

# Evaluation of Tape Construction on Wear Time for Various Tapes on Human Volunteers: 15-day Study

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Wearable technologies in the healthcare market have been available for a very long time, for example, hearing aids, temperature monitors, pulse oximeters and the like. A study in 2014 by MSI and McAfee reported that 70% of people think that wearable technologies will soon send health vitals readings to physicians.<sup>1</sup> The use of adhesives to hold a device on to the skin is not a novel idea. Over time, improvements have been made to adhesives, with adhesives demonstrating a variety of properties to consider. The purpose of this white paper is to provide solutions for choosing adhesives and adhesive systems for creating a well thought through device. 14 days are considered 'long term wear' for the wearables market. In order to document 14 days, (good practice procedure) a study needs to extend to 15 days to substantiate that statement. The studies are presented in the order they were conducted.

Consider for a moment alternatives to an adhesive-based device. For example, the use of microchips, which are implanted in the body for collecting information or transmitting data. Although a viable solution, it is fraught with difficulties. First, it is an invasive procedure. The human body is created to reject foreign bodies; therefore, a chip can be rejected or migrate within the body. Will it be painful to remove? An appropriate scanner for each chip is essential. Would the chip need periodic replacements? Are all the components safe for implantation? Engineers may find that a more agreeable solution is a chip adhered to the body vs. implanted in the body.

For these reasons, a variety of tapes with different properties exist and it is important to choose the correct construction for the desired application. Whether synthetic rubber-based adhesives, acrylate adhesives or silicone adhesives, there are features and benefits to each of these medical adhesives to evaluate.



<sup>1</sup> Eichorn, Kim; Ross, Eva (16 September 2014). "U.S. Consumers Predict Unprecedented Connectivity in 2025, but Security and Privacy Concerns Linger" – via ProQuest.

# About this study

We have been examining various tapes for use with attachable devices. Prior to conducting these studies, three longer term clinical studies were completed (8-day, 15-day, and 21-day). These studies led to narrowing adhesive choices along with investigating other adhesive properties that impact duration. To establish a long-term guideline, we conducted two 15-day human studies, one with 20 volunteers and one with 16 volunteers.

With the previous study outcomes in mind, we designed follow-up studies to investigate the efficacy of these tapes in securing a mock device to the body. The primary objective of **Study 1: Impact of Extended Adhesive Edge on Wear Time** was to confirm or deny the use of an extended border (or skirt) as a method to promote longer wear.

Extrapolating lessons learned from **Study 1, Study 2: Effect of Overall Tape Construction** was designed by taking the adhesives with the greatest likelihood for long term wear, and combining them with a skirted design. The investigational silicone adhesive, which is perceived as gentle to remove by the subjects, was part of this study to determine the feasibility of seven-day wear time.

In summary, whether synthetic rubber-based adhesives, acrylate adhesives or silicone adhesives, there are features and benefits to each of these medical adhesives to evaluate and consider. The results showed clearly that the addition of a skirt increased wear time. Silicone adhesive is the gentle-to-the-skin solution, the duration of wear does not match that of acrylate adhesive, up to eight days is still significant.\* Chemistry of the adhesive is important.

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## Recommendations:

- Even when using a tape of the same construction, an extended tape edge (“skirted”) helps holds the device better than a “non-skirted” tape edge.
- Chemistry of the adhesive is important. These studies showed that not all adhesives or tape systems perform equally.
- Silicone adhesive is the gentle-to-the-skin solution. And while the duration of wear does not match that of acrylate adhesive, up to eight days is still significant.\*
- The need to explore a range of adhesives and backings cannot be stressed enough when choosing materials.
- Future innovations point to longer wear adhesives.

\*Disclaimer: Based on this investigational study of experimental, non-commercialized product. Further study needed.

## Study Notes:

- The studies outlined here were approved by an Institutional Review Board.
- 14 days is considered to be long-term wear. In order to document 14 days, a study needs to be 15 days to substantiate that statement.
- The mock devices used in the studies are small polycarbonate discs approximately 30mm x 46mm x 3mm. These discs simulated occlusive devices and added four grams of weight to the underlying tape.
- Over the course of the study, healthy participants engaged in normal activities including showering and exercise. Participants refrained from swimming and hot tub use.

With over 55 years in the medical adhesive business, no one knows skin better than 3M. We understand the unique challenges of this delicate surface and of the larger design process. Working together, we can help medical device users Wear It Well.

**We'll stick with you—by providing the right tape for your device.**

**Working together, we can help your customers Wear It Well.**

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