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Incorporating Informed Consent in 3d Bioprinting Medical Treatment

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Abstract

3D Bioprinting is a rapidly emerging technology and has the potential to benefit future medical and healthcare sectors. However, 3D bioprinting are facing challenges in its implementation particularly with regards to patient's consent. There are two research objectives in this study, firstly, to examine the doctrine of informed consent and its application in medical treatment using 3D bioprinting and secondly, to recommend changes in Consent Guidelines in Malaysian Medical Council incorporating informed consent guideline for medical treatment using 3D bioprinting. This study contributes in the field of 3D bioprinting and it has expanded the discussion on doctrine of informed consent by applying it into 3D bioprinting. This is a qualitative study which employs content analysis method. Findings shows that there is a dire need for a clear guideline for medical practitioner to get patient's consent in receiving medical treatment particularly by using 3D bioprinting in order to avoid any claims and suits that occurs due to medical negligence in specific, failing to ensure informed consent is obtained from patient before medical treatment is done. It is recommended to update the Malaysian Medical Council to update the guideline on obtaining informed consent in 3D bioprinting medical treatment. Future studies can address the application of informed consent in medical treatment using 3D bioprinting through quantitative study.

Keywords: Bioprinting, 3D Bioprinting, Informed Consent, Transplantation, Medical Treatment

Introduction

Three-dimensional (3D) bioprinting or also called biofabrication is relatively new technology in tissue engineering made by advancement of 3D printing technology, cell biology and materials science which has the capability to build a three-dimensional construct containing biological cells (Murphy & Atala, 2014). Bioprinting could be defined as a "computer-aided transfer processes for patterning and assembling living and non-living materials with a prescribed layer-by-layer stacking organization in order to produce bio-engineered structures serving in regenerative medicine and other biological studies" (Guillemot et al., 2014). 3D bioprinting technology provides an alternative for medical

treatment by fulfilling the needs for cells and human organs such as heart, liver, pancreas, kidney and lungs for transplantation. However, 3D bioprinting are facing socio-ethical and regulatory challenges in its implementation. Issues arising are such as in the area of intellectual property protection, cyber security and patient's data and material (Hoffman, 2018). In the area of medical and healthcare sector, issue of informed consent arises in medical treatment using 3D bioprinting particularly in transplantation procedure. Study shows that the use of living cells placed into a human body is risky as it can potentially give side effects such teratoma and cancer, dislodgement and migrations of implant (Vermeulen et al., 2017). Therefore, it is vital for medical practitioners to inform patient on the risk involved in the procedure as to avoid medical negligence claims resulting from the medical treatment. Currently, there is lack of specific guideline governing patient's consent in medical treatment involving 3D bioprinting. This is supported by Radzi et al (2020), that there is no clear guideline to govern the experiment conducted for tissue engineering in the current practice. This is supported in other research where it stated that requirements for obtaining consent from a donor for participation in research, as well as requirements for the processing and transfer of genetic information as a special category of personal data, are not defined in the existing legislation (Kirilliova et al., 2020). There are two research objectives in this study, firstly, to examine the doctrine of informed consent and its application in medical treatment using 3D bioprinting and secondly, to recommend changes in Consent Guidelines in Malaysian Medical Council incorporating informed consent guideline for medical treatment using 3D bioprinting.

3D Bioprinting Process

Bioprinting is present in various biologically applied printing systems, such as inkjet, micro-extrusion and laser-assisted bioprinting. The technique of deposition and patterning of biological materials used by these printing devices varies. The inkjet printer heats the printer head electrically, creating a pressure pulse that forces the droplets of the materials out of the nozzle (Murphy & Atala, 2014). Micro-extrusion based bioprinter use pneumatic air pressure or mechanical (piston or screw) dispensing systems to extrude continuous beads of materials (Dababneh & Ozbolat, 2014). Laser-assisted bioprinter works by focusing a laser pulse on the ribbon's energy absorbing layer, which causes a high-pressure bubble to form, propelling the materials toward the collector substrate (Murphy & Atala, 2014). Among these three types of bioprinters, micro-extrusion bioprinting is the most widely utilised approach for printing cell and biomaterial scaffolds.

Generally, bioprinting process can be divided into three sequential technological steps which are pre-processing, processing (actual printing), and post-processing. The desired cell that will be used in printing must first be identified and expanded or proliferated before these three procedures can begin (Mandrycky et. al., 2016). The process of constructing a scaffold, tissue, or organ utilising imaging and computer-aided design tools is known as pre-processing. This steps also involve the preparation of the materials and incorporation of the cells into the materials for bioprinting process or called as bioink. Then the processing step where designed is printed through a bioprinter is take place. The post-processing of 3D bioprinted construct involves the process of tissue remodelling and maturation in a specially designed chamber bioreactor, which accelerates tissue maturation (Dababneh & Ozbolat, 2014) These bioprinted constructs, also known as scaffolds, could be used in the therapeutic area as a drug screening and discovery platform, an in vitro disease model system, or even directly for transplantation (Mandrycky et. al., 2016).

3D bioprinting has additional complexities compared to 3D printing, such as material selection, cell types, growth and differentiation factors, and technical challenges related to the sensitivities of living cells and tissue construction, necessitating the integration of technologies from engineering, biomaterials science, cell biology, physics, and medicine fields (Gungor-Ozkerim et. al., 2018). 3D bioprinting has several advantages include accurate control of cell distribution, high-resolution cell deposition, scalability, and cost-effectiveness which makes the development and applications of bioprinting greatly increased (Kačarević et. al., 2018). 3D bioprinting also have wide ranges choices of materials as compared to 3D printing. 3D printing choices of materials are limited to thermoplastic polymer, whereas 3D bioprinting can use including liquid and gel materials such as hydrogel (Vanaei et. al., 2021). 3D bioprinting has the ability to rapidly prototype and customise designs, allows for the precise co-deposition of cells and biomaterials, and can create highly accurate microstructures for cells to grow on (Tan et. al., 2021). Apart from that, constructs fabricate by 3D bioprinting are closer to genuine biological tissues, thus it is now possible to design anatomically correct tissue or organ by using medical imaging data.

The Doctrine of Informed Consent

Obtaining patient's consent is an expression of respect for patient as a person. It is a form of respect towards patient's moral right to bodily integrity and self-determination of one's own life and actions. No surgery, treatment, procedure or examination may be undertaken on a patient without the consent of the patient. The purpose of obtaining consent from a patient is to confirm that he or she agrees to the procedure and is aware of any risks involved. According to Malaysian Medical Council (MMC) Guideline 2016 consent is defined as a voluntary acquiescence by a person to the proposal of another; the act or result of reaching an accord; a concurrence of minds; actual willingness that an act or an infringement of an interest shall occur. There are two types of consent, firstly is express consent. Express consent is a permission given either verbally or in writing. Written consent can be made in form of signing a consent form as a proof of consent. Once a patient sign a consent form prior to a medical procedure, it is assumed that the patient give consent to the procedure in question. Despite verbal consent is recognised, however, it will give rise to the issue on verbal evidence. Secondly, is implied consent. It is a form of consent where the permission is given without utterance of words but using gestures and voluntary action such as offering one's arm for injection.

However, a mere signature in the consent form does not diminish doctor's liability in the medical procedure and does not prove that valid consent to treatment has been duly obtained. Factors such as the quality, extent and accuracy of the information given to the patient before signing the consent form plays a role in determining the validity of the consent. In the case of *Chatterton v Gerson* (1981) 1 All ER 257 the judge stated that "once the parties is informed in broad terms of the nature of the procedure which is intended, and gives her consent, that consent is real if the information is withheld in bad faith, the consent will be vitiated by fraud but it would be no defence to an action based on trespass to person if no explanation had in fact been given". Therefore, it can be observed that patient's consent requires the element of information for it to be valid. It is vital that patient needs to be informed prior to medical treatment particularly before the medical treatment. Informed consent requires doctors to provide their patients with sufficient information so that the patients could assent to or withhold consent before performing a medical treatment.

Informed Consent Involving 3d Bioprinting Medical Treatment

Malaysian Medical Council has introduced several guidelines that guide medical practitioner's and patients in receiving medical treatments. A particular guideline for obtaining patient's consent is known as MMC Guideline: Consent for Treatment of Patients by Registered Medical Practitioners ('MMC Guideline'). Provision 2 states that failure to obtain patient's consent may result in disciplinary inquiry for transgression of ethical professional codes and/or legal action for assault and battery instituted against the medical practitioner. While provision 3 of the MMC guideline states that a medical practitioner is obliged to disclose information to the patient and to warn the patient of material risks before taking consent and failure to obtain a patient's consent or disclose material risks may be interpreted as a failure of the standard of care resulting in a disciplinary inquiry by the Medical Council or may even be construed as a breach of duty of care and legal action instituted.

The shortage of organ donor posed a serious issue for organ transplantations. Therefore, with the emergence of 3D bioprinting technology, it provides alternative for patients to receive organ transplantation. However, various risks are exposed in treatment using bioprinting products such as transplantation procedure which requires implanting bioprinted cells and organs into patient's body. One of the risks in transplantation procedure is that there is a risk where the body can reject the new organ implanted. Thus, it is vital to ensure that the medical practitioner must inform the patient, in a manner that the patient can understand about the condition, investigation options, treatment options, benefits, all material risks, possible adverse effects or complications, the residual effects, if any, and the likely result if treatment is not undertaken to enable the patient to make his own decision whether to undergo the proposed procedure, examination, surgery, or treatment. Whether the risk is material to be informed would be determined by the "prudent patient" test which was introduced in the case of *Canterbury v Spence* (1972) 464 CLR 772 and later adopted in the case of *Rogers v Whitaker* (1992) 175 CLR 479. In Malaysia, what is material risk can be observed from the several cases. In the case of *Foo Fio Na v Hospital Assunta & Anor* (2007) 1 MLJ 593, it was said that that the risk of paralysis in a spinal cord operation was considered to be a material risk of which the patient should have been warned. While in the case of *Lechemanavasagar a/l S. Karuppiah v Chenk & Anor* (2008) 1 MLJ 115, it was decided that the risk of esophageal perforation on the upper part of the esophagus is a material risk that needed to be warned before undertaking the surgery to remove the fishbone. It is observed that the current MMC guideline does not provide any specific provision in obtaining patient's consent in medical treatment involving 3D bioprinting. Therefore, to prevent medical negligence in medical treatment using 3D bioprinting, it is recommended for the MMC to include a specific provision which states the standard procedure to obtain patient's consent before performing the procedure, this include making sure that the patient is fully informed of the purpose of the procedure, the risks and side effects of the medical treatment.

Conclusion

Industrial Revolution 4.0 demands the application of technology in medical and healthcare sectors. The development of 3D bioprinting can improve the service in medical and healthcare sectors and at the same time provides access for patient to opt for alternative medical treatment. This study shows that there is a dire need for a clear guideline for medical practitioner to get patient's consent in receiving medical treatment particularly by using 3D bioprinting in order to avoid any claims and suits that occurs due to medical negligence in specific, failing to ensure informed consent is obtained from patient before medical

treatment is done. This study contributes theoretically to the field of 3D bioprinting and it has expanded the discussion on doctrine of informed consent by applying it into 3D bioprinting. Practically, this study has contributed to the medical practitioners, Ministry of Health Malaysia and private healthcare institutions as it provides a view about the importance of getting informed consent in treating patients by using 3D bioprinting and how to improve the MMC guideline for future directions.

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