



Pulse Newsletter Health Care Practice

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Developments in 3D printing for medical purposes

3D printing for medical purposes shows great promise for future medical procedures and even for use in courtroom illustration. Also known as additive manufacturing, 3D printing has been around for more than 30 years. But recent advances in the technology have spiked the interest of the health care industry. Below are several recent developments in, and uses for, 3D printing in the medical world.

Low-cost prosthetic parts

Researchers in Canada and California have been successful in creating low-cost prosthetic limbs and sockets for patients in developing countries. The advantages are two-fold: economic and tailor-made prosthetic devices.

Tissue

Researchers at Harvard University have designed a 3D printer and a dissolving ink to create a swatch of tissue containing skin cells interwoven with structural material that can potentially function as blood vessels. There has also been success with other research in developing replacement liver cells.

Less animal testing

It is anticipated that the need for animal testing will be less as 3D tissue can be used for research and testing, instead of live animals or human subjects.

Medical models

Printed models of cancerous tumors used by a group of researchers in China and the U.S. have aided in the discovery of new anti-cancer drugs, helping researchers and doctors to better understand how tumors develop, grow and spread. Creating patient-specific models from CT and MRI scans can drastically reduce surgery times.

Bone

3D printers have been used to promote bone growth by binding chemicals to a ceramic powder, creating intricate scaffolds that facilitate the growth of bone in any shape. This technique was developed by Professor Bose in 2011. The goal is to, one day, implant the bone scaffold with bone growth factors in such a way that the implant is dissolved by natural bone material in load-bearing bone structures.

Heart valve

At Cornell University a heart valve has been printed. A combination of smooth muscle cells and valve interstitial cells was created which can control the valve's stiffness. It will soon be tested in sheep.

Ear cartilage

3D photos of human ears have been used to create ear molds. These molds are then filled with a gel containing bovine cartilage cells suspended in collagen, which holds the shape of the ear while cells grow their extracellular matrix. This technique has also been used to print vertebral discs.

Medical equipment

Certain medical manufacturers are using 3D printing to create medical equipment in poverty stricken areas of the world. 3D printing has produced the ability to manufacture low-cost items that would be difficult or expensive to obtain by traditional means. This has changed access to care and treatment for many people

Cranium replacement

A cranium replacement has been the first 3D printed polymer implant to receive FDA approval.

The top portion of a young woman's skull was replaced by a team of Dutch surgeons at the University Medical Center in Utrecht using a customized printed implant made from plastic. There are several other examples of patients needing repairs of crushed or damaged skulls for which 3D printing has offered a chance for recovery.

Synthetic skin

The Wake Forest School of Medicine in the U.S. has developed a device that can print skin straight onto the wounds of burn victims. Capable of scanning a wound, the printer can then fabricate the appropriate number of skin layers to fill the wound.

Organs

3D printed liver cells that can function for more than 40 days have been successfully created. While, at the moment, the product is used for testing new pharmaceuticals, it is predicted that within a decade we will be able to print solid organs, such as livers, hearts and kidneys.

Medical malpractice courtroom illustration

3D printing has also been used successfully to illustrate medical anatomy, physiology and function in medical malpractice cases. Check out this YouTube site for a look at what's new in courtroom illustration: <https://www.youtube.com/watch?v=HG2VjXpZikQ>

3D Printing liability issues

As with all cutting edge medicine, the liability picture is not yet in focus and there are no real identifiable standards of care. However, we can anticipate some of the potential liability risks with this technology. The use of 3D medical manufacturing requires the collaboration of researchers, manufacturers, computer technologists, software engineers and physicians. Liability for organ or medical product malfunction would arguably be shared among those who participate in its design, manufacture, distribution, placement and treatment —

creating a scenario with multi-professional liability exposures: product, engineering and medical, as well as intellectual property.

Risk management techniques for 3D printing

1. Follow all government regulations concerning medical products in this area.
2. Follow all manufacturers recommendations.
3. Develop policies and procedures that adhere to all regulations.
4. Ensure credentialing of physicians and surgeons for these products.
5. Obtain appropriate informed consent that includes the risks and benefits associated with the surgery, the implant or product, the risk if the product fails or malfunctions.
6. Involve appropriate ethical committees in decisions involving 3D organ printing.
7. Review insurance policies for adequate coverage in this area.
8. Communicate with insurance brokers and underwriters about activity concerning 3D medical printing.
9. Review all contracts involving products for appropriate indemnification clauses.
10. Manage media attention.

Ostensible/apparent agency liability

Claims involving ostensible agency have been around for a long time. We have learned from these claims, but changing health care delivery models have refocused our attention on this issue. With the advent of an increased number of employed physicians, changing network relationships and health systems' extended activity, it is sometimes confusing for a patient to understand who is an independent contractor and who is an employee of the hospital or health system.

In general, hospitals can be held liable for the negligent acts of physicians, nurses and others when they are employed by the facility. However, they can also be held liable when it only APPEARS that these individuals are hospital employees and the patient relied on this fact to their detriment.

This type of vicarious liability is known as ostensible agency or apparent authority. Although it can be treated differently in different jurisdictions, most states have similar rules.

In general, courts have reasoned that, since hospitals have fostered the impression that they provide medical services directly to the public — which creates likelihood that patients will look to the hospital, as an institution, rather than an individual physician for care, a finding of ostensible agency resulting in hospital liability can occur. The increasing number of courts recognizing this rationale demonstrates that such social reliance is deserving of legal protection.

Recent examples:

Ostensible agency/apparent authority is more likely to be found if:

- The physicians practiced exclusively at the hospital.
- The physician's forms/questionnaires bore the hospital's logo.
- The hospital or the patient specifically chose the particular physician or if the hospital assigned the physician for a patient's surgery.
- The patient went to the hospital seeking medical services and was forced to rely on the hospital's choice of physician to render those services.
- Physician independent contractor wears a lab coat with the hospital logo on it.
- Emergency room physicians are often seen as hospital employees.
- Surgeons and operating room personnel are confused with hospital employees.
- Hospital attached clinics, the proximity of the physician's office or clinic can be seen as an extension of the hospital.
- Hospital diagnostic services can also be seen as hospital-owned and controlled.



Risk management techniques to avoid ostensible agency/apparent authority

- Consent forms should describe the relationship of independent contractor physicians.
- Signage throughout the hospital should be clear.
- Admission forms should include information on the relationship of physicians to the hospital.
- Independent physician offices on hospital grounds should be identified as non-hospital property.
- Assignment of physicians to patients for care should describe and document the relationship.
- Hospital letterhead should not be used for independent physician communication to patients.

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If you would like more information on these topics, would like to share your experience or discuss this information in more detail, please contact us.

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