White Paper:

Biomedical Textiles Advance Development of Orthopedic Implants

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Medical device manufacturers are expanding their portfolios with biologically based products for the repair of musculoskeletal defects ranging from bone grafting and fusion, motion preserving spinal repair, to cartilage repair and ligament and tendon tears. The advances in orthobiologic materials is opening the doors for biomedical textiles to take a more active role in the intensely competitive orthopedic medical device market by offering choice and flexibility in design options.

Fabric structures are advancing the development of orthopedic implants with the necessary mechanical and biologic properties designed in to the textiles to serve as load-sharing scaffolds, minimally invasive containment vessels, or resorbables to facilitate osteoconductive healing.

The design flexibility of woven, knitted or braided textile structures is a major feature device designers are leveraging in orthobiologic device concepts. Textiles are inherently compressible and possess shape transformation qualities which allow them to be used in minimally invasive delivery applications. Fabrics can also contain varying orientations in the fabric geometry to affect porosity in eliciting tissue in-growth in certain areas while serving as a tissue barrier in others. Polymers, metals and emerging biologic material filaments can be formed into an ordered composite fabric structure using traditional textile forming methods to attain the desired device form and function.

A Bright Orthopedic Future

Biomedical textile materials are an excellent orthobiologic design option and are making headways into the field for a number of reasons:

- Changing demographics in the patient population are a big driver. A younger, active population and patients in the "actively aging" group are more apt to consult with their surgeons about treatment options and minimally invasive surgical techniques that return a patient to health in a shorter time than traditional larger-scale surgical procedures. Spinal devices, in particular, are being reengineered with flexible and compliant fabric structures to minimize the loss of natural movement.
- Because of biomedical fabric versatility (i.e. compressibility and ability to transform shape at the delivery site), textiles are now being considered in procedures such as

the internal stabilization of a long bone fracture, annular repair and the dynamic stabilization of the spine.[1]

- Implantable biomaterials offer surgeons options in the treatment of joint and cartilage degeneration, tendon and ligament repair, bone grafting, etc. Development in tissue engineering such as hybrid biologic/synthetic osteoconductive composite scaffolds, bone morphogenic proteins (BMP), demineralized bone matrices (DBM), stem cells, and gene therapy are among the cutting-edge treatment options for musculoskeletal repairs.[2]

Soft Tissue Applications

Implantable biomaterial textile structures can be formed via four major technologies – weaving, knitting, braiding and non-woven – each with its own distinctive properties that can be leveraged to facilitate a certain set of physical and mechanical properties unique to the device form and function. In addition, the composite effect of interweaving or "controlled entanglement" of fibers can be enhanced by mixing various fiber-based biomaterials (i.e. polyethylene, PEEK and polyester with metallic elements such as stainless steel, titanium and shape-memory Nitinol). This "mix and match" composite is designed to meet the specific biologic needs of the medical device.

When used in orthopedic applications where bony soft tissue is the intended area of growth, scaffolds take on the role as osteoconductive materials. Osteoconductive materials generally do not have the innate ability to induce new tissue formation; rather, they serve as a conduit for facilitating tissue response due to their porous nature. It is possible, however, to design an osteoconductive scaffold that responds in a controlled manner to provide the body a platform on which to rebuild tissue while offering some mechanical integrity during the process.

Typically, a fabric scaffold is designed to bear load immediately after the implantation while providing a porous region to facilitate growth in and through both the xenograft and allograft tissue and the textile over time. This hybrid repair method strikes a balance between reducing the amount of synthetic materials left behind in the body while facilitating an immediate surgical repair of the damaged tendon, ligament or meniscus.

The Current and Future Landscape

The potential combination of synthetic biomaterials with osteoinductive materials, such as bone morphogenic proteins and demineralized bone matrices, can produce a multi-component scaffold structure with the innate ability to form new tissue using the body's cellular response to biochemical signals[3]. These biomedical textile composites offer an additional benefit with their level of control and containment not available with other common scaffold materials such as sponges, foams and porous metals. These textile composite technologies have been used in spinal fusion, long bone fracture and bone void applications.

Fabric structures also serve well as containment vessels that are engineered with specific porosity characteristics to control the flow of materials and to facilitate biologic healing in a localized treatment site. Additionally, these engineered fabric structures can be formed from resorbable synthetics to allow the "controlled" resorption of the polymers to coincide with the healing rate of the tissue for a full repair.

Ongoing development in fabric-based biomaterials offers enormous benefits unmatched by the more common device materials. For example:

- Investigation into mesenchymal stem cells has shown that they have the unique ability to differentiate into a multitude of different tissue types including cartilage, tendon, bone and even skin. This raises the potential for developing a multi-layered, multi-material fabric structure of varying densities to promote stem cell growth and full biologic repair.
- Research and development in biologic materials such as collagen has the potential to advance biomedical textiles beyond the scaffold and hybrid materials to offer better patient recovery time and repair effectiveness due to the "total biologic" nature of these materials and the biologic response from the body.

Biomedical textiles designed for use inside the body continue to build on a broad implant history where few alternative technologies deliver results. Those who are at the leading edge of innovation will continue to spur both technological and industry growth. Biomedical textiles present an exciting design option with a multitude of variables that can provide flexibility and choice to enable device designers to advance orthobiologic innovation.

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