Thermotape High-adhesion Medical Tape Comparison Study

June 21, 2022

University of Washington

Consent Form

[Thermotape]

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We would like you to participate in a research study. This form will provide information for you to determine if you would like to be part of this study. Please read this form carefully, before deciding. Please do not hesitate to ask any questions about parts of the study that are unclear.

A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Purpose of this Study

Medical tapes are important as it is used to hold medical devices, such as an IV line, in place. However, patients often experience lingering side-effects, like skin redness or minor injuries during removal of high adhesion medical tape. The process of removing high adhesion medical tape is also time consuming and challenging for nurses. As a result, many nurses turn to use low adhesive medical tape as an alternative, however these tapes are often much weaker resulting in medical devices failing to properly hold in place.

The purpose of this study is to compare three different medical tapes for its safety and performance. The study will take place for 24 hours. Afterwards, the level of pain, safety, and potential effects after the tape is removed, with and without the use of a heat pack, will be monitored. The application and removal of the tape will be conducted by the research team in the lab with training from consultant and Thermotape team member Ms. Ann Marie Taroc, MSN, RN, CPN.

Study Procedures

You will go to the Fluke Hall, room 104, and sit in a chair. A member of the research team will explain the procedures that has been approved by our consulting nurse. Both forearms will then be cleaned by an isopropyl wipe. The areas where the tapes are to be applied will then be inked using a skin marker. Three pieces of tape will be applied on each forearm, for a total of six tapes. You will be asked to not participate in any activities that may get the tapes wet for the duration of the 24-hour study. An activity log will then be given to document the next 24 hours of the study.

After 24 hours, you will return to the same location as before and sit in a chair. A member of the research team will provide you with a survey to rate the pain felt from each tape removed. For one forearm, a medical grade, commercial heat pack will be applied for tape removal. After all tape has been removed, photos will be taken of both forearms. You will then wait 15 minutes to examine for any signs of skin irritation.

If social distancing guidelines disallow two people to be in the lab at a time, then the testing will be performed by you. Instructions will be provided through Zoom. Heat packs and remover solvent will be provided, in the event this is necessary. You can stop the procedure at any time for any reason and all your data will be removed. Only your forearms will be recorded or photographed.

The application and removal process should take no more than 45 minutes. No personal questions will be asked, and you may refuse to answer any questions. You may also be asked to be removed from the study at any time, with no consequences.

Risks, Stress, or Discomfort

A low degree of risk will occur when removing tape from you. The heat pack applied is a commercial product designed for human skin use and will only be applied for a few seconds. Side effects that may occur are skin injuries, such as skin tearing, stripping, redness, irritation, or inflammation. If skin tearing or stripping occurs, an adhesive remover will be used to remove the tape from your skin. Cold packs will be available for use in case of injury. There is also a low risk of an infection occurring in the event of a skin tear. To migrate this risk, Neosporin™ and band-aids will be provided.

Benefits of the Study

There will be no direct benefits if you choose to participate in the study, however the knowledge obtained will be used to benefit society.

Source of Funding

The research team and/or the University of Washington is currently receiving funding through the WE-REACH program at the University of Washington, which acquires funding from the National Institutes of Health.

Use of Information and Specimens

The data and/or specimen obtained from you may be used in future research. We may remove any information that may identify you from the data and specimen gathered. If done, the gathered data and specimens will be provided for other researchers or studies without further permission from you. If we want to use or share data from this study, that identifies you, then a review board will decide whether further permission is required from you.

Confidentiality of Research Information

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

We have a Certificate of Confidentiality from the federal National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out information, documents, or samples that could identify you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the institution(s) conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form;

The Certificate expires when the NIH funding for this study ends. Currently this is October 10th, 2022. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected."

Other Information

You may withdraw and/or refuse to participate in this study at any time without any consequences. Your decision to participate will not impact your academic status or any future opportunities that may occur. Being a subject in this study is not required to be a research assistant on any project.

A $50 Amazon gift card will be given to those who complete the study. Completion of the study will involve coming in for tape removal, even if no tape is left on the skin, and completion of a post-removal survey. It will be delivered 1 to 2 weeks after the subject has completes the study.

After tape removal, there is a high possibility that there will be lingering redness, from tape removal, and skin marker ink. This is normal and the redness and ink should fade after a few days.

Research-Related Injury or Inquiry

If you think you have been harmed from this study, please contact Eric Seibel at 206-235-0447.

If you have any questions about the study, please contact one of the researchers listed below:

Shawn Swanson - sshawn@uw.edu

Vivian Luu – vluu2@uw.edu

Joelle Tudor - tudorj@uw.edu

Subject's Statement

This study has been thoroughly explained to me and I have had an opportunity to ask questions. I volunteer to take part in this research. If I have any additional questions or have been harmed by this study, I can contact any of the researchers listed on the first page of this consent form. If I have any questions about my rights as a research subject, I can call the Human Subjects Division at (206)-543-0098 or call collect at (206)-221-5940. I will receive a copy of this consent form.

Printed Name of Subject Signature of Subject Date

Copies to: Researcher

Subject