



Scapa MEDIFIX® Long-term Wear Solutions

Second Evaluation of Adhesive Wear Duration for Wearable Devices

Sticking to our commitment to develop long-wear adhesives for secure medical device fixation

That's why we have conducted a series of human wear studies to evaluate different adhesive formulations and substrate combinations for varying wear times.

Long-term wear solutions for optimal outcomes

New technology is rapidly expanding the wearable medical devices market. With over 90 percent of wearable medical devices being adhered directly to the patient's skin, requirements call for skin friendly solutions that can be worn for longer periods of time.

Scapa Healthcare crafts custom skin interface solutions that deliver comfort, compliance, and ultimately better patient outcomes. We consider the following factors when developing a wearable adhesive solution:

Materials:

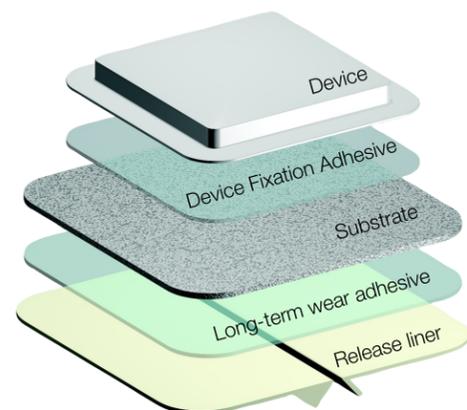
- Substrate/adhesive interactions
- Skin friendly, biocompatible, safe
- Performance and fixation

Human behavior:

- Ease of application
- Comfort, breathability, gentleness
- Ability to wear in water

Clinical considerations:

- Skin cell rate renewal
- Moisture and oxygen transmission rates
- Relationship and size of occlusion to adherence area



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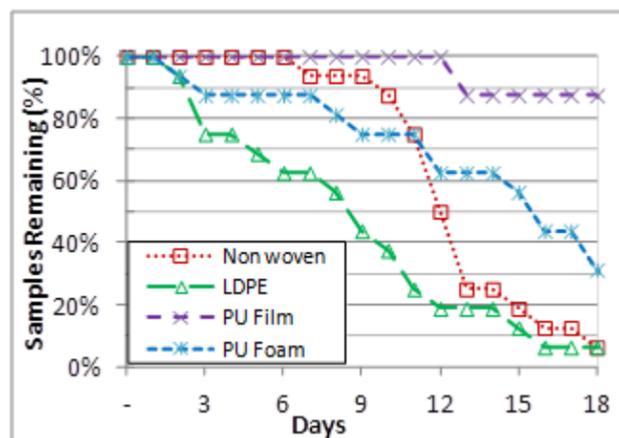
Further evaluations of our most promising acrylic adhesive

In our first wear study, Adhesive A demonstrated 80% wear durations of 10.5 and >18 days when coated on a Nonwoven PET and PU Film, respectively. Adhesive A is not a straight adhesive, but a highly formulated adhesive, which can be readily altered. Further wear studies were conducted using five formulations of Adhesive A coated on a Nonwoven PET and PU Film.

No statistically significant difference was observed in the effect of sample location, age, gender, hours of sweating or bathing on the wear duration of the samples in these studies.

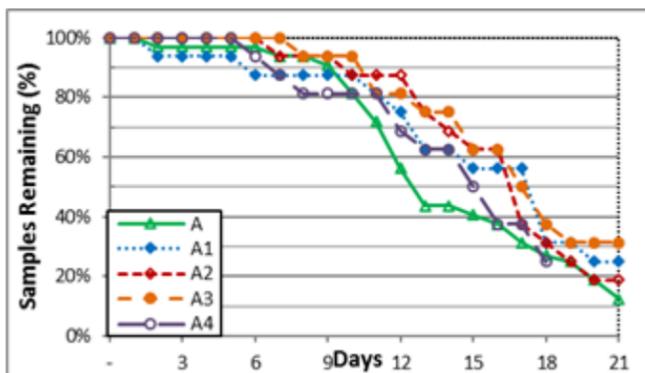
First Study Results

Adhesive A on All Substrates

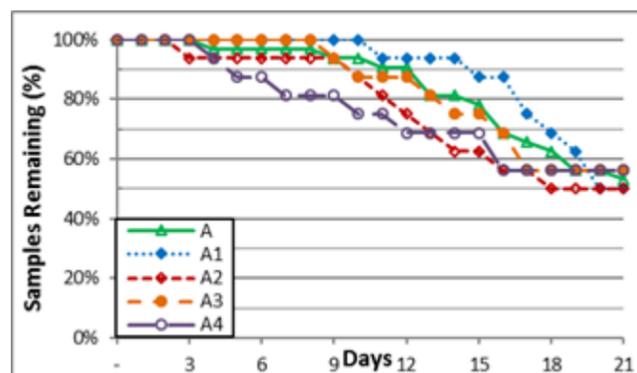


Second Study Results

Adhesive 'A' Formulations on Nonwoven PET



Adhesive 'A' Formulations on PU Film



Conclusion

This extension of the Healthy Human wear duration studies focused on identifying formulations of the Adhesive A that would have longer wear times than the original Adhesive A formulation. Coated on the Nonwoven PET substrate, all of the alternative Adhesive A formulations (A1-A4) demonstrated better 80% wear: ranging from 11.5 to 12.5 days versus the 9.5 day wear of the original A formulation. On the PU Film substrate, two of the alternate Adhesive A formulations (A1 and A3) demonstrated better 80% wear: ranging from 13.5 to 16.5 days versus the 12.5 day wear of the original A formulation.

These additional studies carried out by Scapa Healthcare have identified even more candidates for long-wear adhesives for wearable medical devices out to as long as 16.5 days (for 80% wear).

1. Bobo J, Morenz J, Evaluating the Wear Duration of Acrylic Wearable Device Adhesives on Healthy Human Volunteers. Scapa Healthcare, 2016.

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scapahealthcare.com/literature/

healthcare@scapa.com
 scapahealthcare.com

North America
 +1 860 688 8000

Europe
 +44 (0)161 301 7400

Asia
 +852 2439 4330

South America
 +55 11 2589 6003

