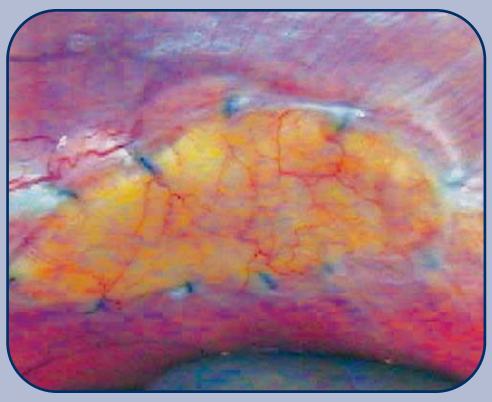
Technical Review

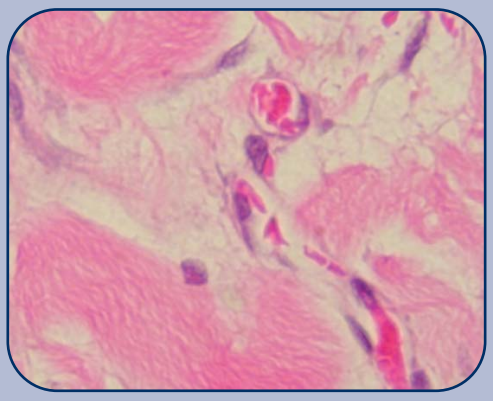
Veritas® Collagen Matrix #2

Veritas: a remarkably remodelable reconstructive material

EVIDENCE OF REMODELABILITY



Veritas Collagen Matrix explant exhibits a pronounced angiogenic response resulting in the seamless integration of the Veritas implant into the surrounding tissue. 28 days post implant in rabbit abdominal wall model.



Host fibroblasts have repopulated the Veritas implant and have begun to deposit new collagen. In addition, the development of blood vessels through the implant (angiogenesis) is clearly seen. 29 days post-implantation. Original magnification: 400x.

Benefits of a remodelable product: the difference between remodelability and resorption

The Veritas® Collagen Matrix, a soft tissue implant, is a non-crosslinked bovine pericardium manufactured using a proprietary chemical process that decellularizes and stabilizes the tissue immunologically by capping free amine groups.

The biocompatiblity and acellularity of Veritas have been confirmed through testing. No evidence of systemic toxicity or histologic changes indicative of a foreign body response have been found.[1] In addition, when compared to a variety of alternative materials, Veritas contains an exceptionally low level of extractable DNA.[2]

Because Veritas is very acellular and biocompatible, it provides an ideal "scaffold" for reconstructive surgery; it allows the process of normal wound healing, including connective tissue protein synthesis and host tissue ingrowth, to occur. After implant, hemostasis and inflammation are followed by remodeling, during which angiogenesis and collagen deposition are observed. The result is the seamless integration of the Veritas Collagen Matrix into the surrounding tissue.

NORMAL WOUND HEALING[3,4]

The body's normal wound healing process consists of three stages: hemostasis, inflammation and remodeling. The remodeling stage in connective tissue begins with repopulation of the wound site by endothelial cells and fibroblasts. Endothelial cells revascularize the wound site through angiogenesis (the formation of new capillaries). This process is critical to the systematic restoration of tissue. At the same time, wound fibroblasts deposit new connective tissue proteins, such as collagen. These activities create a transitional form of connective tissue called granulation tissue, which has extensive vascularization and abundant connective tissue.[3]

As normal remodeling progresses, newly-synthesized collagen is systematically reorganized and stabilized while vascularity decreases. Ultimately, the new tissue filling the void left by the wounded tissue is indistinguishable, both structurally and functionally, from the uninjured tissue surrounding it.

VERITAS: A REMARKABLE, REMODELABLE MATERIAL

The Veritas Collagen Matrix is indicated for use as a prosthesis for:

- Repair of rectal or vaginal prolapse
- Reconstruction of the pelvic floor
- Urinary incontinence treatment

VERITAS COLLAGEN MATRIX FACILITATES REMODELING AND TISSUE INTEGRATION

The Veritas Collagen Matrix fosters remodeling by supporting both angiogenesis and cellular ingrowth. Angiogenesis within the Veritas implant establishes new capillaries, thereby making the implant environment hospitable. This is essential because the body's ability to repopulate the implant with new cells is dependent on the presence of a blood supply.

Fibroblasts within the body then use the Veritas Collagen Matrix as a framework or "scaffold" for deposition of new collagen cells. The remodeling stage progresses within the Veritas implant with continued deposition of cells and reorganization of the new synthesized collagen and blood vessels. The result is the seamless integration of the implant into the surrounding tissue. Animal studies demonstrate that after as little as one month, the Veritas Collagen Matrix is histologically indistinguishable from the host's native tissue.[5]

REMODELING IS NOT EQUIVALENT TO RESORPTION

Veritas' remodeling process should not be equated with the resorption process that occurs with some products. In contrast to Veritas' remodeling process, the mechanism of "resorption" (as is observed with resorbable sutures) is a spontaneous chemical process in which the implanted material breaks down at a predetermined, fixed rate that is not controlled by the body. Even if the healing process is not complete, a resorbable material will decompose.

Bioresorption is a form of resorption in which the polymers of a material decompose when they come in contact with a specific biological molecule, such as an enzyme. Bioresorption is an important aspect of the remodeling process. However, it is the coupling of bioresorption with the process of biosynthesis that results in remodeling.

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Because remodeling of the Veritas Collagen Matrix is a balanced process of biosynthesis and bioresorption, it helps ensure the long-term, structural integrity of the implant, resulting in the seamless integration of the Veritas Collagen Matrix into the normal tissue.

REMODELING: A BALANCED PROCESS OF BIOSYNTHESIS AND BIORESORPTION

Remodeling of the Veritas Collagen Matrix consists of two simultaneous processes: biosynthesis of new host collagen and bioresorption of the Veritas Collagen Matrix scaffold. While the Veritas Collagen Matrix undergoes some degree of bioresorption, this process is tightly controlled by the body's fibroblast enzymes and occurs as new tissue is also being synthesized. In addition, the rate of remodeling is dependent upon the host's metabolic rate.

Remodeling is a balanced process in which both bioresorption and biosynthesis occur at similar rates so the total mass of the implant remains essentially unchanged. This is similar to the body's normal processes of bone resorption and synthesis, during which osteoclasts remove old or damaged bone while osteoblasts synthesize new bone, yet total bone mass remains generally the same.

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REMODELING DOES NOT OCCUR WITH SYNTHETIC IMPLANTS[6]

When synthetic materials, such as prolene or polypropylene, are implanted in the body, a capsule of connective tissue may form that "biologically insulates" the host from the implant.[6] An implant insulated in this way may continue to function, but remodeling and replacement of the implant by new host tissue do not take place.

BENEFITS OF VERITAS COLLAGEN MATRIX TISSUE REMODELING

Veritas exhibits exceptional physical characteristics, making it an ideal product both during and after implantation. The multi-directional collagen fibers of the Veritas Collagen Matrix provide excellent strength and ease of suturing -- even without doubling the tissue. After implantation remodeling occurs, resulting in the integration of the surrounding tissue with the implant. This binds the surrounding host tissue to the implant interface. The end result is an implant that is histologically indistinguishable from the native tissue. This contrasts with synthetic implants for which integration with surrounding tissue may be minimal and the interface remains distinct.

The body's ability to fight infection depends on the capability of its vasculature to deliver infection-fighting cells throughout the body. Because the Veritas Collagen Matrix becomes vascularized, it may assist infection-fighting properties over time. In contrast, certain synthetic materials that cannot be vascularized may harbor infection and resist treatment with antibiotics.

REFERENCES:

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