CARTIS Evidence to Commission on the Future of Surgery

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Present and Expected Impact of 3D Imaging, 3D Planning and 3D Printing on Surgery over the next 20 years

The Commission's literature review provides a useful oversight into technological innovations in surgery. Having reviewed the document, with particular focus on the 3D imaging, planning and printing section (3D printing is itself rather a confining term), we believe we can provide additional comment that could help form part of this review (Fig 1). We will not repeat the information provided in that review but will comment on it in the areas where we have specific experience.

CARTIS has been researching and developing applications of technologies including all forms of three-dimensional imaging (3D surface scanning, photogrammetry, CT, MR, US etc), computer aided design (CAD) and 3D printing in surgery and prosthetics since 1999 ([1]www.cartis.org/publications, [2]Bibb R et al 2000). This experience has given us technical understanding and, most importantly, detailed knowledge of current best practice and the limitations of current methods.   Firstly though we need to try to summarise the current application of these technologies in surgery, or at least some of them, because the scope of these applications is increasing all the time.

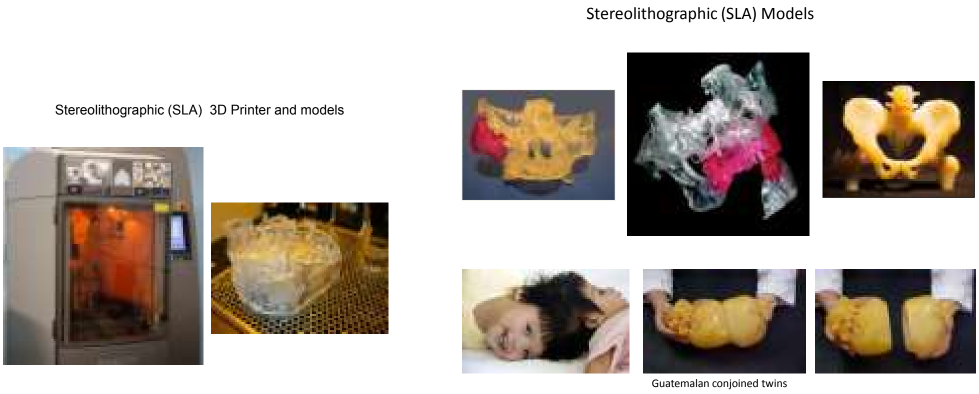


Fig 1

Neurosurgery

The increased use of decompressive craniectomy following severe traumatic cranial and brain injury has resulted in a substantial increase of survival rates following such injuries ([3]Hutchinson PJ et al 2016) and the subsequent need for repair of large defects. High quality CT and in particular 3D CT images are now routine, can generate 3D virtual and physical models of the cranium and the defect and these are now commonly used to manufacture and/or to 3D print (another term for rapid prototyping or additive manufacture) implants to reconstruct accurately the defects in materials such as titanium (Fig 2) and implantable plastics such as PEEK ([4]Bibb R et al 2002) although 3D printed PEEK is not widely used yet.   In one form or another, these are becoming the norm and are already the gold standard.

Fig 2a shows (top left) a haptic device being used to manipulate and build on a 3D image on screen. Top right shows the cranial defect. Bottom left shows the reconstructed defect and bottom right the titanium cranioplasty plate manufactured on a 3D physical model

Fig 2a

Fig 2b Other examples of Cranioplasty plates, the left showing a large titanium plate pressed on a 3D plastic SLA model and the right a 3D printed titanium alloy plate fixed on a plastic model with titanium screws

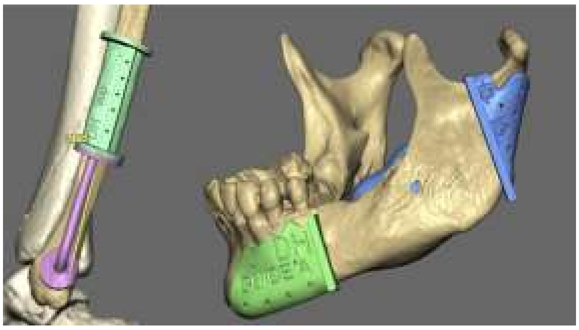
Craniofacial Surgery

We use this term to refer rather specifically to collaborative work between neurosurgeons and cranio-maxillofacial surgeons. This encompasses craniofacial deformity surgery on congenital anomalies such as craniosynostosis especially in babies, craniofacial including brain trauma surgery and the sequelae of such surgery and also craniofacial tumour surgery. In many of these, 3D planning is being used to visualise the problem, plan the surgery, manufacture (with 3D printing) guides to help the surgeon to carry out the surgery accurately, and to custom-make fixation plates (to be used with screws) as well as cranial and facial implants to restore the defects ([5]Peel S et al 2017, [6]Eggbeer D et al 2007, [7]Eggbeer D et al 2012).   This is particularly useful for cranio-orbital tumours, and anomalies especially after trauma with reconstruction of the fragile bones of the orbital walls which is crucial to the correct position of the eye and for its movements, vision and appearance.

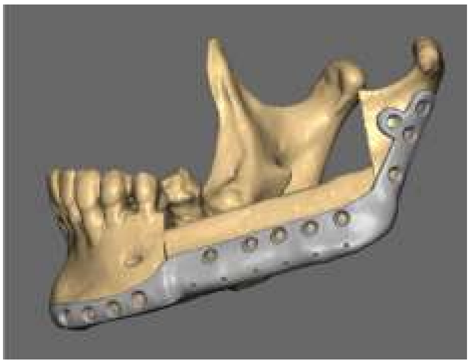
Head and Neck Cancer Surgery

The resection of tumours, especially malignant tumours of the head and neck, is multi-disciplinary. The principal surgical specialties involved are Maxillofacial (OMFS), ENT and Plastic. Reconstruction with vascularised free flaps using microsurgical techniques and the use of plating systems adapted to the complex shapes of the facial skeleton has become routine.   Increasingly the planning of this surgery, both ablative and reconstructive, is being carried out using 3D software especially in the mandible with free fibular flap reconstruction using 3D printed cutting guides and plates to transfer the plan to the patient during surgery ([8]Culié D et al 2016, [9]Goodson A et al 2017, Fig 3).

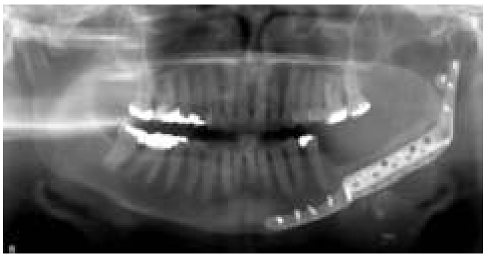
Fig. 3



Three-dimensional plan of the position of the fibular and mandibular cutting guides (fibromyxoma highlighted in blue). Note the fibular locator that is designed to position the distal fibular cutting guide 63 mm from the lateral malleolar prominence.



Fibula sitting in the virtual "Cradle" 3D printed titanium plate



Radiograph showing the outcome some months after surgery

The challenge, as in most of these applications, is to ensure close collaboration between the surgeon and the people doing the planning and designing the guides/implants as well as the manufacture of the guides/implants. Some hospitals are developing their own planning, design and sometimes manufacturing facilities ([10]Sugar A et al 2004) and others are commissioning these from external commercial companies.

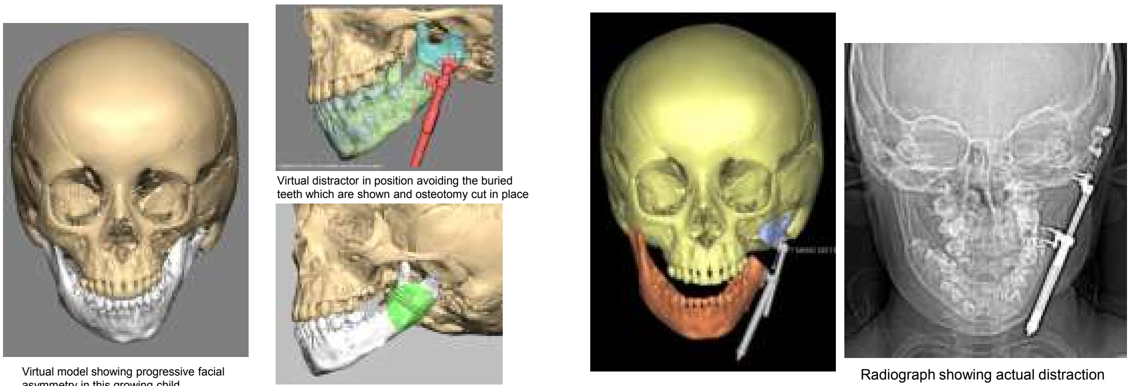
The big disadvantage of external commissioning is the lack of close involvement between planners, technologists, design engineers and surgeons and the cost. On the other hand the manufacture of guides and implants commonly requires metal printing and the machines involved are expensive (good ones in the order of £500,000 plus ancillary equipment and post-processing facilities) and require substantial support and maintenance. Morriston Hospital was probably the first NHS hospital in the UK to employ a full time 3D Scientist (3 years ago) to work on 3D planning alongside a well developed Maxillofacial Laboratory already employing 16 staff (Reconstructive Scientists). We have calculated that, for mandibular cancer resection and fibula reconstruction cases alone, carrying out the planning and most of the printing in house has saved the hospital more than £50K in a full year compared with outsourcing that work.

Orthognathic and Related Facial Deformity Surgery

It has been routine for more than 30 years to carry out computer based planning of surgery to correct facial and jaw deformities but in 2D ([11]Eales EA et al 1995). Increasingly, this is now being replaced by 3D CT or cone beam CT (CBCT) planning and often with custom made implants and/or 3D printed positioning splints to fix the facial bones into their corrected positions accurately ([12] Aboul-Hosn Centenero S et al 2012).

Such planning is particularly valuable for complex congenital often syndromic deformities and for asymmetries. Applicable to surgery in adolescents and adults, it becomes incredibly valuable when managing young children with complex anomalies such as the birth deformity of Hemifacial Microsomia ([13]Sugar AW 2002). Reconstruction with bone grafts or vascularised flaps needs to meet the three dimensional needs of the deformity and often mirror imaging of a normal side will be a useful guide to surgery. Gradual bone lengthening by distraction osteogenesis (after Ilizarov) can be planned in 3D (Fig 4), the selected distractor device inserted on screen and activated to simulate the desired movements. Guides can then be constructed by 3D printing to allow the chosen device and its position to be accurately replicated at surgery.

Fig 4



Virtual model showing progressive facial asymmetry in this growing child

Virtual distractor in position avoiding the buried teeth which are shown and osteotomy cut in place

Virtual guide in position to enable the osteotomy cut and the distractor to be placed in exactly the planned position at surgery

Simulation of the distraction required

Radiograph showing actual distraction achieved and bone formation in the gap
Incidental showing of implants for an ear prosthesis

Facial Trauma Surgery

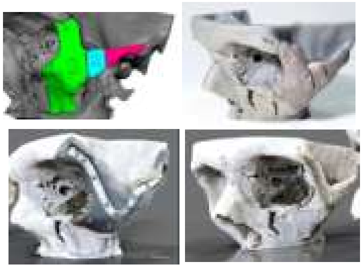
The major limitation of the use of 3D planning in acute facial trauma management is time. At present, most trauma cases need to be treated within hours or at least days and this may make it practically impossible for simulated surgery to be carried out and custom made fixation plates produced without inappropriately delaying surgery. It is also the case that putting fractures back together in the acute phase is much less challenging than moving the bones into a new position as is often required in revision trauma surgery, deformity surgery and tumour surgery. Nevertheless mistakes can occur and as better software and faster manufacturing (3D printing) become available, this situation could change.

There are however some areas in which 3D planning and printed plates and sheets are already of routine value. One is in the management of complex mandibular fractures, which often indicate the use of strong and rigid reconstruction titanium plates and screws, the plates being challenging to bend in situ at surgery. Provided the fragments can be relocated on virtual (and sometimes on physical) models, custom made plates can be manufactured and used.

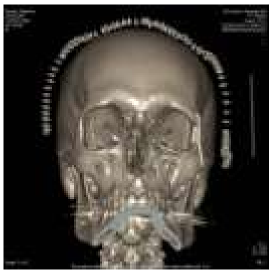
Another example is in late secondary revision surgery after complex midface trauma (Fig 5) which is especially challenging to achieve good results without much guess work and often multiple interventions ([14]Peel *et al* 2016)

Fig 5

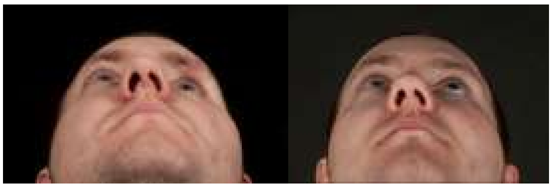
3D model from CT data with plates and screws digitally removed and residual deformity of position of the left Zygomatic bone and enlargement of the orbital cavity evident



Virtual and physical planning models showing the osteotomies required to correct the malunion and the guides and plates required



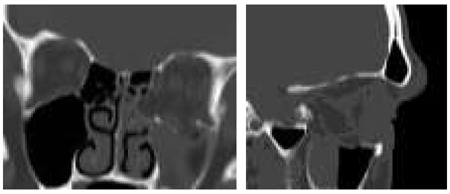
Post-operative 3D CT after reconstructive surgery



Before and After
correction of enophthalmos

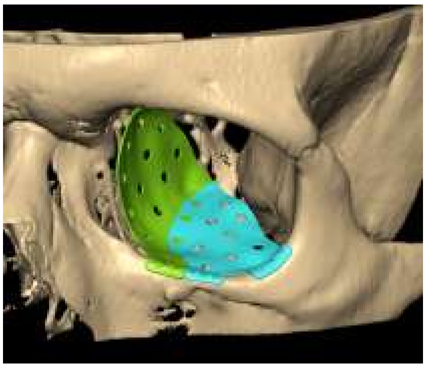
Before and After
Single stage reconstruction as described above

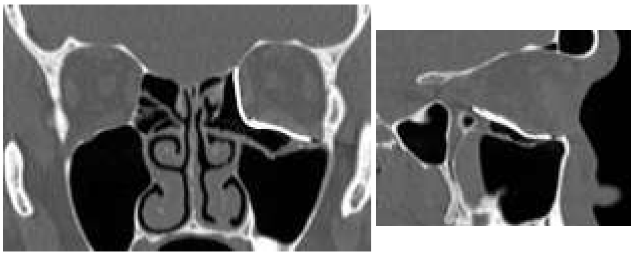
3D planning and the use of custom made implants is also valuable in the treatment of orbital floor/wall blow-out fractures where high quality 3D imaging is crucial and the precise replication of the orbital anatomy critical to good outcome of both vision (eye movement) and aesthetics (prominence of the eye) ([15]Hughes *et al* 2003 and [16]Mustafa *et al* 2011). In the latter group we now treat the majority of such injuries with custom made titanium implants with very good published outcomes (Fig 6).



CT scan showing left orbital blow-out fractures with almost no orbital floor and medial wall remaining

Virtual 3D CT with the normal orbital walls mirror imaged to enable 2 sheets to be designed to lock together to reconstruct the missing wall and floor





Post-operative CT showing the reconstructed left orbit

Fig 6

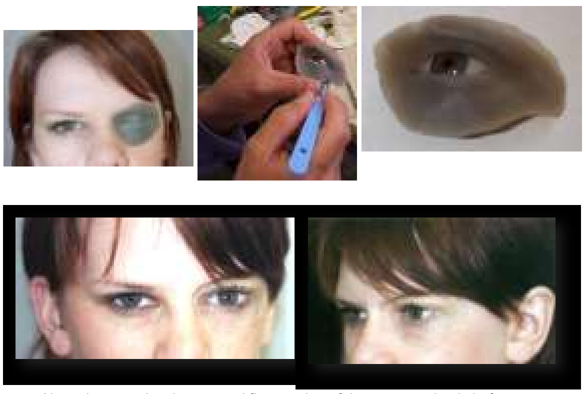
In orbital trauma and other reconstruction cases too, it is sometimes desirable to check the position of guides and implants using navigation. Intra-operative cone beam CT (CBCT) can also be valuable to confirm the exact position of the implant before wound closure.

Facial Prosthetics

The facial reconstruction of patients following ablative surgery, trauma and congenital deformity is not always possible with the patient's own tissues. Facial prostheses retained on osseointegrated titanium implants offer such patients the chance of rehabilitation with a life-like prosthesis.
This has traditionally been a highly artistic skill but 3D planning for the placement of the implants to retain the prosthesis and the use of 3D design and printing has given the opportunity for dramatically reduced treatment time ([17]Bibb *et* al 2009, [18]Bibb et al 2010, [19]Peel et al 2016b, [20]Daniel & Eggbeer, 2016 and [6]Eggbeer *et al,* 2007) and better aesthetic results (Fig 7). Much of the development in this area has been through, and continues to be from, the CARTIS group.

3d Printing in Wax

3d Printed Wax Orbital Prosthesis



Above images showing manual fine carving of the wax prosthesis before conversion to silicone and fitting as shown below

Fig 7

The manufacture however remains in the main traditional but it is hoped that recent developments in direct silicone 3D printing will eventually enable cost effective production.

Other Disciplines

It is in the head and neck specialties that we have most of our experience but these techniques are increasingly applicable to other disciplines. For example, good 3D imaging is crucial to **trauma**

and orthopaedic surgery and the above techniques useful in especially complex cases, revision surgery and in teaching. 3D planning is also useful in **plastic surgery** especially for example in breast reconstruction using surface scanning, and also in planning other aesthetic corrections. There are applications in minimal access for **vascular surgery**, and in planning some **cardio-thoracic surgery**. We have already started working with our thoracic surgeons in Morriston Hospital and have manufactured in titanium a rib/sternum custom replacement which has been used and fixed in situ at surgery. We are aware of similar work being carried out by thoracic surgeons in Taiwan.

There is also considerable experience among laboratory based research workers in the design, manufacture and use of 3D scaffolds within the sphere of **tissue engineering**. Our academic plastic surgeons are going in this direction in their work on cartilage.

Challenges

The review correctly reports that 3D printing methods have improved in speed, the range of available materials and, in parallel, some have reduced in price. The way 3D planning and printing is used has evolved away from making patient specific anatomically based plastic models from computer tomography data through to the production of metallic transient use devices/guides and long term biocompatible implants. Considering 3D printing as an isolated technology has become a significant limitation on the effective use of 3D planning in surgical applications.

The vast majority of the academic literature citing the application of 3D printing consists of clinical papers about individual cases (or case series) and often overlook detailed reporting of device design specifications, device modelling operations, or device detailing decisions. This could be because the reported production process undertaken by some external implant companies is one of relative detachment from the surgeon with limited collaboration beyond an initial device request ([19]Peel & Eggbeer 2016b). Without detailed knowledge of why 3D printing is used and the design decisions made during the evolution of 3D printed end use devices, it risks becoming a technology constrained to simple applications or one that is used unsafely.

Improved Information Technology (IT) infrastructure with the ability to transfer large datasets combined with computing power has allowed centralised planning services to develop within the NHS. The majority of these are for head and neck reconstruction as maxillofacial surgeons and technicians have been keen early adopters. These services are starting to extend to other areas such as orthopaedics and cardiology.

Many units throughout the UK have invested in ‘in house’ 3D printing (often stereolithographic, polyjet or low cost extrusion) capabilities and some are purchasing, in collaboration with other organisations and companies, metal printing. We would expect these ‘seed’ centres to develop as design and manufacture hubs for their region and will come to be regarded as essential services.

A recent paper, published by CARTIS members and collaborators, reviews the numerous reasons why 3D planning and additive manufacture/3D printing is at present and in most hospitals still not fully integrated into everyday practice [[19]Peel & Eggbeer 2016b]. It identified that the “economic viability of the techniques and how they may best fit the constraints of healthcare systems and existing workflows” are not reported widely in the literature, and that this could be the cause for some scepticism.

As the Commission's literature review also identifies, cost is also an oft-cited reason for there being scepticism towards the adoption of 3D planning in surgery. This can be broken down further into high machine costs (associated with purchase, maintenance and materials) and, perhaps more importantly, cost effectiveness. Cost effectiveness is often poorly addressed in the published literature, which typically reports casual statements on how 3D planning and printing have saved time or improved accuracy with no rigorous or statistically significant supporting data.

The 2016 paper published by Peel & Eggbeer also maps a much wider range of factors that affect the efficient adoption of 3D planning and printing in surgery. Design process is considered a key factor. As an early paper noted, best practice in planning for complex maxillofacial surgery involves close collaboration between surgeons and technicians [[10]Sugar *et al,* 2004]. This has become especially important as the application of 3D printing has evolved as a method to produce high-risk, long term implantable devices. It is also in the context of an increasing number of NHS hospitals wishing to design and produce their own devices. Design, or rather control of the design process to achieve a safe and effective result, has become extremely important. As with any manufacturing method, lack of design control can result in the production of poor performing and even unsafe devices. Good design and design control methods mitigate these risks. Therefore, we propose that the NHS should be considering the future role of design as a discipline that supports rigorous and appropriate use of technologies, such as 3D printing. Perhaps this fits well with the concept of 'seed' centres of regional excellence previously discussed.

This proposition also comes in the context of changing regulations, specifically the Medical Device Regulations, which entered into force in May 2017 and are in a three-five year transition period. In order for the NHS to continue and develop its expertise in planning and design it will become necessary to implement quality management systems akin to those required by industry. The NHS is, however, unlikely to require the same level of conformity assessment that industry will have to undergo. Nevertheless, NHS specialists who intend to design and/or fabricate medical devices using 3D printing are likely to require a quality management system which is compatible with industry suppliers who fabricate metallic devices. This means the NHS will need to implement components of the harmonised ISO 13485:2016 quality management system. This represents a step change in the type of expertise required by the NHS in order to effectively operate these technologies.

Materials and Processing

The materials used routinely as part of surgical planning and device production will also continue to impact on NHS adoption. There is an increasing range of polymer materials with some claimed as suitable for end use device production.

Titanium is a commonly used material for cranioplasty and reconstruction plate fabrication. It can also be 3D printed to create extremely complex geometries that are otherwise impossible or extremely difficult to produce using swaging or bending. Polyether Ether Ketone (PEEK) is another and increasingly used material used for patient specific cranioplasty although it is currently limited to being subtractive manufactured (that is, by the use of a multi-axis 3D milling machine to reduce a block of material to the required shape and dimensions, all driven by CT data). There are some reported advantages of PEEK over titanium: the mechanical properties are more similar to bone; it does not conduct heat/cold thus making it potentially more suitable in extreme climates; it can be modified in theatre if necessary; and it is radiolucent, which means it is potentially more suitable where people may require radiotherapy.

PEEK is however an extremely expensive material. Its advantages have encouraged research into the possibility of 3D printing PEEK using additive manufacturing (or perhaps other similar thermopolymers within the same family, such as Polyetherketoneketone - PEKK). Current manufacturing processes used to 3D print PEKK or PEEK include selective laser sintering and fused deposition modelling. Neither is able to replicate the small detail features it is currently possible to achieve with titanium 3D printing but it is highly likely that 3D printing in implantable polymers will continue to develop into a practical and more affordable process.

It is equally important to provide evidence that the processes used to fabricate devices in polymer material are also safe. Manufacturers must supply detailed analysis that illustrate material and process safety using, for example, relevant components of ISO 10993. These tests must also be supported by additional documentation that describes how devices should be handled, sterilised etc. Based on our experience, these same standards are not ubiquitous across NHS hospitals producing surgical devices. The situation is further hindered by the lack of reported literature in this area – most articles do not report details that describe how devices have been designed for decontamination, how they were sterilised or the tests undertaken to prove they will not cause harm. There is a need to develop standards in this area to avoid risks associated with unsafe device production.

What of the Future of 3D Planning and Printing in Surgery and its medium to long term Impact on Surgery?

We have described above some of the developments of 3D imaging, planning and printing in various surgical disciplines and especially in the head and neck specialties. We have also discussed some of the challenges in terms of quality control and meeting device regulations which are only just being considered. Digital image data, whether it be CT, MR or US, has improved hugely in quality and (with the exception of MR) in massively reduced image acquisition times (30 minutes for a whole head CT scan 20 years ago, 1 sec now for images which are much better). The imaging is also being increasingly standardised (e.g. the DICOM format, Digital Imaging and Communications in Medicine) such that it can easily be imported into dedicated simulation software and used for planning surgery.

It is indisputable that these technologies, which have been in development for more than 20 years, have now reached a very high level with excellent software available that is customised for surgical simulation in several fields and that many of these software packages are user friendly. There are scientists inside the NHS and outside it who have and are increasingly acquiring appropriate education and training in its use. Design engineers, 3D planners, reconstructive scientists and even some surgeons are increasingly grasping and applying the technology to routine and especially complex surgical cases. 3D virtual models on screen allow 3D surgical simulation which can be saved and changed later as many times as the surgeons and planners wish. The development of rapid prototyping and manufacture using many different materials (plastics, polymers, metal etc) is already contributing to major advancement in the production of accurate physical models, sterilisable guides and devices and biocompatible implants which can be inserted into patients and retained.

The number of major units which are using these technologies is increasing all the time and we are aware of significant numbers who are seeking to appoint to NHS posts dedicated 3D planners at this time. We envisage that within the next 5 years, in most if not all the disciplines mentioned above, the use of 3D planning and printing will become the norm for any major unit. We would envisage that on a longer time scale, the technology will move forwards further in the fields of improved imaging, software and printing. Whereas most progress has been made with CT,

perhaps that might be replicated in MR and this could be particularly useful in soft-tissue cancer surgery and in surgery for children, if acquisition times can be reduced.

A hospital of the future may embrace some of the principles and methods involved in industrial fabrication, such as "just in time" (https://en.wikipedia.org/wiki/Just-in-time_manufacturing). We imagine a time when stocks of plating systems and devices are reduced through the use of bespoke, on-demand and ultra-fast manufacture. 3D CT/MR scan durations will be dramatically reduced and linked to automated planning and design software that will take account of other personal/clinical data needed to undertake procedures within a few hours. Planning and design will be linked to super-fast in-hospital fabrication of bespoke surgical devices, ready within the hours following trauma if necessary. Regulatory compliance will be built into the entire system through automated record keeping, technical parameter measurement and linking to long-term clinical follow-up.

Of course, this scenario does not account for the nuances of clinical care and the many unforeseen scenarios encountered as part of running a busy, diverse hospital. It would also require huge advances in the speed and capacity of 3D technology, changes to the types of staff employed and development of an entirely new way of working especially for surgeons who need to have the opportunity during their training to acquire the basic understanding and potential of these technologies.

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