# Team LowCostomy: dedicated toward creating a high-quality, low-cost colostomy appliance for those in Sub-Saharan Africa and other low resource settings.

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Research Abstract:
There is an immense need for low-cost colostomy appliances among ostomy patients living in low-income countries in Sub-Saharan Africa. There are an estimated 1.2 million new cases globally of colorectal cancer annually (*1*). Additionally, instances of colorectal cancer and the need for colostomies is increasing in Sub-Saharan Africa at an annual rate of up to 6.8% in certain countries *(2).*

Without access to colostomy products, low-income patients often resort to handmade solutions, such as taping a plastic bag to one's stoma. However, these makeshift solutions are not safe, odor-proof, or leak-proof, which lead to a decreased quality of life for these individuals. To combat this problem, we have developed LowCostomy: a highly affordable (<5 cent) colostomy appliance that capitalizes on utilizing low-cost, recycled materials in addition to a novel, all-natural formula of beeswax and pine resin that replaces the expensive adhesive material found in traditional adhesives for colostomy appliances. Existing skin-care products that separately contain beeswax and pine resin have been proven to be safe, non-toxic, and non-corrosive (*7, 8,9, 10*); however, there are still potential risks for rash, irritation, infection and other topical reactions upon the combination of these two substances.

The purpose of this study is to investigate the safety of a beeswax-pine resin mixture as it acts as a buffer between the patient's peristomal skin and the colostomy appliance. Rather than testing the entire LowCostomy system, this study will focus solely on the safety of the beeswax-pine resin buffer. The effect of having the beeswax-pine resin buffer adhered to the skin on the abdomen over a one-week period will be analyzed independently by a licensed physician, with an emphasize on assessing changes in color, texture, and overall skin health using the Draize skin irritation test. Subject surveys will also be utilized to record subject experiences and will include quantitative sections like the 5-D itch scale. Compiled results will be analyzed by an accredited statistician.

Study Objective:
To determine whether the beeswax-pine resin mixture used in the LowCostomy buffer can be safely applied to intact human abdominal skin for the duration of a one-week period.

## Standard Research Summary

### Purpose of the Study:

The objective of the study is to determine whether the beeswax-pine resin mixture used as part of the LowCostomy appliance as a buffer can be safely applied to human skin. "Safe" is defined as no greater external skin irritation or injury compared to standard commercially available ostomy appliance products such as the Hollister Adapt Seal barrier ring, used in a similar manner to the beeswax-pine resin buffer as part of the LowCostomy appliance (*3*). The hypothesis to be tested is that the beeswax-pine resin mixture is safe for topical application to human skin.

### Background and Significance:

Colorectal cancer plagues approximately 1.2 million people annually as the third most common cancer worldwide, causing 600,000 deaths per year (*1,3*). The incidence of colorectal cancer in Sub-Saharan Africa is estimated to be around 4.04 per 100,000 population with this value increasing (*3*). In fact, incidence of colorectal cancer in Sub-Saharan Africa is increasing annually at an average rate of 4% *(2).* Common treatment for those diagnosed with any stage of colorectal cancer is to receive surgical intervention, commonly segmental colonic resection with an end colostomy. Unfortunately, colorectal cancer is only one factor contributing to the rising number of colostomy patients; trauma patients with intestinal obstruction via intestinal volvulus is another factor that leads to the increased number of colostomy patients seen in Sub-Saharan Africa (*4, 11*). A study performed in Ethiopia demonstrated that of the 33.95 surgical admissions per 100,000 population per year, 10.3% were due to intestinal obstructions *(4).* Despite the increasing number of cancer and intestinal trauma patients who receive colostomies, there has yet to be an affordable colostomy appliance created for the low-to-medium income patients for post-surgical maintenance care in low-to-medium resource countries. This is precisely the demand that the LowCostomy colostomy appliance aims to meet.

All colostomy patients deserve high-quality, affordable colostomy appliances that enable them to continue their daily lives with the least amount of disruption from stool leakage, foul odor and skin irritation. However, high-quality colostomy appliances commercially available today are expensive and unavailable to those in less developed countries. For many colostomy patients in Sub-Saharan Africa, spending $6-10 on a high-quality colostomy appliance that only lasts two to three days inflicts an immense financial burden *(5).* In most cases, the cost of routinely purchasing high-quality colostomy appliances that last only a few days exceeds the average income per year for people in Sub-Saharan Africa. The high cost and lack of access forces many patients in Sub-Saharan Africa to resort to creating homemade solutions with rubber bands, tape, miscellaneous bags, and other available materials. Such methods often cause leakage, foul odors, discomfort, and further health complications which disrupt the daily life activities and overall quality of life for a colostomy patient. Surgical procedures impact one's ability to monetarily provide for themselves and their families; in fact, a staggering economic productivity loss of $12.3 trillion due to poor provision of surgical car in low-to-middle income countries was projected for the period between 2015 and 2030 (*6*). With major health disparities among mortality rates and treatment options/availability, action must be taken to remedy the lack of healthcare equity in low-resource areas (*1, 4*). With these shortcomings in mind, the LowCostomy appliance is designed to improve the quality of life for colostomy patients in low-resource settings.

Despite the increase in demand for colostomy products, such supplies are still cost prohibitive; the high cost of colostomy appliances largely stems from the fact that companies are continually trying to outcompete each other's novel adhesive formulas. The research and development involved in this endeavor in turn increases the prices of colostomy products. With the effort to mitigate the cost of

effective adhesives, we evaluated various adhesive formulas that had the potential to be inexpensive and readily available for those in Sub-Saharan Africa. After various stages of testing, we formulated a mix of beeswax and pine resin that could replace the high-cost adhesive of most colostomy products on the market today. Beeswax was chosen because of its high availability and low cost in Sub-Saharan Africa; the pine resin is also an all-natural substance readily available that adds a more adhesive quality to the beeswax appliance-stoma buffer used in the LowCostomy system. Beeswax was not only chosen for its high availability and low cost, but beeswax is known to have antiseptic properties, making it beneficial for the peristomal skin which is prone to infection if skin irritation occurs.

The concept of being environmentally friendly was another significant aspect that went into the design of the LowCostomy appliance. A typical colostomy appliance is discarded after a few days' use. Additionally, many countries in Sub-Saharan Africa are already dealing with plastic pollution, resulting in these countries adopting a plastic bag ban. To avoid these conflicts, the LowCostomy appliance was designed to be made completely of recycled material, excluding the beeswax-pine buffer. Being composed of recycled material not only creates an environmentally friendly product, but it also provides a way for the appliance to be low cost. Colorectal cancer and intestinal trauma rates in Sub-Saharan Africa are high, and there are not adequate, low-cost solutions for post-surgical care. With this problem in mind, the LowCostomy appliance's purpose is to improve the quality of life of all patients, regardless of socioeconomic status. However, a major component of the system has not yet been tested for safety: the beeswax- pine resin buffer. Thus, this study will aim to determine the safety of beeswax and pine resin as applied to the skin.

## Design and Procedures:

The purpose of this study is to examine the safety of the LowCostomy appliance's peristomal adhesive interface composed of a mix of beeswax and pine resin. Since this study is not directed at analyzing the efficacy of the entire LowCostomy system, only the beeswax mixture will be tested against test subjects' skin. Upon consultation with ostomy nurses, the peristomal skin was determined to be comparable to normal abdominal skin. Thus, rather than recruiting colostomy patients, the subject pool will include any willing healthy adults with age +/>18 years (n=50). This subject pool must be heterogeneous in terms of ethnicity which ensures that a broad range of skin colors are being tested with the aim of removing bias toward a certain type or color of skin. The goal is to recruit 50% of subjects who self-identify as having a medium to dark skin tone and 50% who self-identify as having with a light skin tone. Subjects will be given $50 as compensation.

Each study subject will be tested with two thin rings of the beeswax-pine resin formula—one being a domestic beeswax-pine sample while the other ring will be a Tanzanian beeswax-pine sample. Using both a domestic and international sample, we can test whether regional differences in these products might yield significantly different results. Such beeswax-pine samples will be tested alongside a control adhesive in the form of Hollister's AdaptTM Barrier Rings. The length of the study will be 7 days. The beeswax-pine ring will be created to match the dimensions of the control (width: 4.5 mm, outer diameter: 48 mm). The beeswax-pine buffer will be composed of the same beeswax-pine resin ratio that will be used in the LowCostomy appliance's overall design. Such tests will be performed on the subjects' abdomen. Prior to application, a licensed physician will record observations concerning the condition of the abdominal skin including color, odor, texture, and hygiene. Pictures will be obtained for documentation purposes as well using a Nikon D5600, 24.2M pixel camera. During picture taking we will limit identification by choosing an area of skin with limited identifying marks or tattoos. The camera will automatically date stamp the picture however, there will be no other identifiers captured. A single dedicated camera will be used for all photos. At the screening visit on Day 1, a member of the research team will obtain a current medication

list and a medical history regarding known pre-existing skin conditions and history of skin reactions to elements of the study and control adhesive rings, to validate that there are no additional associated risks with participating in this study. If the area of application is too hairy to obtain a clear view of the skin, the healthcare professional will shave the pertinent area. The three areas of application will be marked with a medical marker to ensure even and consistent placement of the samples. A measurement device will be included in each picture for documentation and quantification of adverse skin reactions. The control ring will be applied according to the manufacturer's instructions; the beeswax-pine rings will be placed in a similar fashion but in addition, will need to be massaged against the skin to build friction and heat, allowing for a more effective adhesion. To fully seal the rings with the skin, Tegaderm will be placed over the rings, which allows the study subject to shower over the 7-day period with minimal interference with the study results. If the initial adhesives are not able to endure the full 7 days due to adhesive or application failure, such results will be noted and excluded from final analysis.

Each subsequent day after the initial placement of the samples, the subject will be asked to remove the tegaderm and the three adhesive ringsbriefly for less than 20 minutes, then promptly reapply in the exact same location with new tegaderm. The act of daily removal and reapplication of the samples will simulate
the typical routine of colostomy patients as they remove and reapply their ostomy products. Twenty-four pieces of tegaderm will be provided per subject for the purpose of reapplying the samples. During the education session, subjects will be shown how to properly apply tegaderm over the three samples. Subject participation ends at Day 7.

Photo documentation with the dedicated camera will occur on Day 1 at the initial screening visit as noted above, as well as Day 7. Photos will be collected by trained personnel in a private room without windows. A licensed physician will grade the blinded photos, indicating the appropriate level of skin irritation and rash by utilizing the Draize skin scoring system. Subjects will be given contact information to report any skin irritation or other adverse events during the 7-day trial period. Should a severe skin reaction occur, subjects will be directed to the licensed physician reviewer or a consult with a dermatologist. All subjects will record their experience through a RedCap survey which will include the 5D itch scale. After quantitative values have been assigned to each of the blinded photos, data visualizations will be created, and appropriate statistical analysis will be completed to evaluate for significant differences between each of the samples applied to subjects' skin.

### Selection of Subjects/Inclusion-Exclusion Criteria:

Subjects (N = 50) will be healthy adults with age +/>18 years and will be recruited from Duke University along with local community members. Subjects must verbally confirm the absence of any pre-existing skin conditions, skin allergies to tegaderm or other adhesive products contained within the study and control ringsnd pregnancy.

### Subject Recruitment and Compensation

Potential participants will be recruited from the community. Advertising materials in the form of flyers that contain a QR code directing interested participants to the study's website will be placed around Duke's campus and clinical settings as well as broader public spaces. Additionally, Duke's ListServ email system will be utilized to recruit participants. Potential participants that express interest will be contacted by phone to further discuss study details, answer questions, review pertinent eligibility criteria, and preschedule study activities. Potential participants will not be contacted more than three times, including via letter, phone, email, and face-to-face interaction. If a participant states they would like to opt out, the study team will follow the Duke Recruitment and Engagement policy. Those who are

interested will be able to participate if they meet inclusion and exclusion criteria. A minimum of 50 subjects will be recruited. Incentive payment for subjects to participate in the study will be $50.

### Subject's Capacity to Give Legally Effective Consent:

The study will not include subjects without the capacity to give legally effective consent.

### Risk/Benefit Assessment:

The main risk of the study is a reaction or skin irritation caused by the beeswax-pine resin mixture. This could include an allergic reaction, local skin irritation, redness, itchiness, or in severe cases blistering. Based on background research of existing beeswax-pine resin products, it has been hypothesized that a reaction is unlikely, but still possible. If a reaction occurs that is too uncomfortable to continue the study for the entire 7 days, the subject may stop early, and the reaction will be noted. The risks of the study are not being borne by the likely beneficiaries. The test subjects will likely not gain any health benefits from participating in the study; such subjects are not colostomy patients and hence not the target consumers of the LowCostomy appliance. Further, if an ostomy patient happens to participate in the study, he/she will likely return to the use of higher-priced medical-grade colostomy appliances without the use of the beeswax-pine resin mixture as the LowCostomy device will be marketed to populations in low-resource settings. The analysis expected to result from the tests is more valuable to the target low-income patients of Sub-Saharan Africa, who would be using this mixture on their skin. This is the main purpose of providing a monetary incentive to American patients who participate.

The loss of privacy and confidentiality is an additional risk. However, every reasonable effort will be made to limit breaches of privacy and confidentiality.

### Costs to the Subject:

There will be no costs to the subjects. All necessary supplies will be provided for the duration of the study.

### Data Analysis and Statistical Considerations

Data from subjects who successfully complete the seven-day study will be used for analysis. The photos from Day 1 and Day 7 will be reviewed by the licensed physician using the Draize skin scoring system. Subjects will fill out a survey of their experiences of wearing the beeswax-pine resin adhesive. The 5-D itch scale will be used to quantify subjective experiences. All photos included in the dataset will be blinded before a licensed physician quantitatively indicate the level of skin irritation. Only the data of subjects who completed data collection for the entire 7-day duration will have their results quantified. Statistical tests will be completed on the results to draw conclusion about whether the beeswax-pine resin samples, in comparison to our control, caused skin irritation.

### Data and Safety Monitoring

Adverse side effects of the beeswax-pine resin mixture placed on the skin may include redness, rash, skin irritation, and infection. In the duration of the seven-day period, subjects will be provided a survey at the end of each day to assess their overall well-being and to provide them a space to express any concerns they may have. Any significant infection or irritation of the skin that causes serious concern for the subject will be evaluated by a licensed physician to evaluate whether they can continue in the study. Any signs of infection or other adverse side effects will result in the immediate cessation of the seven-day period for that subject.

### Privacy, Data Storage & Confidentiality

Any data that is stored in paper or non-digital format will be locked in a file cabinet within a key-accessed office. The office will be locked when not in use by the study team. Picture data stored via camera will be stored in a portable lock box when transportation is needed. However, picture data will be deleted as soon as possible after data is transferred to a secure server. Any data that is stored in electronic format will be housed on a secure server behind the Duke University Medical Center firewall and/or REDCap. Any personnel involved with data collection will be trained on the study's Secure Data Collection SOP.

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