

Three-dimensional Medical Printing and Associated Legal Issues in Plastic Surgery: A Scoping Review

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Summary: Three-dimensional printing (3DP) represents an emerging field of surgery. 3DP can facilitate the plastic surgeon's workflow, including preoperative planning, intraoperative assistance, and postoperative follow-up. The broad clinical application spectrum stands in contrast to the paucity of research on the legal framework of 3DP. This imbalance poses a potential risk for medical malpractice lawsuits. To address this knowledge gap, we aimed to summarize the current body of legal literature on medical 3DP in the US legal system. By combining the promising clinical use of 3DP with its current legal regulations, plastic surgeons can enhance patient safety and outcomes. (*Plast Reconstr Surg Glob Open* 2023; 11:e4965; doi: 10.1097/GOX.0000000000004965; Published online 27 April 2023.)

INTRODUCTION

Three-dimensional printing (3DP) or additive manufacturing is the construction of a 3D object based on a digital blueprint such as a computer-aided design (CAD) model or a digital 3D model. In surgery, 3DP can be used in different clinical scenarios, including preoperative planning, intraoperative assistance, and postoperative follow-up.¹⁻⁴ Currently, there are 113 hospitals with centralized 3D printing facilities in North America, and the medical 3D printing market is projected to be worth around \$1.2 billion by 2024.^{5,6}

Promising feasibility studies have expanded the potential application fields of medical 3DP for the surgeon.⁷⁻⁹ For example, Choi et al proposed a 3D-printed model for individualized cleft repair and more detailed visualization of palatal anatomy, whereas Chae et al used 3D-printed

templates to visualize abdominal flap anatomy during breast reconstruction.^{4,10} Medical 3DP has also been shown to enhance the surgical education of both residents and medical students.^{10,11} Ethical recommendations for patient education in medical 3DP include outlining the cornerstones of this upcoming field and discussing different production materials, as well as frequent outcomes and safety reviews.¹²

In contrast to the mounting body of knowledge on the clinical benefits and application areas of medical 3DP, there is a paucity of studies summarizing the legal framework of 3DP. This knowledge gap represents a precarious pitfall because surgeons already face a 15% annual risk of medical malpractice lawsuits, with novel techniques posing additional legal weak points.¹³

To date, and to the best of our knowledge, US legal regulations have not been analyzed with a focus on medical 3DP and its implications for the surgeons of today and tomorrow. We aimed to fill this research gap by reviewing the US legal framework and outlining the standpoints of jurisprudence toward medical 3DP.

US REGULATION OF 3D-PRINTED MEDICAL DEVICES

According to the Federal Food, Drug and Cosmetic Act, 3D-printed medical devices are regulated and controlled by the US Food and Drug Administration (FDA).¹⁴ In the tension field of ensuring patient safety, promoting product effectiveness, and shortening the regulatory process, the FDA subdivides medical devices into three different classes, based on their risk and regulatory profile.¹⁵ These three different classes differ in terms of their regulatory requirements, which were established by the

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Medical Device Amendment of 1976 and determine the premarket submission.¹⁶

Broadly speaking, medical devices falling into Class I or II (ie, low to moderate and moderate to high risk) need to be cleared by the FDA in advance, meaning they require a 501(k) clearance. Therefore, by registration of a product, the manufacturer has to declare their intention to sell and market the medical device. Class III products (ie, high risk) require premarket approval, meaning the manufacturer has to provide evidence of the product's quality, safety, and effectiveness, which results in an overall stricter regulatory process.¹⁷

Furthermore, manufacturers have to implement the so-called current Good Manufacturing Practices (cGMP) to maintain compliance with federal regulations.¹⁸ The cGMP includes that (1) quality, safety, and effectiveness have to be proven for the product; (2) quality cannot be tested in the finished product; (3) quality and design specification need to be ensured by controlling each step of the manufacturing process.¹⁹

LEGAL ISSUES ASSOCIATED WITH MEDICAL 3DP

Although the FDA differentiates the regulatory process between over-the-counter and direct-to-consumer devices that are directly sold to the consumer and point of care (POC) devices that are printed in the healthcare facilities), in particular, POC 3D-printed devices raise compliance-related challenges.²⁰ In fact, the process of POC printing closes the gap between the device manufacturer and healthcare provider by reducing dependence on global supply chains. POC printing for plastic surgeons can be used to assist surgeons intraoperatively. For example, 3DP models to guide the harvest of an iliac crest flap in patients undergoing maxillectomy for maxillary osteomyelitis or mandible reconstruction can be directly produced at healthcare institutions after an intraoral scanning procedure. Such guides have been shown to improve functional outcomes and reduce intraoperative bleeding.^{4,21} However, particularly in liability questions, hospitals face an increased litigation disclosure.

US PRODUCT LIABILITY

In the US product liability system, parties can be held responsible for strict product liability, negligence, and breach of warranty.²⁰ Generally, product liability claims are based on strict liability, meaning the plaintiff has to prove that the product is defective, while the manufacturer is liable regardless of damage or harm caused by an allegedly insufficient product.²²

Nevertheless, cases can be dismissed by the ruling court if the defendant is exonerated. Thus, liability cannot be justified if (1) the risk utility-test shows that the product's utility exceeds its probability of risk of harm or damage or (2) the consumer expectation test states that for a reasonable consumer the product is not deficient when used in a reasonable fashion.²³

Takeaways

Question: We aimed to delineate the legal framework of three-dimensional (3D) medical printing.

Findings: Medical 3D printing represents a potential pathway to expand the boundaries of surgery, but surgeons have to be aware of legal pitfalls. Surgeons should critically assess the quality and functionality of medical 3D-printed devices before application, reinforce preoperative patient education, and revise the surgical indication for each patient.

Meaning: More efforts are needed to expand the legal framework on medical 3D printing, thus generating more legal safety for both surgeons and patients.

PITFALLS IN LIABILITY FOR 3D-PRINTED MEDICAL DEVICES

To file a product liability claim as a harmed plaintiff, it needs to be depicted if the 3D-printed medical device falls into the scope of the product liability system and who is actually liable for eventual defects.

The term product is defined under the Restatement of Torts (Third) as tangible personal property distributed commercially for use or consumption.²³ Therefore, the digital CAD file, which is the base of the following 3D-printed device, cannot be considered a product according to the Restatement of Torts.²⁴ In contrast, 3DP products fall into the scope of strict product liability and can be determined as products in a legal sense. Thus, traditional manufacturers can be held responsible for strict liability.²⁵

The strict product liability depends on the concept of chain of sale, meaning that all parties involved in the manufacturing or selling process can be held liable (Fig. 1).²⁴ Therefore, the term manufacturer in 3DP needs to be more thoroughly defined. Besides the manufacturers who actually print the finished product, the manufacturer of the printer, the CAD designer, or the supplier of the raw printing material could possibly be considered a manufacturer. Theoretically, the plastic surgeon implanting a 3DP model could be also seen as part of this chain of sale. Plastic surgeons should carefully consider this aspect as 3D-printed prostheses are already used in different scenarios. For example, Hirohi et al reported the use of customized 3D forehead implants for temporal wasting, whereas Ahn et al. reported promising results of 3D scaffolds for alveolar cleft reconstruction.^{26,27}

Further, hospitals and other healthcare institutions could be considered manufacturers in a legal sense if they aim to increase their profits by selling preprinted products to third parties in a commercial matter. In that case, hospitals would be considered manufacturers and could be held responsible for defects in their printed products, which is particularly relevant for POC printing in healthcare institutions.²⁸ Especially in the profitable field of aesthetic surgery, the implementation of 3DP models may render healthcare institutions manufacturers. 3DP models are already used for cosmetic conditions. For example, Arias et al reported promising outcomes when deploying

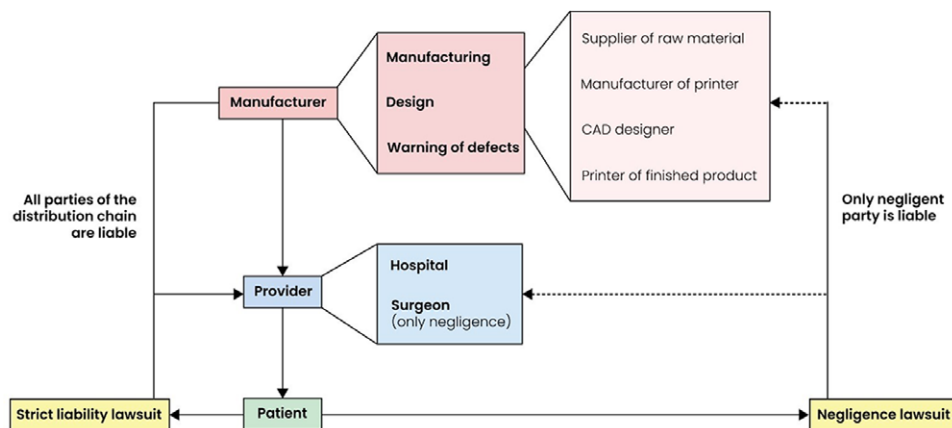


Fig. 1. In the US product liability system, parties can be held responsible for strict product liability and negligence. With strict product liability, the chain of sale should be considered, whereby all parties involved in the manufacturing or selling process can be held liable. Who exactly is liable depends on at which step the product defect occurred: (1) manufacturing, (2) design, or (3) warning of defects. A manufacturer in 3D printing is not limited to the manufacturer who printed the finished product, but also the supplier of the raw printing material, the CAD designer, and the manufacturer of the printer. Both the hospital and the surgeon can be considered a provider. In general, surgeons can mainly be held responsible for medical malpractice in case of negligence.

3D-printed hemifacial masks on the unaffected side to determine the fill volume of fat for the target site.²⁹

LIABILITY FOR SURGEONS

In general, surgeons can mainly be held responsible for medical malpractice in cases of negligence.²⁸ In favor of the surgeon, it is the patient's duty as the plaintiff in a potential trial to prove that their damage is a consequence of medical malpractice by the physician.³⁰

In *Longnecker v. Loyola University Medical Center*, Mr. Longnecker needed a cardiac transplant. The attending doctors approved a donor heart, although the transplant was severely hypertrophic, leading to Mr. Longnecker's death. In trial, the plaintiff accused the responsible surgeons of not testing and inspecting the donor heart appropriately. This case underscored that physicians can be held responsible, even if the surgery per se is performed in an appropriate manner, but the device/transplant is defective and has not been examined properly before use.³¹

In plastic surgery, 3D-printed devices are used for different clinical scenarios, including educational purposes, nipple tattooing after mastectomy, or to visualize abdominal flap anatomy during breast reconstruction.^{7,32} A recent study by AlAli used 3D-printed models in teaching medical students about cleft lip and found that students who were given 3D-printed models during instruction showed improved knowledge of the respective anatomy.⁸ Of note, 3D-printed educational models may generally require little to no oversight from the FDA because such models are classified as "very low-risk devices."³³ Further, 3D-printed devices typically serve as intraoperative guides to facilitate the surgical workflow. In case, 3D-printed guides are defective and therefore result in poor surgical outcomes or even complications,

physicians can be held responsible for negligence in medical malpractice. Although jurisdiction regarding 3D modeling is about to evolve and remains blurry by now, general liability principles can be applied. Therefore, surgeons have to apply the same care and intention as depicted above. Furthermore, hospitals could also be held accountable for strict product liability if the printed model was manufactured at the POC. In such circumstances, hospitals will be considered manufacturers because those models are also viewed as medical devices, even if the product itself is only used for preprocedural simulation for the operating surgeons. It is also important to add the use of 3D-printed medical devices to the informed consent form. For example, plastic surgeons may add the following statement: "The 3D-printed medical device's intended purpose is to help visualize potential outcomes of [please enter the respective surgery]. It does not replace a consultation with a physician and does not guarantee an actual surgical outcome. For an accurate evaluation based on your unique [please enter the respective body part] structure, please consult with your attending surgeon."

Overall, doctors face an obligation to test and inspect the transplant and/or 3D-printed medical device if it is defective and could potentially harm the patient.³⁴ In addition, surgeons have to warn against possible complications when using a 3D-printed device and educate their patients about the side effects of medical devices to ensure an informed decision-making process (ie, learned intermediary doctrine).³⁵

CONCLUSIONS

Medical 3DP represents a potential pathway to expand the boundaries of surgery. Yet, surgeons have to be aware of legal pitfalls. In general, it is mandatory

to critically assess the quality and functionality of the medical 3DP before application. Regarding the US legal system, surgeons may reinforce preoperative patient education and thoroughly revise the surgical indication for each patient. Overall, more efforts are needed to update and expand the legal framework on medical 3DP, thus generating more legal safety for both surgeons and patients.

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DISCLOSURE

The authors have no financial interest to declare in relation to the content of this article.

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