during renorrhaphy, Ecoflex 00-30 silicone was used to create a soft end overhanging the plastic connector.

Fig. 10. Casting of kidney. Left: Tumour in mould with artery. Middle: Mould about to be chilled. Right: Completed model after chilling.

Adding food colouring to water and pushing it through the tube using a syringe would simulate the blood flow within the kidney and tumour. The resulting model is presented in Fig. 11.

Fig. 11. Complete renal malignancy model

Model costs

One of the aim of this research was to produce a cost-effective RALPN training model (Table 3). Being cost-effective was considered critically important as it would make the simulation accessible to more urology surgical training programs. The highest cost involved was 3D-printing the moulds (£24.34), although this is excluded from the per unit cost because they are infinitely reusable if they are used and stored correctly. The cost of single-use materials per unit is £1.72, this cost rises to £4.02 when the silicone tube and Y-shaped connecter are included. These components are used to simulate the artery; the tubing is used for clamping and as such is not damaged during the RALPN procedure and the Y-shaped connector is hard plastic and again is not damaged, only the soft silicone component is single-use.

Table 3. Costs involved in renal malignancy simulation production.

Reusable Materials	
Material	**Cost (£)**
Polysmooth filament for moulds	24.34
Silicone tubing	1.00
Y-shaped connector	1.30
Single-use Materials	
Material	**Cost per unit (£)**
240 Bloom pig skin gelatin	0.48
Sodium alginate	0.13
Vegetable glycerine	0.32
Sorbitol	0.56
Cotton wool	<0.01
Deionised water	0.16
Ecoflex 00-30 silicone	0.07
Material mesh	<0.01
Total cost of single-use material per unit	**£1.72**
Total cost per unit (excluding moulds)	**£4.02**

Evaluation

One objective of this research was to evaluate the face and content validity of the renal malignancy simulation for RAPN. The term face validity is used here to describe how realistically the model has reproduced the feel and appearance of a kidney and tumour, and

content validity describes how successfully the model allows for simulation of the steps involved in performing a PN. An experimental procedure was designed to validate the model.

Participants

A purposive expert sampling strategy was used to recruit participants as the study required individuals with specific clinical skills and experience (consultants *n*=2, surgical trainees *n*=3, theatre staff *n*=3). To participate in evaluating the face validity of the simulation, participants had to have previous experience in handling a human kidney and tumour. To evaluate the content validity of the simulation, participants had to be urology surgeons or trainee urology surgeons. There were no other exclusion criteria.

Experimental Methods

Surgical experience, face validity and content validity data were collected using a questionnaire, which was developed for the purposes of this evaluation. At the start of the questionnaire, participants were asked to write their job title and then indicate the number of years of surgical experience they had; this was the only demographic data collected.

No validated questionnaires for face or content validation of physical surgical models used in surgical training, were found through analysis of the literature. In lieu of a validated questionnaire, the researchers have developed a tool to measure the face and content validity.

To evaluate face validity, participants were asked to handle and inspect the model then score the appearance and feel of the kidney, tumour and artery on a 5-point Likert scale (1= poorly reproduced, 2, 3= somewhat realistically, 4, 5= realistically reproduced) and a free text box was available for additional comments.

To evaluate content validity, participants were asked to complete a RALPN procedure on the model using the da Vinci Surgical System (https://www.davincisurgery.com). Steps included in the simulation for experienced urology surgeons were instrument choice, clamping of the artificial renal artery, tumour resection and renorrhaphy (Fig. 1). Trainee urology surgeons performed the same steps but were guided where necessary by an experienced urology surgeon. Participants were then asked to score how successfully the model reproduced the three keys steps in completing a RALPN (artery clamping, tumour resection and renorrhaphy). Six

markers of content-validity were scored on a 5-point Likert scale (1= poorly reproduced, 2, 3= somewhat successful, 4, 5= successfully reproduced). Free text boxes were available for participants to provide any additional feedback on their experience and the model.

Data Analysis

As this research aimed at the creation of an initial prototype, only a small number of participants tested the model to allow for preliminary feedback to be collected, therefore only descriptive statistics were computed. Analysis of the face validity data included calculating the overall mean for each construct and then calculating the standard deviation around the mean to determine the level of variation within amongst participants. The minimum and maximum values are also reported. This same analysis was repeated when the participants were separated into level of surgical knowledge. The content validity data was analysed in the same manner.

Results

Face validation

All 8 participants took part in evaluating the face validity of the model; this included 2 consultant urologists, 3 surgical trainees and 3 theatre staff. Every participant had previously handled a kidney and kidney tumour. The results show that both the appearance and feel for all components of the model were consistently scored highly, with six out eight constructs scoring over 4.13 on average (Fig. 12). The standard deviation is less than 1.0 for all 8 constructs, indicating there is little variation between the scores. Both the overall appearance and overall feel of the model were scored the same on average (*M=4.13 ± 0.35, M=4.13 ± 0.64,* respectively), although average overall feel had a higher standard deviation, showing increased variation in given scores. This is also seen in the minimum and maximum scores received for each (Table 4). It is worth noting that consultant urologist provided overwhelming feedback about the tactile feel of the tumour and kidney, compared to surgical trainees, who appeared slightly more reserved.

Fig. 12. Mean scores with standard deviation for the face validity

Table 4. Face-validity outcomes

	Mean	SD	Min	Max
Face validity				
Kidney Appearance	4.38	0.52	4	5
Tumour Appearance	4.13	0.35	4	5
Artery Appearance	3.88	0.64	3	5
Overall Appearance	4.13	0.35	4	5
Kidney Feel	4.38	0.92	3	5
Tumour Feel	4.00	0.76	3	5
Artery Feel	3.88	0.64	3	5
Overall Feel	4.13	0.64	3	5

SD = standard deviation. Min = minimum score. Max =Maximum score

Additionally, participants had a positive opinion of the look and feel of the model "*Kidney looked and felt real externally…. The silicone tube had a similar feel to an artery, especially the moulded portion*", "*I thought the appearance of the kidney was very similar to those I have seen in theatre. The feel and texture were very good.", "Looked and felt like the real thing*" and "*I thought the model was excellent. It looked like a kidney prior to transplant*". Although one participant made a recommendation regarding the visual aspect of the tumour "*Tumour was very homogenous, would have been more erractic in reality*."

Content validation

4 participants took part in evaluating the content validity of the model; this included 2 consultant urologists and 2 urology surgical trainees. One of the consultants had over 25 years of surgical experience and had been performing laparoscopic PN for 6 years and training to perform RALPN for less than 6 months. The other consultant had over 17 years of surgical experience and had been performing laparoscopic PN for 7 years and RALPN for 3 years. One trainee was at the end of their specialty training and had over 8 years of surgical experience with 3 years assisting in laparoscopic procedures and 1 year in robot-assisted procedures. The

other trainee was in year 3 of specialty training and had 3 years of surgical experience with 1 year assisting both laparoscopic and robot-assisted procedures. Content validity assessment occurred in the surgery theatre as shown below (Fig. 13).

Fig. 13. Experimental setup - Top left: Model set up with da Vinci Surgical System. Top right: Tumour resection seen on screen. Bottom right: Close-up of model during renorrhaphy (artery sutured). Bottom left: Image of kidney model with completed renorrhaphy.

The average score, standard deviation, minimum score and maximum score for each construct can be seen in Table 5. The results show that all six constructs of content-validity achieved consistently good scores with all six scoring beyond 3.25 (Fig. 14). The lowest average scores were given to "tumour and kidney differentiation" ($M= 3.50 \pm 0.58$), "tumour resection" ($M= 3.75 \pm 0.5$) and "blood loss" ($M= 3.25 \pm 0.5$), all three were measures of how well the model allowed for simulation of tumour resection. The highest average scores were given for "needle driving" ($M= 4.75 \pm 0.5$) and "suture holding" ($M= 4.25 \pm 0.96$), which are both measures of how well the model allows for simulation of renorrhaphy. The highest variation of scores were given to "suture holding" (SD =0.96). Artery compressability also scored highly ($M= 4.00 \pm 0.0$).

Fig. 14. Mean scores with standard deviation for the content validity

Table 5. Content validation mean scores

		Mean	**SD**	**Min**	**Max**
Content-validity					
Key PN step being simulated					
Artery compression	**Artery compressibility**	4.00	0.00	4	4
Tumour Resection	**Tumour and kidney differentiation**	3.50	0.58	3	4
	Tumour resection	3.75	0.5	3	4

	Blood loss	3.25	0.5	3	4
Renorrhaphy	**Needle driving**	4.75	0.5	3	5
	Suture holding (tear strength)	4.25	0.96	3	5

Additionally, participants provided encouraging feedback regarding the content validity of the model suggesting the model was the "*Best model for robotic surgery I have seen. Gives opportunity to take virtual simulation skills to the next level. Allows for tactile/haptic feedback which cannot be achieved on online modules*" which consisted of " *A very good reproduction of a kidney with a tumour. The suturing was particularly good and very realistic. Compressability was very good.*", and despite there was "*Good differentiation between tumour and kidney tissue. Tumour could have been bonded to kidney more strongly. Sutures held well in renal "capsule" and artery similar feel to reality.*". However, it has also been reported that the "…*spongey*" and "*friable*" texture of the kidney material was a bit a drawback to a more realistic performance of the two last key steps of the partial nephrectomy (Tumour Resection, Renorrhapy).

Discussion

This research aimed to develop and evaluate a cost-effective, high-fidelity renal malignancy simulation for surgical training of RAPN. This was considered to be of relevance and importance due to the increasing incidence of kidney cancer within the UK (Cancer Research UK, 2019), the additional benefits to eligible patients of having a RAPN (Choi., et al. 2015), the reported underutilisation of RAPN due to surgical skill shortage (Hsu., et al. 2018) and the correlation between improvement of surgical outcomes and increasing RAPN surgical experience (Larcher, et al. 2019).

Production of the models

One of the research objectives was to develop a functional workflow for the production of a renal malignancy model for surgical training simulation. This has been achieved processing a patient DICOM dataset through medical visualization and 3D modelling platforms towards the digital reconstruction of relevant anatomical structures used in conjunction with Boolean

operands for generating of negative mould spaces in a file format that are suitable for 3D printing technologies. Developing the colour of the tumour and kidney model and the hydrogel material was a cyclical process of trial, evaluation and revision using the expertise of senior urology consultants. With their ability to retain large amount of water (Chai., *et al*. 2017) and their capability to be easily mixed with other compounds as glycerine, sorbitol and food colorants, hydrogels offer opportunities for the generation of materials, with subtle degrees of flexibility and elasticity, which close tactile resemblance with soft anatomical tissues, are likely to be of use in the development of physical simulation in surgical context. In addition, hydrogels being low-cost, readily accessible, safe and easy to use, this research has demonstrated that renal malignancy models supporting the performance of the three key steps involved in partial nephrectomy (Artery Clamping, Tumour Resection, Renorrhapy) for practical rehearsal can be reliably produced with low production unit cost. These costs would be under £25 for the reusable moulds of the kidney and tumour, and up to £4.02 for the tangible training model. An additional point to consider about this model, is that almost all the single-use components of the model are made of natural materials and thus will biodegrade after use. It is important to design and engineer products which meet the specification requirements, however it is also important and responsible to consider the lifecycle of products and how they are disposed of.

Evaluation

Validity

The results from the validity evaluation indicate that within this sample population the renal malignancy prototype was found to look and feel true to life. The model was shown to realistically simulate the appearance and feel of a kidney with a tumour, as all components of the model were consistently scored highly, with six out eight constructs scoring over 4.13 on average (Table 4). There was little variation seen between the scores as indicated by a SD below 1.0 for all eight constructs. This infers the model has good reliability for consistently scoring high face validity approval, although a larger sample size would be required to provide stronger evidence of this finding. At this stage of testing it is possible to say face validation was achieved within this sample population.

The prototype achieved high scores overall when subject to the RALPN procedure. The highest average scores were given for simulation of renorrhaphy (needle driving and suture holding) although "suture holding" had the highest variation in standard deviation, which may be explained by the material used to simulate the kidney. The kidney had a mesh embedded in its outer surface, which was found to effectively simulate a strong renal capsule with a high tear strength, and this received very positive feedback; *"The suturing was particularly good and very realistic."* -Consultant Urological Surgeon; *"Sutures held well in renal "capsule""* - Consultant Urological Surgeon. Whereas the inner bulk of the kidney, which was not reinforced with a mesh did not exhibit the same level of tear strength and this may have been perceived less favourably. This research is the first to our knowledge, to use mesh-reinforcement in combination with hydrogel casting to produce a surgical simulation model. This technique could prove to be a useful and low-cost technique in developing future tissue mimicking materials for surgical training.

One of the main issues identified with the model during content validity evaluation was the less realistic texture of the kidney material, which was reported as "*too spongey*" and "*friable*". The lack of rigorous material testing is indeed a limitation of this research. Time restrictions to complete this project was the main reason not to conduct a more thorough investigation into hydrogels material properties. From a limited review of the literature, hydrogels were found to be a promising material for use in the model as they can closely resemble the feel of anatomical soft tissue due their ability to hold large volumes of water (Chai., et al. 2017). With more time, it would have been beneficial and insightful to engage in a more robust review of hydrogels to determine objective measures of their elasticity and plasticity properties by calculating their elastic modulus, yield strength, ultimate strength and fracture strength materials from the stress-strain curve (Roeder, 2013) and contrast them to the mechanical properties of those anatomical soft tissues considered in this research, in attempt to improve material tactile textures.

Despite a few limitations, the prototype was highly regarded by the participants as a useful training tool; one additional comment made about the overall experience of using the model from a surgical trainee was *"Great opportunity to practise skills I would otherwise not get to until much later in training/ post-grad fellowships."*, which highlights a current lack of accessibility to RALPN training simulations. This is also evidenced by the finding that a

surgical trainee at the end of their urology specialist training (8 years) reported having only 1 year of experience in robot-assisted procedures.

This model is a potential solution to providing junior surgeons with earlier access to training simulations of RALPN, which would result in earlier development of the skills required to perform the procedure. This ultimately has the potential to impact on the current surgical skills shortage for RALPN through surgeons gaining competency earlier and this in turn would increase the number of patients who have access to the best surgical care. One Consultant Urological Surgeon commented; *"Overall I thought this model provided an excellent opportunity to practice a complex surgical technique in a non-virtual reality environment and would be very keen to incorporate it into surgical training."*.

Future work to this project would include developing and optimising the materials used to produce the model, with the aim of further increasing the validity of the model. The model could also easily be re-designed with tumours of varying complexity to allow for a set of models which become progressively more challenging as surgical skills increase. Future validity testing of the prototype would include larger numbers of participants to increase the strength of the evidence with regard to the usefulness of the model as a surgical training tool.

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References

See Reference file

Appendix I – Review of Key papers

Author, date	Model/ Procedure	Production methods	Production time	Cost	Measurements of validity	Results	Comments
Adams, 2017	Adult kidney parenchyma with collecting system. No blood vessels. For use in simulating urological endoscopic procedures and testing medical devices.	CT scan segmentation and model resurfacing. Model scaled down to 80%. 3D wax-printing and mould casting. Moulds created by 3D-printing in VeroClear. Casting materials tested– agarose (4%), silicone elastomer and polydimethylsiloxane (PDMS).	2 working days	"Preparation is inexpensive"	Inner structure comparison of real organ and model – tested by overlaying CT scans. Ultrasound examination Endoscopic examination Comparison of material properties: Shore hardness, elastic modulus, tensile strength	Mean error of distance between the location of the model renal pelvis and organ renal pelvis =0.6mm. The agarose model best resembled real kidney during ultrasound examination. Agarose and the silicone elastomer showed most similar material properties to	Model was not coloured. No validity testing with surgeons. First to describe 3D wax printing.

						kidney tissue (see paper for full results)	
Maddox, 2018	Adult renal malignancy model; kidney parenchyma, tumour, blood vessels and ureter. For use in pre-surgical rehearsal. 7 patient-specific models were created (6 patients, one with bilateral tumours)	CT scan segmentation and model resurfacing. 3D-printing of entire model. Various unnamed materials blended to create model. This created a hollow renal capsule which was injected with agarose gel solution.	Not given	Not given	Pre-surgical rehearsal including tumour resection and renorrhaphy using da Vinci surgical robot. Comparison of surgical outcomes of the 6 patients to an in-house IRB approved database of RAPN outcomes.	Paper states surgeons report the model felt similar to actual kidney tissue (no mention of data collection method.	Kidney parenchyma coloured white. All other structures coloured black. No renal artery clamping – arteries solid. No mention of formal measurements of validity from surgeons
Monda, 2018	Adult renal malignancy model; kidney parenchyma, tumour and renal artery.	CT scan segmentation and model resurfacing. 3D-printed moulds of kidney plus tumour and kidney minus tumour were created	Moulding required 15 minutes of active work.	Cost of material per unit $3.90 (USD) Cost of 3D-prinitng	24 surgeons of varying levels of experience tested the model using the da Vinci surgical robot.	Highest measurements of model realism were: suturing, cutting and appearance.	No perfusion of simulated arteries.

	No collecting system. For use in PN training.	for a 2-step moulding process. Moulds cast in Dragonskin 20 silicone and Slacker silicone deadner (ratio 9:4). Surgical tubing was stitched to the model to create a renal artery.		moulds $260	Skills tested included: instrument choice and placement on box trainer, using intraoperative ultrasound, renal artery clamping, tumour resection, renorrhaphy, and tumour entrapment. Face and content validity measured using a questionnaire with responses given on 100-point Likert scale (useless-useful, unrealistic – realistic) NASA Task Load Index was used to measure self-assessed	Lowest measurements of model realism were: kidney malleability, differentiation between the tumour and kidney.	

					workload of each task Global Evaluative Assessment of Robotic Surgeons (GEARS) was used to measure surgical performance by blinded experts.		
von Rundstedt, 2017	Adult renal malignancy model; kidney parenchyma, tumour, No blood vessels or collecting system. For use in pre-surgical rehearsal. 10 patient-specific models were created.	CT scan segmentation and model resurfacing. Model described as 3D-printed. Not stated if 3D-printing is moulds or a capsule. Model made with silicone and silicone thinner. Silicone properties: shore hardness 10A, Die B tear strength of 17.863 N/mm (102 pounds/linear inch), tensile strength 3.2750 MPa (475psi).	Not given	Not given	Pre-surgical rehearsal of tumour resection using da Vinci surgical robot. Comparison of tumour volumes between the digital image, surgical model and patient tumour.	Similar measures of resection time and tumour volume between model and patients. Paper claims construct validity.	Kidney parenchyma coloured brownish and tumour coloured orange. No measures of face validity testing with surgeons.

		Silicone to silicone thinner ratio for tissues: Parenchyma – 70:30 Tumour – 85:15					
Cheung, 2014	Paediatric pyeloplasty model: kidney, renal pelvis and ureter and peritoneum For use in laparoscopic paediatric pyeloplasty training.	3D-modelling was used to create the kidney, renal pelvis and ureter by combing geometric shapes. These shapes were used to create 3D-printed negative moulds. Moulds were cast in Dragonskin 30 at a pre-determined ratio with Slacker silicone deadner. Thin vessel structures were created using a silicone drip method – painting on silicone until the desired thickness is achieved.	"Several hours"	$100 USD	Initial face validity testing with 4 surgeons. Lead to changes in thickness of renal pelvis, ureter and peritoneum. 24 paediatric urology surgeons performed a laparoscopic pyeloplasty on the model. Face validity was evaluated using a 5-point Likert scale asking about usability, aesthetic, overall feel, feel of peritoneum, feel	Face validity results (Mean $\pm$ SD) Experts: Usability 3.67 $\pm$0.58 Aesthetic 3.33 $\pm$0.58 Overall feel 3.50 $\pm$0.71 Peritoneum 3.33 $\pm$1.15 UPJ 3.00 $\pm$1.00 Novices: Usability 3.63 $\pm$1.22 Aesthetic 3.55 $\pm$0.74 Overall feel 2.82 $\pm$0.91 Peritoneum 3.77 $\pm$0.75	First to describe silicone drip method.

					of ureteropelvic junction (UPJ)	UPJ 3.09 ±1.23 Comments included need for improved realism of tissue properties and better colouring	
Garling, 2018	Paediatric third ventriculostomy model: skull and brain. For use in surgical training of endoscopic third ventriculostomy.	CT and MRI image segmentation. Skull model was 3D-printed. Brain model was used to create 3D-printed negative mould. Only opensource software was used. OsiriX and Freesurfer to segment the scans MeshLab – checking STL file for defects. Meshmixer – inspector tool and autorepair function.	48 hours total time required	$122.78 USD	Uniaxial compression and shear tests performed on material 15 neurosurgeons evaluated the model and then completed a face validity and content questionnaire consisting of 10 questions that were answered using a 5-point Likert scale	All 10 markers of validity received an average score of >4.60. 73% strongly agreed that the silicone model properties resembled human brian tissue. The other 27% agreed.	Time required to develop the model not mentioned

		Blender- used to create negative mould. Boolean operator function to create negative space. Mould printed in acrylonitrile butadiene styrene (ABS) filament. Brain model cast in Ecoflex silicone and Silicone Slacker (5:3)			(strong disagree – agree)		
Weinstock, 2017	Full head model of 14 year old with hydrocephalus: external features including skin, hair, eyelashes, eyebrows, skull, brain Used for training of endoscopic third ventriculostomy	MRI image segmentation. Skull 3D-printed. Outsourced team of Hollywood special effects specialists created the external model. Method for production of brain tissue not described.	12 month development period	Not given	Face validity and content validity testing – 14-item questionnaire answered on a 5-point Likert scale assessing measures of the models appearance and the reproducibility of the surgical procedure.	Mean face validity score = 4.69 Mean content validity score 4.88 Construct validity – significantly better performance from experts compared to	Segmentation and 3D-printing method lacks informative details. Likely to have high costs

		Mention of fluid flow through ventricles and basilar artery using manual and subsequent electronic pump. Method not described.			Construct validity testing if the model can evaluate performance was assessed by 2 blinded assessors using the Objective Structured Assessment of Technical Skills (OSATS) scale.	novices (p<0.001)	