1 Introduction

Gerald T. Grant and Frank J. Rybicki

We are in the midst of a technological revolution in customized patient care. Advances in imaging techniques with digital 3D and 4D rendering and advances of 3D printing have allowed healthcare professionals the ability to view and document hard and soft tissues in such a manner that meaningful, accurate measurements can be used for fabrication of medical models for presurgical planning/patient education, fabrication of surgical templates, and medical/dental devices for implantation or quality of life. In addition, 3D print technologies in printing biological tissues will provide a future for many patients with the eventual printing of human organs.

The media continues to highlight the impact of 3D printing on patient care on local and national newscasts, and many have taken a social media approach to publicize the impact on this new, innovative way to deliver medical data. However, until recently, a single healthcare organization leader has not emerged as a home to release technologies, to disseminate the peer review literature, to manage the roles and future responsibilities of 3D printing in education, and to lead discussions with regulatory bodies geared for reimbursement. This, in turn, has left much of the responsibilities of current development and direction to the manufacturers, in response to individual medical and dental requests.

At the forefront of this entire process is medical imaging and dental imaging, as radiology and applied imaging science professionals largely manage the studies that identify patient-specific anatomical areas of interest for design and fabrication of customized models, surgical guides, and medical devices that are 3D printed. Moreover, much of 3D printing is from medical images, and several of the more complex steps, where errors can be introduced, are in image post-processing. This has historically been performed in radiology departments, using customized software packages and expertise inclusive in the training to become a radiologist. For this reason, radiologists feel that much is "at stake" with medical 3D printing, with enormous opportunities in the field that are tempered with the fear that "if we don't do it, someone else will…." Radiology has, in turn, stepped up to the plate. The Radiological Society of North America (RSNA) recently created its first ever "Special Interest Group," focused on 3D printing. In addition, the Journal of *3D Printing in Medicine* was recently launched and is enjoying increasing success as a resource for the peer-reviewed literature.

This book, edited by a senior dentist/prosthodontist with over 20 years of experience in 3D

G.T. Grant, D.M.D., M.S.
Department of Oral Health and Rehabilitation, University of Louisville, School of Dentistry, Louisville, KY, USA
e-mail: gerald.grant@louisville.edu

F.J. Rybicki, M.D., Ph.D. (✉)
Department of Radiology, The University of Ottawa Faculty of Medicine and The Ottawa Hospital Research Institute, Ottawa, ON, Canada
e-mail: frybicki@toh.ca

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printing and an academic radiologist with 7 years' experience, is intended to introduce the field with straightforward language that will be consumable for a large audience. This book is not a comprehensive survey of all 3D printing in medicine. Moreover, bioprinting is not covered in these pages. However, the book explains 3D printing fundamentals and will serve as a highly useful reference guide to keep handy in the interpretation of the increasing body of knowledge in the literature. Dedicated chapters that focus on hardware and software applications should prove indispensable for those who are eager to enter the field. The book also has important chapters in starting a laboratory within a medical facility and the key factors in quality and safety that are an essential part of a 3D printing organization. We include authorship from close allies at the FDA who, like us, share a great interest in stewarding 3D printing from its current niche applications to more widespread use in the medical community. The book extends to include chapters on some of those niche applications. At this point in the exponential growth of 3D printing, assembling a chapter on each organ system is challenging, since the field changes dramatically between the time of writing and the date of publication. However, we have included several representative chapters so that the readership can be enriched with many examples of how 3D printing is positively influencing medicine.

1.1 History of 3D Printing in Medicine

In the mid-1990s, groups from Canada, Wales, German, and the United States (USA) as well as the US military began to experiment with the use of 3D printing for head and neck reconstruction. as a collaborative organization known as the Advanced Digital Technologies Foundation (www.adtfoundation.com). With the help of the software company Materialise (Leuven, Belgium), they were able to convert DICOM images into a Standard Tessellation Language (STL) file to 3D print. Early images were of bones, for example, the skull, and these models changed the fabrication techniques for cranial implants.

In the mid-1990s, Medical Modeling of Golden Colorado under the leadership of Andy Christensen offered a commercial service for medical models, surgical guides, and customized devices used by both healthcare professionals and the commercial medical industry. They became one of the leading groups in making this technology accessible to healthcare providers worldwide. Mr. Christensen sold the business to 3D Systems in 2014 at which point it became a pillar of 3D Systems new healthcare vertical.

In 2005, the Institute for Reconstructive Sciences in Medicine (iRSM), as part of the Alberta Health Services, Universtity of Alberta, Edmonton, Canada, developed a virtual simulation and 3D print lab. Under the direction of Dr. Johan Wolfaardt (a prosthodontist), the lab offers virtual surgical simulation, guide design and fabrication using digital techologies and 3D printing in support of head and neck reconstruction. The facility has designers, engineers, and a varity of priniting capabilites. They have been one of the international leaders in this technology along with similar facilities in Wales and Germany.

The Mayo Clinic, Rochester, MN, USA, led by Jane Matsumoto and Jonathan (Jay) Morris, was to our knowledge the first group to organize a 3D printing laboratory within a radiology department outside of the US military in the United States, and their lab has been one of the leaders in the field since. They have pioneered the production of in-house, physician-managed 3D printing within radiology, and they have the most experience globally with providing medical models, from physicians to physicians, for presurgical evaluations, patient education, and medical education, outside the US military. Drs. Matsumoto and Morris are also leading educators in the field, with extensive continuing professional development courses hosted by the Mayo Clinic.

1.2 History of 3D Printing in the US Military Medical Community

A great example of 3D printing's power is how the military leveraged the technology in its infancy and contributed greatly to its current uses. Routine use of digital planning and fabrication of medical models for the military began in the mid-1990s when Capt. Charlie Richardson, DC, USN, designed and fabricated medical models working with the Radiology Department at the National Naval Medical Center (NNMC), Bethesda, MD, USA. Medical models were fabricated of craniofacial and orthopedic bony structures that required extending manufacturing by 3 or 4 days, depending upon the model, using fused deposition modeling technologies. However, through his efforts, it was realized that computed tomography (CT) scans could provide the information needed to provide three-dimensional presurgical data. By the late 1990s, the Maxillofacial Prosthetics Department at the Naval Postgraduate Dental School (NPDS) began to apply this technology to fabricate cranial implants. A model of the skull was used to sculpt a cranial plate from wax, a mold was developed, and a polymethylmethacrylate (PMMA) implant was processed. The result was a well-fitting implant requiring little to no adjustments, with a concurrent 50% reduction in operating room time. However, the fabrication process was still time-consuming. By early 2000, stereolithography (SLA) additive manufacturing technology became available at the Walter Reed Army Medical Center (WRAMC) under contract to Stephen Rouse, DDS (retired USA), shortening the model fabrication time. This launched fabrication, not only for models in support of cranial implants with NPDS but in support of orthopedics and neurosurgery. The direction of the development and use of this technology became paramount for reconstruction and rehabilitation of wounded warriors with the beginning of the war on terrorism in late 2001. The collaboration of the WRAMC and NPDS team became essential, in that they were able to pioneer many different techniques to fabricate cranial implants and cutting guides that provided unprecedented care in wounded warrior craniotomy/cranioplasty, and by 2005 the residual calvarial bone from the osteotomy that was usually saved for reimplantation was no longer used.

While design software techniques worked well when one could "mirror" a non-affected (presumed to be normal) side, solutions for midface defects were more difficult to develop. In 2007, Capt Gerald Grant DC, USN, was awarded funding to develop a method to capture pre-combat craniofacial records. This resulted in the introduction of dental cone beam computed tomography (CBCT) technologies to the Department of Defense as well as 3D photographic technologies of the individual that could be registered to the CBCT. They were able to put together a team, NPDS Craniofacial Imaging Research, that began to work closely with WRAMC and develop techniques for registration, surgical guide fabrication, and implant designs. A SLA device and design software's were purchased and installed at NPDS, and the development of presurgical teams was introduced to NNMC and WRAMC in craniofacial reconstructions to neurosurgery, oral maxillofacial surgery, otolaryngology, orthopedic surgery, and plastic surgery. From this laboratory, several relationships were formed, including one with academic medical centers such as John's Hopkins Hospital, Baltimore, MD, and the Brigham and Women's Hospital, in Boston, MA, USA. It was in this capacity that Dr. Frank Rybicki began collaborating as part of the face transplantation program led by the innovative and brilliant surgeon Bohdan Pomahac, MD.

The BRAC (Defense Base and Realignment and Closure) initiative provided an opportunity to combine the assets at WRAMC with those at NPDS, and a site was selected that co-located the facilities to provide better collaboration with the BRAC assets co-located with the Maxillofacial Prosthetics Laboratory. The new 3D Medical Applications Center (3DMAC) fell under the Department of Radiology at Walter Reed National Military Medical Center Bethesda (WRNMMCB), and the services were expanded to include many different additive manufacturing systems, such as titanium which allowed direct fabrication of cranial implants, and access was expanded worldwide via a public secured website. This expanded the use of these technologies to orthopedics, pediatrics, ophthalmology, limb prosthetics, occupational health, maxillofacial prostheses, dental, and a host of research activities worldwide. The staff was expanded to include a PhD biomedical engineer, a metals engineer, and two CT technicians to design anatomical models that worked in conjunction with NPDS's craniofacial imaging team, which included an aerospace engineer, two staff maxillofacial prosthodontists, rotating residents, and rotating midshipmen from the United States Naval Academy as part of the Capstone Program to increase development of advanced medical/digital technologies in treatment of wounded warriors.

3D printing continues to be used for customized patient-specific treatments at WRNMMCB. Custom fabricated cranial and reconstruction titanium implants are fabricated for patient-specific implantation. Presurgical medical models, medical devices, and custom attachments for prosthetic limbs have been developed to accommodate wounded warriors to improve surgical outcomes, quality of life, assist in medical research, and provide customizable devices for occupational health.

1.3 Current 3D Printing

Medical 3D printing centers span both industry and civilian medical centers. There are several service models to obtain printed models, including outsource images (e.g., a CT scan or MR images) to vendors such as Materialise who in turn provide consultation and 3D printing. Similarly, recent years have seen collaboration between software and hardware companies, for example, Vital Images and Stratasys, two leaders in their respective fields of 3D visualization and 3D printing hardware, have marketed a service model designed to leverage expertise from both sides to accept auto segmented STL files and provide models.

Many medical centers have begun to emulate the organization and infrastructure from the Mayo Clinic, capitalizing on the medical expertise in house and assembling the physical and human resources needed for a functioning lab. These are detailed in a chapter in this book, based on the laboratory at the University of Ottawa Faculty of Medicine. Education has provided a bridge to other centers. Beginning in 2013, the RSNA has hosted didactic sessions in 3D printing, and for the past several years, hands-on courses have been available, with the number of students in these teaching sessions exceeding 1000.

To meet the needs of medical 3D printing, the manufacturers such as 3D Systems and Stratasys have begun to develop printers that provide the ability to print open vessels, different colors, and a variety of materials. For more than a dozen years, the medical sector has been featured at the Society of Mechanical Engineers (SME) RAPID meeting. Finally, workgroups within the SME have begun to engage with the community, in particular to work, as other groups have, to look at medical reimbursement. Comments on these important discussions are also covered in later chapters.

3D printing is truly one of the leading technologies of our time; we hope that this book will provide essential information and that it will help you understand the impact that 3D printing can have on medicine in the hopes of improving the outcomes and quality of life for many patients around the world. Finally, we genuinely believe that the leaders in the next generation of 3D printing will be reading this book and that we can inspire others to enter the field and make gainful contributions.