



Biodesign™

SURGISIS® ADVANCED TISSUE REPAIR PRODUCTS

The Dermis Disconnect in Biologic Grafts

All dermis-based biologic grafts have a high elastin content

Normal elastin content varies widely among tissues of the body. For instance, major arteries have an extremely high elastin content; dermis an intermediate amount; and submucosa or organs like the liver a very low amount.

Many dermis-based biologic grafts are harvested from human cadaveric tissue. Although very carefully controlled for their disease transmission potential, these donors are not screened for their smoking or sun exposure history. Both smoking and sun exposure have been shown to dramatically increase the appearance and size of elastic fibers in the skin, and this apparent increase is due primarily to elastin damage.¹ Thus, many of these harvested dermis-based biologic grafts have a high likelihood of containing damaged elastin.

Many studies have shown that elastin and collagen ratios in tissues affect their function. For dermis-based biologic grafts, the elastin provides a significant amount of the mechanical characteristics of the graft. As this elastin is not replaced, the repair requires this strength to perform. However, it has also been shown that the degradation of elastin leads to tissue stretch and failure of the “recoil” mechanisms in normal tissue.² Particularly, elastin does not get stronger over time, only weaker. This is likely why dermis-based biologic grafts have been reported to stretch over time.³

Complete remodeling of a tissue graft requires that all parts of the material be replaced by new tissue. Studies of the turnover rate of elastin in humans show that it has an average residence time in tissues of approximately 74 years.⁴ Thus, in the case of elastin-containing dermis-based biologic grafts, the elastin

cannot be replaced in a reasonable amount of time and it is left behind to stretch.

In stark contrast, Biodesign is made from submucosa, does not contain structurally meaningful amounts of elastin and results in a repair that does not suffer from long-term stretch.

Elastin is like rubber—collagen like steel

Collagen and elastin are both structural proteins. They are arranged together to provide the appropriate strength (collagen) and elasticity (elastin) for each tissue. A review of elastin and collagen mechanical properties shows some striking differences.⁵ As seen in Table 1, collagen is nearly 100 times stronger and about 1,000 times stiffer than elastin. In other words, elastin is much “stretchier” than collagen. Additionally, collagen has one-tenth the strength of steel.

The presence (or absence) of collagen and elastin in biologic grafts can affect the ability of the device to completely remodel. Both recent animal studies⁶ and human studies out to 2.5 years after implant⁷ show that elastin remains after non-cross-linked dermis-based biologic grafts are used. If elastin is still present, so is the “stretchiness” of the device.

Table 1: Material Properties⁵

Material	Strength _{max} (GPa)	Stress in use (MPa)	Stiffness E_{init} (GPa)
Elastin	0.002	0.55	0.0011
Collagen	0.12	60	1.2
Spring steel	1.5	600	200

For more information about Biodesign, please contact your Cook Medical representative or visit www.cookmedical.com/biodesign.

EVOLUTION OF
TISSUE REPAIR



Table 2: Biologic Grafts Data/Literature Review¹¹

	Publications* (PubMed)	Patient Numbers	Overall Recurrence Rates (%)	Average Follow-Up (months)
Biodesign	30	562	8	19
AlloDerm®	20	481	15	11
Permacol®	8	47	9	16

* Meta-review of PubMed for hernia. Complete as of the end of 2007.

Long-term outcomes are sacrificed with dermis, not with Biodesign

One dermis-based biologic graft, touted to completely remodel, has been shown histologically to retain elastin in the patient tissue even 2.5 years later.⁷ There is clinical evidence that use of dermis-based biologic grafts, and the consequent laxity, results in diastasis and/or hernia recurrence even with "pre-stretching" of the graft.^{3,8,9} At least one manufacturer of human dermis-based biologic grafts advocates manual stretching ($\leq 50\%$) at the time of implant in order to minimize postoperative elasticity.¹⁰ Placing a highly elastic tissue in a low-elasticity site is inadvisable. As one group states,⁹ "[Human acellular dermis] should not be used as an interposition graft because of unacceptably high recurrence rates." The requirement of a follow-up surgery to repair laxity is a significant consequence.³

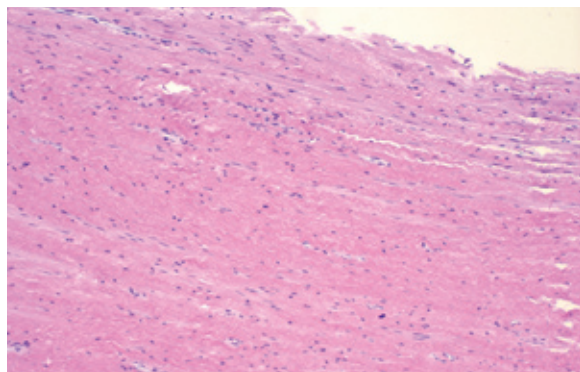
A systematic review of the hernia repair literature using dermis-based biologic grafts shows that average follow-up times are approximately 11-16 months, with failure rates as high as 15% (Table 2).¹¹ This is significant, as recurrence rates can be assumed to increase over time as the graft continues to weaken.⁹ The same cannot be assumed about Biodesign, an advanced tissue repair graft made from small intestinal submucosa, not dermis. Structurally meaningful elastin is not found in submucosa. Biodesign communicates with the body, signaling host tissue to infiltrate the scaffold, facilitating rapid tissue remodeling.¹²⁻¹⁴ The result is completely

remodeled, strong, vascularized host tissue within 3-6 months,¹⁵ without the presence of a permanent material (Fig. 1). Unlike in repairs in which elastin is left behind, recurrence due to laxity is not an issue with Biodesign.

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Figure 1



Biodesign completely remodels, creating complex tissues appropriate for the site of repair after only a few months.

(Biopsy courtesy of Dr. Henry Flournoy, Coastal Associates of Obstetrics & Gynecology, Brunswick, GA).