Good essay on slide #2

Business, Manufacturing

\n[toc title="Table of Contents"]\n

\n \t

\n[/toc]\n \n

Tissue engineering, when applied to focus on bone biology, is referred to as bone tissue engineering (BTE), and it involves understanding the structure, mechanics, and the formation of bone tissues. The main aim of BTE is to induce the formation of new and functional bone tissues (Gothard et al.). In this case, to successfully repair, regenerate or replace bone and joint tissues, knowledge on bone biology and bone development is crucial (Amini, Laurencin and Nukavarapu).

BTE has however proven to be a challenging emergent field for researchers and clinicians due to autograft and allograft failures in numerous pathological conditions. These failures have in turn prompted researchers to seek for new biomaterials that can promote bone repair and regeneration with particular characteristics of biocompatibility, osteoinductivity and biodegradability (Romagnoli and Brandi).

Cell-based therapies used in BTE have now reached human trial stages, and while the initial trials have shown great promise, there is still need for further development of these therapies.

Slode#3:

While there are many BTE strategies under investigation, only few have been approved for clinical use, and most are single component strategies that involve cells, factors or defect filler materials. In order for BTE applications in bone repair and regeneration to become a clinical reality, it is necessary to incorporate recent technologies that utilize all the necessary requirements (i. e. scaffolds, cells and growth factors). However, technologies that include more components may experience difficulties in acquiring regulatory approval (Amini, Laurencin and Nukavarapu).

The commercial development of BTE products based on cell therapies has also progressed but with significant obstacles to overcome before they reach the market. These barriers include scaling up and good manufacturing practices (GMP) of human cell-based therapies. In its current form clinical application of BTE may also pose a healthcare burden due to its patient-specific nature and high manufacturing costs (Stegemann et al.).

While the field has been very rigorous in its efforts to improve bio-manufacturing standards, safety concerns such as tumors risks are yet to be resolved fully despite their critical relevance in approaches that involve totipotent progenitor cells. The heterogeneous nature of patient responses to some BTE treatments has also made it difficult to improve the effectiveness of therapy, and this has made patient selection and matching of treatments to be key issues (Stegemann et al.).

Slide#4:

While there are many BTE strategies under investigation, only few have been approved for clinical use, and most are single component strategies that

involve cells, factors or defect filler materials. In order for BTE applications in bone repair and regeneration to become a clinical reality, it is necessary to incorporate recent technologies that utilize all the necessary requirements (i. e. scaffolds, cells and growth factors). However, technologies that include more components may experience difficulties in acquiring regulatory approval (Amini, Laurencin and Nukavarapu).

The commercial development of BTE products based on cell therapies has also progressed but with significant obstacles to overcome before they reach the market. These barriers include scaling up and good manufacturing practices (GMP) of human cell-based therapies. In its current form clinical application of BTE may also pose a healthcare burden due to its patient-specific nature and high manufacturing costs (Stegemann et al.).

While the field has been very rigorous in its efforts to improve bio-manufacturing standards, safety concerns such as tumors risks are yet to be resolved fully despite their critical relevance in approaches that involve totipotent progenitor cells. The heterogeneous nature of patient responses to some BTE treatments has also made it difficult to improve the effectiveness of therapy, and this has made patient selection and matching of treatments to be key issues (Stegemann et al.).

Slide# 5:

The challenges observed thus contribute to the regulatory burden that needs to be overcome when introducing BTE products into the market. Additionally, cell-based therapies for bone and joint replacement also require to have favorable cost-benefit profiles for them to gain reimbursement and acceptance in the market (Stegemann et al.).

According to Stegemann et al. any new therapy needs to be at least as effective as, and probably less expensive than autogenous bone grafting commonly used in bone repair. Cell therapies have the potential of meeting this challenge, but there are critical technical, regulatory and policy obstacles that need to be addressed before this vision can be achieved. While acknowledging all these challenges, it is also important to note that great improvements have been made in the field of BTE in the past decade. However, there is still need for integrating the latest high quality research with clinical practice so that the impact of these scientific advances can be felt from a therapeutic stance. On the other hand, regulatory bodies need to have some level of flexibility in standards and policy enforcement while clinical practitioners may be required to adopt new technology and ensure it reaches their patients.