SURGISEAL® Topical Skin Adhesive: A 190 Patient Multi-Center Study

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BACKGROUND: 2-Octyl Cyanoacrylate has become the topical skin adhesive of choice for most physicians, as evidenced by the growing popularity of the use of these products for surgical wound closure and as a replacement for dermal skin sutures. Adhezion Biomedical's SURGISEAL® is one such 2-octyl cyanoacrylate skin adhesive that has challenged other topical skin adhesives, including the long time market leader, Dermabond® (Ethicon, Inc.) since its U.S. market introduction in early 2010.

TRIAL DESIGN: Five (5) physicians from five (5) separate health care facilities provided prospective data from a total of one hundred ninety (190) patients who underwent twenty-one (21) different procedures utilizing SURGISEAL Topical Skin Adhesive. Data collected was based upon a 45-question patient data collection form completed after each procedure.

RESULTS: 99.5% of the respondents reported an overall positive benefit from the use of SURGISEAL as an adhesive and wound care sealant, while 100% reported better or equivalent cosmetic results compared to sutures. The data also revealed that in 100% of the procedures physicians were able to dispense and apply SURGISEAL adhesive without the applicator clogging.

CONCLUSION: SURGISEAL adhesive performs exceptionally well as a topical skin adhesive compared to surgical sutures and other available skin adhesives.

In early 2010, Adhezion Biomedical, LLC launched its 2-octyl cyanoacrylate SURGISEAL® Topical Skin Adhesive. Unlike other 2-octyl cyanoacrylate skin adhesives, SURGISEAL adhesive is an ultra-pure formulation that is created through a proprietary activation process after complex polymerization, de-polymerization and distillation processes. The result is a solvent- and plasticizer-free solution with exceptional flexibility, strength and the highest Moisture Vapor Transmittance Rate (MVTR) of any surgical cyanoacrylate adhesive available. The product is stored in a sterile, blister pack applicator that will not clog and provides the widest path of microbial protection available.

Between January and June 2011, a multi-center product trial was conducted at five (5) separate health care facilities by five (5) individual surgeons. These physicians had prior experience with Dermabond and other skin adhesives available in the market. Data was collected from 190 surgical cases that represented 21 different procedures.

METHOD

Each physician was provided a three page, forty-five question patient data collection form for use with each surgery. The data collection form included questions relating to, among other items, the surgical procedure, the health of the patient, the surgical incision and the performance of SURGISEAL.

Data was collected post-operatively at one or more of the following intervals: 1-4 days, 5-7 days post op and 25-30 days post op. Physicians completed and signed the patient data collection form prior to returning to Adhezion Biomedical

to be reviewed for completeness and then, data compilation.

PATIENT DATA COLLECTION FORM RESULTS

77.3% of the data forms were collected on day 1-4, while 21.6% were collected on day 5-7 and 1.1% was collected 25-30 days following surgery. 88.9% of the patients were in fine to good health at the time of surgery. 43.1% were male versus 56.8% female. 45.8% were 60 years of age or older, while 54.2% were under 60.

TYPES OF PROCEDURES

Twenty-one different surgical procedures were performed including plastic & reconstructive, orthopedic and gynecological surgeries. These are represented in Table 1.

TABLE 1. Procedure Type & Quantity

Abdominoplasty	10
Liposuction	9
Bilateral Subpectoral Silicone Augmentation	59
Bilateral Subpectoral Saline Augmentation	18
Implant Exchange	3
Mastoplexy	3
Mastoplexy with Subpectoral Silicone Augmentation	6
Bilateral Breast Reduction	6
Bilateral Removal of Axillary Tissue	1
Laparoscopic Hysterectomy	21
Laparoscopic Hysterectomy/LOA/RSO	3
Laparoscopic LAO	10
Laparoscopic RSO	7
Laparoscopic Myomectomy	1
Scar Revision	3
Capsulotomy	1
Total Knee Arthroplasty	18
Total Hip Arthroplasty	6
Gluteus Medius Repair	1
Lateral Unicompartmental Knee Arthroplasty	1
Shoulder Rotator Cuff Repair (3)	3

WOUND CHARACTERISTICS

The location, number, length, depth and width of wounds were recorded and depicted below in Table 2. 42.1% of the wounds were 0-2.0 millimeters, 14.7% were 2.1 – 4.0 millimeters, while 43.1% were greater than 4.0 millimeters. 80.5% had widths of 0 – 3.0 millimeters and 57.9% had incision depths greater than 6.0 millimeters. There were no reports of wound dehiscence and 1 observation (0.5%) of partial dermal breach at day one. Physicians reported that in 96.8% of the cases, approximation time (edges held before releasing) was less than 60 seconds and holding strength expectations were met 97.4% of the time. Finally, in 97.9% of the cases, SURGISEAL was reported to have approximated wound edges adequately and without difficulty.

TABLE 2. Wound Sizes (based on completed data collection forms)

Wound Length	Procedures	Percentage
0mm – 2 mm	80	42.1%
2.1mm – 4.0mm	28	14.7%
>4.0mm	82	43.1%

Wound Width	Procedures	Percentage
0mm – 3.0mm	132	69.5%
3.1mm – 6.0mm	44	23.1%
>6.0mm	14	7.4%

Wound Depth	Procedures	Percentage
0mm – 3.0mm	36	18.9%
3.1mm – 6.0mm	44	23.1%
>6.0mm	110	57.9%

COSMETIC RESULTS AND WOUND HEALING

In 80% of the patient data collection forms, physicians noted that SURGISEAL® adhesive provided a better cosmetic result than sutures. In 20% of the cases, physicians reported that the cosmetic result observation was equivalent to sutures. In 129 or 68% of the cases, physicians indicated that wound healing occurred sooner than expected (as compared to sutures).

FLEXIBILITY

Physicians also compared the flexibility of SURGISEAL to that of other skin adhesives with which they had experience. In 154 surgeries or 81.0% of the time, physicians found SURGISEAL to have "better flexibility" compared to other adhesives. See Figure 1.

EASE OF USE

SURGISEAL adhesive is stored in a foil and Barex blister applicator that can be opened and applied very easily as evidenced by the high rate of positive confirmation observations, i.e. in 97.4% of surgeries, SURGISEAL was reported as "easy to use". See Figure 2.

COVERAGE AND DURATION

In 72.6% of the cases, physicians found that one (1) applicator of SURGISEAL was an adequate volume for the procedure. Since some of these procedures require extraordinarily long incisions, i.e., abdominoplasties, breast augmentation, etc., these results substantiate the excellent coverage of the SURGISEAL 0.35ml applicator. Importantly, physicians also noted that in 129 cases or 67.9% of the time, SURGISEAL was observed to "stay on the wound longer than other adhesives." In 57 surgeries, or 30% of the cases, physicians reported that SURGISEAL was equivalent in product duration. See Figure 3.

DISCUSSION

In this study, SURGISEAL® Topical Skin Adhesive demonstrated favorable results in a variety of plastic and reconstructive, orthopedic and gynecological surgical procedures. As an alternative 2-octyl cyanoacrylate topical skin adhesive to *Dermabond*®, the current market leader, SURGISEAL adhesive provides many important physical properties that substantiate its value in these and other surgical procedures.

Most gratifying in this study, 99.5% of the respondents reported an overall positive benefit from the use of SURGISEAL as an adhesive and wound care sealant, while 100% reported better or equivalent cosmetic results compared to sutures. Finally, on 100% of the data collection forms, physicians noted that they were able to dispense and apply SURGISEAL without the applicator clogging, a well-acknowledged characteristic of other topical adhesive applicators on the market.

FIGURE 1. Flexibility vs. Other Skin Adhesives

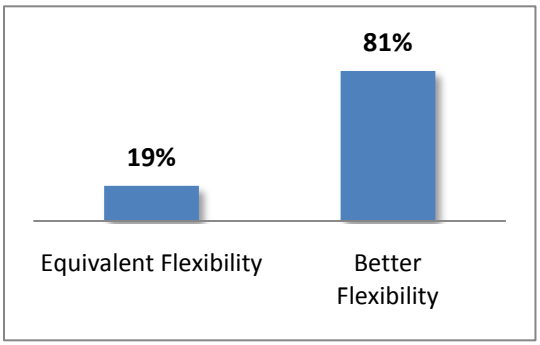


FIGURE 2. Ease of Use in Number of Responses

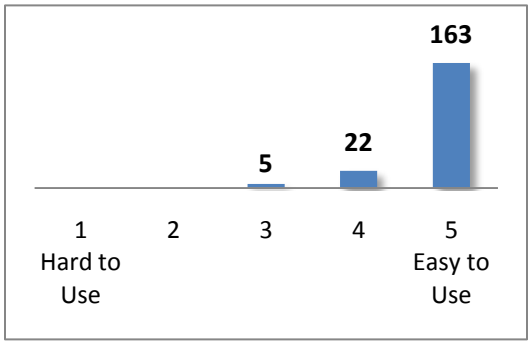
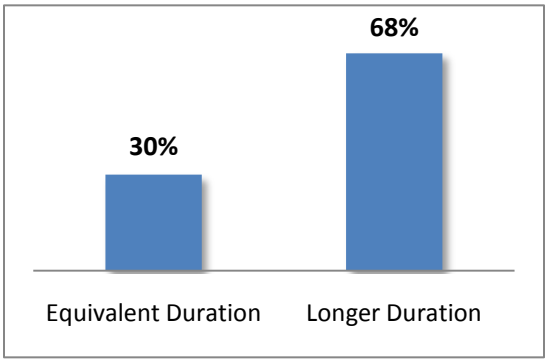


FIGURE 3. Coverage and Duration



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