Animal models that help translate regenerative therapies from bench to bedside

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Clinical testing and development of novel therapies based on advances in tissue engineering and regenerative medicine that will one day enable the repair and replacement of diseased or damaged human muscle, bone, tendons, and ligaments depends on the availability of good animal models. The highlights of a recent workshop that explored the need for and current status of animal models for musculoskeletal regenerative medicine are presented in a special issue of *Tissue Engineering, Part B: Reviews,* a peer-reviewed journal published by Mary Ann Liebert, Inc.

The production of specially engineered tissues to restore the function and viability of cartilage or meniscus in the knee, for example, or of degenerating intervertebral discs in the spine, will likely one day be commonplace. In the meantime, however, there is substantial need for better and standardized animal models for the development and testing of these innovative techniques. At the National Institutes of Health (NIH)-sponsored workshop "Translational Models for Musculoskeletal Tissue Engineering and Regenerative Medicine," leaders in the field described available models, outlined the unmet needs, and discussed the translational pathways for clinical testing and therapeutic use.

Mark Lee, PhD, and colleagues from the U.S. Food and Drug Administration (FDA, Rockville, MD) explained how the complexity of engineered tissue constructs, often containing a combination of cells, scaffolds, and other factors, creates challenges for product characterization and manufacturing. In their paper "Considerations for Tissue-Engineered and Regenerative Medicine Product Development

Prior to Clinical Trials in the United States," they provide resources and recommendations to help product developers optimize the safety and effectiveness of engineered tissues ready for testing in clinical trials.

Focusing on the challenges of applying regenerative medicine technologies to the surgical repair of torn rotator cuffs, Kathleen Derwin, PhD, and coworkers from the Cleveland Clinic in Ohio identified appropriate animal models for research, development, and testing of repair strategies. In their paper, "Preclinical Models for Translating Regenerative Medicine Therapies for Rotator Cuff Repair," they emphasize the need for discriminating preclinical models in which researchers can experiment with the materials and procedures that will ultimately be used to treat human patients.

Damage and degeneration of cartilage is a leading cause of pain and disability associated with the development of osteoarthritis. In their review article "Animal Models for Cartilage Regeneration and Repair," Michal Szczodry, MD, Stephen Bruno, and Constance Chu, MD, from the University of Pittsburgh (Pennsylvania), emphasize the value of animal studies to understand the disease process underlying joint degeneration and to develop effective treatments for cartilage injuries.

"The workshop and manuscripts they produced provide an excellent summary of the tools we have available to translate new technologies forward, toward clinical studies. They also identify the critical gaps in our current knowledge," says Anthony Ratcliffe, PhD, President and CEO of Synthasome, Inc., and a guest editor of this special issue.

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