SurgiSeal Topical Skin Adhesive Used for Clinical Wound Closure

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BACKGROUND: The cleft lip is a common malformation that affects nearly 1 in 700 newborns worldwide. Repair has been completed utilizing a variety of wound closure devices, including sutures and topical skin adhesives. Evidence suggests repair with a new 2-octyl cyanoacrylate adhesive is an acceptable wound closure method.

STUDY DESIGN: The surgical results of 45 cleft lip repairs and 5 other types of pediatric surgical repairs completed with the use of *SurgiSeal*® topical skin adhesive by 6 pediatric plastic surgeons were reviewed The patients were evaluated at the immediate post-operative period and 4 to7 days after surgery. The patients were evaluated by one pediatric plastic surgeon to assess the resultant scarring, wound leakage, and wound dehiscence.

RESULTS: Physicians reported positive usage and patient results utilizing *SurgiSeal* for the procedures. Key positive feedback was reported in lower rates of cracking or peeling, better flexibility, improved ease of use, better ability to visualize wound healing, and better overall performance than the leading topical skin adhesive in the market.

CONCLUSIONS: Repair of cleft lips with topical skin adhesive as an alternative to sutures has seen positive results in patients, and *SurgiSeal* adhesive performs well in many key clinical attributes.

The cleft lip is a common malformation that affects nearly 1 in 700 newborns worldwide. Clefting of the lip results from a malfusion of the embryological facial elements during the development of a fetus at approximately 6 weeks of gestation.

The resulting cleft lip is repaired when the child is healthy enough to undergo elective surgery. There are many types of repairs used to approximate cleft lips. No cleft lip repair technique has been conclusively shown to give better results than another. Also during cleft lip repair with various techniques, different wound closure methods are utilized by surgeons. These involve different types of suture material as well as skin adhesives.

SurgiSeal is a new skin adhesive developed by Adhezion. This product is FDA approved for use in surgical skin closures. *SurgiSeal* is a 2-octyl cyanoacrylate and provides a water-proof antimicrobial barrier with wound strength properties. The addition of this adhesive to wound closures may improve cosmetic scar results. This study is a review and evaluation of surgical wound closures using *SurgiSeal* skin adhesive in the repair of cleft lip patients.

METHODS

The surgical results of 45 cleft lip repairs and 5 other types of surgical repairs done by 6 pediatric plastic surgeons were reviewed. The patients were selected with the criteria of having a unilateral or bilateral cleft lip repair. There were 5 patients who had did not have a cleft lip repair. These patients had a cranioplasty, lesion removal, or scar revision. The locations of these surgeries were at the Children's Hospital of the King's Daughters in Norfolk, Virginia and at the Operation Smile mission hospital in Guwahati, India. All 50 of the patients had *SurgiSeal* skin adhesive placed onto the wound at the completion of surgery. Each patient had one *SurgiSeal* packet used per wound. The types of sutures used for each incision repair were different and surgeon dependent.

The patients were evaluated at the immediate post-operative period and 4 to7 days after surgery. The patients were evaluated by one pediatric plastic surgeon to assess the resultant scarring, wound

leakage, and wound dehiscence. The *SurgiSeal* questionnaire was answered by the 6 pediatric plastic surgeons taking part in the study.

RESULTS

45 (90%) of the patients who received *SurgiSeal* skin adhesive as a wound closure dressing were primary cleft lip repairs or cleft lip revisions. 2(4%) patients had cranioplasty procedures done, 2(4%) had lesion excisions, and 1(2%) had a scar revision. 37(74%) of the patients were operated on at the Operation Smile mission hospital in Guwahati, India and 13(26%) were done at the Children's Hospital of the King's Daughters in Norfolk, VA and its subsidiary hospitals.

50(100%) of the patients had surgical incisions for which the *SurgiSeal* was used. 50(100%) of patients were evaluated on the day of surgery as well as 4 to 7 days later to assess for inflammation, infection, wound leakage and breakdown.

50(100%) of the patients had surgical sutures used. 50(100%) of the patients had dermal sutures and transcutaneous sutures used. The wording of the questionnaire was confused at this point by several surgeons. All 6 surgeons use both dermal and transcutaneous sutures as opposed to the stated subcuticular and dermal sutures as this terminology was not specific enough.

Approximate wound size table:

Length:

0cm-2cm	15(30%)
2.1cm-4cm	29(58%)
>4cm	6(12%)

Width:

0mm-3mm	50(100%)
3.1mm-6cm	0
>6mm	0

Depth:

0mm-3mm	19(38%)
3.1mm-6cm	29(58%)
>6mm	2(4%)

Post-procedure:

	Yes	No
Improvement in healing	26(52%)	24(48%)
Reduced inflammation	14(28%)	36(72%)
Wound Dehiscence	2(4%)	48(96%)
Wound Infection	1(2%)	49(98%)
Wound leakage	11(22%)	39(78%)

Post-procedure *SurgiSeal* use:

	Yes	No	Not Applicable
Any cracking or peeling of *SurgiSeal* during this procedure	8(16%)	42(84%)	
Any cracking or peeling with *Dermabond*	29(58%)	12(24%)	9(18%)

One of the six surgeons had not used *Dermabond* in the past and could not answer the question regarding cracking and peeling of that product. This surgeon could also not answer question 18-21 due to its comparison opinions of *SurgiSeal* vs *Dermabond*.

Question 17-21: Answers ranked by 6 Pediatric Plastic Surgeons for each of the 50 patients

	1	2	3	4	5	N/A
Cosmetic results of *SurgiSeal* vs sutures alone			1(16.6%)	3(50%)	2(33.3%)	
Flexibility of *SurgiSeal* relative to *Dermabond*				3(50%)	2(33.3%)	1(16.6%)
Ease of use of *SurgiSeal* relative to *Dermabond*			1(16.6%)	1(16.6%)	3(50%)	1(16.6%)
Ability to visualize wound healing of *SurgiSeal* relative to *Dermabond*				1(16.6%)	4(66.6%)	1(16.6%)
Overall performance of *SurgiSeal* relative to *Dermabond*				2(33.3%)	3(50%)	1(16.6%)

(1 being the worst, 3 being equivalent, 5 being the best)

Comparison of *SurgiSeal* to *Dermabond* by 5 Pediatric Plastic Surgeons (Questions 17-21):

17) How did you find the cosmetic results of utilizing *SurgiSeal* vs. sutures alone?

- 5 of 6 surgeons (83.3%) said they find *SurgiSeal* better than sutures (4 or 5)
- 1 surgeon (16.6%) found it equivalent to sutures (3)

18) How would you describe the flexibility of SurgiSeal relative to Dermabond?

- 5 of 5 surgeons (100%) found it more flexible than *Dermabond* (4 or 5)

19) How would you describe the ease of use of *SurgiSeal* relative to *Dermabond*?

- 4 of 5 surgeons (80%) found it easier to use than *Dermabond* (4 or 5)
- 1 of 5 surgeons found it equivalent to *Dermabond* (3)

20) How would you describe the ability to visualize wound healing of *SurgiSeal* relative to *Dermabond*?

- 5 of 5 surgeons (100%) found it easier to see wound healing (4 or 5)

21) How would you describe the overall performance of *SurgiSeal* to *Dermabond*?

- 5 of 5 surgeons (100%) found *SurgiSeal* to be overall better than *Dermabond* in overall performance (4 or 5)

CONCLUSION

There are many products available to close a surgical wound. Most surgeons use various types of sutures to perform this task. Recently there has been an introduction of surgical skin adhesive which has been shown to have favorable results and it is used by many surgeons.

In this study, we were able to have 6 pediatric plastic surgeons use *SurgiSeal* skin adhesive during their cleft lip repair surgeries. 5 of the 6 surgeons in this study have used *Dermabond* in the past. This was the first opportunity for all 6 surgeons to use the *SurgiSeal* skin adhesive product.

The wound types and sizes were very similar for the 50 patients used in this study. All of the wound closures were done on surgical incisions which had dermal and transcutaneous sutures used. All of the surgeons used the product as they would *Dermabond* skin adhesive or as they were instructed as with the surgeon who had not used *Dermabond* in the past.

When reviewing the wounds at 4 to 7 days post surgery the numbers were positive for the *SurgiSeal* use. Improvement in healing was equivocal (52% vs. 48%). Wound infection and wound dehiscence rates were very low, however(3 patients or 6% total). We believe one of the dehiscences occurred in a patient who had wound healing problems that were discovered at the later surgery on the patient's palate. One of the infections and one dehiscence occurred at the surgery site in Guwahati, India. On a previous mission to Guwahati the infection/dehiscence rate for cleft lip repairs was 5.6%. The findings of 2(4%) with *SurgiSeal* use is therefore slightly lower.

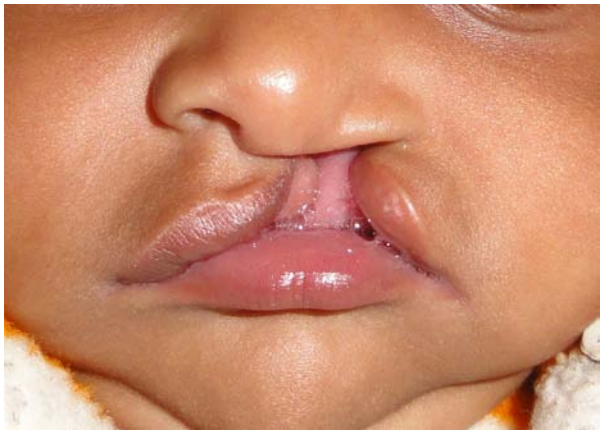
A majority of the surgeons found low rates of cracking or peeling with the *SurgiSeal* product (84%). This is good compared with the 58% of surgeons in this study who experienced cracking or peeling with *Dermabond* in the past. We believe this is mainly due to the flexibility of the product which bends better with the soft tissue movement underneath. The *SurgiSeal* also is applied with more ease so that the material may be placed in a thinner more evenly distributed layer over the tissues.

When reviewing the questionnaire it was easy to see the surgeon's appreciation of the *SurgiSeal* product. 5 of 6(83.3%) surgeons noted they thought the cosmetic result of using *SurgiSeal* was better(4 or 5 on the ranking scale) than sutures alone. 83.3% thought the flexibility of the *SurgiSeal* was better than that of *Dermabond*, and this was shown to be 100% by the surgeons who had used *Dermabond* in the past. 66% of the surgeons found the ease of use to perform better than *Dermabond*. 100% of the surgeons who had used *Dermabond* in the past noted that visualization of the wound was better than with *Dermabond*. Most significantly, 100% of surgeons who had experience with *Dermabond* preferred the performance of *SurgiSeal* to *Dermabond*.

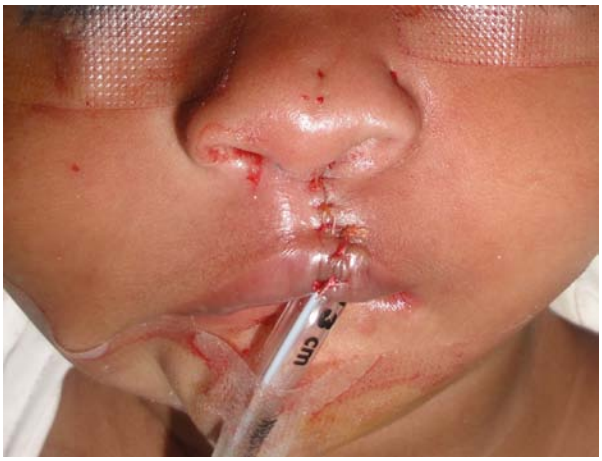
This study was an excellent way to evaluate the use of *SurgiSeal* in pediatric plastic surgery patients. The product held up very well under extreme surgical conditions such as those found in Guwahati, India. The 6 surgeons evaluating the product agreed that they found the use of *SurgiSeal* to be improved over their experience with *Dermabond* especially with its flexibility and visualization properties. All 6 surgeons commented that they would like to use the product in the future. Several ways this study could be improved would be to put *SurgiSeal* and *Dermabond* into a randomized study to evaluate its healing and antimicrobial properties. Also developing a scale to rate the wound appearance cosmetically would lead to a better standardization of results which could be more easily compared to *Dermabond* in competing trials.

Overall, the use of *SurgiSeal* by this group of surgeons had favorable results when used for surgical patients. Additional study to compare its antimicrobial properties and cosmetic advantages would be desired. However, at this time it is easy to see that *SurgiSeal* is an excellent addition to the wound closure product family and a viable skin adhesive that can be used in similar situations in which *Dermabond* had been used in the past.

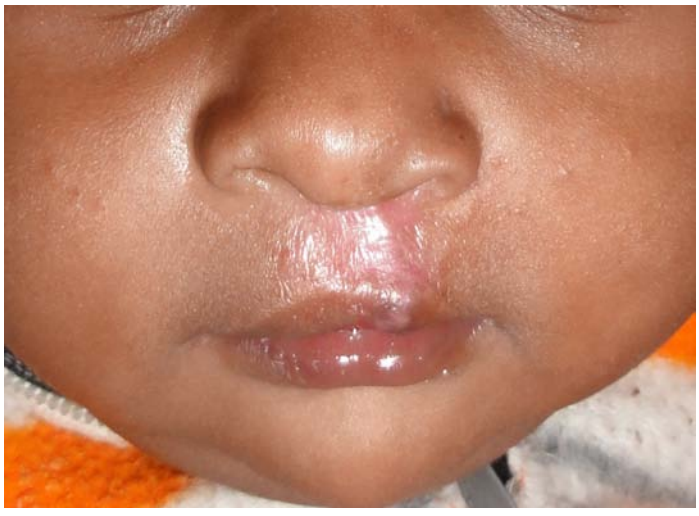
PRE OP PHOTOS

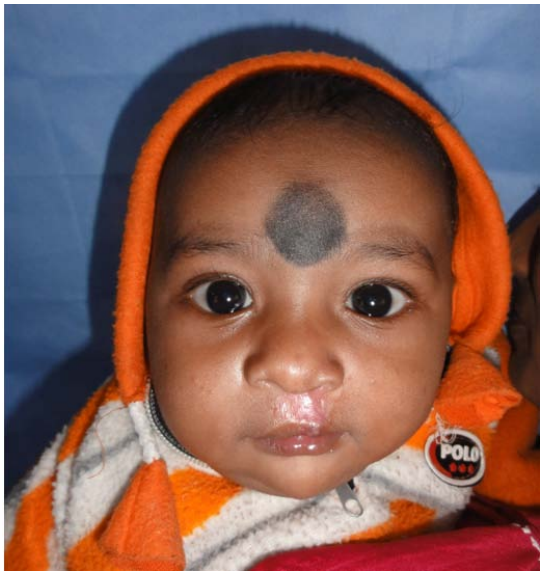


IMMEDIATE POST OP PRIOR TO PLACEMENT OF SURGISEAL WITH VICRYL SUTURES IN PLACE



4-7 DAYS POST OP





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