Wound Edge Approximation

Design Matrix

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<u>Designs</u>

- 1. Bow-Shaped Design
- 2. Hook and Loop Design
- 3. Barrette Design

<u>Criteria</u>

Effectiveness (25 points):

Effectiveness is a top priority for our design, which is why this category received the highest weighting of 25 points. This criterion is a measurement of how well the device can accurately and consistently approximate the wound edges in order for the wound to be glued or sutured. The device should bring the edges of the wound into contact and not interfere with suture or glue application. Additionally, effectiveness includes the ability of the design to consistently provide wound eversion.

Patient Comfort (20 points):

Patient comfort was given a weight of 20 points, as it is of the utmost importance while the device is in use. Clinicians must be able to utilize the device without the use of local anesthetic on the tissue surrounding the laceration. The wound approximation system must not be uncomfortable while placed on the patient.

Safety (20 points):

Safety is important for this product, as the device must avoid causing more damage to the patient's skin. The wound approximation apparatus must not cause any further damage to the tissue from excessive force or leave any deep skin marks after product removal. Additionally, the device must not harm or pinch the user during application. Since safety is always a vital consideration when designing a product, this category received a 20 point score.

Practicality (15 points):

Practicality refers to the ease with which the user can operate the device. The user should be able to hold the wound closed with the device in one hand, while simultaneously gluing the wound with the other hand. This means the design should be lightweight and ergonomic. It should also be easy to operate the closing mechanism and draw the wound edges together. Since practicality is important for the design, this category received a weighting of 15 points.

Novelty (10 points):

There are currently many designs for wound closure available to clinicians. Therefore, this product should be unique in some way. The majority of these devices are used to both approximate and close a wound, while the client has asked for a product to approximate wound edges only. The product should hold the skin together while a clinician closes the wound using Dermabond or sutures. The mechanism of wound approximation should be different from devices currently on the market. Because there are few devices that solely approximate wounds, the team does not expect novelty to be a major challenge. For this reason, this criterion was awarded a ten point value.

Cost (5 points):

Cost is a factor that the team must consider because low product cost is conducive to mass production, which is desired if the product makes it to the market. With a budget of \$300, the team does not foresee major issues arising from product cost, so this criterion was given a five point weight.

Ease of Production (5 points):

As this product has excellent market potential, it must not be too difficult to fabricate. If the product makes it to the market, a design that can be mass produced is highly desirable. The team does not foresee this device being complicated to fabricate, so this criterion was only given a weight of five points.

Design Matrix

Design Criteria	Bow-shaped Design		Hook and Loop Design		Barrette Design	
Effectiveness (25)	(4/5)	20	(4/5)	20	(3/5)	15
Patient Comfort (20)	(3/5)	12	(5/5)	20	(3/5)	12
Safety (20)	(4/5)	16	(4/5)	16	(3/5)	12
Practicality (15)	(5/5)	15	(3/5)	9	(4/5)	12
Novelty (10)	(5/5)	10	(3/5)	6	(5/5)	10
Cost (5)	(4/5)	4	(3/5)	3	(4/5)	4
Ease of Fabrication (5)	(4/5)	4	(3/5)	3	(4/5)	4
Total (100)	81		77		69	

Bow-Shaped Design:

The bow-shaped design includes two curved arms connected at the apex by a locking-hinge system. This will allow the arms of the apparatus to be opened beyond the wound width, adjusted to approximate the wound edges, and locked into position. The ends of the arms will be fitted with a slender piece of rubber or silicone (a material will a high coefficient against the skin). These edges will be placed on either side of the wound, and will provide enough frictional force to pull the wound edges together once the arms of the device are brought together.

The bow-shaped design scored the highest in effectiveness because the design will offer the most control over the wound edges and be able to repeatedly approximate wound edges. However, the design lost points because the arms of the apparatus may interfere with the suturing or gluing of the wound as they are directly above the wound. In terms of patient comfort, the design lost points because the design may pinch or hold the patient's skin in a way that is not comfortable to the patient. This pinching is not expected to harm the patient but may provide a sense of discomfort. For safety, the bow-shaped design was rated the highest because the ends of arms are protected with a soft material that will contact that skin. However, the device lost points because the hinge may provide a pinch hazard for the user or could potentially provide excessive force and pinch the patient if used incorrectly. In the category of practicality, the bow-shaped design scored the highest since it will likely be easy and simple to use by the healthcare professional. Additionally, the design scored the highest in novelty, for there are currently no devices on the market with this structure and function. As for cost, this design scored the highest because the equipment is reusable and made of simple parts. The device lost points because it consists of multiple components that will be made from various materials that need to be purchased. For the last category, ease of fabrication, the bow-shaped design scored the highest because the device requires a rather simple assembly, but the process may require some machining.

Hook and Loop Design:

The hook and loop design consists of two adhesive patches- one with a hook and one with an elastic loop. These patches are adhered to the skin on opposing sides of a laceration. To close the wound, the loop is pulled across the laceration and is secured around the hook, pulling the wound edges together.

In the category of effectiveness, this design would likely be effective at closing the wound, but once the adhesive patches are placed on the skin, they cannot be adjusted. While the other designs could pinch the skin and cause discomfort, the hook and loop simply adheres to the skin and would cause minimal discomfort to the patient. Therefore, the design scored highest in patient comfort. The hook and loop is also relatively safe, with the only danger being the adhesive patches pulling at the patient's skin or hair (similar to removing a bandage), so it scored high in the safety category. The hook and loop design lost points for practicality, as it would be more complicated to use than the other designs and more time consuming to apply as there are multiple working components. While there are no products exactly like it, there are other products on the market that use a similar method of wound closure, causing this design to lose points in novelty. In terms of cost and ease of fabrication, the hook and loop design would likely be more expensive and more difficult to produce than the other designs due to its various materials and adhesive quality.

Barrette Design:

The barrette design consists of two long, curved arms that lay flush to the skin while in use. The arms open and close via the spring loaded hinge located at one end of the device. During operation, the clinician pinches the end of the device to spread the arms to a width greater than

that of the laceration. The device is then placed directly against the skin and slowly closed such that the wound edges are everted and the entire laceration is encompassed by the arms. Sutures or glue can then be applied. Removal of the barrette design simply involves the clinician pinching the end of apparatus to reopen the arms and lifting it away from the skin.

The barrette design scored low in the effectiveness category because it would not be very precise when approximating wound edges, as it only has one setting of closure. It also scored low in the categories of patient and safety comfort because it might pinch the skin in the hinge corner of the device and therefore be uncomfortable for the patient. Additionally, the skin nearest the barrette hinge could be damaged more severely and bruising could result. The barrette design lost points in the practicality category because it would require a significant amount of effort to orientate the device so that the wound edges are properly aligned. This apparatus was awarded full points in the category of novelty because it is unlike the other devices that are currently on the market. The barrette design also scored high in the cost and ease of fabrication categories because it would require few materials and the assembly would be rather straightforward. This device would also be reusable, so the cost of repeated use would be minimal.