they were taken within 14 days after placement of the covering, most specimens showed early myxoid or early fibrosing granulation tissue. As expected, the grafts that were in place longer tended to have more fibrosis and more mature granulation tissue.

In summary, what was seen under the microscope correlated with what was seen by the clinical investigators. There was little inflammation, but in no case was this interpreted as an immunologic response. Infection and foreign body responses were rare. Probably the most significant finding was that granulation tissue was more frequently seen and was more abundant in control specimens. Long-term clinical results will determine what this means for outcome.

Estimating the Economic Cost Offsets of Using Dermagraft-TC as an Alternative to Cadaver Allograft in the Treatment of Graftable Burns

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Treatment of large, full-thickness, graftable burns constitutes an extremely resource-intensive process. The necessary surgical procedures are often long and cannot be straightforward, because every patient's burn presents a unique challenge to a burn surgeon. Advanced Tissue Sciences, Inc., has developed Dermagraft-TC, a bioengineered temporary skin replacement for surgically excised burn wounds requiring autografting.

Multicenter clinical trials show that Dermagraft-TC can be a safe and effective temporary covering as a substitute for cadaver allograft[1,2] and holds several advantages. Specifically, Dermagraft-TC stays on the wound bed, is not rejected, and does not exhibit the epidermal sloughing encountered with cadaver allografts. In addition, wound beds exhibit less bleeding, less surgical excision is required to remove Dermagraft-TC than cadaver allograft, and there are virtually no risks of communicable disease, because Dermagraft-TC is a sterile product grown under aseptic conditions in a cassette.[2,3] These assets and several other "convenience" attributes of this temporary skin replacement hold the promise of significantly reducing the labor and material resources consumed during therapy for large full-thickness burns.

Any new technology capable of offsetting the risk of viral transmission and significant treatment costs of burn care would be valuable. The cost of burn care is one of the most highly scrutinized reimbursements by public and private insurers, because the average treatment cost per patient with a large full-thickness burn can be 100 times or more than the cost for an average hospital admission.[4,5]

This article presents an economic model of the attributes of Dermagraft-TC that offset the treatment costs of burn care with cadaver skin. Explication of the model's rationale and framework lays the foundation for application of the model. The data sources, cost-offset calculation methods, results, and summary of the model are then presented.

RATIONALE AND FRAMEWORK FOR AN ECONOMIC MODEL OF BURN CARE

An economic model is intended to capture the subtle changes in time, risk, and resources that arise from use of a new technology such as Dermagraft-TC. Because this type of modeling has not been developed in burn care, the model presented breaks ground in providing burn teams with tools to evaluate a new technologic process. In general, an economic model of burn care would be valuable for the following two reasons: (1) the scrutiny of the economic benefits of new medical methods and devices has grown, and resource use is critical to understand, and (2) a model furnishes a frame of reference for discussion of integrating new techniques into the management of clinically complex burns. An economic model regarding Dermagraft-TC provides a framework for evaluating the resource consumption attending use of tissue-engineered skin as a substitute for cadaver allograft before autograft. In addition, because the Dermagraft-TC pivotal clinical trial[3] used each patient as his or her own control, modeling efforts were needed to

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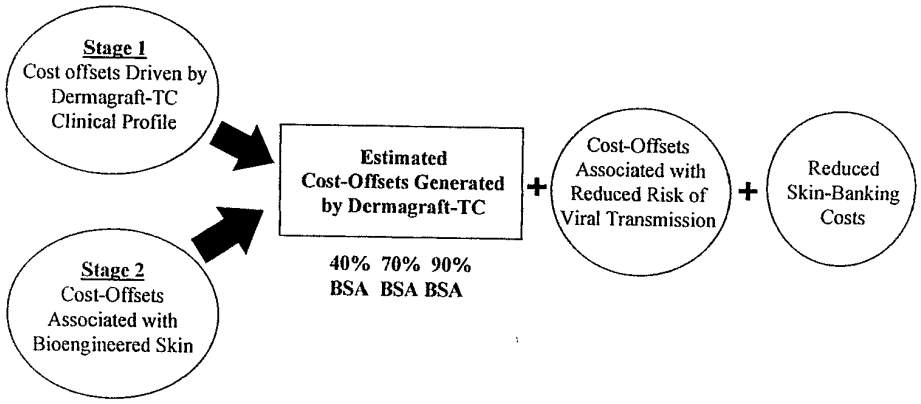

Figure 1. Estimated cost offsets of Dermagraft-TC as alternative for cadaver allograft.

estimate cost-offset comparisons to the use of cadaver allograft.

The framework for the economic model is described as a series of steps in Figure 1. In stage 1 the "direct" cost offsets are estimates based on the clinical profile of Dermagraft-TC used as a substitute for cadaver allograft including the cost of allograft and reductions in resources such as operating room (OR) time, blood, hemostasis products, and hospital days. In stage 2 the "indirect" cost offsets associated with the use of bioengineered skin are modeled. These include the impact of tissue transparency and the constant availability and supply of Dermagraft-TC on the number of days a patient spends in a burn care intensive care unit.

Computation of stage 1 and stage 2 required several assumptions. First, as a way of characterizing very complex burns into "consistent categories," 40% body surface area (BSA), 70% BSA, and 90% BSA burns were assumed as base cases for resource use. Second, resources used were estimates of what was necessary to cover a 20% BSA area. That is, a 20% BSA is taken as a basic "unit" of measurement for calculating resource. Third, it is assumed that the first 20% BSA would be autograft and that the remaining area would require a temporary covering (such as Dermagraft-TC or cadaver allograft) until the patient was ready for additional autografting. Fourth, uniform characteristics of the patient treated were assumed: male, age 30 years, healthy, with a total BSA of 15 square feet. As a result a surgeon operating on the patient would be treating an area 3 square feet when working with a 20% BSA.

The results of stage 1 and stage 2 are combined to generate patient-level cost-offset estimates for 40% BSA, 70% BSA, and 90% BSA graftable burns. The framework also considers the potential cost offsets from the reduced risk of viral transmission with Dermagraft-TC and the possible reductions in skin-banking costs. However, at the time the data sources were insufficient to allocate such costs given the model method. It is obvious that any product that can reduce risk of disease transmission and does not depend on a limited and highly variable donor pool would be valuable despite the fact that the data are not present to furnish a reliable economic estimate.

Data. The data sources used to create the model are clinical literature, Advanced Tissue Sciences Dermagraft-TC pivotal clinical trial data, the expertise of the Advanced Tissue Sciences National Burn Advisory Panel (NBAP), administrative records from insurers, provider interviews, and medical resource cost references from the American Red Cross and Medicaid. The Dermagraft-TC pivotal trial data and the NBAP were used to generate the clinical data inputs for the model with a combined survey and Delphi panel methods. When the survey results produced a wide variation in responses, a Delphi panel approach was used with the NBAP to generate consensus regarding resource consumption and Dermagraft-TC cost offsets. In this way estimates of resource use were developed for calculations in the model.

Resource use and potential cost offsets of Dermagraft-TC compared with cadaver skin were estimated in reference to a standard percentage of BSA, which was estimated as 20% BSA. Thus a patient with a 70% BSA burn was assumed to have 20% autograft initially and then a temporary covering for the remaining 50% BSA. Resources and costs were then estimated for treating each 20%. Larger burns obviously involve multiple locations consisting of 20% BSA.

At the heart of the model is the idea of a "cumulative number of 20% BSAs" that must be covered initially with a temporary covering and ultimately with autograft. The cumulative number of 20% BSA units varies by burn size, type of temporary covering used, and whether the temporary covering requires reapplications before sufficient autograft becomes available to fully cover the patient. In this model the cumulative number of 20% BSAs is generated by multiplying the initial number of 20% BSAs by the number of sites likely to require a reapplication of the covering. This calculation was estimated by a leading panel of burn experts for both cadaver allograft and Dermagraft-TC.

Table 1. Medical treatment cost inputs based on the Dermagraft-TC clinical profile

Medical input	Dermagraft-TC clinical profile attribute	Unit cost
Allograft costs	Avoiding reapplications due to cadaver sloughing	$800/sq ft
Fixed OR charges	Per operative event avoided for reapplications (operating room charge, anesthesia, recovery)	$4,000/OR charge
Reduced hospital days	Avoided operative events: allograft reapplications	$2,900/burn ICU day
Units of packed red blood cells	Reduced allograft reapplications, less excision	$200/unit PRBC
Blood preparation costs	Associated with less PRBCs consumed	$75/unit PRBC
OR time to hemostasis	Due to less wound bed bleeding	$50/min
Hemostasis products	(e. g., thrombin) due to less bleeding	$120/vial
OR time savings	Faster application (standard shape, size)	$50/min
OR time savings	Easier removal and less excision	$50/min

Source: Project HOPE Center for Health Affairs Burn Care Center Interview, Advanced Tissue Sciences National Burn Advisory Panel.

The economic model estimated Dermagraft-TC cost offsets by incorporating the fixed and variable costs of the medical resources consumed in the treatment of large graftable burns (Table 1).

METHODS

The cost-offset calculations were computed separately in the two model stages by the three different burn size categories. The calculation of a cost offset illustrated as follows uses as an example the estimation of the cost offset for OR time to remove the temporary covering on a 70% BSA burn.

Estimated total OR removal time cost offset when using Dermagraft-TC for a 70% BSA burn

Given:

- OR time to remove cadaver allograft: ***50 minutes*** (from NBAP survey)
- Cost of OR time per minute: ***$50***
- Cumulative number of 20% BSA areas Allograft: ***5***
- Cumulative number of 20% BSA areas Dermagraft-TC: ***4***
- Dermagraft-TC OR time removal offset factor: ***0.30*** (from NBAP survey), ***meaning if 50 minutes are required to remove allograft, 30% less time, or 35 minutes, would be required to remove Dermagraft-TC.***

Cost offset 30% decrease in removal time:

⇒ (***$50 · 50 minutes***) · (***4*** 20% TC BSA · ***0.30*** TC offset factor) = $3,000

Cost offset from avoided reapplications:

⇒ (***$50 · 50 minutes***) · (***5*** 20% Allograft BSA − ***4*** TC 20% BSA) = $2,500

Total OR removal time cost offset when using Dermagraft-TC: $3,000 + $2,500 = $5,500 (70% BSA)

The two components of the calculation shown are the share of costs associated with the lower number of reapplications of temporary covering when Dermagraft-TC is used (i.e., $2500) and the share of costs associated with the estimated OR time savings per application of temporary covering when using Dermagraft-TC instead of human cadaver allograft ($3500).

A similar approach is used to compute the stage 2 results. The transparency of Dermagraft-TC enables easy evaluation of the wound bed, which as reported in the Dermagraft-TC pivotal trial,[3] may result in earlier detection of infections. This attribute may improve management of infections and potentially lead to reductions in the length of hospital stays. Many hospitals currently have no on-site skin-banking facilities and thus experience delays in securing cadaver allograft. Dermagraft-TC constitutes a consistent source of tissue so that availability is not the cause of delays in patient treatment. In stage 2 this factor was estimated to have a potential impact on length of stay. The incremental cost of an additional day in a burn center intensive care unit is multiplied by an offset factor that takes into consideration the NBAP's estimate of the number of intensive care unit days that could be saved by using Dermagraft-TC.

RESULTS

The stage 1 results of the model are presented in Tables 2 through 4; each table corresponds to one of three different burn care situations (i.e., 40% BSA, 70% BSA, and 90% BSA). With Table 2 as an example to interpret the results, we find that for a 40% BSA burn the estimated cost of using allograft is $30,200. The estimated cost offset associated with Dermagraft-TC is $20,175. No cost of Dermagraft-TC was incorporated into the model, because the price had not been set when this article was submitted for publication. The estimated stage 1 cost offsets driven for Dermagraft-TC for a 70% BSA burn and a 90% BSA burn are $57,774 and $101,386, respectively.

The stage 2 results are displayed in Table 5. The features of Dermagraft-TC that may contribute to costs offsets as a result of being bioengineered include the product's trans-

Table 2. Estimated cost offsets of Dermagraft-TC as a substitute for cadaver allograft

Stage 1: 40% BSA calculation of cost offsets driven by Dermagraft-TC clinical profile

			40% BSA			
Number of 20% BSA sites w/allograft			1.5			
Number of 20% sites w/Dermagraft-TC			1			
Medical resources consumed	**Unit prices**	**Units per 20% BSA coverage**	**Unit cost per 20% BSA coverage**	**Total cost of using allograft**	**NBAP Survey Dermagraft-TC offset factor***	**Estimated Dermagraft-TC cost offsets**
1 Allograft (including reapplications due to sloughing)	$800‡	3.00¶ sq ft	$2,400‡¶	$3,600	1.00	$3,600
2 Fixed OR charge per operative event for application	$4,000*	1.00*	$4,000*	$6,000	Nonapplicable	$2,000
3 LOS avoided: multiple reapplications cadaver allograft			See below	$8,838	See below	$8,838
4 PRBCs avoided: less excision, fewer reapplications	$200†	4.44‖ units	$888†‖	$1,332	0.30	$710
5 Blood preparation costs (cross-matching, etc.)	$75†	4.44‖ units	$333†‖	$500	0.30	$266
6 OR time hemostasis to achieve hemostasis	$50*	30.00*§ min	$1,500*§	$2,250	0.30	$1,200
7 Hemostasis products (i. e., thrombin) to contain bleeding associated with removal of temporary covering	$120§	1.00§ mL	$120§	$180	Nonapplicable	$60
8 OR time to apply temporary covering	$50*	60.00	$3,000*§	$4,500	0.20	$2,100
9 OR time remove to remove temporary covering	$50*	40.00*§ min	$2,000*§	$3,000	0.20	$1,400
Total				**$30,200**		**$20,175**

Offset factor based on NBAP survey results.
Sources:
*Clinical input (surveys & interviews).
†American Red Cross (blood services).
‡American Red Cross (tissue services).
§Maryland Medicaid claims.
‖Assumption: 1 U of blood (pint) = 450 ml, 1% BSA = 100 ml, 20% BSA = 2,000 ml, 2,000 ml = 4.44 U.
¶Assumption: Patient = 15 sq ft; 20% BSA = 3 sq ft.
The length of stay cost offset is based in the NBAP survey estimate that a minimum of 3 days (@$2,946 per burn ICU day) could be avoided by using Dermagraft-TC instead of allograft for a 40% BSA burn.
With the exception of (3) cost offset calculation equals [Unit cost per 20% BSA] * [(Offset factor * # 20% BSA sites with Dermagraft-TC) + (#20% BSA applications w/allograft − #20% BSA applications w/Dermagraft-TC)].

parency and its constant availability and supply from a manufacturer. These attributes of bioengineered skin may yield cost offsets ranging from $4714 for a 40% BSA burn to $9722 for a 90% BSA burn.

Adding the results of stages 1 and 2, the estimated total cost offsets driven by Dermagraft-TC for 40%, 70%, and 90% BSA burns are $24,889, $66,317, and $111,108, respectively. These results estimate the potential cost offsets attributed to the clinical profile and bioengineered nature of Dermagraft-TC as a temporary covering for graftable burns.

DISCUSSION

The Dermagraft-TC economic model approximates cost offsets for three specific burn situations: 40% BSA, 70% BSA, and 90% BSA. Although these findings characterize only cost offsets for 40%, 70%, and 90% BSA full-thickness burns, they provide a framework for discussion and baselines for estimating cost offsets for other sizes of graftable burns.

Not included in the aforementioned cost offsets are the following additional cost offsets that may be realized when

Table 3. Estimated cost offsets of Dermagraft-TC as a substitute for cadaver allograft

Stage 1: 70% BSA calculation of cost offsets driven by Dermagraft-TC clinical profile

				70% BSA		
Number of 20% BSA sites w/allograft				5		
Number of 20% BSA sites w/Dermagraft-TC				4		
Medical resources consumed	**Unit prices**	**Units per 20% BSA coverage**	**Unit cost per 20% BSA coverage**	**Total cost of using allograft**	**NBAP Survey Dermagraft-TC offset factor***	**Estimated Dermagraft-TC cost offsets**
1 Allograft (including reapplications due to sloughing)	$800‡	3.00¶ sq ft	$2,400‡¶	$12,000	1.00	$12,000
2 Fixed OR charge per operative event for application	$4,000*	1.00*	$4,000*	$20,000	Nonapplicable	$4,000
3 LOS avoided: multiple reapplications cadaver allograft			See below	$23,568	See below	$23,568
4 PRBCs avoided: less excision, fewer reapplications	$200†	4.44‖ units	$888†‖	$4,440	0.30	$1,954
5 Blood preparation costs (cross-matching, etc.)	$75†	4.44‖ units	$333†‖	$1,665	0.30	$733
6 OR time hemostasis to achieve hemostasis	$50*	30.00*§ min	$1,500*§	$7,500	0.30	$3,300
7 Hemostasis products (i. e., thrombin) to contain bleeding associated with removal of temporary covering	$120§	1.00§ mL	$120§	$600	Nonapplicable	$120
8 OR time to apply temporary covering	$50*	60.00*§	$3,000*§	$15,000	0.30	$6,600
9 OR time remove to remove temporary covering	$50*	50.00*§ min	$2,500*§	$12,500	0.30	$5,500
Total				**$97,273**		**$57,774**

Offset factor based on NBAP survey results.

Sources:

*Clinical input (surveys & interviews).

†American Red Cross (blood services).

‡American Red Cross (tissue services).

§Maryland Medicaid claims.

‖Assumption: 1 U of blood (pint) = 450 ml, 1% BSA = 100 ml, 20% BSA = 2,000 ml, 2,000 ml = 4.44 U.

¶Assumption: Patient = 15 sq ft; 20% BSA = 3 sq ft.

The length of stay cost offset is based in the NBAP survey estimate that a minimum of 8 days (@$2,946 per burn ICU day) could be avoided by using Dermagraft-TC instead of allograft for a 70% BSA burn.

With the exception of (3) cost offset calculation equals [Unit cost per 20% BSA] * [(Offset Factor * # 20% BSA sites with Dermagraft-TC) + (#20% BSA applications w/allograft − #20% BSA applications w/Dermagraft-TC)].

Dermagraft-TC is used on graftable burns: (1) cost offsets resulting from reduced risk of viral transmission and (2) cost offsets associated with reduced need for skin banking at burn centers or tissue banks.

Reducing the risk of viral transmission could result in a combination of direct and indirect cost offsets. Direct costs associated with treating diseases contracted from infectious agents in cadaver allograft or blood and indirect costs associated with hospital risk management for possible disease transmission from cadaver allograft could be avoided.[6] Dermagraft-TC could reduce risks of viral transmission in two ways: by decreasing the exposure to cadaver allograft and by potentially reducing the number of transfusions, because bleeding is less when Dermagraft-TC is used.

The integral assumptions to this cost-offset model are the increasing incidence of viral diseases (especially human immunodeficiency virus, hepatitis B, hepatitis C, and cytomegalovirus) among the donor population and the decreasing number of eligible donors, given the increase in governmental regulations.[7-9] Because there is often only a limited social history available concerning the deceased donor and because of the window of seroconversion for human immunodeficiency virus, HBV, and HCV, the probability of viral transmission is greater with cadaver

Table 4. Estimated cost offsets of Dermagraft-TC as a substitute for cadaver allograft

Stage 1: 90% BSA Calculation of cost offsets driven by Dermagraft-TC clinical profile						
				90% BSA		
Number of 20% BSA sites w/allograft				8.5		
Number of 20% BSA sites w/Dermagraft-TC				6.5		
Medical resources consumed	Unit prices	Units per 20% BSA coverage	Unit cost per 20% BSA coverage	Total cost of using allograft	NBAP Survey Dermagraft-TC offset factor*	Estimated Dermagraft-TC cost offsets
1 Allograft (including reapplications due to sloughing)	$800‡	3.00¶ sq ft	$2,400‡¶	$20,400	1.00	$20,400
2 Fixed OR charge per operative event for application	$4,000*	1.00*	$4,000*	$34,000	Nonapplicable	$8,000
3 LOS avoided: multiple reapplications cadaver allograft			See below	$38,298	See below	$38,298
4 PRBCs avoided: less excision, fewer reapplications	$200†	4.44‖ units	$888†‖	$7,548	0.30	$3,508
5 Blood preparation costs (cross-matching, etc.)	$75†	4.44‖ units	$333†‖	$2,831	0.30	$1,315
6 OR time hemostasis to achieve hemostasis	$50*	30.00*§ min	$1,500*§	$12,750	0.30	$5,925
7 Hemostasis products (i. e., thrombin) to contain bleeding associated with removal of temporary covering	$120§	1.00§ mL	$120§	$1,020	Nonapplicable	$240
8 OR time to apply temporary covering	$50*	60.00	$3,000*§	$25,500	0.30	$11,850
9 OR time remove to remove temporary covering	$50*	60.00*§ min	$3,000*§	$25,500	0.30	$11,850
Total				**$167,847**		**$101,386**

Offset factor based on NBAP survey results.

Sources:

*Clinical input (surveys & interviews).

†American Red Cross (blood services).

‡American Red Cross (tissue services).

§Maryland Medicaid claims.

‖Assumption: 1 U of blood (pint) = 450 ml, 1% BSA = 100 ml, 20% BSA = 2,000 ml, 2,000 ml = 4.44 U.

¶Assumption: Patient = 15 sq ft; 20% BSA = 3 sq ft.

The length of stay cost offset is based in the NBAP survey estimate that a minimum of 13 days (@$2,946 per burn ICU day) could be avoided by using Dermagraft-TC instead of allograft for a 40% BSA burn.

With the exception of (3) cost offset calculation equals [Unit cost per 20% BSA] * [(Offset factor * # 20% BSA sites with Dermagraft-TC) + (#20% BSA applications w/allograft − #20% BSA applications w/Dermagraft-TC)].

allograft and other tissue donors than with a bioengineered product. Tissue engineering by definition enables cell expansion and development of tissues from fibroblasts over an extended period of time and enables safety testing that exceeds worldwide testing standards currently in place for donor tissues.

The potential for additional cost offsets associated with reduced need for skin banking is possible given the "off-the-shelf" nature of tissue-engineered products. Burn centers and tissue banks that currently harvest cadaver allograft could reduce or eliminate capital expenses, labor costs, and the variable costs of tissue testing. In addition, trends in governmental regulation may make donor tissue more difficult to obtain and more costly to test for safety.

There are several caveats and potential limitations to the model. One important issue is the complexity and variability of burn care and the fact that the unit resources will vary across the United States. However, increases in the complexity and variability of burns are likely to occasion greater costs for allograft than Dermagraft-TC, which as a bioengineered tissue product is constantly available and of consistent size.

Table 5. Estimated cost offsets of Dermagraft-TC as a substitute for cadaver allograft

Stage 2: Estimated cost offsets associated with Dermagraft-TC as bioengineered skin							
		40% BSA		70% BSA		90% BSA	
Dermagraft-TC features	Incremental cost	Units offset	Cost offset	Units offset	Cost offset	Units offset	Cost offset
Early detection of infection based on transparency‡							
Additional burn ICU day	$2,946*	0.60†‡	$1,768	1.40†‡	$4,124	1.80†‡	$5,303
Constant availability and supply‡							
Additional burn ICU day	$2,946*	1.00†	$2,946	1.50†	$4,419	1.50†	$4,419
Total			$4,714		$8,543		$9,722

Sources:
*Assume 1 Burn ICU day is valued at $2,946, based on estimates from 4 hospitals in Washington/Baltimore area.
†Data Source: NBAP survey and Delphi method.
‡Data Source: Dermagraft-TC clinical trial results.

The model may have some overestimates. Specifically, some operative events occur for reasons other than application of a temporary covering such as autografting. In addition, stage 2 cost offsets for additional Dermagraft-TC attributes may not be additive as assumed in the model.

The model may have some underestimates as well. Results from the physician survey yielded OR charges ranging from $17 to $101 per minute. The model assumed variable costs of $50 per minute of OR time.

The inherent variability and complexity of burn care and the fact that key assumptions are being made by a small sample of clinical experts should also be considered when these findings are interpreted. Despite these caveats the overall method is solid, and reproducible findings are expected once burn centers gain more experience with Dermagraft-TC and conduct similar research. The model is developed in a manner to enable readers to determine whether their own costs are close to the model's and to decide whether all data inputs should be included.

In summary, the Dermagraft-TC cost offset model incorporates a complex array of factors affecting burn care while holding constant all patient attributes except size of burn. The model predicts possible cost offsets from Dermagraft-TC used as a temporary covering for graftable burns even under a set of conservative scenarios. As such the model provides a starting point for testing the assumptions made in the cost-offset calculations with actual data.

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