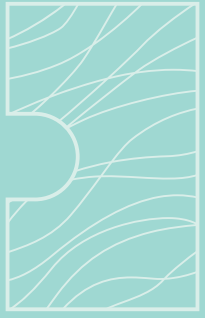
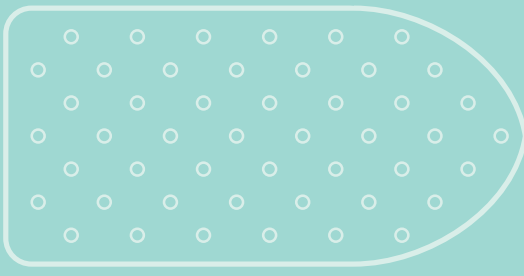
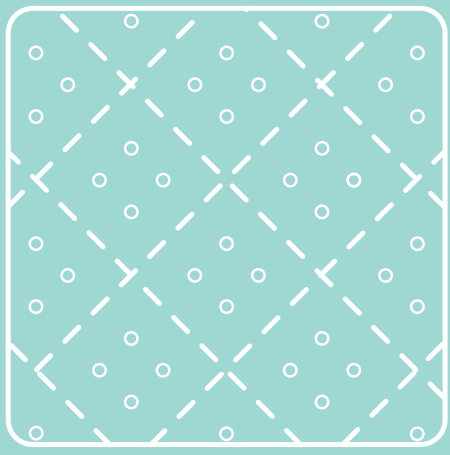
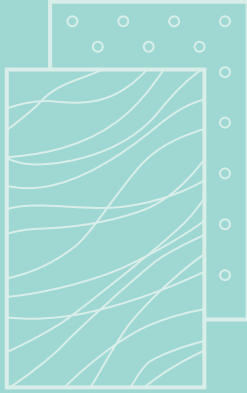
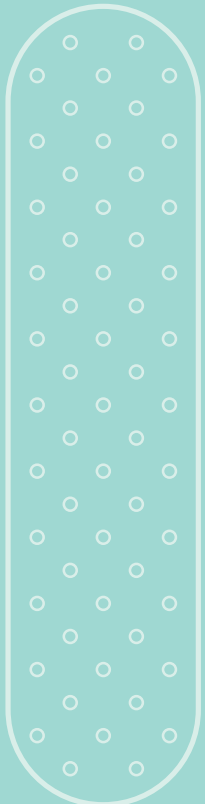




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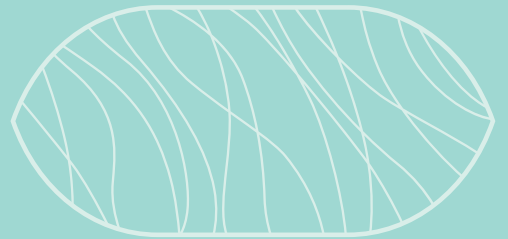
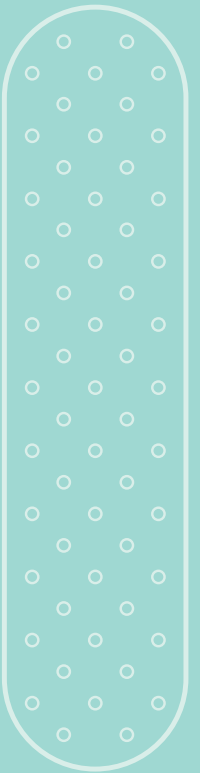
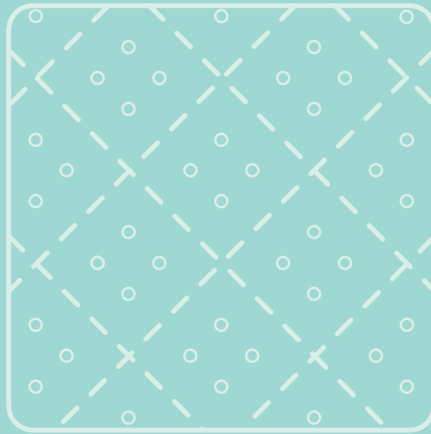
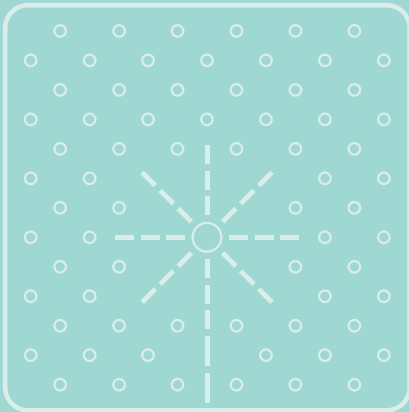
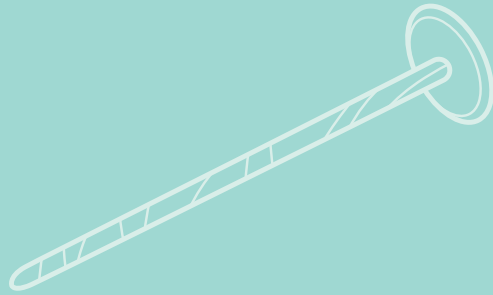


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Cost-Benefit Analysis

Ventral Hernia Repair





Abstract

The art of complex ventral hernia repair has an economic component that in today's society cannot be easily overlooked. Biologic grafts are state of the art with respect to these procedures, and two major costs associated with these are procedure- and material-related. This document is an economic comparison of three highly relevant graft materials—Biodesign, human dermis and porcine dermis—in a hypothetical, average-sized complex ventral hernia repair. When both procedural and material costs are tabulated, Biodesign Hernia Graft provides an overall economic benefit per surgical patient of \$1,000 to \$3,000 when compared to the other biologic grafts and a savings of approximately \$5,000 over a staged approach.

What is Biodesign?

Biodesign is an advanced tissue repair graft. A breakthrough technology, it incorporates the best attributes of a biologic graft—resistance to infection and complete remodeling—with the added benefits of long-term strength, moderate price, ease of use and widespread availability that are often found only in synthetic mesh.

Unlike other biologic grafts, Biodesign communicates with the body, signaling surrounding tissue to grow across the scaffold, allowing the body to restore itself.¹⁻³ This action supports the remodeling process by attracting cells and nutrients to the wounded area.⁴ Biodesign provides an environment that promotes rapid tissue remodeling. The result is completely remodeled, strong, fully vascularized host tissue.

If a graft is to permanently repair a complex and often contaminated defect, it must be able to signal the influx of host defenses to fend off infection. Because Biodesign rapidly remodels into vascularized host tissue, it allows the body's own defense mechanisms to reach and respond to infection. This combination of biologic activities gives Biodesign an advantage over other synthetic mesh and biologic grafts, may reduce the need for repeated procedures, and provides short-term results leading toward long-term outcomes.

Biodesign facilitates complete remodeling within three to six months.⁵⁻⁶ This new tissue displays the same physiologic and morphologic characteristics as native tissue.⁷⁻⁹ Once the healing process is complete, the graft is undetectable, leaving a permanent repair without a permanent material. Synthetic mesh or cross-linked biologic grafts may incorporate, but do not remodel. Over time, Biodesign remodels to become as strong as the patient's own tissue. It is a repair that can even grow with the patient.¹⁰

To date, Biodesign products have been used in a vast array of clinical applications. These include, but are not limited to, pelvic floor repair,¹¹ anal and recto-vaginal fistula repair,¹²⁻¹⁶ and multiple hernia procedures such as ventral/incisional,¹⁷⁻²⁰ inguinal,²¹⁻²³ hiatal,²⁴⁻²⁷ umbilical and parastomal. In addition, Biodesign has been used in complex ventral hernia procedures in which the field may be potentially contaminated (e.g., strangulated bowel) or grossly contaminated (e.g., presence of pus or feces).^{18,20,28} In fact, multiple reports have addressed the ability of Biodesign products to

A remodeled Biodesign Hernia Graft displays the same physiologic and morphologic characteristics as native tissue, rendering it undetectable.

resist infection.^{29,30} Its ability to remodel provides the basis for infection resistance. This is important because the more traditional methods of complex ventral hernia repair are more likely to result in infection^{31,32} or recurrence.³³ As an added benefit, subsequent surgical procedures, if necessary, following Biodesign implantation may be conducted with minimal difficulty, as only host tissue remains following graft incorporation. With synthetic mesh and cross-linked biologic grafts, removal is very difficult, as tissue encapsulation and chronic inflammation create chaotic tissue at the site of repair.³⁴⁻³⁵

In all, the ideal graft for use in complex ventral hernia repair should

- signal the body.
- be resistant to infection.
- remodel completely.
- provide long-term strength.
- be of moderate cost.
- have widespread availability.
- be available in various shapes and sizes.
- be ready to use.

Biodesign encompasses all of these attributes, combining the best qualities of a biologic and a synthetic. Working with the patient's own body to allow tissue repair and remodeling, Biodesign provides lasting results at an affordable cost.

Cost Model

Our proposed cost analysis model compares the costs associated with Biodesign and two clinically relevant biologic grafts, human dermis and porcine dermis, as used in complex ventral hernia repair. Further, the costs associated with a staged, or Fabian,³⁶ approach to complex ventral hernia repair are used as a cost comparator. The model is divided into two major cost categories, assessing both clinical and economic variables: material costs and procedural costs. Ideally, material cost should not be the ultimate factor in any decision regarding material selection. However, the issue of price cannot be avoided in today's cost-conscious landscape.

Material Cost

Proper graft size selection is critical to any ventral hernia repair, both in terms of cost and clinical outcome. When assuming the total material cost in any cost-benefit analysis, one must take into consideration average defect size, appropriate overlap and availability of desired graft size. The average defect size of a ventral hernia is 87.2 cm² (approximately 9 x 10 cm) for open or laparoscopic ventral hernia repair.^{17,37-40} Many leading surgeons have advocated the practice of selecting a graft larger than the defect size, ensuring 4 to 6 cm of overlap of graft and fascia.⁴¹ Assuming a 5 cm overlap on all sides of the defect and an average defect size of 87.2 cm², the average graft size should be approximately 374 cm². **Table 1** lists

Biodesign provides considerable cost savings in average size hernias. As defect size increases, Biodesign becomes an even more cost-effective solution compared to porcine dermis and human dermis.

the cost calculations for each material, as derived from 2007 manufacturers' price lists. The total per-patient material cost for each device is determined by multiplying the material cost (per cm²) by the average graft size (374 cm²).

A recent cost-benefit analysis, detailing the use of human dermis in ventral hernia repair, optimistically utilizes a single 8 x 12 cm (96 cm²) sheet as the basis for comparison with synthetic mesh (polypropylene).⁴² The total per-patient material cost is reported as \$2,580. However, given the average defect size described in recent literature and the amount of overlap advocated by leading surgeons, it is unrealistic to assume a single 8 x 12 cm sheet of human dermis can adequately cover the average complex ventral hernia. Multiplying the normalized, per-patient material cost (\$31.33 per cm²) by the average graft size (374 cm²) yields a total material cost of \$11,717 for human dermis. Because at least one manufacturer of human dermis states that up to 50% manual material stretch at the time of implant is necessary to minimize postoperative elasticity,⁴³ the total material cost has been adjusted to \$7,811, as shown in **Table 1**.

Inserting this figure into the manufacturer's previous cost analysis model negates most of the savings from using the material in complex ventral hernia repair, in comparison to permanent synthetic mesh.⁴²

Porcine dermis has a moderate price (\$26.52 per cm², or approximately 15% less than human dermis⁴⁴) compared to other biologic grafts on the market. Surprisingly, given the recommended graft size, the total material cost for porcine dermis is approximately \$9,918 for the average complex ventral hernia, or \$2,107 more than human dermis. Biodesign Hernia Graft has a cost of \$18.17 per cm², resulting in a total material cost of \$6,796 for the average complex ventral hernia repair. Thus, considering only material cost, the use of Biodesign provides an average savings of \$3,122 and \$1,015 compared to porcine dermis and human dermis, respectively.

Table 1. Per-patient material cost assumptions for each graft.

	Biodesign Hernia Graft	Porcine Dermis	Human Dermis	Human Dermis with 50% material stretch⁴³
Cost per cm ²	\$18.17	\$26.52*	\$31.33 [†]	\$31.33 [†]
Avg. mesh size	374.0 cm ²	374.0 cm ²	374.0 cm ²	249.3 cm ²
Total Material Cost	\$6,796	\$9,918	\$11,717	\$7,811

* Material cost was discounted 15% from the cost of human dermis.⁴⁴

[†] Average material cost was derived from 2007 price lists for two human dermis manufacturers.

Procedural Cost

Next, we analyze the direct procedural costs associated with complex ventral hernia repair using material-specific care pathways (**Fig. 1**). The costs associated with a staged, or Fabian, approach to complex ventral hernia repair are used as a cost comparator.

The average operative time for ventral hernia repair, derived from an average of open and laparoscopic times published in recent literature, is approximately 122 minutes.^{37,45-49} An extra 10 minutes of operative time is added to allow sewing multiple sheets of human dermis together, resulting in a total OR time of 132 minutes. Based on a review of published literature, the average length of a hospital stay is approximately 5.8 days

following complex ventral hernia repair.^{47-48, 50-54}

We estimate that two of the 5.8 days are spent in an intensive care unit following surgery.

Additional procedural cost variables (i.e., OR rate, ICU cost, etc.) are derived from our survey of 20 midwestern U.S. hospital price lists (**Table 2**). Adding the material, OR, and hospitalization costs yields a total procedural cost of \$17,068 using Biodesign, \$18,413 using human dermis, \$20,190 using porcine dermis and \$22,391 using the staged approach.

Table 2. Procedural cost assumptions for complex ventral hernia repair by material

	Biodesign Hernia Graft	Human Dermis	Porcine Dermis	Staged Approach [†]
Material cost	\$6,796	\$7,811	\$9,918	\$1,604 (Vicryl™) ⁴¹ \$243 (Prolene®) ⁴¹
OR Cost (\$33/min x 122 min)	\$4,026	\$4,356*	\$4,026	\$8,052
Hospital Cost ICU (\$1,736/day x 2 days)	\$6,246	\$6,246	\$6,246	\$12,492
Standard Room (\$730/day x 3.8 days)	\$3,472	\$3,472	\$3,472	\$6,944
	\$2,774	\$2,774	\$2,774	\$5,548
Total Cost	\$17,068	\$18,413	\$20,190	\$22,391

* OR cost for human dermis includes an additional 10 minutes for suturing multiple sheets together.

[†] Staged approach costs include two surgeries and two hospital stays.

Conclusion

Overall, the per-patient procedural cost associated with using Biodesign in complex ventral hernia repair of average size is estimated at \$17,068. In comparison, porcine dermis and human dermis have an estimated per-patient cost of \$20,190 and \$18,413, respectively. Thus, the cost analysis ultimately yields a net savings of \$3,122 and

\$1,345 for Biodesign when compared to porcine dermis and human dermis, respectively, and a net savings of \$5,323 when compared to the staged approach.

Complex ventral hernia repair is a difficult procedure in itself, even without the added difficulty of choosing the proper graft. Biodesign provides the long-term benefits of biologic grafts at a lower cost.

When considering material and procedural costs, Biodesign Hernia Graft saves approximately \$3,122 per patient compared to porcine dermis and \$1,345 per patient compared to human dermis.

Fig. 1. Material-specific care pathways for complex ventral hernia repair

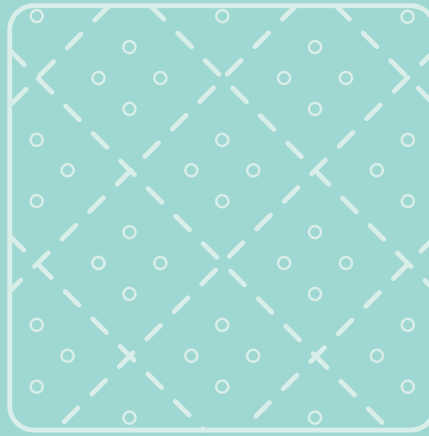
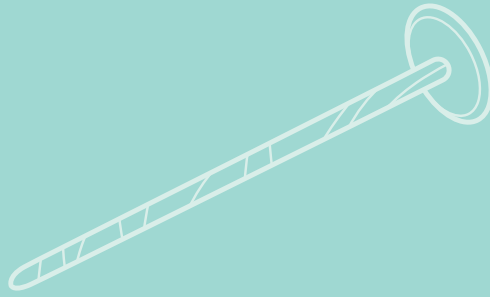
Biodesign Hernia Graft	Human Dermis	Porcine Dermis	Synthetic Mesh Staged Approach ³⁶
Implantation in contaminated field	Implantation in contaminated field	Implantation in contaminated field	Implantation in contaminated field
<ul style="list-style-type: none"> • Surgery (122 min) • Hospital Stay (5.8 days) 	<ul style="list-style-type: none"> • Surgery (132 min) • Hospital Stay (5.8 days) 	<ul style="list-style-type: none"> • Surgery (122 min) • Hospital Stay (5.8 days) 	<ul style="list-style-type: none"> • Surgery (122 min) • Hospital Stay (5.8 days) • Vicryl
Total Cost \$17,068	Total Cost \$20,190	Total Cost \$18,413	Secondary Surgery
			<ul style="list-style-type: none"> • Surgery (122 min) • Hospital Stay (5.8 days) • Prolene
			Total Cost \$22,391

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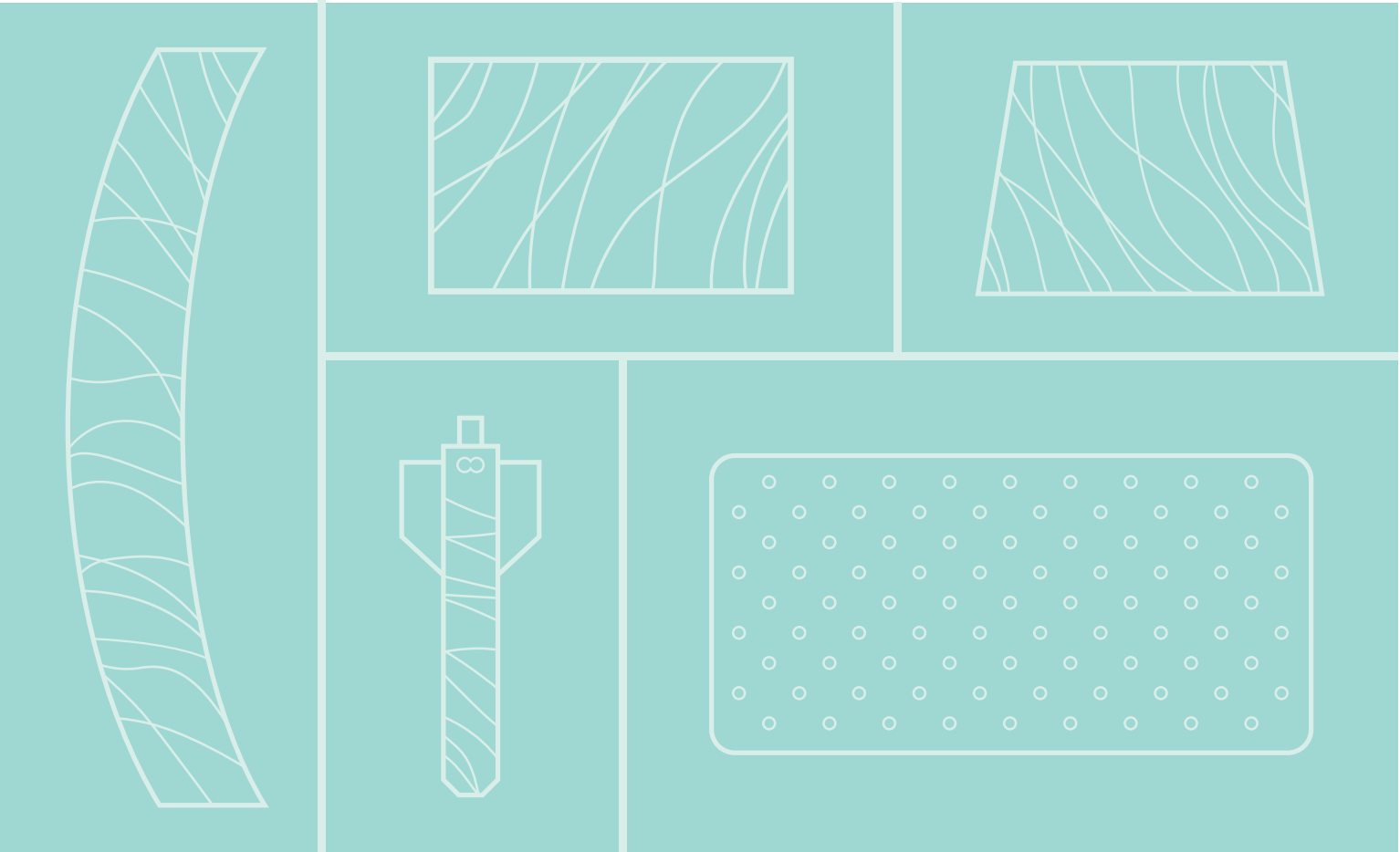
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To determine whether and to what degree savings may be realized by you and your institution,
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