Title: Main clinical use of Additive Manufacturing (3D printing) in Finland restricted to the Head and Neck area in 2016-2017.

Short title: Clinical use of Additive Manufacturing in Finland 2016-2017

Pettersson A[1,3], Salmi M[2], Vallittu P[5], Serlo W[6,7], Tuomi J[2], Mäkitie A[1,2,4]

[1]Department of Otorhinolaryngology – Head and Neck Surgery, University of Helsinki and Helsinki University Hospital, P.O. Box 263, 00029 HUS, Finland

[2]Department of Mechanical Engineering , Aalto University, P.O. Box 14300, FI-00076 Aalto, Finland

[3]Department of Surgery, South-Karelia Central Hospital, Valto Käkelän katu 1, 53130 Lappeenranta, Finland

[4]Division of Ear, Nose and Throat Diseases, Department of Clinical Sciences, Intervention and Technology, Karolinska Institutet and Karolinska University Hospital, SE-171 76 Stockholm, Sweden

[5]Department of Biomaterials Science and Turku Clinical Biomaterials Centre, Institute of Dentistry, University of Turku and City of Turku, Welfare Division, Lemminkäisenkatu 2, FI-20520 Turku, Finland

[6]Department of Pediatric Surgery, Oulu University Hospital, P.O Box 23, 90029 OYS, Finland.

[7]PEDEGO research group, Oulu University and MRC Oulu, P.O. Box 8000, FI-90014 University of Oulu, Finland

Corresponding author:
Ante Pettersson (ante.pettersson@helsinki.fi)

Department of Otorhinolaryngology – Head and Neck Surgery, University of Helsinki and Helsinki University Hospital, P.O. Box 263, 00029 HUS, Finland
Tel +358443546867

Acknowledgments:
The authors wish to thank all the respondents and interview subjects for offering their time and insights. In addition, we wish to thank the funders for the financial support provided for this work.

Declaration of Conflicting Interests:
The Authors declare that there is no conflict of interest, except for:
Vallittu P: shareholder and Member of the Board of Skulle Implants Corporation.

Funding:
This study was supported by the Helsinki University Hospital Research Fund, the Viipuri Tuberculosis Foundation, the South-Karelia Medical Association, and the Eksote Research Foundation.

Abstract:

Background and Aims: Additive Manufacturing (AM) is a novel production methodology for producing patient specific models, medical aids, tools and implants. However, the clinical impact of the technology is unknown. In this study we sought to characterize the clinical adoption of medical AM in Finland in 2016-2017. **Materials and Methods:** A questionnaire containing 5 questions was sent by email to all operative, radiologic and oncologic departments of all university hospitals in Finland. Respondents who reported extensive use of medical AM were contacted with additional, personalized questions. **Results:** Of 115 questionnaires sent, 58 received answers. Of the responders, 41% identified as non-users, including all general/GI and vascular surgeons, urologists and gynecologists, 21% identified as experimenters or previous users and 38% as heavy users. Usage was concentrated around the head area, by various specialties (neurosurgical, craniomaxillofacial, ENT, plastic surgery). Applications were repair of cranial vault defects and malformations, surgical oncology, trauma, and cleft palate reconstruction. Outside the head, there was some routine usage in orthopedics. In addition to these patient specific uses, we identified several off-the-shelf medical components being produced by AM, while some important patient-specific components were produced by traditional methodologies such as milling. **Conclusions:** In Finland in 2016-2017, medical AM was in routine use at university hospitals for several applications in the head area. Outside of this area, usage was much less common. Future research should include all patient specific products created by a CAD/CAM workflow from imaging data instead of concentrating on the production methodology.

Key words:

Computer-Aided Design, Medical model, Computer-Assisted Surgery, Three-Dimensional Printing, Additive Manufacturing.

Introduction

Additive Manufacturing (AM) or 3D printing (3DP) refer to a production methodology where, instead of subtractive manufacturing like milling or drilling or formative manufacturing like forging or bending, 3-dimensional products are built by addition of material, usually successive layers of material on top of each other[1]. Instead of focusing on specific AM technology names, which even for similar techniques may differ between different producers of 3D-printers, the recent ISO/ASSM standard speaks of seven groups of technologies: vat photopolymerization, material jetting, binder jetting, material extrusion, powder bed fusion, sheet lamination and direct energy deposition[1]. For a review on 3DP technologies, medical applications and the required image processing, see [2].

During the past decades, AM has edged its way into medicine. AM has for the first time allowed reproducing complex patient geometry in preoperative models for clinical use. In addition to models for surgical planning and education, AM has been used for producing patient-specific implants, tools such as saw guides, and to some degree custom-made supports and splints. Using AM, implants may be constructed to include mechanisms for site-specific drug delivery and radio-frequency identification [3]. Bioprinting, i.e. the printing of biological tissues or organs, while of potentially revolutionary clinical implications, is at the moment still restricted to the lab. [4]

The literature of AM still mainly consists of case reports and small case series. Published applications illustrating the scope of possibilities include orbital reconstruction with a patient-specific implant (PSI)[5], endovascular aortic aneurysm repair facilitated by a 3D-printed hollow model[6], a printed gynecological training simulator[7], and creating a printed death mask to cover the face of a facial allotransplant donor[8]. However, reports on one-off cases typically offer a proof of concept and their level of evidence regarding practicality and efficiency is low. In order to impact daily practice a medical AM application must be clinically and economically justifiable, providing better outcomes or less costly operations, e.g. through shortening of time spent in the operating room. To date, there have been no randomized trials comparing AM based methodologies with traditional approaches, and published articles usually report only subjective surgeon satisfaction with the technology[9]. Recently several reviews concerning AM in a specific medical specialty have been published, such as otorhinolaryngology – head and neck surgery[9], spine surgery[10], urology[11], and plastic surgery[12]. However, the true scale of utilization and the impact of AM technology on clinical practice to date has not been studied. The mainstream reporting regarding AM in general and its medical applications in particular is confusing due to a large amount of hype, and while the technology is rapidly developing, it is, at least for people outside the community, sometimes difficult to separate facts from science fiction.

In this study, we attempt to characterize the clinical adoption and use of medical AM technologies and their impact on medical practice in Finland during 2016-2017. Our aim was to identify fields, if any, where medical AM has reached routine status, and best practices have been established which could potentially be transferred to other applications. Furthermore, we sought to identify fields where AM adoption has met with problems, providing opportunities for further research and problem solving. We chose to focus on non-dental applications of AM, though dental use is dealt with in the Discussion.

INSERT IMAGE 1

Figure 1: Previously realized medical AM products from collaborations between Aalto university and Helsinki university: a) Prosthetic mask to cover face of facial allotransplant donor (training model based on volunteer) b) Heart with congenital malformation and previous repair c) Model of orbital floor fracture and custom-made implant, both manufactured by AM

Materials and Methods

A structured questionnaire consisting of five questions (Table 1) was sent by email to all operative (i.e. surgery and associated subspecialties, orthopedics, ENT, gynecology etc.), oncologic and radiologic departments at each of the five university hospitals in Finland. The questionnaire was addressed to the head of department or professor of the field, as determined by the hospital's web pages or by contacting the department secretary. One of the questions asked was whether the respondent knew of anybody else using additive manufacturing at their hospital, and these persons were then in turn sent the same questionnaire until a saturation point was reached and no further users were identified. In addition, clinicians with whom the authors had previously discussed the prospects of utilizing AM in their field were contacted with the same questions.

Question nr.	Question
1	Does your department utilize additive manufacturing (3D-printing) for clinical or research purposes? If yes, in which way?
2	Do you use other methods of manufacturing patient-specific products (e.g. machining)
3	Do you buy patient-specific products from an outside provider, such as a company? If yes, what products and from where?
4	Are you aware of another person or department in your hospital, which uses the above-mentioned methods?
5	Can you or another person at your department be contacted for further questions? (email/telephone)

Table 1 : Questionnaire

Respondents who had used AM more than once were sent some follow-up questions. The information gained from these individualized, open-ended questions are dealt with in the

Discussion. If the person contacted did not reply to the email, a reminder was sent by email, after which contact by telephone was attempted

Data were cross-checked by contacting industrial service providers of AM active in Finland and asking whether they had any substantial clients in the medical sector besides those mentioned.

Results

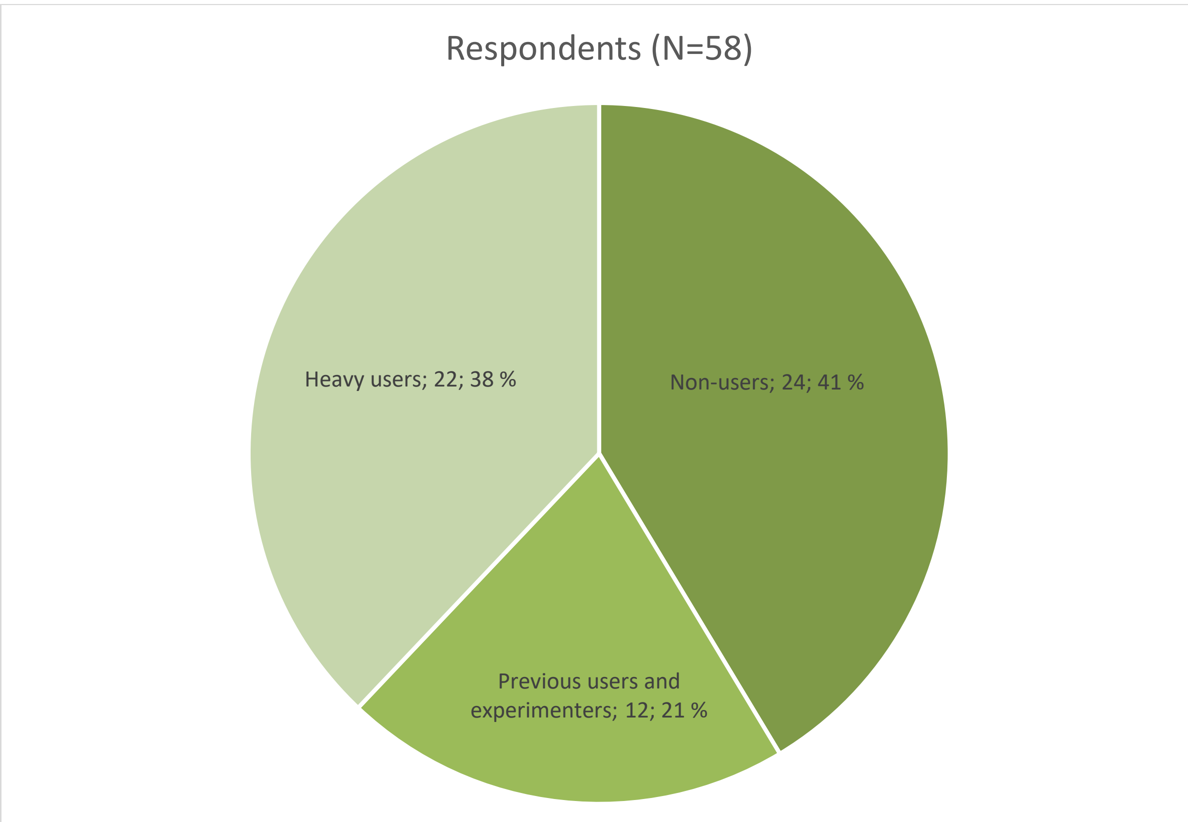

Figure 2: Breakdown of respondents by usage

Specialty	Experimenter	Previous user	Heavy user
Plastic			3
CMF			4
ENT			5
Neuro			6
Orthopedic	4	2	2
Thoracic	2		
Pediatric			1
Cardiology	1		

Table 2 : Usage by specialty

The questionnaire was sent to 115 people, of whom 68 (59%) eventually answered, either by email or telephone. Excluding those who only referred to another person we recorded 58 responses (51% of the people to whom the questionnaire was sent), some of which were from different people at the same departments.

Non-users

Of the 58 answers, 24 (41%) had never used AM. This group of non-users included all responders from departments of general/GI surgery, urology, vascular surgery and gynecology.

Of these 24, the majority (19, or 33%) had not used any other manufacturing method for producing patient-specific products (i.e. implants or planning aids), had not ordered any patient-specific products from outside providers, and did not plan on doing so in the foreseeable future. One gynecologic department used manually produced vaginal dilatators, which could potentially be manufactured by AM in the future. In addition, one urological department indicated that AM-produced preoperative models might in the future be useful as planning aids.

Three responders from departments of radiation oncology used various patient-specific products, namely positioning devices, radiation shields etc. which were either commercial (thermoplastic, water cured or vacuum-based systems) or manufactured by on-site CNC-milling of foam. Using AM for these applications in the future was viewed as a possibility, but no solutions existed in the foreseeable future.

Previous users and experimenters

Twelve out of the 58 responders (21%) had experience of AM but were not active users. Excluding answers referring to the same usage, nine distinct users were identified. The represented specialties were bone tumor, pediatric and lower limb orthopedics, cardiothoracic surgery, and interventional cardiology.

Two orthopedic surgeons from different bone tumor units had previously used patient-specific implants and patient-specific instrumentation (saw guides) for scapular and pelvic tumors but had been disappointed with the results and had since moved to modular prosthetics, in one case combined with virtual planning and intraoperative navigation. The number of implants previously used was undetermined.

One pediatric cardiothoracic surgeon had ordered a single model of a child's heart with a congenital malformation, and another cardiothoracic surgeon had modelled a sternum to test the possibilities of AM applications.

One interventional cardiologist had ordered two models of hearts with complex congenital deformities, which had been used to plan and practice a catheter-based endovascular repair. The model had been viewed as helpful, however, while the true heart is a beating, constantly changing object, the printed 3D-model represents only one phase of the cardiac cycle, thus potentially leading to unrecognized problems in the real operation. Acquiring the data for the model using a CT scan was also difficult because of lower difference of density compared to bony models and the short and uneven effect of contrast agent.

Orthopedic surgeons from three different lower limb units reported previous experience with AM. One user had printed two preoperative models of a foot and a leg, another used had printed one model of a leg, and a third one had modelled one foot. In addition, one pediatric orthopedic surgeon reported having experimented with preoperative models for bone deformities. All cases were especially complex deformities, either congenital or the result of malunited fractures.

Excluding the bone tumor users, all the cases were mainly experimental, ordered for especially complex, "one-off" cases to see if a printed preoperative model would be helpful. The models were seen as moderately useful but ultimately not worth the investment for further routine use. One user explicitly cited the difficult ordering process as the reason why the usage had not developed further.

Heavy users

	Preoperative models	Saw/drill guides	Implants
CMF	20	20	250
ENT	10		10
Plastic (Helsinki)	10-20	10-20	10?
Neuro			50
Pediatric (Oulu)	10		20
Orthopedic	10-20 (Tampere)	5-10 (Oulu)	

Table 3 : Estimated yearly volumes (AM products used) per specialty

Heavy usage (22/58 responders, or 38%) of AM was largely concentrated towards the head region, with users coming from maxillofacial surgery, ENT, plastic surgery, pediatric surgery, orthopedics, and neurosurgery.

Six neurosurgeons from four different departments reported using patient-specific skull reconstruction implants for hemicraniectomy repair, ordered from various companies, which in turn are known to use AM at least as a part of their manufacturing process. The cumulative volume of patient-specific implants ordered was estimated to be around 50. The process of ordering patient-specific implants had strongly modified practice in that neurosurgical departments had stopped freezing autologic bone flaps since the results with synthetic implants were superior.

Four maxillofacial surgeons from three different departments, five ENT surgeons from four different departments and 3 plastic surgeons from one department reported extensive use of AM for preoperative planning models, osteotomy saw guides and implants. The CMF surgeons cumulatively used about 250 patient-specific implants/year, 20 planning models and 20 saw guides. The use of printed planning models had diminished because of these users moving to virtual planning. Cited improvements were shortened operative times and improved precision, especially in mandibular surgery where surgeons credited patient-specific implants with being able to produce truly precise results for the first time. Fields of use were tumor resection, orthognathic surgery, and trauma. The fields of ENT and CMF surgery overlap to some extent and the largest user of AM, a CMF department that used about 150 patient-specific implants/year, reported operating on about 50 orbital fractures per year, all of them using patient-specific implants (even for simple blow-out type fractures), contributing to their volume. Complicating the interpretation of these volumes, however, is the fact that some of these orbital floor implants are produced by milling and some by AM, and the company from which these were sourced did not divulge the specific ratio.

The plastic surgeons estimated using 10-20 planning models and saw guides per year and a lesser number of patient-specific implants, mainly in cleft palate reconstruction and tumor surgery. The ENT surgeons reported using cumulatively about 10 planning models and a similar number of patient-specific implants per year.

One pediatric surgeon, specializing in skull deformity repair, also reported using both printed planning models and patient-specific implants and plates, with about 10 models and 20 implants used per year. This usage was also mentioned by another responder (a physicist from the radiology department which operated the university's own 3D-printer) Outside the head region, one upper limb orthopedic surgeon reported using 10-20 planning models per year, mainly for planning corrective operations of fracture malunions. This user found these models very helpful in planning complex operations and preferred them over virtual planning.

Another orthopedic surgeon specializing in shoulder surgery estimated using about 5-10 commercial drill guides per year for positioning certain shoulder joint replacements. These drill guides, which include a model of the glenoid that it is modelled to fit, theoretically make positioning the implant foolproof, though in practice the user found the results varying. While ordering drill guides for only some cases, the surgeon used the virtual planning software which the prints were ordered through on all patients.

All patient-specific implants and saw guides were ordered from commercial companies. In addition, almost all planning aids were ordered from commercial companies, with two exceptions. The pediatric surgeon listed as a heavy user produced preoperative models on a printer owned by the university, operated by the radiology department. This had previously been done in collaboration with a local university of applied sciences, but the activity had been brought in-house because of regulatory issues. In addition, the largest user of 3D printing, a maxillofacial department, reported owning a printer which they used for preoperative models, however, they also bought models from commercial providers and were in general moving towards virtual 3D planning instead of printed models.

Discussion

In this study, we attempted to characterize the clinical use of medical AM in Finland occurring in 2016-2017 via email questionnaires and telephone interviews. We found that AM had found routine use at university clinics for many applications dealing with the skull, i.e. neurosurgery, ENT, plastic and maxillofacial surgery. Outside of the head region, usage dropped off sharply, with orthopedic surgery having some routine usage by a limited number of clinicians, and most other usage being experimental. The vast majority of prints (planning models, sawguides/drillguides and patient-specific implants) were ordered from commercial providers.

To our knowledge, this is the first nationwide survey concerning clinical adoption of medical AM. Finland has a population of about 5.5 million[13], universal publicly funded healthcare, and five tertiary care, university affiliated hospitals. Many advanced forms of treatment are centralized to one or more of the five university hospitals, and an ongoing health care reform is further concentrating care to university hospitals and a few secondary level central hospitals. Finland's health care system ranks high on many indicators of quality of care, such as cancer survival, while receiving lower scores for accessibility, such as waiting times for certain procedures[14]. We assumed that the majority of non-dental AM applications would currently be found at tertiary care hospitals, since they provide treatment for the more complex cases. This was later confirmed by cross-referencing with providers of AM in Finland, which reported no major medical customers outside of tertiary-level hospitals.

The current study has several limitations. First, the nature of the study questions, limited and biased number of responders and non-random sampling preclude a meaningful quantitative analysis. Therefore, this study aims to characterize the adoption of AM technology in clinical care in a qualitative manner.

Second, there is a distinct possibility that, despite our efforts to follow the "web" of AM users, there is some activity which has been missed by this study. Our focus on tertiary level hospitals might also lead us to miss some minor usage. For instance, it is known that 3D-printed drill guides for shoulder joint replacement are used by individual orthopedic surgeons outside of university clinics, and since this is a commercial service provided by the prosthetic manufacturer these surgeons are not part of the academic "web of users" and therefore not recognized. The usage mentioned in the example, however, is not large enough to significantly impact the study results.

Third, since all numbers given are estimates or recollections, and not based on reliable registries or statistics, there is a possibility of significant over- or underestimation. However, we believe the order of magnitude of the numbers given to be correct and to give a fair representation of whether usage is routine, widespread, uncommon or purely experimental.

Barriers to adoption

A common (though not universal) theme in interviews with heavy users was that AM is priceless for certain applications, even though there are no good studies to prove this. Nevertheless, in health care systems with rising cost pressures, widescale adoption of a new clinical technology requires evidence of efficacy. Many of the applications mentioned in the head area such as cancer and complex trauma are such that a comparison trial between an AM-assisted and a traditional approach are impossible because of strong clinician preference for AM. However, many other applications such as prosthetic dentistry and orthopedics have a large number of practitioners currently using traditional means and studies of efficacy would therefore seem feasible.

A number of respondents reported the difficulty of the ordering process and delays caused by ordering as a barrier to large scale adoption. Since very few users produced and planned products in-house, the design and ordering was usually done through online collaboration with engineers from the vendors of 3d-printing (e.g. Planmeca, Materialize). For the heaviest users of AM, the imaging, design, production and delivery of an implant and patient-specific guides can all be done within 24 hours if needed, based on an optimized and familiar workflow and co-location with the actual producer. Familiarity with the process makes ordering easier, but depending on the provider a 24-hour timescale may not be possible for most applications.

Another possibility for making the production process easier and faster is to bring the design and production of products in-house. Several hospitals outside of Finland either employ their own design engineers or the clinicians perform the design themselves, and many institutions also have their own 3d-printers, especially for applications other than implants. While somewhat time consuming, many clinicians view this as a rewarding and ultimately more educative and even faster process than utilizing outside providers. In Europe, this process is somewhat complicated by regulations equating even preoperative planning models with medical devices requiring registration of the producer, a quality control system etc. The regulation of medical AM is a complex issue internationally as well, and currently it remains the responsibility of the clinical end-user to ascertain that the producer of their prints has the required certification. In Finland, Oulu University has its own 3D printer to produce their own medical models. However, the hospital cannot serve other hospitals, due to different regulations in place when producing for in-house and outside customers.

AM in off-the-shelf production and other invisible uses

Numerically, the largest impact of additive manufacturing on medical care has been invisible to clinicians (and indeed, not recognized by the current study) and of a non-disruptive nature, consisting not of patient-specific products, but of off-the-shelf implants, namely, components for both total hip replacement and knee replacement. While the exact percentage is unknown, several of the largest producers of joint replacement prosthetics are already producing (currently used products include tibial components of knee prosthetics, cup components of hips, and augments for hip revision) or are in the process of moving towards producing parts of their products by additive manufacturing. With over 22 000 total replacements of the hip or knee joint done in Finland in 2015[15], and similar numbers estimated to continue throughout the study period, the volumes are several orders of magnitude larger than those of 3D-printed patient-specific implants. The reasons why implant companies have adopted AM as a production methodology echo those of other fields (e.g. aerospace), namely economics when producing limited runs of a product, and geometries and structures (for instance, controlled surface porosity) not possible by traditional methodologies. The increased usage of additive manufacturing in production of off-the-shelf products is also seen in other industries, with AM being used more and more as a manufacturing technology for final products and less for prototyping and planning[16].

Another unrecognized usage is hearing aids, where the majority of hearing aid earpieces or even shells are now produced by 3D printing[9]. Instead of direct scanning, most implants are currently produced based on scanned moldings of patient's ears, so the process is invisible to the clinicians. Here again the product, which has already been patient specific, is now produced by AM purely for economic reasons.

Dental usage of AM

The dental sector in Finland is more decentralized than other health services, with both primary and specialized dental care being provided by numerous private dental clinics and the publicly funded healthcare system, both at primary care health centers and referral hospitals. Characterization of the usage of AM in this sector is therefore more unreliable. Most dental labs buy their supplies from two large distributors who also sell milling and additive manufacturing services. No other service providers of industrial AM in Finland reported producing dental products, and both distributors used the same subcontractor for metallic AM products. This subcontractor's volumes could therefore be seen as representative of the whole of domestic metal-based AM in Finland's dental sector. However, we also interviewed a dentist who uses AM extensively in his practice, printing his own drill guides for prosthetics on his own 3D printer, and buying some other 3D-printed products directly from foreign providers.

Adding the data together, we estimate that the main use of metallic AM is currently in substructures for fixed prosthetic devices, a component difficult to produce by traditional methodologies, with 4-15 CoCr substructures being produced weekly by the domestic service provider, or about 500/year. For other prosthetics in general, AM is still not a mainstream technology, with only about 20 bridges and 1-2 individual crowns being produced by AM per year. One reason for this is that these products are often produced from ceramics like zirconia, the printing of which is not currently as successful as that of metals. Moreover, many labs are already heavily invested in CAD/CAM milling technology for prosthetic and restorative devices, making them reluctant to switch to AM. A commercial orthodontic product, utilizing a series of printed corrective dental films, is available through certain private dentists, but most orthodontic work is done through traditional means. The usage of plastic drill guides and planning models is not mainstream, but certain dentists use them extensively. In dental prosthetic work, preoperative imaging is usually available, work may be spread out over many sessions with ample time for producing prints, and prints may be produced at a low cost using "prosumer"-level vat photopolymerization devices. Therefore, the biggest obstacle to wide-scale adoption seems again to be lack of proven benefit, either in results, operative time, or cost.

Physical preoperative planning aids vs. Virtual planning

A common suggested use of medical AM, and indeed the earliest application, is the production of physical planning aids before complex operations, allowing surgeons (or other specialists such as interventional cardiologists) the possibility of planning their operation in advance. While this usage was recognized by our study, many responders did not seem very enthusiastic about it. While some surgeons found printed models useful, others in the same field felt that they did not get any added value of printed models, or for some surgeons even 3D-reconstructed CT images, preferring to make the reconstruction "in their head" from individual CT slices. Some surgeons felt that the initial 3D-printed models of complex pathologies had helped them understand them, but that after having associated the models with certain imaging findings, they did not need prints of individual cases anymore.

Virtual planning using reconstructed CT images is another option for preoperative planning[17, 18]. It may be extended to the operating theatre through intraoperative navigation, or even assistive robotics such as currently commercially available for joint replacement operations[19], which can be seen as the virtual planning-alternative to printed saw guides. Augmented reality (AR) applications are currently in development. Compared to physical models, virtual models have certain benefits and certain drawbacks. Benefits include no time waiting for print completion, ability to zoom, section and manipulate at will, ability to try several destructive approaches like cutting the model without requiring a new printed object, computer-assisted planning such as structural integrity planning using Finite-Element Modeling (FEM) and the aforementioned continuation into the operating theatre. A virtual model may also change over time, thus being more of a "4D model" and potentially better approximating real-world organs such as the heart which constantly changes its geometry during the cardiac cycle. Drawbacks include inability to test tools or devices that have not been modelled or the influence of the actual physical dexterity of the operator. There are studies suggesting better grasp of proportions and relationships between structures, and especially a quicker ability to grasp these concepts, when using physical planning models compared to virtual 3D reconstructions or unprocessed CT slices[20]. Current AR solutions are still quite cumbersome and do not approach the level of authenticity of a printed model. However, summing up the pros and the cons, it would seem that virtual planning has a larger potential for wide-scale adoption, with physical planning aids being better suited for learning and unique cases.

Concentrating on AM vs. Patient-Specific products in general

The lay public nowadays has a general concept of what 3D printing is (often equating it with material extrusion type devices) but may not have a grasp of machining or foundry technologies or their capabilities. From an engineering point of view, AM is just one of many production methodologies (although a very unique one) for producing patient-specific products using computer aided design/manufacture (CAD/CAM). In addition, AM may not equal patient specific and can be used for producing off-the-shelf products as well, as discussed earlier.

AM allows the creation of unique geometries not achievable through other production methodologies and complex internal and surface structures are available "for free", i.e. no extra machining cost. However, when neither of these properties are required, AM may not always be the most economical or otherwise preferable methodology. Indeed, in our study certain patient-specific products (metallic orbital floor implants) thought by clinicians to be 3D printed were in fact often produced through machining, and those clinicians who were aware of this fact did not have the technical knowledge to describe the process further, for instance to differentiate between lathing and milling. Production methodology influences factors such as osteointegration, fatigue strength, biocompatibility etc. and a significant part of the medical AM literature is concerned with investigating these issues. Problems associated with metal-on-metal hip replacements in Finland illustrate how medical engineering issues may turn into clinical problems. However, for the individual clinician, lacking good quality clinical evidence of one production methodology over another, possible engineering and biomedical benefits usually remain of minor importance compared to cost, ease of planning, ordering, usage and the changes caused to clinical practice/operative technique. Therefore, patient-specific products in general may be seen as a novel and disruptive technology regardless of the underlying production process, and it might be more productive to include all products produced through a CAD/CAM workflow and individualized for the patient instead of focusing only on 3D printed products.

In conclusion, we found that while medical AM has become routine for certain applications dealing with the head area, most specialties did not utilize it in any way. Orthopedic surgery had the largest variation of usage and perceived benefit between clinicians, and thoracic surgery and cardiology had some experimental use with unique methodological challenges. Instead of technological issues such as lack of geometrical fidelity, the largest obstacles for not adopting AM into new applications were either the complexity of the ordering process or lack of perceived benefit. Further research into the clinical adoption of these novel technologies should choose whether to concentrate on the production methodology of AM, including off-the-shelf components in the discussion, or on patient-specific CAD/CAM products regardless of whether they might be produced by more traditional methodologies.

References:

[1] ISO/ASTM International. ISO/ASTM 52900:2015(E). Additive manufacturing — General principles — Part 1: Terminology.

[2] Mitsouras D, Liacouras P, Imanzadeh A, et al. Medical 3D Printing for the Radiologist. Radiographics 2015; 35: 1965–1988.

[3] Akmal J, Salmi M, Mäkitie A, et al. Implementation of Industrial Additive Manufacturing: Intelligent Implants and Drug Delivery Systems. J Funct Biomater 2018; 9: 41-55.

[4] Tuomi J, Mäkitie A, Salmi M, et al. Medical Applications of Rapid Prototyping – from Applications to Classification. In: Paulo Jorge Bártolo et al. Innovative developments in design and manufacturing: advanced research in virtual and rapid prototyping. CRC Press/Taylor & Francis, Boca Raton, FL, 2010: 701-704.

[5] Salmi M, Tuomi J, Paloheimo K, et al. Patient-specific reconstruction with 3D modeling and DMLS additive manufacturing. Rapid Prototyp J 2012; 18: 209–214.

[6] Tam MD, Latham T, Brown J, et al. Use of a 3D Printed Hollow Aortic Model to Assist EVAR Planning in a Case With Complex Neck Anatomy: Potential of 3D Printing to Improve Patient Outcome. J Endovasc Ther 2014; 21: 760–762.

[7] Bartellas M, Ryan S, Doucet G, et al. Three-Dimensional Printing of a Hemorrhagic Cervical Cancer Model for Postgraduate Gynecological Training. Cureus 2017; 9: e950. DOI 10.7759/cureus.950.

[8] Mäkitie A, Salmi M, Lindford A, et al. Three-dimensional printing for restoration of the donor face: A new digital technique tested and used in the first facial allotransplantation patient in Finland. J Plast Reconstr Aesthet Surg 2016; 69: 1648–1652.

[9] VanKoevering K, Hollister S, Green G. Advances in 3-Dimensional Printing in Otolaryngology: A Review. JAMA Otolaryngol Head Neck Surg 2017; 143(2): 178-183 . doi:10.1001/jamaoto.2016.3002.

[10] Wilcox B, Mobbs R, Wu A, et al. Systematic review of 3D printing in spinal surgery: the current state of play. J Spine Surg 2017; 3: 433–443.

[11] Youssef R, Spradling K, Yoon R, et al. Applications of three-dimensional printing technology in urological practice. Bju Int 2015; 116: 697–702.

[12] Chae M, Rozen W, McMenamin P, et al. Emerging Applications of Bedside 3D Printing in Plastic Surgery. Frontiers Surg 2015; 2: 25. DOI: 10.3389/fsurg.2015.00025.

[13] OECD. Finland - OECD data. Finland - OECD data, https://data.oecd.org/finland.htm (accessed 22.11.2017).

[14] THL. Quality of care in Finland among the best in OECD countries, https://www.thl.fi/fi/web/thlfi-en/-/quality-of-care-in-finland-among-the-best-in-oecd-countries. (2015, accessed 28.8.2018).

[15] Järvelin J, Haapakoski J. Lonkan ja polven tekonivelet 2015, Tilastokatsaus 15/2016. THL, http://urn.fi/URN:NBN:fi-fe2016121331109 (2016, accessed 14.1.2018).

[16] Wohlers T. Wohlers Report 2017. Wohlers Associates Inc, Fort Collins, CO, 2017.

[17] Mazzoni S, Badiali G, Lancellotti L, et al. Simulation-Guided Navigation: A New Approach to Improve Intraoperative Three-Dimensional Reproducibility During Orthognathic Surgery. J Craniofac Surg 2010; 21: 1698-1705.

[18] Stokbro K, Aagaard E, Torkov P, et al. Virtual planning in orthognathic surgery. Int J Oral Max Surg 2014; 43: 957–965.

[19] Stryker. Mako Robotic-Arm Assisted Surgery, https://www.stryker.com/us/en/joint-replacement/systems/mako-robotic-arm-assisted-surgery.html (accessed 11.4.2018).

[20] Cromeens B, Ray W, Hoehne B, et al. Facilitating surgeon understanding of complex anatomy using a three-dimensional printed model. J Surg Res 2017; 216: 18–25.