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REVIEW
MISCELLANEOUS

Trends in use of 3D printing in vascular surgery: a survey

Patrizia MARTI [1] *, Flavio LAMPUS [1], Domenico BENEVENTO [2], Carlo SETACCI [3]

[1]Department of Social Political and Cognitive Science, University of Siena, Siena, Italy; [2]Senese University Hospital, Siena, Italy; [3]Department of Medical, Surgical Science and Neuroscience, University of Siena, Siena, Italy

*Corresponding author: Patrizia Marti, Department of Social, Political and Cognitive Science, University of Siena, Via Roma 56, 53100, Siena, Italy. E-mail: patrizia.marti@unisi.it

ABSTRACT

Introduction: The purpose of the following research was to provide a systematic survey on the use of additive manufacturing in vascular surgery. The survey focuses on applications of 3D printing in endovascular surgery like endovascular aneurysm repair (EVAR), a quite unexplored application domain. 3D printing is an additive production process of three-dimensional objects starting from a three-dimensional digital model. This kind of manufacturing process is getting great attention in the medical field and new applications have emerged in recent years especially thanks to the combination of additive printing with 3D imaging techniques. The purpose of the study is to reflect on additive manufacturing and its potential as an inclusive manufacturing practice which can provide benefits at economic and societal level.

Evidence acquisition: The article first introduces the use of 3D printing in surgery by summarizing the results of previous reviews which reveal three main usages of 3D printing: anatomic models, surgical tools, implants and prostheses. These studies point out that vascular surgery is still an unexplored field of application of 3D printing. Starting from this result, a new survey was carried out in databases Pubmed, Elsevier, Research Gate and ACM Digital Library for terms related to 3D printing in vascular surgery using the following keywords: 3D printing, vascular surgery, EVAR, aneurysm. The search screened articles published up to 2019 for relevance and practical application of the technology in vascular surgery, in particular the topic is related to the treatment of complex abdominal aortic aneurysm.

Evidence synthesis: Initially 437 records published up to 2019 were found, but then were narrowed down to 29 full-text articles. The findings reveal that in addition to the applications found in the previous studies, new experiments are ongoing related to the use of 3D printing in the "Off label" practice to manually fenestrate the stent to improve the accuracy of the EVAR.

Conclusions: Different applications of the use of 3D printing and digital imaging in vascular surgery have been experimented with a different maturity level. Whilst the technology has increased its potential in the latest years, the number of studies documented in the literature is still quite narrow. Further research is necessary

to fully test the potential of 3D printing, also in combination with other technologies (*e.g.* 3D imaging and CNC cutting). Early experimentations show that these technologies have the potential to radically change the vascular surgery practice in the near future, in particular in treatment like EVAR, to improve the planning and therefore the success of the surgery.

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Key words: Printing, three-dimensional; Vascular Surgical procedures; Aneurysm.

Introduction

Although 3D printing technology was born around the mid-1980s, it has seen rapid expansions over the last few years thanks to the cost savings of both 3D printers and materials, which has allowed, among other things, the proliferation of several online communities focused on 3D printing applications in the medical field.[1]

From computerized tomography (CT) it is possible to create a digital model of a limb or an organ, to design prosthesis, and manufacture it with reduced costs and time.[2] Previously, in order to obtain such a result, it was necessary to use moulds or very long mechanical manufacturing processes, which made the realization of a single prosthesis too expensive to be amortized with a single surgical operation.

The use of this technology in the medical field is growing and it opens up new scenarios and new possibilities in different branches of surgery[3] with a strong social impact. In vascular surgery for example, almost 40% of patients with aortic aneurysm may not undergo standard treatment due to challenging anatomy. Some studies show how 3D visualization rather than screen, has helped several surgeons in operational preplanning both in choosing the way or in modifying a decision taken earlier.[4] This paper will provide a systematic state of the art of the current use of 3D printing in vascular surgery, with a focus on the so called "Off label" practice in endovascular aneurysm repair. Although 3D printing is still seldom unexplored in this field, emerging applications show a great potential of the use of additive manufacturing.

The use of 3D printing in surgery is increasing.

Recent surveys[5-7] analyzed three main applications: for developing anatomical models, for surgical instruments, and for implants and prostheses. The technology is mainly applied in maxillofacial surgery, cardiothoracic surgery and orthopedic surgery.

In maxillofacial surgery[8] 3D printing is used to improve the visualization of complex sections. Furthermore, it is used to simulate beforehand the healthy mandibular area resulting from the surgery, making the planning easier and accurate.

In cardiothoracic surgery where interventions with reduced visibility are constantly growing, 3D modelling and printing are used to identify the size of hostile necks and of the implantation of new cardiac valves.[9]

In orthopedic surgery, the technology is used for modeling and printing ad hoc prostheses customized to the patient's anatomy, while preserving the capability of bones and muscles to self-regenerate.[10]

Since the use of 3D printing in various medical fields, different applications of 3D printing are documented in literature.

Display of critical or delicate steps in preoperative phase. The possibility to manipulate the model allows to acquire a deep knowledge of the problem, since touch provides additional information that enriches the overall picture.[11] Moreover, the sense of touch reinforces the visual perception by allowing a more accurate perception of depth.[12]

Creation of models for training of young surgeons, who can benefit from the manipulation of precise and low-cost representations of the human body anatomy.[4]

Patient empowerment: through the use of 3D printing, surgeons can more easily explain to the patients their clinical situation and share the kind of surgery they will undergo. Studies demonstrated that this use of 3D printing positively contributes to empower the patients and increases their "consensus" for the surgical treatment.[13]

Studies published in 2018[7, 14] show a growing interest in the application of 3D printing in vascular survey. This field of application is the focus of the present survey.

Evidence acquisition

Our research focuses on the use of 3D printing in vascular surgery, with particular reference to complex abdominal aortic aneurysm. The review was carried out in databases Pubmed, Elsevier, Research Gate and ACM Digital Library for terms related to 3D printing in vascular surgery using the following keywords: EVAR, aneurysm, vascular, endovascular. The search screened articles published up to 2019 (until April 2019) for relevance and practical application of the technology in vascular surgery, with specific reference to the treatment of abdominal aortic aneurysm.

Initially 437 records published up to 2019 were found according to the following inclusion criteria:

- original articles;
- 3D printing as the key topic;
- practical applications to vascular surgery of the complex abdominal aortic aneurysm;

The exclusion criteria were:

- 3D bio-printers and biomaterial;
- non-English articles;
- work deemed irrelevant to 3D printing;
- work deemed irrelevant to current vascular surgical practice;
- work related to cerebral aneurysm;
- 3D printing of cardiac valves.

The initial set of 437 articles was narrowed down to 29 full-text articles. Figure 1 shows the process of identification and screening from the initial recording until the final selection of records.

The main applications of 3D printing in vascular surgery are preoperative planning, training for young surgeons and patient empowerment as revealed in the surveys.[5, 6] An additional use was highlighted in a recent study,[14] the so-called "Off label" practice (Figure 2). The applications are described below.

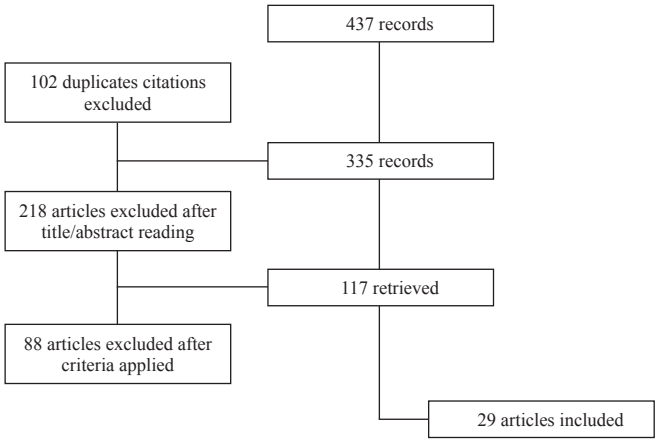

Figure 1.—Flow diagram summarizing the identification, screening, and data collection of resources.

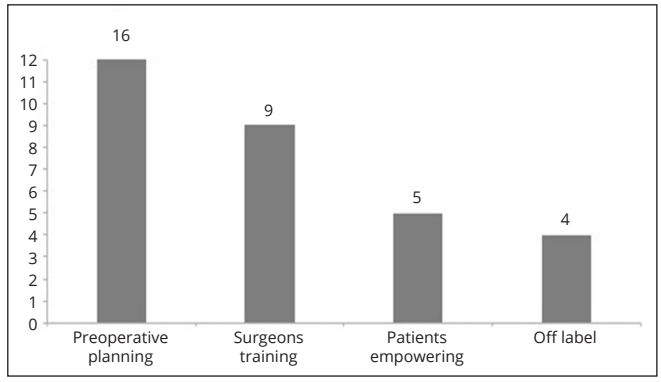

Figure 2.—3D printed models uses in vascular surgery.

Evidence synthesis

Preoperative planning

The main use of the 3D printing in vascular surgery, in particular in EVAR, concerns the planning of the aorta repair against an aneurysm,[15] particularly when the anatomy of the patient is complex or difficult to read through a computerized image.

Complex EVAR treatment is currently the preferred intervention method,[16] both in election and emergency.

Unfortunately, 55% of patients with aortic aneurysm cannot be subjected to EVAR treatment for a specific vascular anatomy or other problems.[17] There is currently no operating practice for interventions with a hostile anatomy.[18]

3D printing is used to guide the surgeon in choosing the kind of operation that better fits the problem.[19-22]

A case[23] published in 2016 reports that a team of French surgeons preferred a robotic resection of the splenic artery aneurysm, rather than an open-air operation or an EVAR intervention, basing their choice in preoperative planning on the screening of a 3D print artery.

3D printed vessels also allow to precisely appreciate the diameter of the lumen and the characteristics of the aortic proximal neck.

In two cases, 3D printing has been applied to support the preoperative planning of renal artery aneurysm.[24, 25]

Furthermore, printed models help in choosing the optimal endovascular prosthesis to use during surgery.[6, 26]

A study conducted in 2016 reported that surgeons docu-

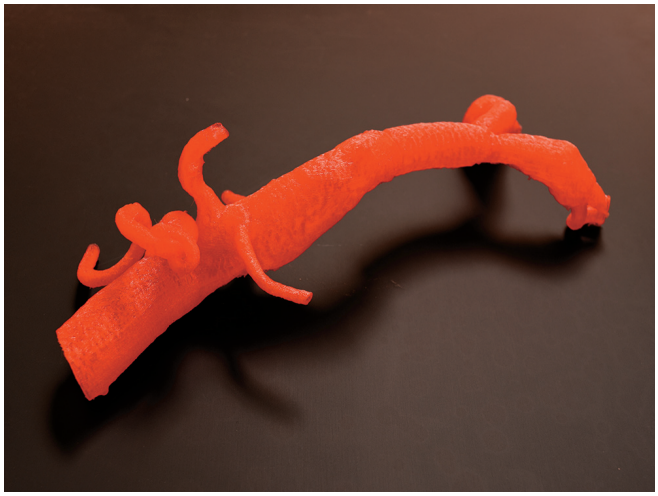

Figure 3.—3D printed abdominal aorta.

mented their decisions based on the observation of CT images first and using a 3D printed model afterwards[18] (Figure 3). A remarkable outcome is that in 41% of cases there was an increase in confidence in the clinical case, and in many cases there was a change in decision-making regarding what kind of intent to perform.[27]

Surgeons training

Employing cadaveric materials to train and study anatomy has always been controversial. Nowadays it is reasonable wondering whether it is still a relevant as practice for young surgeons training: the main problems are linked to the availability, the price of the cadaveric materials, and to ethic-related problems.[28]

3D printing has proved useful in surgeons training because it allows the reproduction in details of different body parts and of the disease related to those parts. It is actually possible to print actual size with 1:1 dimension in order to have perfect duplicates, or to scale them up or down in order to get highly precise replicas.[28]

Notably,question that the adoption of endovascular surgery may make young vascular surgeon less familiar with the treatment of open aortic aneurysm repair.[29] Thus, the exploitation of 3D printing can help in better training young surgeons in open surgical repair.

The option of printing the same duplicate with varied materials and colors helps producing a more vivid training tool.[30]

Finally, several studies[31-34] documented the use of a transparent 3D printed aorta to simulate an EVAR operation.

Patients empowerment

Most of the analyzed papers suggest using 3D printing to improve patients understanding and informed consent. Yet only 4 papers reported concrete cases with a positive judgment about this particular application.[23]

In a study conducted at the Marino Hospital in Cagliari (Italy), researchers documented the surgeon's activity from diagnosis to the surgery. The study described the way in which the surgeon used a 3D printed model of the knee joint to explain the operation's rationale and phases.[35] A similar approach could be adopted also in vascular surgery cases.

In another study case,[36] a 3D model was used to inform 25 patients who were about to receive complex aortic surgery. All of them gave their consent to the proposed procedures, even when they implied disadvantages such as longer hospitalization after treatment.

Off label

Trying to manually fenestrate the endoprostheses in situ is a common practice for surgeons. They use CT images in order to take the measures of the holes and the exact position.

This practice has been recently empowered using 3D printing in three aortic aneurysm cases. In the first case[37] the aorta was printed in two separate sections following the longitudinal axis, while in the last two[38, 39] the 3D model was printed as a single model using transparent materials.

Holes were made in all cases and the 3D printed models were used as "masks" applied to the stent to guide and simplify the stent graft fenestration.

Discussion

The outcomes of the survey highlight an increased use of 3D printing in vascular surgery and an increased number of published articles on this topic, from 24 papers until 2016, to 42 papers until 2019. Nevertheless, the modes of use of 3D printing did not substantially change over the years.

The use of 3D printing for preoperative planning mainly regards the support to decision making on surgical intervention alternatives. In the time frame covered by the survey, the usage of 3D printing in this context did not change significantly: a 3D printed model of the patient's anatomy can enable personalized preoperative planning and improve the visibility of anatomical complexity of the surgery site. In fact, two dimensional or virtual images might be not sufficient to successfully convey structural

details. However, this mode of usage of 3D printed models has started to increase thanks to an improved accuracy of the models due to the availability of new printing materials in different colors, a lower price and affordability, and an overall improved quality of the output.[20, 21] These aspects contribute to favor a widespread use of 3D printed models to support preoperative planning.

The surgeons training remains an open possibility offered by 3D printing since 3D printed anatomical models can clearly show organs and blood vessels of interest and also reduce the use of human organs which are difficult to come by. However, until 2017, this possibility was not widely spread as a routine practice probably due to the availability of printing materials with limited variability in flexibility, durability and colors. Recent articles published from 2017 onwards witness an increasing use of 3D printing for surgeon training.[31-34]

The idea of using 3D printing as a means of patient empowerment remained substantially unchanged. On the contrary, the off-label practice is receiving an increased attention.[37-39] Currently the technique is mainly applied manually with the help of 3D printing to guide the customization. Studies about the stent modifications based on computer numerical control machines are still to come.

Limitations to the use of 3D printing in vascular surgery

The Food and Drugs Administration (FDA) in the USA has partly regulated the use of 3D printing in the medical and surgical field. The European Medicines Agency (EMA) deals mainly with pharmacology in Europe and leaves the use of 3D printers and 3D prints in the medical field to individual states judgement.

In 2014, the European Commission created a 3D printing task force to experiment with 3D biomedical printing in the framework of the NET – New and Emerging Technologies program. The task force, led by Roberto Liddi, will release a white paper in collaboration with the Joint Research Center of Ispra (the Commission's technological and executive arm) to advise the European legislators on the problems related to the use of 3D printing of medical devices. The white paper has the objective to support the legislator in defining a new European regulation on medical devices[40] to include the use of 3D printed devices.

In Italy there is no specific regulation concerning 3D printed devices, especially for the management of custom-made devices of class III, which is the class of reference for 3D printed objects (Directive 93/42 / EEC), often used as implants (as in maxillofacial surgery and orthopedic surgery).

Current legislation states that the responsibility for designing specific requirements of the device stays with the physician, while the responsibility for the technical characteristics of the device lies with the manufacturer.

Conclusions

The systematic survey on the use of 3D printing in surgery, provided in this paper, highlighted a growing role of additive manufacturing in this field.

Additive manufacturing affects economy since it promotes the use of low-cost technologies and materials. 3D printing has the advantage of complementing pre-existing manufacturing processes, which results into a decrease of costs and manufacturing time. In the use of 3D printing in endovascular surgery, the development of one-to-one 3D printed model requires design and engineering skills as well as competencies in understanding the application domain. This raise the need of training new professional profiles with design, engineering and communication skills to boost interdisciplinary practices.

Additive manufacturing in surgery can have an impact at societal level since it allows to enlarge the number of patients admitted of EVAR. Studies[37] documenting the use of 3D printing to create masks to fenestrate the stent grafts in FEVAR (Fenestrated EndoVascular Repair) and EVAR, identified an innovative approach to solve the fenestration problem, although the stent customization is still a manual process that is subjected to imperfections and is very dependent from the surgeon ability to execute the procedure. In this scenario some technologies such as 3D modelling and 3D printing can significantly reduce the time between the diagnosis of the disease and the actual EVAR treatment. Furthermore, they can help the surgeon establishing a course of action and increase accessibility for those patients that are usually excluded from this medical procedure.

More research, like the one for the optimization of 3D printers[41] is necessary to fully test the potential of 3D printing in surgery, also in combination with other technologies like 3D imaging and CNC cutting. Early experimentations[4] show that these technologies have the potential to radically change the vascular surgery practice in the near future[42] in particular in treatment like EVAR, to improve the planning and therefore the success of the surgery.

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Conflicts of interest.—The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

Authors' contributions.—Patrizia Marti and Flavio Lampus defined the methodology of the survey, collected and analyzed the records and drafted the paper; Carlo Setacci coordinated the research and contributed to the discussion of results; Domenico Benevento reviewed the article.

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