

3D PRINTING PROSTHETICS MEDICAL TECHNOLOGY—RISKS AND REWARDS

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The last decade has seen significant developments in 3D printing of limb prostheses. Here we discuss the current status of the prosthetic and orthotic industry in Australia, the perceived advantages and disadvantages of the method, concerns within the medical community, and the potential causes of action that may result if errors are made or if there are deficiencies in the end product.

What method is involved?

The method of creating the prosthesis involves joining material to make objects from data and building it up, layer by layer. The method has caused concern within the medical profession because those undertaking the construction do not have medical qualifications and there is no supervisory body to keep the manufacturers accountable.

Who regulates the prosthetic industry?

In Australia, the prosthetic industry is self-regulated by the Australian Orthotic Prosthetic Association (**the Association**), and although this means it is not subject to government registration or licensing, the Association has established standards, codes and guidelines. Membership to the Association is voluntary but individuals applying to become a member must meet qualification and residential requirements. Since membership is voluntary, not all individuals undertaking 3D printing are required to be a member; recent statistics show that only 80% of orthotists and prosthetists are members of the Association.

What are the advantages and disadvantages of the technique?

The main advantage of the technique is that the final product can be produced at reduced cost and in a timely manner, allowing greater accessibility to such products and rapid design improvements and customisation. 3D printing of prosthetic limbs is particularly attractive for children, as the prosthesis can mould to a child's development needs.

Despite the advantages of the 3D printing method, experts are increasingly worried about prosthetics being made by people without medical qualifications.

Currently a large global community is printing prosthetics, consisting of individuals from a wide professional background, including teachers, engineers, occupational therapists, students, professors, designers and artists, as well as parents and families. The creation of devices by unqualified persons creates risks arising from ill-fitting devices, which can cause people to fall and suffer injuries, as well as blisters, pressure sores and consequential infections. The technology has been described as being "disruptive" due to the small-scale product development, which circumvents the expertise and checks that usually operate in established manufacturing of consumer products.

What causes of action may arise?

When complications occur, we expect to see an increase in claims for negligence, breach of contract and breach of the Australian Consumer Law.



Photo by Malikov Aleksandr.

The Australian Consumer Law

Schedule 2 of the *Competition and Consumer Act 2010* (Cth) (**Australian Consumer Law**) applies to the supply of goods or services “in trade or commerce”.

Given the nature of the 3D prosthetic limb printing industry, various organisations are providing the products for free and as a measure of goodwill. Given the products are being provided without charge, it is unlikely Australian Consumer Law would apply because the products were not supplied in trade or commerce, that is, for a fee.

Even if the prosthetic limb is supplied in trade or commerce, forensic problems could arise due to the lengthy manufacturing chain involved in 3D prosthetic limb printing. The manufacturing chain includes manufacturers of the printers, producers of raw printing materials, digital designers of Computer Aided Design or CAD files (data files similar to architectural blueprints) and producers of the 3D printed products. This long manufacturing chain will inevitably result in the joinder of multiple parties, which in turn will result in expensive litigation.

Negligence

In order to establish liability, a claimant would need to prove that the defendant did not exercise reasonable care to prevent harm to that claimant. Liability could rest with suppliers of raw materials or the users of the 3D printing machines who print the defective products. For instance, the manufacturers of the product will more likely bear the primary responsibility for defective products if they create the risk or fail to warn users of a known defect. Liability may also arise if suppliers fail to issue proper warnings about the proper fitting and use of the device for example.

Breach of contract

If an agreement or contract is entered concerning the printing of 3D prosthetic limbs then claims may arise concerning the reliability of the

product, which has been communicated to the users when taking possession of the product. However, in the case of products supplied for free, it may be difficult to determine that a contract exists, as no consideration (in this case, payment) has been provided.

We have observed that suppliers and manufacturers of 3D printed prosthesis limbs have attempted to minimise their liability by using waivers. Some companies are requesting that clients sign waivers to the effect that the supplier has not given warranty about any of the designs and do not guarantee they are fit for particular purposes, and that no representations have been made concerning the devices. However, we query whether such attempts to limit liability would succeed, particularly when the supplier is required to accept responsibility by law.

Our view

The lack of regulation around this rapidly developing industry is a cause for concern. Without appropriate training and qualifications, ill-fitting and inappropriate devices may be supplied, which ultimately may cause personal injury. Lawmakers are yet to implement recommendations regarding how Australian Consumer Law can be modified to properly address industries involved in new forms of technology, and the potential adverse impact such products can have on the end-users—who are typically patients in an already compromised position.

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