

Thermotape High-adhesion Medical Tape Comparison Study

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Background:

Currently, modern medical tapes can be classified into two categories, high-adhesion tape, and low-adhesion tape. Both tapes, however, are not sufficient for use in a medical environment; high-adhesion tape, when removed, can cause medical adhesive related skin injuries (MARSI), which is liable to cause patients to have to return to the hospital to treat it, resulting in a dramatic increase in medical expenses once fully recovered. Conversely, low-adhesion tape is ill-suited for securing medical devices, such as IV lines, in place because of having low adhesion. As a result, a patient's ability to recover is impacted, overall increase medical expenses from an extended stay at the hospital.

Thermotape is designed to combat both flaws, by acting as a high-adhesion tape until heated, where it can be removed as easily as low-adhesion tape.

Objective:

This objective of this study is to compare the safety and performance of Thermotape compared to Tegaderm™ tape and Kind™ tape over the course of 24 hours. In regard to safety, pain inflicted during removal and any potential effects will be monitored for Thermotape versus Tegaderm™ and Kind™ tape.

Design:

A single blinded comparative clinical study, where researchers will know the tape being applied while the subjects do not.

Methods:

Consent will be obtained from the subject as they enter the building for tape application. This will be done by providing a paper consent form detailing the necessary details concerning the trial. If consent is obtained, they will be allowed into the room for tape application.

Before tape application, both forearms will be cleaned using an isopropyl alcohol wipe and skin markers will be used to draw lines, with two inches of spacing between, to separate areas of tape application. The marks began at the elbow and continued down the forearm. Following the pre-tape preparations process, Thermotape, Kind™ tape, and Tegaderm™ tape will be applied horizontally, in vertical

succession. Following Thermotape's application, a finger will be used to rub Thermotape in a vertical motion to ensure that the tape, especially edges, are fully adhered. The same procedure will be used for Kind™, however Tegaderm™ will not require the same adhesion procedure, as noted by a nurse practitioner. The tapes will be applied in a random order. Once all tapes are applied, researchers will give the following speech: "Now that the tapes have been applied, please do not do any physically extraneous activities, like swimming in the ocean, running a marathon, or storm chasing. Basically, any activities that make you sweat. Additionally, please do not shower until we remove the tapes, even if you really want to. If you do end up getting the tapes wet, through sweat or by showering, please note it down in the activity log on the back of your activity log. Also, try not to pick at the tapes, even if the corners start lifting. Thank you and we'll see you back tomorrow!" The speech requests that subjects are to not participate in strenuous physical activity or shower for the duration of the 24-hour study. One researcher is to apply the tape to the participants. Each tape will be cut 1 inch wide by 2 inches long.

When subjects return for tape removal, they will be given a pain survey, with a 0-to-10 Wong-Baker scale, to fill out after each piece of tape is removed. One photo will also be taken of the forearms to document the state of the subject's forearms 15 minutes after tape removal. Each piece of tape is then to be analyzed for wear using a 0-to-7 point scale.

When removing the tapes, an edge will first be lifted and then it will be peeled at an angle of 180° at a consistent rate. If a hair is encountered, the tape will be removed following the root of the hair to its tip. After the removal of each piece of tape, it will be placed on a glass slide and taped down for later quantification of cell and hair counting caused by tape removal. No gloves will be used throughout the process. During removal, if a subject shows signs of extreme discomfort or the skin appears to start tearing, manual removal will be stopped and a commercial silicon-based remover, Brava, will be used to remove the tape instead. To do so, Brava will be rubbed all over the tape, including the edges, and under the skin after removal of the tape. Gloves will be used in the case of using Brava to remove tape.

Removal of tape from both forearms will stay consistent, however one forearm (left), will use a Dynarex heat pack to assist in tape removal. Prior to heat pack activation, a corner for each tape sample will be lifted. After, the heat pack will be activated and kneaded for one minute before application onto the subject's skin. Then, the heat pack will be folded in half and applied to each piece of tape for 30 seconds before removal. The heat pack will be kneaded for 20 seconds between each tape removal.

Following the removal of all pieces of tape, the pain survey is collected, and each subject will be asked to wait 15 minutes following removal to examine for any redness that may have occurred. A 0-to-4 point scale will then be used to assess for erythema present on the forearms.