THINK

The Impact of Implementing 3D Printing at the Point-of-Care

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By Todd Pietila,
Global Business Development, Materialise

Past and Present of 3D Printing in Medicine

The creation of patient-specific anatomical models derived from medical imaging data is reported as early as 1981. These first anatomical models, generated by contouring computed tomography (CT) images and milling manufacturing techniques, were low resolution, labor intensive and prohibitively expensive to produce at scale. This work, however, laid the foundation which would later be established as a valuable application for 3D Printing. By 1986 the first sterolithography printer was commercialized by Chuck Hull, opening the door for anatomical models to be created more rapidly and with a higher accuracy.

With 3D Printing in healthcare becoming a viable solution for creating patient-specific models, the barrier of the process was quickly recognized as a data handling and software limitation. Materialise founder Wilfried Vancraen 3D printed his first anatomical model in 1990 and in response to the workflow challenges he faced, developed and later commercially released the first version of the MIMICS (Materialise Interactive Medical Image Control System) software in 1992. Mimics was an innovation that enabled the stack of cross-sectional CT images to be converted to the series of contours needed to drive the 3D printer, building the patient's anatomy one layer at a time.

Fig. 1:
Medical Software:
Mimics logo, 1992

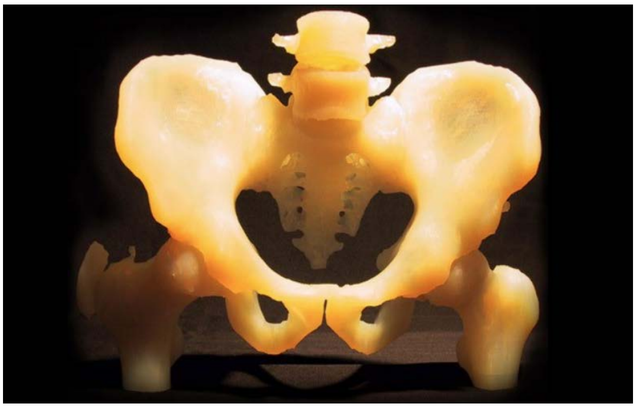


Fig.2:
3D-printed
anatomical model:
pelvis model, 2004

Looking to understand and demonstrate the clinical effectiveness of 3D-printed anatomical models, Materialise acted as the project manager for the Phidias project in the mid-1990s.
This study supported maxillofacial surgeons with 3D-printed replicas of their patients anatomy in order to understand the influence of the additional tool on the planning of the procedure. In total, 253 surgical procedures were supported with the aid of 3D-printed anatomical models which provided valuable data on the effectiveness of this new technology. The results of this study showed a positive impact on the surgeon's ability to plan and communicate the procedure with unanimous agreement of the added value over using imaging alone.

Fig. 3:
3D-printed anatomical model: skull with bone tumor in color stereolithography, 2000

Fig. 4:
3D-printed anatomical model: skull with bone tumor in color stereolithography, 2000

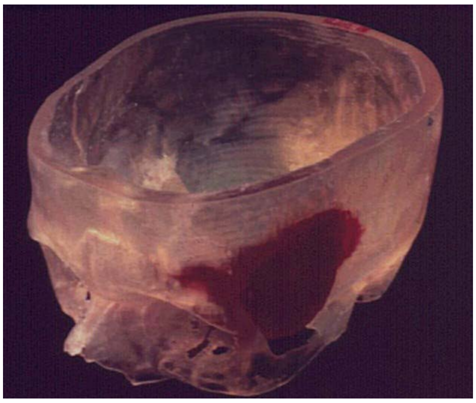


Fig. 3

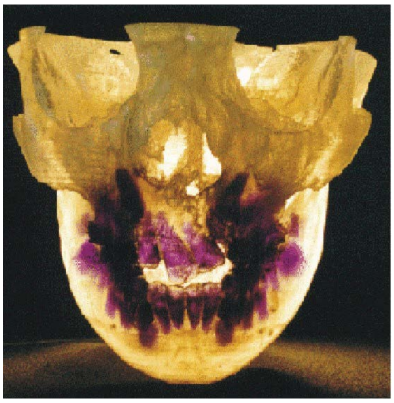


Fig. 4

Fig. 5:
Phidias project: The impact of 3D preoperative planning

How did preoperative planning change the decision?	
Planning on skin incision	34
To operate or not	66
General surgical concept	131
Detail of the surgical concept	167
Composition of the surgical team	77
Positioning of patient on operating table	22
Selection of the osteosynthetic material	94
Selection of instruments and devices	115
Implantation site of osteosynthetic material	108
Sequence of steps of intervention	121

n=253

Compared to other imaging modalities the planning model had influence on			
	Little	Average	Heavy
Precision and quality of bone transplant	1	4	35
TThe precision and quality of osteotomies	3	2	94
Communication with other medical doctors	8	11	134
Communication with patient	17	6	164
The "safety feeling" during the intervention	17	19	156

n=253

In the years following the Phidias project, the industry began to leverage 3D printing technology to deliver patient-specific products with many of these innovations driven by Materialise technology. Hearing aids, dental surgical guides and computer-based preoperative planning were all pioneered in the late 1990s. Custom craniomaxilofacial and orthopedic devices were brought to the market during the 2000s. By 2010, the software and hardware had matured to a level where it became more feasible to adopt the technology, increasing accessibility and broadening the potential use cases. This is the period where we saw increased adoption of medical applications of 3D Printing being implemented at the point-of-care, or within the footprint of a hospital, primarily for the purposes of anatomical modeling, to improve patient care through better planning and communication, to save costs by reducing operating room times and medical errors, and to more efficiently educate trainees and patients.

Trending towards point-of-care 3D Printing

Increased accessibility of 3D Printing in the medical field has led to significant growth in the applications of the technology in medicine. This is demonstrated by the growing body of literature featuring clinical work and medical research with 3D Printing. Physicians and hospitals are also driving this growth as they look to leverage medical 3D Printing with greater autonomy by implementing in-house operations, thus reducing the reliance on external medical 3D printing companies. This model enables more rapid turnaround times and broadens the potential use cases where the technology may be applied. 3D Printing within the footprint of the hospital has also shown to increase the collaboration of the provider teams resulting in the ability to work iteratively and capture intellectual property that may be generated through the routine use of the technology.

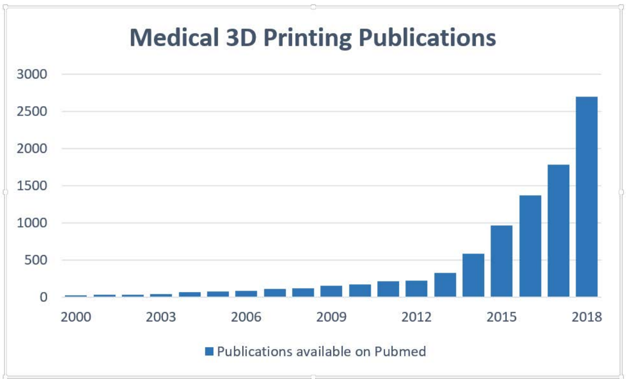


Figure 6:
3D printing references available on Pubmed *2018 projected

Further driving the adoption of 3D printing in the healthcare industry in recent years is the convergence of multiple factors, including increased awareness and demand from surgeons, improvements to medical software for preparing imaging data for 3D Printing, new 3D printers and materials, improved industry support and increasing engagement from medical societies and regulators. Prominent societies such as the Radiological Society of North America (RSNA) have shown support for the development of medical 3D Printing by establishing a Special Interest Group in order to develop and educate physicians on best practices, clinical appropriateness criteria, and laying the foundation for eventual reimbursement from medical payers[1]. The engineering organization Society of Manufacturing Engineers, who hosts annual 3D manufacturing exhibitions such as RAPID, has also created a dedicated medical working group to address challenges and develop resources for the industry.
This group supported the proposal which led to the recent establishment of DICOM standard for 3D printing file formats which will result in a standardized method to store data within existing hospital infrastructure[2].

Ensuring patient safety when applying 3D Printing to patient care is increasingly in focus as the technology grows and shifts to a more mainstream market. From a regulatory perspective, the U.S. Food and Drug Administration (FDA) has supported multiple workshops open to industry, academia and hospitals to collect feedback and facilitate a discussion around safety and effectiveness.
This has enabled the additive manufacturing in medical industry to gain clarity on the regulatory environment and also led to a published guidance document in regards to using 3D Printing in the manufacturing of medical devices[3].

Given the momentum in the industry, the outlook for point-of-care 3D Printing is positive and the growth trend is expected to continue. So much so that Gartner predicts that by 2021, 25% of surgeons will be practicing on 3D-printed models of a patient prior to surgery[4]. Industry, academia, clinical institutions and governments are all investing resources to ensure safety and effectiveness as the market grows to a broader audience of users. In order to support growth in the coming years, further clinical and economic evidence will be needed to justify investments and receive reimbursement through payers.

Figure 7:
Hospital value chain:
3D Printing has potential to
yield benefit throughout

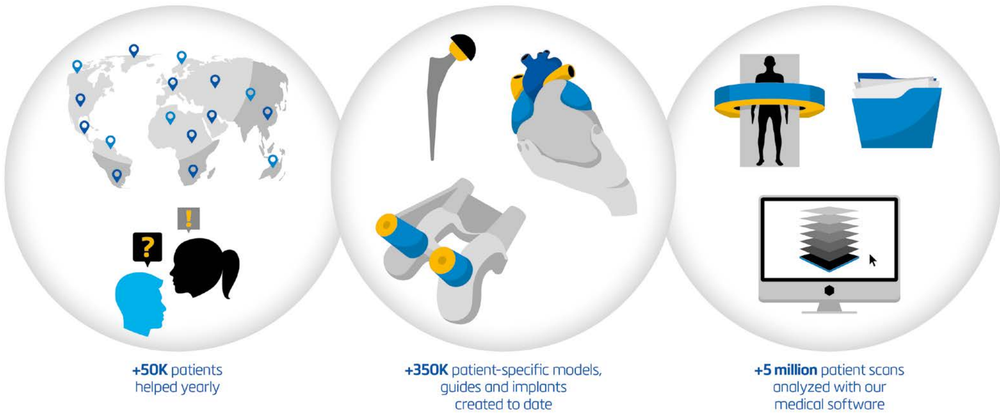


Figure 8:
Materialise 2018:
The volume of the use of
Materialise
Medical Software

Evidence of value for 3D Printing in medicine

Patient care evidence

Evidence for the clinical value of 3D Printing continues to grow as the technology becomes more accessible and awareness spreads to new specialties driving novel use cases. The clinical benefits are derived from superior pre-procedural planning and communication with an interdisciplinary care team, intraoperative reference and guidance and the selection of appropriate devices for a specific patients' anatomies. The potential positive impact on patient outcomes and demand from surgeons is the primary driver of 3D Printing adoption in the clinic. Summarized below are three studies in different specialties which point to the improvement in clinical care that can be achieved using 3D-printed models of patient's anatomy for planning.

In the field of pediatric cardiac surgery, the use of 3D Printing to prepare for complex congenital heart procedures has become common place with many hospitals adopting the technology as a standard for their complex congenital heart disease (CHD) procedures. In a recent multi-center study, surgeons reported that by adding an anatomical heart 3D model to the planning workflow, 19 out of 40 cases or 47.5% resulted in a change to the original planned approach. These included changes to the surgical plan, often changing the decision between a biventricular repair or a univentricular staged palliation; two very different treatment pathways for the patient. Furthermore, out of the 13 surveyed surgeons, 88% strongly agreed that medical 3D models could become a routine tool for surgical planning in CHD procedures[5].

Figure 9: 3D-printed anatomical model: Percutaneous pulmonary valve implantation; 21y, female, complex congenital heart disease history

Early studies have also demonstrated 3D anatomical models can have a significant impact on the planning of renal mass surgical procedures. In a series of 10 patients with complex renal masses, two experienced urological surgeons reported a change in surgical approach to all 10 cases as a result of the additional information offered by a 3D-printed patient-specific model. In 15% of the cases, the model even influenced a difference of performing a partial versus a radical nephrectomy. Other decisions that were influenced in certain cases were the planned approach (open or laproscopic and transperitoneal or retroperitoneal) as well as the clamping strategy for the case[6]. These decisions on approach have tremendous potential implications on the outcome of the surgery.

Figure 10: 3D-printed anatomical model: Renal Tumor

Even with a lack of scientific evidence, surgeons are heavily supporting the use of 3D-printed organ models as an additional tool for complex surgery and believe that it has a positive influence on patient care. At the Mayo Clinic, arguably the most prolific point-of-care 3D printing facility, complex oncologic procedures were studied to understand the impact of 3D-printed models on planning. Out of 52 oncologic cases which included pelvic, spinal, thoracic, head and neck and renal tumors, 19 surgeons rated the models a 5 on a 1-5 scale as 'very helpful' for treatment planning (94%), multidisciplinary discussion (88%), visualization during surgery (82%) and patient education (82%). The surgeons also agreed that the use of the models will 'very likely' improve the quality of care (88%), improve surgical outcomes (82%), improve surgical approach (71%) and patient safety (65%)[7].

Economic benefits through cost savings and avoidance

With the increasing cost pressures on hospitals and the transition to value-based reimbursement models, 3D Printing has been demonstrated as a viable tool to increase the efficiency of planning and executing procedures for a growing number indications. This results in direct economic and patient care benefits through reduced OR time, length of stay and readmissions. Several studies have demonstrated these advantages of which three are summarized.

Boston Children's Hospital published a case series on pediatric midfacial distraction cases studying outcomes of preparing and planning the case with a 3D anatomical model. 29 total cases were included in the study with nine of the cases receiving 3D-printed models pre-operatively. Seven complications, which included premature consolidation, cerebrospinal leak, and hardware malfunction, occurred in the patients from the non-model group while the nine patients treated with the aid of models experienced no complications. The data also showed an average time savings of 31.1 minutes per case which was estimated to convert to $1,036 in savings per case[8]. The time reduction was driven by the better planning and ability to precontour hardware. The authors agreed that reduced operation time and complications offer potential safety related benefits for the patient.

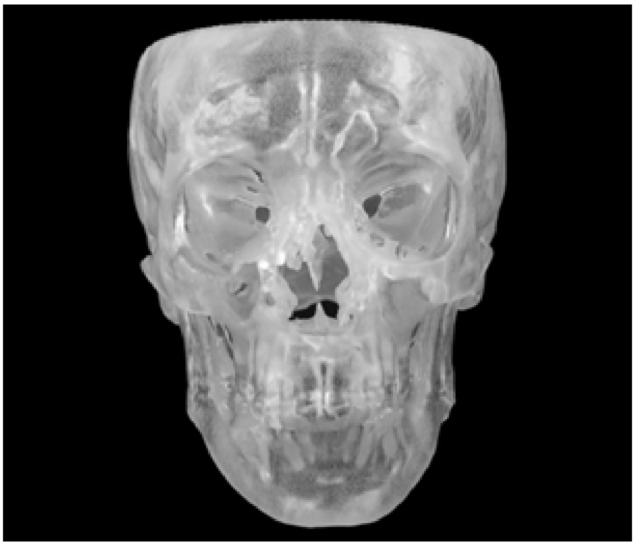


Figure 11: 3D-printed anatomical model: Skull

Corrective osteotomies are needed to treat the hip deformity slipped capital femoral epiphysis. Surgeons from Rady Children's Hospital studied the impact of using 3D-printed anatomical models to prepare for the complex osteotomies required to treat these patients. Ten patients were treated by a single surgeon, split equally into groups who were planned with and without 3D-printed models. Also compared in the study were an additional group of five patients treated by senior surgeons without a patient-based model. On average, the surgical time decreased by 45 and 38 minutes with the model group compared to the non-model groups. Also reported was a reduction in fluoroscopy time of 50% and 25% demonstrating that the use of models for this indication yield positive economic and clinical benefit[9].

Figure 12: 3D-printed anatomical model: Forearm malunion correction and patient-specific surgical guides

Similar results have been reported for the use of 3D-printed models to prepare for challenging cardiac surgeries. A study from Zhao et al, investigated clinical benefits of preoperative planning for the repair of double outlet right ventricle. The enrollment of the study included twenty-five patients of which eight were in the 3D printing group and seventeen in the control. Patients in the 3D printing group experienced shorter cross clamp time (102.88 vs 127.76 min), and cardiopulmonary bypass time (151.63 vs 184.24 min) compared to the control group. They also had much lower mechanical ventilation time (56.43 vs 96.76 h) and significantly shorter intensive care unit time (99.04 vs 166.94 h). All with significant clinical and economic impact and offsetting any costs of the added 3D modeling process[10].

Education and training

Clinical training and education of students and staff is traditionally managed with cadavers, animals or mannequin models used in a simulation environment. These methods can be limiting given the often high cost, low accessibility and lack of representative pathology especially for rare conditions. Many medical schools and hospitals are beginning to use realistic 3D-printed anatomical models for certain training scenarios, which have been shown to increase learning effectiveness and save costs. Two studies are summarized detailing improvements in education using models over medical imaging and traditional methods.

Patient specific 3D anatomical models were used in a study at Children's National Medical Center that included 70 physicians delivering care to patients in the pediatric cardiac intensive care unit post-congenital heart surgery. The models were used to study the impact of training physicians, nurses and ancillary care providers on proper postoperative care of specific patients. Likert scale questions revealed that the enhancement of understanding and clinical ability averaged 9.0 on the 10 point scale showing benefit over the traditional patient 'hand-off' method[11].

In a similar training study, 3D-printed models were used to train medical students on spinal fractures. 120 medical students at a Chinese university were randomized into three groups and were required to complete a 10 question test on 2 different spinal fracture cases. One group was given the CT images, the second a 3D computer model and the third group a 3D-printed model. The 3D groups performed much better than the CT group and the 3D-printed model group was able to complete the questions much faster than the other groups. In addition to the superior performance of the trainees, the training with the printed models also showed a higher level of engagement and pleasure from the trainees[12].

In addition to the growing use of 3D Printing in the education and training of clinicians, it has also been shown as an exceptional tool to aid in the informed consent process with patients. 3D-printed models give patients a better understanding of their situation and the proposed treatment plan, presented in a personalized way. This has the potential to increase the patient's comfort level with their care providers and makes a positive impact on the patient's experience.

Additional opportunities enabled by 3D Printing
With reimbursements declining and pressures to lower healthcare costs, hospitals have to been looking to uncover opportunities for non-traditional sources of revenue. Outside of applying 3D Printing to patient care and education activities, there are also several non-clinical opportunities for value capture if the technology is leveraged in the proper way. The availability of research grants and the solicitation of philanthropic funds is often a successful model to fund the necessary personnel and tools to support a medical 3D Printing program.

Medical 3D Printing has roots in innovation and serves as a means to prototype new ideas. This concept can be leveraged by an in-house 3D Printing resource as a means to generate and monetize intellectual property of physicians. The 3D printing resource may also serve as an opportunity to collaborate with industry through the support of training and education of physicians on new devices by using 3D-printed anatomical models and providing an opportunity to capitalize on the resource.

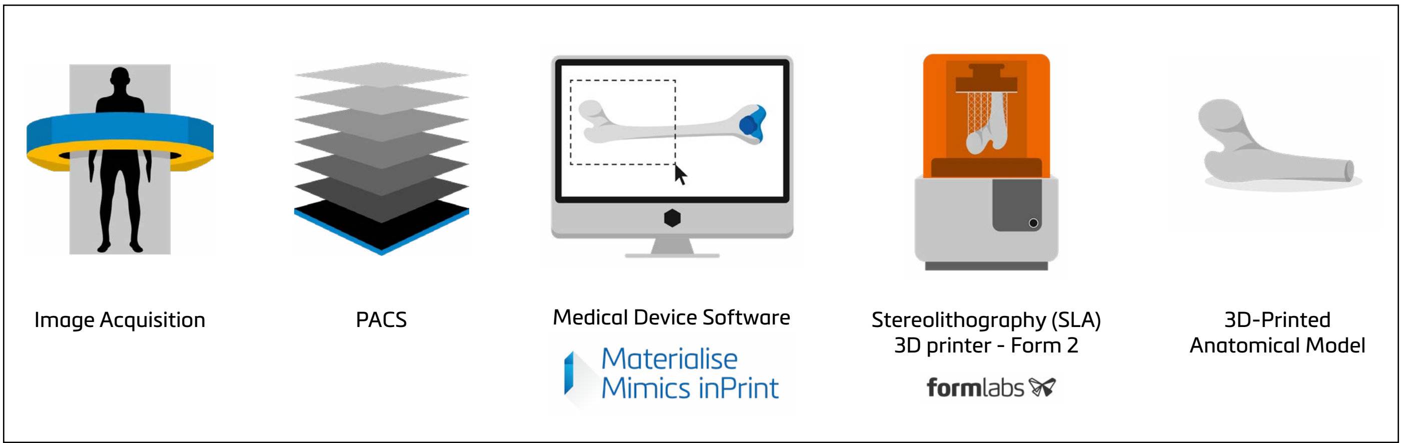
Lastly, there is certainly value in offering cutting-edge technology to patients as a tool for marketing and public relations for the hospital. The value of Medical 3D Printing is highest in the most complex of cases which often garner the greatest interest from the lay public. Many hospitals have leveraged the use of 3D Printing as a central theme in featuring patient cases. The use of 3D Printing and impact on patient care may also increase the ranking of a hospital in certain specialties leading to higher patient recruitment and potentially greater access to grants and funding opportunities.

Outlook for 3D Printing in hospitals

Personalized healthcare is being delivered through the use of 3D Printing at an increasing rate. Much of this is through the ability to build accurate anatomical replicas of patients' anatomies for surgical planning, training and education. As this adoption continues to expand, there will be many market needs to support the growing use.

Medical software and equipment for the 3D Printing workflow has and will continue to become more user friendly for adoption within the clinic. Integration between medical imaging systems, dedicated software for 3D Printing and the 3D printers themselves is being pursued by several firms via strategic collaboration.
Materialise has offered integration of the Mimics inPrint software within the Siemens platform enabling an efficient workflow with the 3D modeling software embedded in the clinical image viewer[13]. Also on the backend, Materialise has enabled integration with specific 3D printers such as Formlabs to reduce the effort needed to translate the anatomical model to the virtual build area[14]. These collaborations have also led to the first FDA clearance to enable 3D-printed models for diagnostic use when the medical software is used in conjunction with a Materialise validated 3D Printer and material[15].

Figure 13:
Strategic integration:
Medical images acquisition manufactures and 3D Printer manufactures



Although the number of case reports and series continues to grow, more robust and multi-center studies will be needed to better support the clinical and economic evidence of 3D Printing for specific indications. In addition to supporting efforts for reimbursement with payers, it will help to drive and understand appropriateness criteria for 3D Printing when it is clinically useful and when it is not.

As regulators and standards bodies take further notice, it will also support the need for better standards and best practices for implementing 3D Printing at the point-of-care, ensuring patient safety and the most effective use of the technology.

Are you interested in learning more about how your hospital can implement 3D technology and take the first steps to successfully deploy Point-of-care 3D Printing?
Contact us today.

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About Materialise

Materialise is a global 3D printing software and services company whose medical division is dedicated to enabling researchers, engineers and clinicians revolutionize patient-specific treatment contributing to innovation health care and saving lives. With over 27 years of excellence, our open and flexible platform enables players in healthcare to build innovative and groundbreaking 3D printing applications that make the world a better and healthier place. Reach out to learn more about Materialise solutions and to set up a 3D lab in your hospital.

Todd Pietila, M.B.A.

Todd is responsible for Business Development at Materialise where he specializes in delivering 3D software and 3D printing expertise to the healthcare field. With degrees in Biomedical Engineering and Master of Business Administration, he has spent more than 9 years at Materialise focused on developing applications of 3D Printing in medicine. He is an active member and contributor to the RSNA Special Interest Group on 3D Printing, the SME Medical Additive Manufacturing Working Group and the Additive Manufacturing Standardization Collaborative Medical Working Group.

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