Final Design Sprint Report

BMED 1000 Friday Section D

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Executive Summary

For this project, the Tegaderm clear wound dressing, which is a type of medical dressing used to secure IVs or cover healing wounds, will be discussed and solutions will be proposed to improve the device's performance and meet unmet needs. The challenge of improving this disposable device was difficult due to the need for it to maintain the needs and requirements already met (e.g., sterile, physical barrier, inexpensive, etc.), target a stakeholder with unmet needs (e.g., pediatric patients), and be reasonable to prototype.

After researching the characteristics and mechanics of the product, several issues were brought to light and potential solutions were proposed. After a thorough discussion, three top solutions were selected based on ranking testability, attainability, efficiency, etc. in a decision matrix. The top three solutions that were selected include a cover flap, an adhesive spray, and a flexible arm band. The specifics of each solution are discussed in the solutions section. The solution selected for prototyping was the cover flap due to the predicted positive psychological impact and therefore physiological effect on not only pediatric patients and patients with trauma-associated wounds or an aversion to wounds. The cover flap is an opaque flap attached to the top of the Tegaderm clear wound dressing that would include designs depending on patient preferences. The flap is designed to cover the wound from patient view while allowing medical staff to easily displace it to monitor the covered area.

Upon prototyping and testing the flap solution, positive results favoring the addition of the flap to the top of the Tegaderm clear wound dressing were observed among the pediatric population tested. In conclusion, it is likely that the flap design is an effective design, and if the design were to become available to the market, the implications of the availability could be large. Like any design, there are potential flaws such as the decrease in cost-effectiveness, however it is likely that in this case, the potential positive effects can outweigh the negative effects. This product would lead to improved psychological reactions to wounds and subsequently increased physiological healing as there will likely be less movement or tampering of the wound and less visibility of the wound can likely lead to a decrease in pain.

Introduction

For this project, the Tegaderm clear wound dressing, which is a type of medical dressing used to secure IVs or cover healing wounds, was discussed and solutions were proposed to improve the device's performance and meet unmet needs. While this product has gone through a lengthy and tedious process to become the product is now on the market, like any other product, there are flaws. After doing research, the problems that held the most interest are associated with pediatric patients. Pediatric patients oftentimes require more specialized care and equipment due to their unique stages of development and size compared to adults. As a result, the issues that were mainly addressed were the sizing of the clear wound dressing and the psychological effects of the transparent, picture-frame film in pediatric patients. This report is a compilation of the work done throughout the semester to understand the product, address the problem, identify the significance of the problem, and identify and test possible solutions.

In general, disposable medical devices are prevalent in wound care. Because of their short life spans, they are usually made to be simple, inexpensive to produce, and easy to use and discard. This makes them very unsustainable because they create a lot of waste which is difficult to avoid when sterility is a requirement for many single use/disposable medical devices. The lack of customization makes physical and psychological comfort during recovery vary which can have a negative impact on overall recovery (Johnston, 1993). As a result, reengineering simple disposable medical devices is a challenge as it requires striking the balance between a stringent standard for costs and market conditions for production, often neglecting the actual quality of patient recovery and environmental impacts. Improving the overall performance or treatment quality of a disposable medical device isn't impossible but making the solution comparable to the level of the original disposable device (i.e., keeping costs low, useful to a large demographic, intuitive, and effective) is the challenge. However, this also makes it a good challenge to approach in a classroom setting because the solution possibilities for redesigning devices are endless. The overall purpose of a disposable medical device is usually meant to be a one-sizefits-all solution for a multitude of problems. Overall, the challenge of redesigning disposable medical devices stems from the need to create an effective, inexpensive, multi-purpose product with a short life span, which is an engineering challenge that can be difficult to approach especially because the human population is not a monolith.

Device Analysis

To begin reengineering the clear wound dressing, initial research on the product was analyzed and characterized using a product archeology canvas (see page 12). This model resulted in a clear definition of the following aspects of the medical device: its purpose, characteristics, stakeholders, needs, requirements, and impacts. Overall, the stakeholders define the device's purpose and needs. The requirements were then developed to fulfill those needs; the impacts were determined by whether the device's current characteristics met those requirements.

Starting with the analysis of the stakeholders, the following list summarized the research on the device's usage, which indicated what stakeholder groups were involved in it:

- **Patients**: They are the direct recipients of the device.
- Healthcare Professionals (Nurses/Doctors): They administer the device to patients.
- **Hospital Administration**: They manage device logistics for hospital professionals.
- **Healthcare/Insurance agencies**: They are the middleman for the device's finances.
- Patient's Loved Ones: They are involved in the patient's support system when treated.
- Manufacturer: They develop the device for purchase and storage by hospitals/stores.
- **Developing Countries**: They are the primary market for the devices due to their cheap/widespread use and greater impacts where less healthcare solutions exist.
- **General Public**: Their view on the device may impact patient efficacy and ultimately health outcomes.

Using this, the purpose and needs were then researched. Starting with the purpose, a variety of resources from different stakeholder groups were used to better understand the device. This ultimately resulted in the following device purpose: the clear wound dressing is intended to be an adhesive, protective barrier for a variety of medical needs to sterilize a wound or infection site for treatment. From here, the specific needs from the device of each stakeholder were analyzed. This research was extensive and is summarized in Appendix B - Stakeholders Needs Matrix (Page 14).

After researching the purpose and specific stakeholder needs, the requirements were formulated. In this section of the product archeology canvas, the needs that were met and not met were identified. This was primarily done by reviewing device user reports and researching the device's efficacy for specific needs. This research is also reflected in Appendix B - Stakeholders Needs Matrix as the bolded needs, which are needs currently unsatisfied by the device.

In concurrence with developing the requirements, in-depth research was performed on the device (primarily from manufacturing reports) to better characterize its functionality and determine which needs were being met by functional operations. This research into the device's characteristics was also necessary later in the device redesigning process.

Finally, looking at the met and unmet requirements, impacts of the met and unmet requirements were quantified. This involved researching applications of the product and its overall impact in the healthcare space. As a result, this research allowed better identification of the areas of most needed improvement that was considered in the reengineering process. As will be discussed in the next section, the area of focus chosen was improving patient physical and psychological comfort (through the device's aesthetics and size).

Problem Definition

Based on the device analysis and research conducted, the following problem statement and inputs were identified to improve the Tegaderm clear wound dressing:

Pediatric patients will need a smaller, more comfortable clear wound dressing to increase patient outcomes and ease concerns for the dressing sterility being compromised.

A user story (Appendix C - User Story on page 16) was also developed to demonstrate the need to address the requirements in the problem statement.

Focusing on the patients' category in Appendix B - Stakeholders Needs Matrix, the needs unmet by the Tegaderm for this stakeholder group focused primarily on physical and physiological comfort. Having limited elasticity and minimal visual appeal, the range of motion of the patient can be hindered upon application along with decreased morale for recovery at the sight of the wound through the dressing.

By considering this and analyzing the patient stakeholder group, it was also determined that these limitations are especially prevalent within pediatric patients. Pediatric patients are more prone to exceeding the amount of tension the Tegaderm can withstand and are more sensitive to the visual appearance of wounds. As a result, this patient demographic could experience a more significant increase in recovery time from discomfort from the visible wound and an increase of infections from movement that compromises the protective barrier provided by the Tegaderm (Johnston, 1993). These ideas became the focal point of the problem statement where pediatric patients were highlighted as a group that was greatly unrepresented by the current nature of the Tegaderm.

To identify the inputs needed to address the problem statement, the unmet needs stated above were then translated to the characteristics section of Appendix A - Product Archeology Canvas which summarized research findings of the device to determine that the size, transparency, elastic modulus, and tensile strength of the Tegaderm could be altered to solve the problem statement. The inputs represent a reduction in the size and transparency of the dressing while also increasing the elasticity and tensile strength to further accommodate pediatric patients. They some of them are listed and quantified as follows:

- Size: 4.5 ± 1 cm x 5.5 ± 1 cm (not including the flaps)
- Transparency on Window: $100\% \pm 5\%$
- **Elastic Modulus**: 5.4 ± 1 MPa (this is 50% greater than the current elastic modulus)
- **Tensile Strength**: $225 \pm 10 \text{ N}$ (this is 50% greater than the current max tensile strength)

At this point, the problem and solution space have been developed leaving ideating solutions as the remaining proceeding step in the design process, which is addressed in the next section (Tegaderm, 2020).

Solutions

In this section, 3 possible solutions to the defined problem are discussed in greater detail as follows.

Solution 1: Flap Design

The concept in Figure 1 was developed to accommodate pediatric patients' visual sensitivity to wounds. One major component of the Tegaderm is its window-frame feature that allows for the center of the dressing to be visible through a clear film. While this is extremely beneficial in ensuring IVs are properly fastened on patients and for monitoring patient wounds, this feature exposes full, open wounds for anyone near the patient to see. The recovery of pediatric patients can be slowed due to negative emotions towards being able to see their injuries which can also impact the patient's acceptance of the dressing being on their skin (Johnston, 1993).

This solution maintains the original window-frame structure but includes a removable flap to allow



Figure 1: Flap Design

for the wound to be covered when requested by the patient while still being easily accessible for

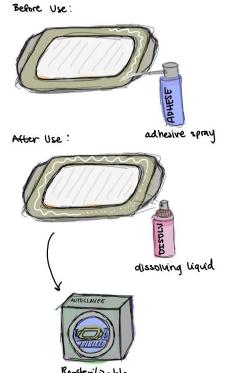


Figure 2: Spray Adhesive Design

health care providers to see once the flap is lifted. In emergency situations, the flap can also be removed completely for easy access. Additionally, the flap can be customized to be more child friendly with stickers or designs that appeal to the patient's interests. In theory, by covering the wound and making its appearance more attractive, pediatric patients are more likely to accept the Tegaderm with less attempts to remove it once it is applied. As a result, this increases the sterility of wound sites while also producing more positive emotions that facilitate a better physical recovery in the patient.

This concept is the preferred solution as it incorporates a practical manner of addressing a current limitation of the Tegaderm that can be implemented easily by manufacturers and healthcare providers. More importantly, it addresses the needs of pediatric patients found in the patient's stakeholder groups (see page 14) who need a protective, comfortable, and appealing dressing to help them recover.

Solution 2: Spray Adhesive Design

The solution in Figure 2 addresses the removal process of the Tegaderm in relation to pediatric patients. With

children being more sensitive to pain and prone to rashes or irritation, the strong adhesive quality of Tegaderm to maintain sterility can lead to difficulties in comfortably removing the dressing from pediatric patients (King, 2014). In hopes of maintaining the Tegaderm's semi-permeability and strength, this solution incorporates both an adhesive spray and a dissolving liquid to make application and removal more comfortable for the patients. This design would also include a sterilizable bandage that can be reused and provide an eco-friendlier option.

The adhesive spray would bind the Tegaderm to the skin and the dissolving liquid would be chemically compatible with the spray to dissolve it allowing for the Tegaderm to simply slide off the skin without any additional pulling or tugging during removal. This solution ensures that the wound sites of pediatric patients will not be further compromised from treatment with the Tegaderm. However, one major downfall of this concept is its need for extensive testing and research to develop a sufficient adhesive spray that could perform these actions while being dissolvable with a compatible spray. Another issue is that the bandage must have waterproof edges, so the bandage would need to be redeveloped to allow for the adhesive under the bandage to be dissolved. This concept could overall decrease the sterility of the product as well which ultimately contradicts the purpose stated in the problem statement of increasing sterility.

Solution 3: Flexible Band Design

Solution three, as shown in Figure 3, addresses both the comfort and removal of the Tegaderm for pediatric patients. With the Tegaderm being an adhesive band aid that is applied directly onto the skin, it has limitations to the amount of tension it can experience and a limited degree in which it can be stretched. This is difficult for pediatric patients as they are generally more active which could potentially compromise the wound healing due to increased tension applied on the wound site. Additionally, the hospital setting can make children more restless which can further jeopardize their recovery.

This solution incorporates an adjustable, flexible band around an adhesive-less dressing to allow for more comfortability and mobility in the patients. Being adjustable, the Tegaderm can become more customizable where the most comfortable fit can be chosen for each patient.

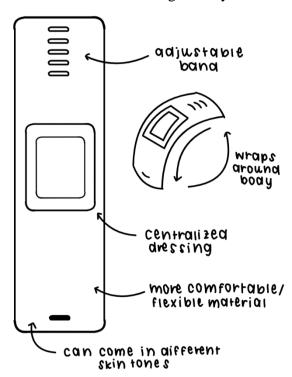


Figure 3: Flexible Band Design

The band also allows for the Tegaderm to be slid on and off the patient resulting in an easier, less irritating removal process. However, like the previous concept, this solution would take more development to find a material that is both hypoallergenic and sterile to be paired with the dressing. Also, being a band, more infectious substances could make it underneath the dressing into the wound which would compromise the overall recovery of the patient regardless of if their comfort while using the device is increased.

Prototyping

The purpose of the prototype was to qualitatively test how effective the chosen solution was when used by pediatric patients. In other words, the question that was tested was "does the Tegaderm prototype with the flap help deter the negative psychological response to seeing wounds, especially in pediatric patients?" This was done by first developing a prototype of the Tegaderm with a decorative flap to cover the wound site for pediatric patients, which was then tested through direct comparison with the original Tegaderm and the in front of two pediatric patients (3-year-old identical twins) over a simulated wound site.

For both dressings shown to the participants, an image of the same wound was placed beneath the clear portion of the dressing to simulate an actual wound on the patient's skin. From this simulation, the behaviors/reactions of the participants were recorded¹; additional questions were asked to assess the overall attitude of the participant towards their hypothetical wound and its dressing. This was done on both participants for both the original Tegaderm and the modified prototype.

From this test, the reactions of the participants can be categorized as seen in the table below.

Dressing Type	Vocal Reactions	Physical Reactions	Wound Impact
Original Tegaderm	Voice sounded flat and quieter	Covered eyes with hands and wanted to hug their guardian	Claimed wound felt painful and uncomfortable
Prototype Tegaderm	Voice got more high-pitched and louder	Excitedly looking at the dressing and showing it if off to their guardian	Claimed they no longer felt any pain on the wound site

A major takeaway from this investigation was that the solution to improve a product does not have to be elaborate. Overall, this was a simple adjustment that ultimately yielded very positive results with minimal changes. Additionally, this helped highlight the importance of both qualitative and quantitative data since both are indicative of the product's success at meeting the needs of its users. In the future, these takeaways can be used to help curate better solutions while also adhering to appropriate inputs and requirements the device must meet.

¹ Audio Recording: https://drive.google.com/file/d/10o2VertGl_7tPseOoqamKTVbWv7wyTWs/view

Conclusion

The preferred design solution discussed in this report is an improvement upon the product presented in the product research section, especially among pediatric patients. While the improvement with the flap with designs seems to mostly serve pediatric individuals, it can serve as an aid for those with phobias or traumas associated with their wounds or IV needles in general. As a result, the patient outlook is improved as patients experience less distress and squirm less, promoting better wound healing and less IV displacement. This solution was selected after a process that began with research on the initial product and its effects on stakeholders. Then, the problems were identified along with possible solutions, and the solutions were ranked based on several factors. A design featuring a decorative flap to cover the clear "picture frame" and a design featuring a reusable bandage with adhesive and removal sprays were ranked as the top two solutions. The flap design was selected as the solution that seemed most viable and most realistic to prototype. Overall, the flap solution has proven to be an improvement among some kids already as demonstrated by the prototype tests. In the future, this solution could also be tested on adults who have a phobia of needles or have trauma-associated wounds. If this improvement were to ever become a solution on the market, it can pave way for improved recovery addressed both psychologically and physiologically.

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Appendix A - Product Archeology Canvas

<u>Purpose</u>	<u>Stakeholders</u>	<u>Requirements</u>	<u>Impact</u>
What does this product do for the user? TegaDerm is a wound dressing that that can act as a protective barrier, an adhesive, a means to securing a device like an IV, and a controlled environment to address a multitude of medical needs and situations such as wound healing or infection protection. What value does this product create? This makes for a versatile and reliable product that maximizes every use to its full potential while also limiting disruption to the body's natural healing process. The product is also relatively cheap, so this allows for more	Who are <u>all</u> the stakeholder groups? Hospital administration, healthcare/insurance agencies, healthcare professionals (nurses, doctors, etc.), developing countries, manufacturer (3M), patients/users, patient/user families, stores. What group traits are relevant to this product? All stakeholders are concerned with the costs of the product because this affects the demand for the product and can decide if it is chosen over others. The manufacturer is concerned with development and distribution which is directly affected by the stakeholders who use and advertise the product like patients/users, healthcare workers, insurance companies/hospitals, and stores. Needs For each stakeholder group, what needs does the design	closed surgical incisions. The clear middle of the dressing also allows for IV sites and wounds to be monitored for infections or improper IV placement. Form: The product's thin, flat, and flexible material makes it easily appliable to almost any site on the body that is needed. Its clear nature also minimizes the need for reapplication when the site needs to be monitored. The "picture frame" border surrounding the clear mid-section also making usage more accurate thus limiting reapplication. The products relative form as described above also makes for easy and efficient storage in clinical settings.	What are the impacts of this design? This product is designed to stop infections before they persist, provide a good environment for wound healing, securing IVs to prevent leakages or movement of IVs into an improper position. Surgical site infections are the second most-common hospital-acquired infection costing up to \$29,000 to care for. This product can decrease the possibility of those costs and ease possible financial burdens associated with those infections or possible injuries from unsecure IVs. This design overall saves money, promotes efficiency, and eases the burdens of the
observe? The product is flat, transparent, and thin. The product has a transparent middle that is shaped like a rectangle with rounded corners and a white, opaque frame that is wider on the right and left side. What is made of? The product is composed of a hypoallergenic, latex free material that is semi-permeable. The product is also "notched and reinforced with soft cloth tape to provide a better seal around catheters and other devices." (3MTM, n.d.)	address? Hospital administration: the materials are low-cost for frequent use and easy, less time-consuming to apply so that more patients can be treated. They are effective and increase patient turnover and encourage patients to return and increase the hospital's reputation. The low cost is beneficial to increase profit margins and avoid suing for poor treatment. Healthcare/Insurance agencies: Insurance agencies hate it when people get sick, so they need the product to be effective to increase patient well-being. The cost should also	that specialize in covering wounds. <i>Life Cycle:</i> The product can be used for extended periods of time and remains sterile as long as the outer package is intact. This product is also claimed to last longer than the traditional tape and gauze dressings, which can save money, time, and supplies ² Once the exterior has experienced.	

² TegadermTM transparent film dressing brochure. (n.d.). https://multimedia.3m.com/mws/media/4479830/tegaderm-transparent-film-dressing-brochure.pdf
³ Food and Drug Administration. (1997, November 12). https://www.accessdata.fda.gov/cdrh docs/pdf16/P160002c.pdf

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How do you interact with it?...

Users remove the dressing's liner and stick it to the desired areas such as a wound or IV site. Users may also cut the dressings into different shapes and sizes to better fit these areas.

progress of the wound or status of whatever the product is covering.

3M (manufacturer): Low manufacturing costs and easily accessible materials increase profit margins and allow the product to be sold at a lower price. The effectiveness of this product matters because there are many comparable products on the market, and they need to be competitive to increase demand.

Patients/users: The bandage needs to be comfortable and not irritate skin or whatever is being covered. The product must be effective so that they can heal quicker and have peace of mind. The product must be sterile to prevent infections and future hospital visits and bills. The product must be low-cost so that they can easily access it and be easy to use so that recovery time is shorter and there is less risk for the everyday person.

Families: The needs of families are the same as patients to decrease mental distress related to loved ones. They also need the product to be cheap to decrease the financial burden that might be created.

Developing countries: The product must be cheap for accessibility. They also must be sterile and easy to transport. They also must be easy to use so that volunteers and patients can easily use them.

Stores: Stock this product for its low cost and high demand/effectiveness.

They also need to be clear so that they can easily monitor the Specifically, two laboratory tests were conducted to measure the Moisture Vapor Transmission Rate (MVTR) of the dressings. Results found that a sufficient MVTR is present, but questions whether the laboratory findings could be used to accurately reflect real life usage remained an unanswered question in the study.

Appendix B - Stakeholders Needs Matrix

Note: The bolded needs are needs that currently aren't being addressed.

Stakeholder	Physiological	Treatment	Usability	Other
Patient	Non-irritating adhesive, sterile, strong seal, stretchy	Physical barrier to infectious agents, secure bandage	Intuitive, easy to remove, compatible with all topical treatments	Aesthetically pleasing, customizable
Patient's loved ones	Ability to see wound/site covered	Physical and chemical barrier to prevent infection	Easy to understand how to use in case they need to help the patient	Aesthetically pleasing
Nurse	Non-irritating adhesive, sterile, strong seal, stretchy	Physical and chemical barrier to prevent infection	Easy to use and efficient application/remo val, compatible with all topical treatments	Unobstructive
Doctor	N/A	Effective results/good patient outcomes	Easy to use and efficient application/remo val, compatible with all topical treatments	Unobstructive
Hospital	N/A	Good patient outcomes	Efficient storage	Not expensive, sustainable, increased patient turnover, resterilizable
Medical Insurance	N/A	Successful/reliab le product	Easily dispersible	Investable and marketable, cheap, sustainable, long-life cycle
Manufacturer	N/A	Effective treatments (for product establishment for	Easy and efficient to manufacture	Cheap to produce, accessible material, distinct product

		future use), good patient outcomes		
General public	Non-irritating adhesive, sterile, strong seal, stretchy	Alleviate pain	Clear instructions	Easy access and sustainable, discrete
Developing countries	N/A	Effective treatments for nationwide improvements in health outcomes	Intuitive, easy to remove, efficient storage	Cheap, easy to transport, easy usage, resterilizable

Appendix C - User Story

Tommy is an 8-year-old boy who was presented to the emergency room with dehydration and is with his father. He is a relatively healthy kid who is apprehensive about hospital visits and seeing blood or needles like lots of kids at his age. He does not really understand what is happening around him and sees the nurse walk in with an IV bag and needle. He is alarmed by the needle and assumes that it is like a shot. He is upset upon receiving the IV but then when he looks over at his arm, he sees the needle through the clear, dull wound dressing that seems too big for his arm and finds that it is not like the typical bandages that he receives from his doctor's office with colorful designs or characters. He starts to become more panicked, and his father attempts to calm him down by bringing some stuffed animals, but whenever he looks over at his arm, he becomes upset because the only thing he notices is the needle in his arm through the clear wound dressing. His stay at the hospital has traumatized him and he walks out of the hospital even more terrified of needles than he was initially due to the TegaDerm Clear Wound Dressing.

Contributions

Ella Elvambuena

Primarily contributed by working on the problem definition, solutions, and prototyping sections. She focused on the discussion aspect of both the problem definition and solutions sections. She also drew two of the solution sketches. For the prototyping section, she contributed by creating and testing the prototype and discussing the results. She also contributed to the references section as well.

Helen Chow

Primarily contributed to the executive summary, introduction, conclusion, and editing/formatting portions of the document.

Ayssia Crockem

Contributed by writing large parts of the executive summary and introduction, adding to device analysis, proof-reading/editing the complete document, in-text citations, and drawing one of the solution sketches.

Akhil Ganesan

Primarily contributed by working on the device analysis, introduction, & problem definition with minor contributions throughout the rest of the document (specifically, the solution, prototyping, & references). He also added the appendices (which were a group product prior to this document) detailing the overall product's design phases.