3D printing – Innovative Technology to Improve Care and Reduce Costs

At the most recent Radiological Society of North America (RSNA 2017) congress in Chicago, a world leading event for new and innovative technologies in healthcare, 3D printing was cited as the number one trend set to transform healthcare. As medical 3D printing enters the mainstream with a focus on surgical care, many healthcare providers are still not yet taking advantage of the patient care improvements and cost savings that are achieved by using this innovative technology. The current and potential uses for 3D printing in medicine has resulted in experts and thought-leaders from varying surgical specialisms trail-blazing in this space and preaching the positive impact. As more and more surgeons use the technology, seeing first hand the impact, hospital management will be forced to review how they can best support the long term integration of this into their hospitals. It is therefore not a question of *if* a hospital should start providing access to 3D printing for its staff, but *when*, and like any new technology, those who are seen as early adopters will position themselves as leaders in this space, helping to establish best-practice for the rest of the industry.

3D Printing - The immediate impact of innovation

The use of 3D printing in surgical planning and preparation offers one of the most studied, and clear application areas for this technology. The use of physical models for treatment planning and visualization, instead of the sole use of CT, MRI data or virtual reconstruction, has many distinct advantages. Typically, CT and MRI are viewed on screen as a stack of 2D black and white images, and increasingly labs are adding software tools to give the illusion of 3D volumes on a 2D screen, however this can cause problems regarding the viewing angle, depth, transparency and lighting anomalies that manifest as viewing orientation uncertainties.

It is common feedback from all users of this technology that complex anatomical relationships (bone fragments near fracture sites, for example) can be better appreciated on 3D solid models 'in hand'. In addition, having access to the 3D printed 1:1 replica of the patient's anatomy supports physical simulations of surgery, as well as pre-bending and pre-fitting of plates prior to surgery. Research also shows that 'touch' re-calibrates the visual perception so that it is better able to infer depth from the retinal projection. The sensory information exploited by the haptic system for the recognition of real objects is made by kinesthetic and cutaneous inputs. Medical 3D printing is offers a host of benefits to service providers and service users across the healthcare lifecycle. Offering 3D printing as a part of a comprehensive care pathway for complex injuries facilitates procedural efficiency, improved treatment outcomes, and reduces downstream re-intervention costs, offering high potential value. Research shows time savings ranging from 27% to 40% on surgery [1]where a 3D print has been used to prepare. This time saving not only has a knock-on impact on costs (less

[1] http://additivemanufacturing.com/2017/11/17/german-university-hospital-mainz-pioneers-surgical-planning-for-life-saving-vascular-surgeries-with-3d-printing/

theater time, only necessary equipment is sterilised, reduction in load kits) but by impacts directly on scheduling efficiency[2], increasing the number of patients being treated.

> *'Theatres represent one of the single biggest productivity opportunities in any acute trust. Even if you think your theatres are working well, the productivity benefits of The Productive Operating Theatre, very quickly add up.'*
>
> *Matthew Lowry — deputy chief executive and chief finance officer, The Rotherham NHS Foundation Trust*

Reduced theater time also contributes to a reduced risk of infections. Deep infection after a joint replacement is a serious complication that requires surgical and prolonged medical management. The costs of treating an infection in England are reported to be around £100,000 per patient.[3]

Procedures with longer operating times, greater risk and uncertainty, and risk of complications are those which will most greatly rationalize the financial and resource cost in creating a medical 3D print, and will result in the greatest impact. In addition, the ability to mitigate the potential litigation from clinical negligence (a figure which has quadrupled in the last decade to £1.6B[4]) through advanced preoperative planning and better patient consenting processes. Patient understanding and satisfaction is increased by seeing and interacting with models of their anatomy[5]. Clinicians report that increased patient understanding aids in informed consent discussions and facilitates improved patient cooperation in the procedures, a area of particular focus given the 2015 Montgomery ruling.[6] An optimally informed patient will have more realistic expectations about a surgical procedure and its associated risks. Well-informed patients will be more satisfied and file fewer legal claims.[7]

Why this technology, and why now?

There are a host of national and international initiatives to drive quality and efficiency improvements in healthcare, and in the NHS one such programme 'Getting It Right First Time'[8] seeks to improve the quality of care within the NHS by reducing unwarranted variations, bringing efficiencies and improving patient outcomes. Additionally, the focus on creating personalized healthcare [9]is part of the NHS 2020 Vision – improving patient treatment, outcomes and safety while catering for their individual requirements.

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[2] http://harmfreecare.org/wp-content/files_mf/Improving-quality-and-efficiency-in-the-operating-theatre.pdf
[3] http://www.wales.nhs.uk/sitesplus/documents/863/3%20%28ii%29%20Getting%20It%20Right%20First%20Time.pdf
[4] https://www.ft.com/content/9a7c010a-9307-11e7-a9e6-11d2f0ebb7f0
[5] https://www.ncbi.nlm.nih.gov/pubmed/25822093
[6] http://www.bmj.com/content/357/bmj.j2224
[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2895877/
[8] http://gettingitrightfirsttime.co.uk/
[9] https://www.england.nhs.uk/wp-content/uploads/2016/09/improving-outcomes-personalised-medicine.pdf

Offering 3D printing as a part of a comprehensive care pathway facilitates precisely this personalized approach along with a proven means of improving quality of care and patient experience through procedural efficiency, improved treatment outcomes, and reduced downstream re-intervention costs, offering high potential value. As outlined above, the figures are clear that this technology is set to transform how healthcare providers think of pre-operative planning and 3D printing. "Planning is the first step in the operative management … and should not be regarded as an optional extra."[10] It is no longer a '*nice to have*' but a '*need to have*'.

Another leading factor for medical 3D printing to be gaining such recognition in the healthcare sector is that the 3D printing industry as a whole has seen a large number of changes. One such change is the shift from only hobby-devices and manufacturing machines, to the growth of a desktop 3D printing market, bringing the costs down, and increasing the quality. There has also been growth in third-party providers specifically focused on supporting the medical sector in accessing this technology in an affordable and efficient way.

Market research published by Research and Markets [11] predicts the year on year growth of 3D printing will be in double digits due to the high demand from North America and Europe coupled with the rise in awareness about these devices in developing countries. The healthcare sector is expected to be the fastest growing segment of the 3D printing market as innovations are integrated into specialisms such as orthopaedics and implants. With an estimated market value of around $500M[12] in 2014, there has been a growing body of industry reporting on the 3D printing in healthcare market, with 10 year predictions ranging from $2.4B [13] to $17.4B [14]according to Frost and Sullivan's latest market report.

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[10] https://www2.aofoundation.org/wps/portal/!ut/p/a0/04_Sj9CPykssy0xPLMnMz0vMAfGjzOKN_A0M3D2DDbz9_UMMDRyDXQ3dw9wMDAx8jfULsh0VAdAsNSU!/?bone=Foot&segment=Midfoot&soloState=lyteframe&contentUrl=srg/popup/further_reading/PFxM2/24_Preop_plan.jsp

[11] https://www.researchandmarkets.com/research/b6jb9h/3d_printing 3D Printing Market - Global Outlook and Forecast 2017 - 2022,

[12] http://www.insightpharmareports.com/Affiliated-Reports/IndustryArc/3D-Printing-in-Healthcare-Market--Role-and-Opportunities/ Insight Pharma Reports - 3D Printing in Healthcare Market: Role and Opportunities

[13] https://www.alliedmarketresearch.com/3d-printing-healthcare-market - 3D Printing Healthcare Market by Technology (Droplet Deposition (DD), Photopolymerization, Laser Beam melting, Electronic Beam Melting (EBM), Laminated Object Manufacturing), Component (System/Device, Materials, Services), Application (External wearable devices, Clinical study devices, Implants, Tissue engineering) and End-Users (Medical and surgical centers, Pharma and biotech companies, Academic institutions) - Global Opportunity Analysis and Industry Forecast, 2014 – 2020

[14] https://ww2.frost.com/news/press-releases/customization-and-cost-benefits-over-traditional-manufacturing-attract-investments-3d-printing-technology-healthcare-facilities/

3D printing and the future for surgical training

It will become increasingly rare for surgeons to undertake a surgical procedure without having first had access to patient specific models to undertake a planning phase. It will facilitate not only the individual surgeon in considering what tools they need and how they approach the procedure, but as an essential starting-point for effective team communication to ensure adequate planning and preparation for each surgical case.

As surgical planning with 3D prints moves from the early adopter stage to standard practice in hospitals, it is important that surgeons are trained on the technology to ensure they are aware of both the potential and the limitations.

It is not advisable or feasible for surgeons to undertake the creation of 3D printable files, due to the cost, complexity and time-consuming nature of the process and software, however they will be integral to the process. Providing clinical requirements allowing dedicated engineers (typically biomedical engineers) to create the 3D printable files necessary will be critical to realizing the benefits the technology can offer. It is important to further strengthen the relationships between surgical departments and radiology/imaging to facilitate the widespread adoption of 3D printing.

Another huge impact of 3D printing is the ability to train new surgeons on specific pathology. Enabling reuse of patient-specific 3D printed models for education of trainees also extends its value, beyond just a one-time use, extending the long term value. As 3D printed patient-specific models become more prevalent in hospitals, associated universities and research facilities, available "stock" of ordered models will increase. Once used for a real-life preoperative planning case, a model could be held by an institution as an educational aid. It is entirely feasible that institutions could hold databases of anonymized models for cross-education and loan to other institutions or Trusts.

As an orthopaedic surgeon, Mr Simon Fleming discusses the reasons he has offered support for the axial3D's vision to make 3D printing routine in healthcare.

> *"As Immediate Past President of the British Orthopaedic Trainees Association (BOTA), a key focus for me was to inspire young surgeons to strive for surgical excellence. Medical 3D printing, particularly for surgical planning, harnesses the passion for innovation and improvement our young medics should aim for. As an orthopaedic surgeon, I see first-hand, the benefits of comprehensive preoperative planning, leading to a more confident surgical team and better patient outcomes. Maximising theatre resource ensures operating slots and staffing requirements can be accurately planned and improved and unnecessary, costly equipment on 'stand-by' can be eliminated. 'Getting It Right First Time' is key to driving improvements across the care pathway and delivering the high quality of care expected in the NHS and beyond and medical 3D printing is integral to that process.*
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> *Providing a tangible, patient-specific and consistent aid for surgical training, whether visually or for simulation, is one of the most important applications for preoperative 3D planning. With a shortage of cavaders for human anatomy practice and training, they act as a driver for competency-based training, where trainees never do a case for the first time on a patient. Patient-specific replica models enable training surgeons to specifically view, assess*

and plan surgical procedures for specific diseases and health conditions requiring surgical intervention."

Considerations

Even when the benefits of 3D printed anatomical models is known to hospital teams, the underlying question over which department pays or which budget should be attributed to the initial cost still remains. With healthcare budgets continually constrained, it would appear that currently, hospital teams often view preoperative planning models as a "luxury" purchase to be used when complex cases dictate a level of surgical precision or surgical procedure which cannot be accurately determined through existing 2D or 3D medical imaging. Instead, surgical teams and associated C Level Management should be encouraged to consider as routine, any innovation which reduces indecision and ambiguity, encourages surgical planning and precision and limits, where possible, the need for revision surgery or extended operating times.

With top level medical education ongoing for surgical staffing and the undisputed expertise and innovative thinking steering our modern surgeons, it is evident that not all surgeries require a 3D anatomical model. Routine procedures do and always will proceed without requirement for the added insight a model provides. However, the opportunity which exists for the future of surgery is the ability to access 3D printing quickly and easily for those complicated patient cases for which surgery which would be more difficult, unpredictable or life-limiting.

A recent case led by world-renowned Consultant Transplant Surgeon Tim Brown at Belfast City Hospital exhibited the opportunity 3D printing provides when anatomical ailments and impairments hinder surgeons from precisely understanding what they and their teams will encounter in operating theatres.

Whilst planning for an incompatible ABO kidney transplant, Mr Brown's team determined the presence of a Bosniak 2F renal cyst on the donor's kidney. To ensure precise and complete removal of the potentially malignant cyst for subsequent allotransplantation, Mr Brown utilised a 3D model, manufactured as clear with contrasting colours to exemplify the exact size and position of the lesion to be removed. The surgery proceeded successfully with extremely positive patient outcomes for both donor and recipient. The described case is a medical first for the complete removal of this cyst type for transplantation without the requirement of revision surgery. [15]

To prepare for widespread adoption of 3D printing models for preoperative planning, improvement is required in hospitals' senior level understanding and endorsement of the benefits of 3D preoperative planning in saving costs, harnessing innovation and improving patient outcomes on a tangible scale. Additionally, clearer budgetary ownership for financial spending on innovative surgical products and techniques within institutions is

[15] http://www.axial3d.com/latest/case-studies/ex-vivo-partial-nephrectomy/

required. It is imperative that surgical progression and procurement processes exist in a cohesive manner which encourages initial monetary outlay on new products and solutions if they have the potential to assist with reduction of long terms costs.

Improved support from private medical cover providers is also recommended for the future. Japan's Central Social Insurance Medical Council, an organization of the Ministry of Health, Labour and Welfare announced in 2016 that the cost of 3D printed organ models used to assist medical treatments and surgeries will be covered under the standard medical insurance payment range. In order to progress widespread expansion on the use of the technology, support from medical insurance providers within the UK and other regions around the world would help make medical models more accessible and affordable to citizens. Improved opportunities for Junior medical teams to learn about 3D printing during education and for experienced teams to develop their knowledge of the innovation should also be available.

Further consideration should also address the improvement in collaboration between UK radiologists and their USA/Canadian counterparts. More often in USA and Canada, radiologists, rather than other surgical specialists have pioneered the experimentation of 3D printed models, with many key hospital sites proceeding to set up an in-house 3D printing function in both small and large hospitals. A key example is Anish Ghodadra MD, an Interventional Radiologist at Yale New Haven Hospital, Prior to his current role, Anish founded and directed the UMPC Radiology 3D printing program where he developed novel low-cost techniques and applications for 3D printing in medicine. This model of implementation could be further explored, and learnings shared, to identify if opportunities exist for UK radiological teams to pioneer this technology in a similar manner

Finally, decisions need to be addressed on whether preoperative planning 3D printing should be outsourced or if a 3D printer should be purchased for use onsite. A linked consideration is addressing skills / staff requirement needed for an in-house service within hospitals. For example, the hiring of a 3D print technician or biomedical engineer with understanding of the materials, software segmentation and post-processing steps involved.

Before healthcare providers and managers purchase a 3D printer it is important the programme is fully researched and medium to longer term investment growth plans are considered relating to necessary kit, space and staff to ensure a successful roll-out. Outsourcing 3D printing work to a 3rd party provider allows healthcare providers to gather accurate data of users and demand in order to make informed decisions about their 3D printing future.

About axial3D

axial3D specializes in medical 3D printing to advance both standards and efficiency of surgical intervention. With a focus on providing unique workflow software and automated DICOM segmentation algorithms to 3D printing laboratories globally; as well as a full 3D printing service offering, axial3D's mission is to improve access to 3D printing for surgeons globally and drive

increased efficiency and reduced costs of medical 3D printing. axial3D is a privately-owned company, headquartered in Belfast, UK.

Images

Adolescent spine

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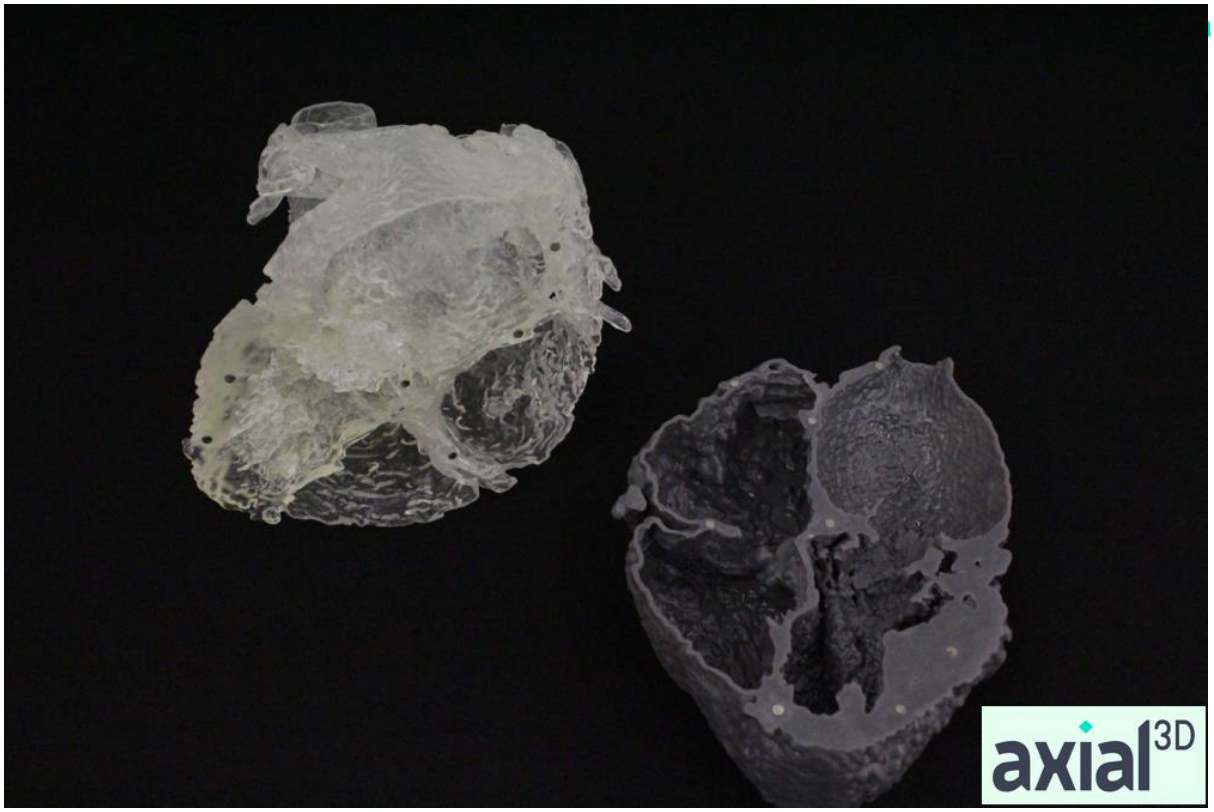
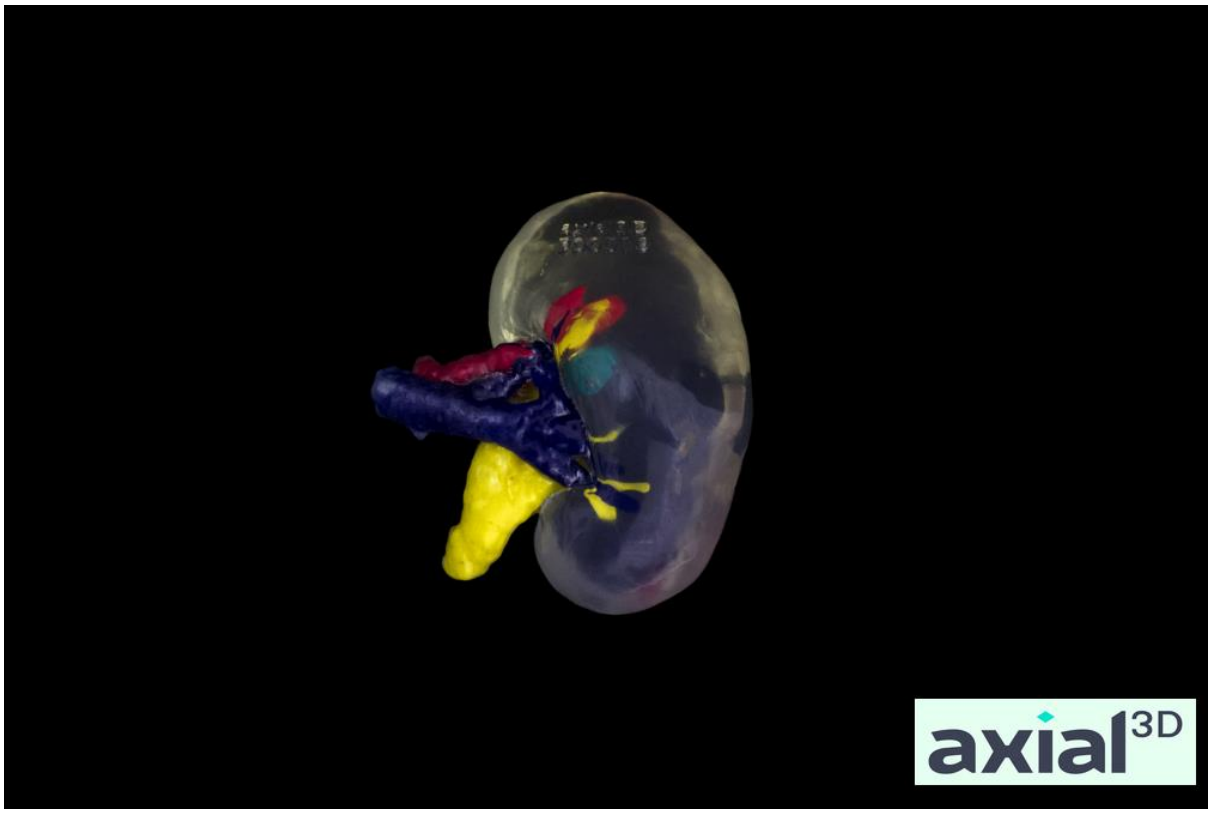


Cardiac model



Kidney oncology model

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