Biocompatibility Issues for the Tissue Engineered Products for Commercialization

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Around 1992 as 20 years ago, Advance Tissue Science Co (USA), now merged to Smith & Nephew Co., USA, had been submitted to approve to USA FDA for first cartilage TEMPs as autologous chondrocyte/polyglycolic acid (PGA) nonwoven scaffold. At that time, no one had doubted to approve cartilage TEMPs since PGA was already approved by FDA in human clinical trial and chondrocyte was used autologous primary cell. At last, this product has been still retard up to approve FDA. Main reason might be in terms of safety. Implanted TEMPs have been reported to induce sequential events of immunologic reactions in response to injury caused by implantation procedures and result in acute inflammation marked by a dense infiltration of inflammation-mediating cells at the materials-tissue interface. Prolonged irritations provoked by implanted biomaterials advance acute inflammation into chronic adverse tissue response characterized by the accumulation of dense fibrotic tissue encapsulating the implants.

In this lecture, we will discuss (1) recent advances for the commercialization trends for the tissue engineered products (TEMPS) including regenerative medicinal products, (2) scaffolds in terms of biocompatibility and safety issue, (3) smart scaffold for the application of clinical trial including improved biocompatibility and the reduction of host response, and (4) biocompatibility issue for the natural and synthetic polymers.