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Applying Perception Science to Medical Tape Design

Medical Materials & Technologies

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Introduction

Medical tapes need to stick to skin and stay— reliably. Then they need to get unstuck — as painlessly as possible. Changing adhesive dressings is considered one of the most painful aspects of long-term wound care (Hollinworth & Collier, 2000). Adhesive removal can cause erythema, edema, stripping of superficial cell layers, and skin tears. These outcomes are collectively referred to as Medical Adhesive Related Skin Injury, or MARSI (McNichol et al., 2013). This paper will examine how patients perceive pain — and how the information may inform and inspire medical tape design.

Pain has a purpose

Pain warns an organism of the potential for tissue damage (e.g. signaling you to pull your hand away from a hot stove; Treede, 2009). To serve as a warning, pain must be triggered before damage has occurred; for example, extreme temperatures cause pain outside the range of actual skin damage (Raja et al., 1999). Experts argue that heightened sensitivity serves a protective function: warning an organism to avoid damage (Treede, 2009).

In the case of tape removal, research has demonstrated that skin stretching and stripping of superficial layers are associated with pain (Dykes & Heggie, 2001; Klode et al., 2010). Yet, the exact mechanism causing pain from adhesive removal is not well understood — and little research explores it. Ultimately, understanding this source of pain and discomfort requires modeling the mechanics of tape removal from skin, understanding how adhesive forces stimulate the sensory receptors, and quantifying the experience of pain.

But subjective experiences like pain are not directly observable. If we want to quantify these experiences, subjects must provide some measurable response to convey what they're experiencing. Gaining generalizable insights from subjective response data requires careful experimental design and analysis based on understanding of human psychology.

Research in 3M labs helps us understand the source of pain to design medical adhesives that come ever closer to the ideal tape for less pain during removal and more holding power.

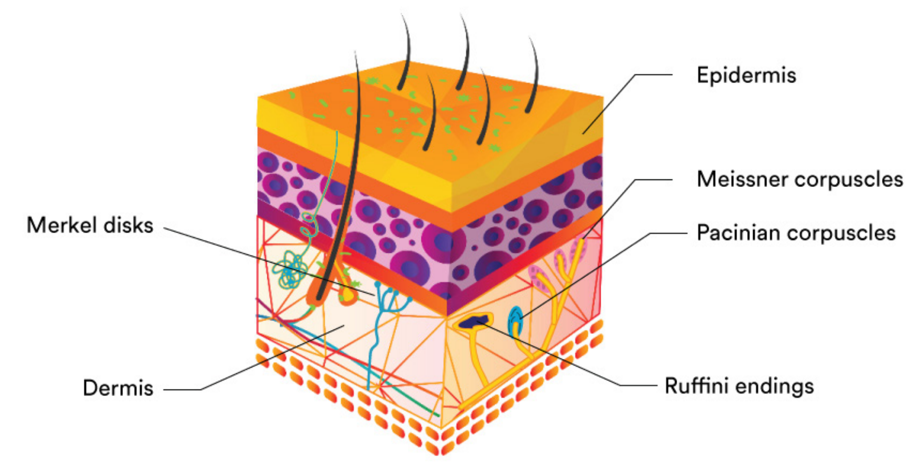

Figure 1. Overview of the sensory receptors in human skin.

Anatomy and physiology of pain

Our sense of touch is unique among the senses – we have a wide array of specialized receptor types with varying distributions throughout the body (unlike our sense of hearing, for instance, which relies on a single type of specialized receptor located in the inner ear). Painful and painless sensations of heat, cold, and mechanical pulling and pushing are sensed by overlapping combinations of sensory receptors both in the skin and in internal organs.

Mechanoreceptors

Skin sensation is mediated by multiple types of neurons found in the epidermal, dermal, and subcutaneous layers. Figure 1 provides an illustration of the common neural receptors found in the skin. The four types of mechanoreceptors (Merkel disks, Meissner corpuscles, Pacinian corpuscles, and Ruffini endings) are triggered by unique types of mechanical changes that occur at the skin. In addition to mechanoreceptors, the skin has specific sensory receptors that respond to hot (e.g., free nerve endings), cold stimuli (e.g., free nerve endings and Krause end bulbs), and free nerve endings that are selectively activated by noxious stimuli or by molecules that are release after tissue damage has occurred (i.e., nociceptors).

Recent research in rodents has also revealed a specialized receptor type responsible for pain from hair pulling — these high-threshold mechanoreceptors are wrapped around the base of individual hair follicles (Ghitani et al., 2017). The receptor type may be responsible for more pain caused by medical tapes ripping out hairs from hairy skin.

Under normal conditions, many of these receptor types do not produce pain. However, injury and conditions like neuropathy can cause hypersensitivity, increasing pain sesn (hyperalgesia) or making otherwise neutral stimuli feel painful (allodynia) (Coderre, 2009). This is important to note because medical tapes that remove painlessly on healthy volunteers may produce severe pain in clinically relevant populations of patients.

Nociceptors

Research has found that the nociceptive free nerve endings extend into the epidermal layer of the skin (Mense, 2009). Given that blood vessels are not present until the dermal layer of the skin, one can experience pain with superficial abrasions of the stratum corneum and epidermal layer without bleeding. The free nerve endings of nociceptors have been shown to respond to thermal, mechanical, and chemical stimuli (for review, see Gold & Caterina, 2009). Changes in the extracellular milieu can trigger the firing of nociceptors. Studies have found that extracellular release of ATP (adenosine tri-phosphate) during tissue injuries (Bleehan & Keele, 1977; for review, see Hamilton & McMahon, 2000), reductions in tissue pH, and chemicals such as capsaicin and substance P can trigger nociceptor firing. Researchers have found that reducing pH below 7 can trigger nociceptor firing and produce subsequent pain (for review, see Deval et al., 2010).

Neural pathways of pain

Sensory receptors: transmit information to the central nervous system along three primary afferent pathways (for review, see Mense, 2009; Roudaut et al., 2012)

Pathway	Infomation Delivered	Fiber	Velocity
Aδ-fibers	Aversive	Myelinated fibers	20 meters/ second
Aβ-fibers	Non-aversive (related to touch)	Myelinated fibers	100 meters/ second
C-fibers	Aversive	Thin, unmyelinated fibers	1 meter/ second

Cutaneous sensory receptors: produce unpleasantness/pain (i.e., nociception)

Type I A mechano-heat receptors	Supplied by Aδ-fibers and Aβ-fibers— have low mechanical, high thermal thresholds.
Type II A mechano-heat nociceptors	Supplied by Aβ-fibers— have high mechanical and low heat thresholds.

Academic studies of pain from adhesive removal

Goals of this section - review academic literature that measured pain from medical tape removal.

While some early academic studies failed to find a relationship between peel force and perceived pain, later experiments — which tested a wider selection of tapes — have shown a reliable effect of peel force. Additionally, multiple studies have shown lower pain ratings for silicone adhesives than the more commonly used acrylate adhesives, without significant differences in peel force.

Our internal research has replicated the correlation between peel force and pain. However, the differences in pain ratings between acrylates and silicones with similar peel forces suggests that pain is not just a product of peel force. Depending on adhesive properties, the same peel force can be distributed very differently across the surface of the skin.

Study 1: Dykes & Heggie (2001)

Measured peel force and pain from the removal of 6 medical dressings from the lower back of healthy subjects after 24 hours dwell time. Dressings peeled at 25mm/second at an angle of 135 degrees. Both initial detachment peak force and steady-state force were measured, but neither measurement showed a clear relationship with pain scores. The silicone dressing had the lowest mean pain score (4 on a 100-point scale), but did not have a significantly lower peak (50 N) or steady-state (39 N) peel force.

Study 2: Waring and colleagues (2008)

Compared an acrylic and silicone wound dressing on peel force, pain, skin stripping, and erythema. The measured peel forces at removal did not significantly differ, but the reported pain was higher for the acrylate (44.18 vs. 17.17 on a 100-point scale). Visual inspection and protein assay revealed more skin stripping caused by the acrylate than the silicone. Higher levels of erythema were also observed for the acrylate.

Study 3: Matsumura and colleagues (2012)

Used a cross-modality matching technique to evaluate the pain experienced during wound dressing removal. Electrodes were attached to the right forearm and increasing current was applied, while adhesive dressings were peeled from the left forearm at the rate of 1 cm/second. Subjects were asked to indicate the point at which the pain induced by the electrical current was at an equivalent level to the pain of the adhesive removal. Numerical pain ratings were also collected. The 11-acrylic dressing was consistently rated more painful than the 3 silicone-containing dressings, both on the numerical pain scale and using the electrical cross-modality matching method.

Study 4: Klode and colleagues (2010)

Compared the pain elicited by the removal of 56 different wound dressings applied to the forearms of healthy subjects, while measuring peel force. Pain was measured on a 10-point scale that was anchored using a

Goals of the next section

Explore:

- Observed peel force/ pain correlation
- Adhesives that offer less pain for a given level of peel force

reference stimulus. On the first day of testing, the dressing with the highest measured peel forces when removed from steel (Cosmopor-E, a hydrocolloid dressing) was applied to subjects' forearms and removed, and subjects were told to rate all other dressing removals relative to it. Breaking down the results by type of adhesive, they found the highest peel forces and highest pain ratings for the hydrocolloids, followed by the acrylates, polyurethanes, and silicones.

Additionally, they computed an adhesion-to-pain ratio for each tested dressing and found that hydrocolloids had the best adhesion relative to the pain caused, followed by silicones and polyurethanes, with acrylates coming in last. However, it should be noted that these rankings reflect the mean values from the set of dressings tested and should not be taken as a general statement about the adhesive types.

Although one of these studies (Klode et al. 2010) found a relationship between peel force and pain, other studies failed to find a significant relationship (Waring et al., 2008; Dykes & Heggie, 2001). Nonetheless, all the studies described in this section found differences between silicone adhesives and other medical adhesives. Controlling the tape type, participants, body location, and peel speed in one location may provide some insight into some of the discrepancies between these previous studies.

Inside the lab: research at 3M

Higher peel forces (a measure of sticking power) often correlate with higher levels of pain (see e.g. Klode et al., 2010). Our studies have replicated this relationship — and we have found it possible to design tapes with similar peel force values that lead to very different pain levels.

The figure below shows pain ratings for two experimental tapes, showing that the range of peel forces observed is similar, while the pain ratings are significantly different across nearly the entire range. In other words, we can achieve the same level of performance while creating a much more pleasant experience for the end user. This is made possible by measuring subjects' pain and treating it as a performance metric to design tapes around.

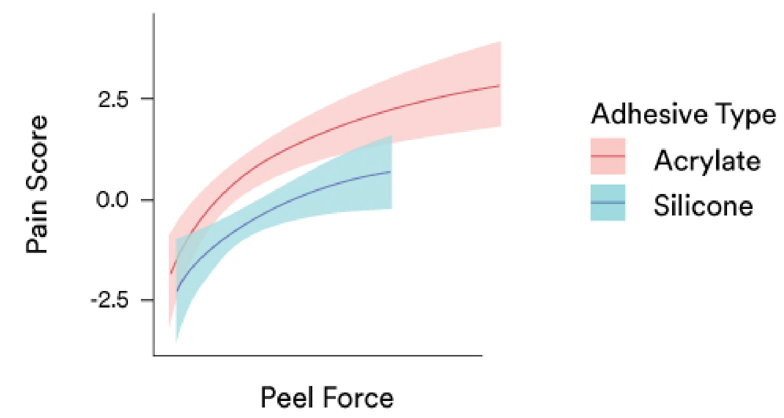

Figure 2. Pain ratings for each tape removal in a recent internal study, plotted over mean peel force (n=16 volunteers). Lines show regression model fits for the two tape types (shaded regions show standard error). While peel forces and pain ratings vary considerably between individuals, the overall fits indicate an underlying relationship between pain and peel force, and an interaction with adhesive type such that the silicone sample elicits less pain for a given level of peel force.

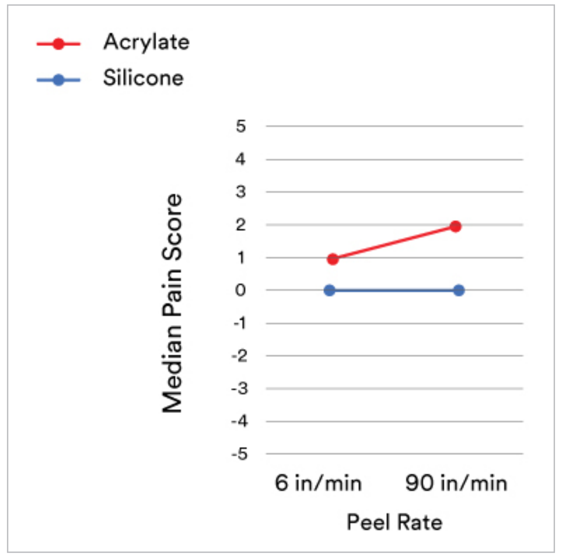

Figure 3. Median pain ratings from an internal study (n=24 volunteers). Removal speed had a significant effect on pain ratings for the acrylate tape, but no effect for the silicone tape.

The pain/peel force relationship can be further influenced by how a tape is removed. In a recent internal study, volunteers had samples of two tapes removed at slow (6 in/min) and fast (90 in/min) rates, and rated their level of pain on a -5 to +5 scale. Removal speed was found to interact with adhesive type – faster removal was more painful for the acrylate sample, while having no effect for the silicone sample. Importantly, the faster removal rate is likely closer to how quickly consumers remove these products; relying on data from the slower rate would lead us to underestimate the amount of pain caused by the acrylate. Removal speed is just one of many factors that influences the overall story of a tape's performance.

Less pain, more performance

Our internal studies have also investigated how individual differences in patients' skin can shift around the level of pain experienced, along with factors like how tape is removed and how long the tape has been on the skin. Continued research that keeps the patient's experience in mind will allow 3M to continue improving our medical tapes so that pain is minimized without compromising performance.

Both peripheral and central hypersensitivity of allodynia and hyperalgesia causes an individual's typical pain/stimulus response function to shift leftward. This leftward shift means that less stimulus intensity is needed to produce a given quantity of pain. Understanding hyperalgesia and allodynia can provide insights into how injuries can impact pain perception during medical tape removal. This is important to note because medical tapes that remove painlessly on healthy volunteers may produce severe pain in clinically relevant populations of patients.

Getting unstuck, moving forward

By focusing on how adhesive properties and skin properties relate to pain, we can begin to make predictions that generalize our observations to the patients who are most vulnerable to pain and injury from medical tapes. While we conduct internal tests on healthy patients, we seek to understand the relationship between adhesive properties and pain —and use that model to inform and inspire designs that serve all patients.

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