The objective of this study was to determine the relative gentleness of a silicone adhesive tape* compared to a control tape. This is recognized for its gentleness and is used as a mainstay in cosmetic surgery and infant care. However, its effect on the neonatal skin has not been well described.

Methods

Overview: This study compared the relative gentleness of two surgical tapes*: 1) the silicone adhesive tape* and 2) the control tape. The study was conducted in a neonatal intensive care unit (NICU) environment where the infants would normally be monitored and treated. The study was prospective and randomized.

Subjects: Twenty full-term infants participated in this study (10 male, 10 female, median age 27.0 weeks). All infants were enrolled in the study within 72 hours of birth and were in the primary NICU environment. The infants were randomized to one of two test sites: a silicone adhesive tape site or a control paper tape site. The infants were monitored for 48 hours after application, the change in adhesion is noted to be 2-4 fold. Therefore, adhesives that have a similar profile are safe and effective. The tapes were applied on the skin and monitored for the time of removal. In contrast, a new silicone adhesive tape* has been introduced that provides more comfortable fixation that remains constant over time.

Silicone Tape Technology Overview

Silicone adhesive tapes have been found to be less irritating than traditional tape. This is because the tapes are able to conform to the skin's surface, allowing for better adhesion and less discomfort. However, studies have shown that silicone adhesives may cause more skin trauma at the time of removal. In contrast, a new silicone adhesive tape* has been introduced that provides more comfortable fixation that remains constant over time.

Figure 1: Schematic comparison of the differences in the mechanism of adhesion of traditional acrylic adhesives and silicone adhesives.

Discomfort Assessment: The infants were videotaped just prior to and during the tape removal process. The videotapes were reviewed by a blinded assessor and scored for discomfort using the Faces, Legs, Activity, Cry, and Consolability (FLACC) published procedure. The net change from baseline score was analyzed and differences were evaluated with a one-sample Wilcoxon signed-rank test.

Tape Edge Lift Assessment: This was accomplished using a validated histocytic collagen assay (BCA) colormetric detection and protein quantification. Differences were assessed with the Wilcoxon matched-pairs signed-rank test.

Hair Removal: This was done by a trained hairdresser using a hair removal tool. The number of hairs removed was counted using a low power stereo microscope.

Face & Leg Assessment: This was accomplished by a trained assessor using a validated histocytic collagen assay (BCA) colormetric detection and protein quantification. Differences were assessed with the Wilcoxon matched-pairs signed-rank test.

Results

Erythema & Edema

Results are presented in Figure 4. There was a slightly higher level of edema and erythema at the site of both test bands compared to baseline (p=0.001). There was no external presence on any of the test sites for any of the two test bands. The mean erythema response for both test sites was significantly lower than the control tape (p=0.0129).

Skin Stripping/Denudation

Results are presented in Figure 5. There was very little skin stripping observed with either tape. None of the infants in the silicone tape group exhibited any stripping at all, and there was only a very slight level of stripping observed with the control paper tape. There was no significant difference in the mean level of stripping between the two test tapes.

Skin Tear

There were no observations of skin tears at either site. It is possible that the use of a randomized, controlled study may not be necessary for this type of comparison.

Discomfort

Results are presented in Figure 6. There was significantly less discomfort at removal for the silicone adhesive tape than the control paper tape. The mean change from baseline score for the FLACC scores was 0.4 for the silicone adhesive tape compared to the control paper tape (0.10).

Skin Edge Lift

Results are presented in Figure 7. There was a low level of edge lift for both tapes and no significant difference in the level of lift expected (0.10 mm). However, the control paper tape was significantly less protein removed from the skin compared to the silicone adhesive tape (p=0.001). These results lend credence to the more comfortable fixation that remained constant over time. One of the most common causes of skin trauma in neonatal intensive care units (NICU) is the removal of adhesive tapes and dressings necessary to secure life support and monitoring equipment to the patient's skin. Epidemic stripping secondary to tape and adhesive removal is most common in premature babies before 27 weeks of gestation and in the primary NICU environment. The traditional acrylic based adhesive products are that the adhesion profile changes significantly over time (Figure 2). Acrylic adhesives have a much shorter adhesive life than do silicone for up to 48 hours after application, the change in adhesion is noted to be 2-4 fold. Therefore, adhesives that have a similar profile are safe and effective. The tapes were applied on the skin and monitored for the time of removal. In contrast, a new silicone adhesive tape* has been introduced that provides more comfortable fixation that remains constant over time.

Figure 2: Gentle silicone adhesive tapes were compared to traditional acrylic adhesive which included the control tape.

Figure 3: Silicone adhesive tapes have been found to be less irritating than traditional tape. This is because the tapes are able to conform to the skin's surface, allowing for better adhesion and less discomfort. However, studies have shown that silicone adhesives may cause more skin trauma at the time of removal. In contrast, a new silicone adhesive tape* has been introduced that provides more comfortable fixation that remains constant over time.

Figure 4: Erythema & Edema

Table 1: The net change from baseline score was analyzed and differences were evaluated with a one-sample Wilcoxon signed-rank test.

Table 2: Skin Stripping/Denudation

Table 3: Skin Tear

Table 4: Discomfort

Table 5: Skin Edge Lift

Tape Removal Measurements

Results are presented in Figure 8. There was significantly less protein removed from the skin with silicone adhesive tape than with the control paper tape (p=0.001). These results lend credence to the more comfortable fixation that remained constant over time. However, none of silicone adhesive tape* was compared to the control paper tape. There was a slight parental preference toward the silicone adhesive tape* compared to the control paper tape.

Study Conclusions

Both the silicone adhesive tape and the control paper tape were both found to be gentle to the skin of healthy infants:

- The silicone adhesive tape* exhibited significantly less erythema than the control paper tape* upon removal 24 hours after application.
- There were no differences observed in visual skin stripping (denudation) scores.
- There was significantly less discomfort at removal for the silicone adhesive tape compared to the control paper tape.
- There was significantly less edge lift compared to the silicone adhesive tape.
- The silicone adhesive tape* removed significantly less skin cell protein (hence skin cells) than the control paper tape* upon removal 24 hours after application.
- There was a slight parental preference toward the silicone adhesive tape* compared to the control paper tape.

References: