

Translational Aspects of 3D and 4D Printing and Bioprinting

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Three-dimensional (3D) printed medical devices include orthopedic and craniofacial implants, surgical tools, and external prosthetics that have been directly used in patients. While the advances of additive manufacturing techniques in the production of medical devices have been on the rise, clinical translation of living cellular constructs face significant limitations in terms of regulatory affairs, process technology, and materials development. In this perspective, the current status-quo of 3D and four-dimensional (4D) (bio)printing is summarized, current advancements are discussed and the challenges that need to be addressed for improved industrial translation and clinical applications of bioprinting are highlighted. It is focused on a multidisciplinary approach in discussing the key translational considerations, from the perspective of industry, regulatory bodies, funding strategies, and future directions.

1. Introduction

With an aging population, rates of tissue defects and organ failure have been increasing.^[1–2] Paralleled with shortages in donor

tissues and organs available for transplantation, and the evident risk for rejection of donor tissue, the problem is magnified.^[3,4] Because of these reasons, as well as the poor health of these patients, many do not survive the long waiting times for a transplant.^[5] The development of tissue engineering and regenerative medicine strategies within the last three decades have enabled us to develop products that make the replacement of several tissues possible.^[6,7] With the exception of skin, engineering tissues and organs is still challenging, largely due to the complexity of the native tissue or organ, vascularization, size, and location within the body, to name a few.^[8] Although many engineered constructs may not be functional in the body, they have found use as *ex vivo* systems to study

physiology, pathology, or test drugs and chemicals.^[9,10] In addition, these constructs also fill gaps for studying diseases that do not have appropriate models. There have been several problems associated with engineered tissues prepared using conventional cell-seeding approaches,^[11] including but not limited to nonuniform distributions within the scaffold, low cell densities, and unrealistic microenvironments for the cells. With the advent of microphysiological systems (MPSs), it became possible to develop biomimetic systems that can better recapitulate the *in vivo* microenvironment and build tissues in a more controllable way.^[12,13] Among these is the adaptation of three-dimensional (3D) printing (3DP) to 3D bioprinting (3DBP), which enabled the use of multiple biomaterials, precise control over their location, as well as cell and additive localization.^[14,15] Additionally, the use of smart materials allows for the development of four-dimensional (4D) constructs that can actively respond to changes in the local environment and to external and internal stimuli, making the creation of dynamic constructs possible.^[16] Despite advances made in bioprinting research, clinical translation has thus far been limited.^[17] In these nascent stages of 3D and 4D bioprinting, a lucid evaluation of the current landscape from a multidisciplinary perspective (since this is a multidisciplinary problem) supports advancement toward industrial translation and clinical application of bioprinting. Therefore, a series of special sessions in leading conferences have been organized^[18] to raise awareness, identify challenges, create new ideas, foster interdisciplinary collaboration, and suggest future directions to guide effective translation of important concepts and technologies for the benefit of patients on a global scale.

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