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In Vitro Wound Closure Strength of SURGISEAL® versus Dermabond Advanced

Test Article: SURGISEAL® (125112) and Dermabond Advanced (DJR680)

Performing Laboratory: Adhezion Biomedical, LLC
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Project Summary:

Wound closure strength of SURGISEAL® and Dermabond Advanced was measured on pig skin after the incision closure procedure is completed. The average wound closure strength of SURGISEAL® is stronger than that of Dermabond Advanced.

Sheng Zhang, Director of R&D

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OBJECTIVE: An in-vitro study to evaluate the wound closure strength of SURGISEAL® versus Dermabond Advanced

MATERIALS:

1. SURGISEAL® – 125112
2. Dermabond Advanced-DJR680
3. The accelerated aging oven
4. Mark-10 tensiometer
5. Pig Skin with supporting fat layer (about 2 × 4 inch).
6. Disposable scalpel
7. Sterile gauze
8. Isopropanol
9. Ruler

DEFINITIONS:
Tensiometer - Tensile strength tester

METHOD: Incisions of 1 inch in length were made on the middle of the pig skin. The incisions were then closed by Stylus SURGISEAL® according to the IFU. The disrupting forces of the closed incisions were then measured by a Mark-10 tensiometer at 25mm/min. Ten pig skins were used for the test article.

PROCEDURE:

1.) Prepare a pig skin (2 × 4 inch) by wiping the surfaces of the skin with sterile gauze saturated with isopropanol and make sure to remove all oily substances from the pig skin.
2.) Then wipe the surface with sterile gauze to remove isopropanol.
3.) An incision of 1 inch in length is made at the mid-section of the sample.
4.) While holding the wound edges of the pig skin substrate together with gloved fingers or forceps, SURGISEAL® and Dermabond Advanced were applied according to their IFUs. For SurgiSeal, lightly apply the first layer of adhesive parallel with the incision following the Wait for 30 seconds and then apply the second layer of adhesive and maintain the approximation of the wound edges of the incision with gloved finger or forceps for an additional 60 seconds. For Dermabond Advanced, slowly apply the adhesive in one continuous layer to the incision while maintaining the approximation of the wound edges of the incision. Maintain the wound edges for 60 seconds after the application.
5.) About 1 hour 15 minutes after application, the skin incisions are to be pulled apart on a Mark-10 tensiometer with a cross-head speed of 25 mm/min
6.) Record the force at which, failure occurred, as shown in the following tables.

RESULTS:

SURGISEAL® or Dermabond Advanced was used to close the incision made in the middle of the pig skin with supporting fat layer. After the incisions were closed by applying SURGISEAL® or Dermabond Advanced, the pig skins were mounted onto a Mark-10 tensiometer to measure the wound closure strength. The disrupting forces were recorded when the incision was pulled apart as shown in Figure 1.

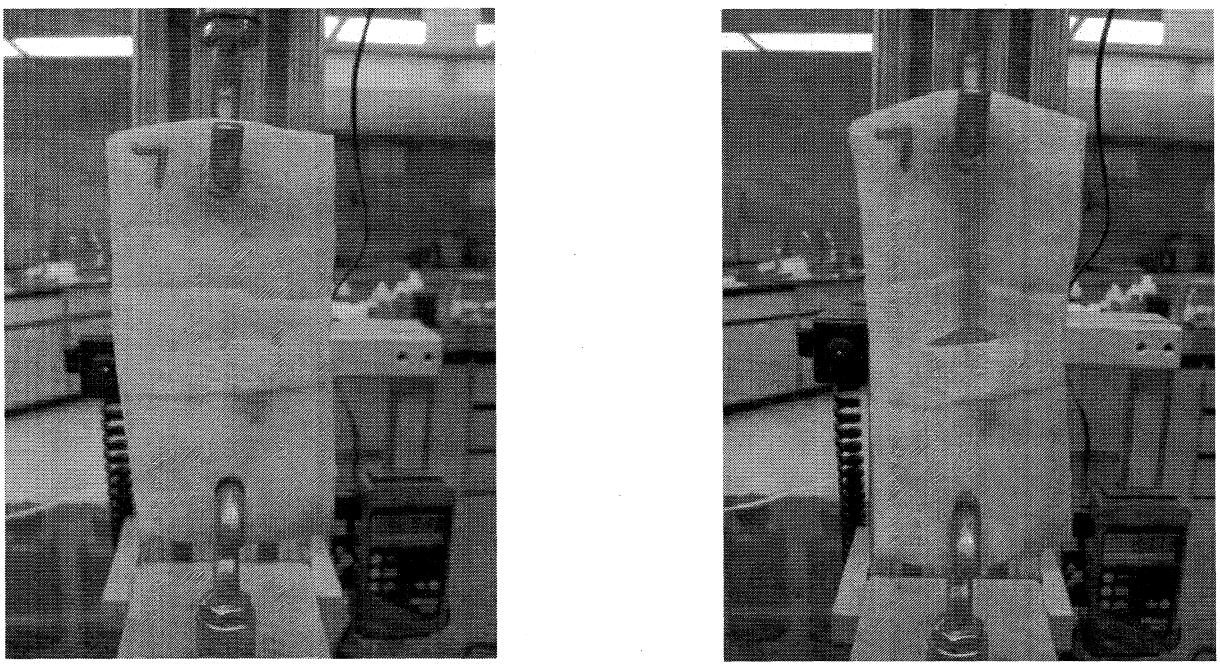

Figure 1. The closed incision pulled apart by tensiometer.

The test was repeated ten times and the results were summarized in Table 1 and Figure 2. The wound closure strength data of OctylSeal obtained on May 24th, 2012 was also included in Table 1 for the purpose of comparison, which was summarized in Adhezion's report # 2012-ABM-012. The average wound closure strength recorded as maximum load for SURGISEAL®, Dermabond Advanced, and OctylSeal is 4.96, 3.26, and 3.36 lb, respectively, with a standard deviation of 1.24, 0.53, and 0.83, respectively.

Sponsor: Adhezion Biomedical, LLC

Table 1: Wound closure strength of SURGISEAL® versus Dermabond and OctylSeal

Product	Wound closure strength (lb)											Standard deviation
	1	2	3	4	5	6	7	8	9	10	average	
SURGISEAL®	6.2	3.0	6.6	4.2	6.4	4.4	6.0	4.0	4.2	4.6	**4.96**	1.24
Dermabond Advanced	3.8	2.8	4.0	3.6	3.2	3.6	3.0	2.2	3.4	3.0	**3.26**	0.53
Octylseal	3.8	2.6	3.6	3.0	3.8	2.6	3.0	3.6	5.2	2.4	**3.36**	0.83

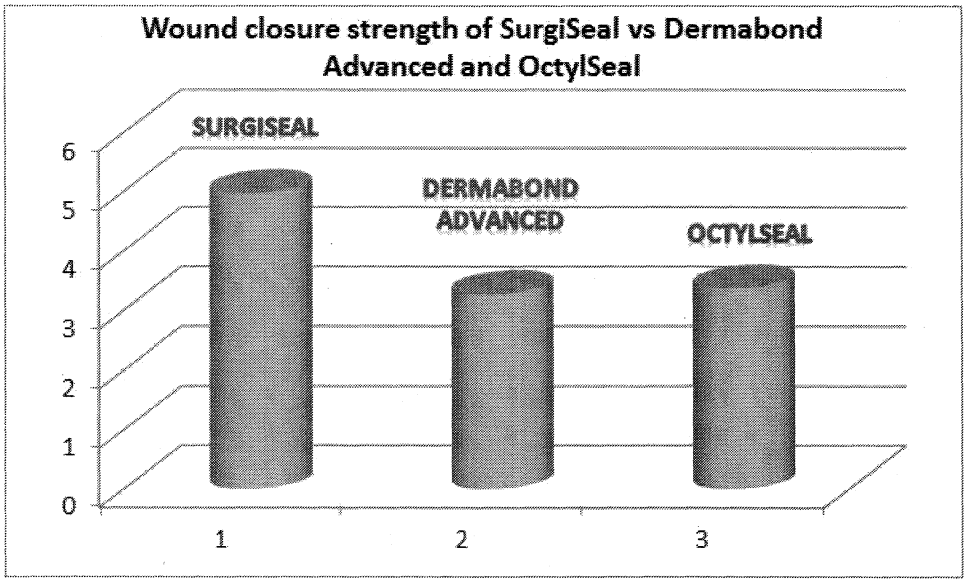

Figure 2. The average wound closure strength of SurgiSeal vs Dermabond Advanced and OctylSeal

CONCLUSION: The test confirms that wound closure strength of SURGISEAL® is stronger than those of Dermabond Advanced and OctylSeal.

Analysts' Signature:

Investigators and analysts for wound closure strength of SURGISEAL® vs Dermabond Advanced and OctylSeal

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