Smart and Bio-compatible Ostomy Bag Hydrogel Adhesive

William Pan[1] (williampan4032@gmail.com), Matt Marshall[1] (mattmarshall@iusd.org), David Monge[1] (davidmonge@iusd.org)
[1]Northwood High School, Irvine, CA, 92620

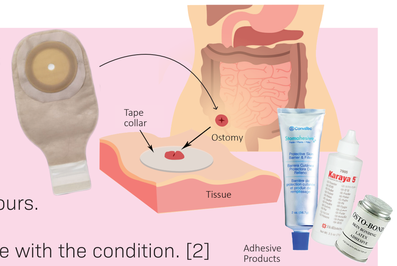
NORTHWOOD HIGH SCHOOL

Background.

Ostomies are digestive and excretory surgeries where waste is redirected through the abdomen, requiring a bag to catch excrement. [1]

Current methods have adhesives along with pastes or powders to create adhesion for 24 hours.

Estimated that 700,000 in the United States live with the condition. [2]



Motivation.

Create a novel and smart hydrogel device that prevents ostomy leaks and has strong adhesion.

Challenge.

- Current adhesives are weak, leading to leakages of bodily wastes onto the skin, which causes dermatitis (34% of patients affected) [3].
- No methods today have strong adhesion to prevent skin damage from accidental ostomy leaks or blowouts.

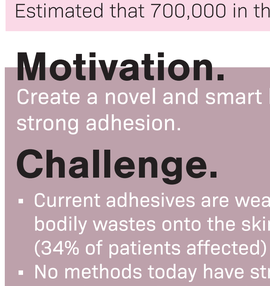
Key Idea. A novel combination of the hydrogel ostomy adhesive (HOA) and chitosan ostomy bonding solution (COBS) was formulated. A bridging-polymer network between the skin and hydrogel creates strong adhesion, allowing for a wide range of movement, long wear times, and less leakages.

Methods.

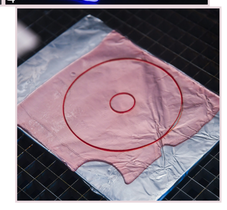
HYDROGEL OSTOMY ADHESIVE (HOA)

1) acrylamide and sodium alginate monomers were dissolved in distilled water.
2) N,N'-methylene(bisacrylamide), N,N,N',N'-tetramethylethylenediamine, calcium sulfate, ammonium persulfate used as covalent and ionic crosslinkers.
3) reagents are mixed, done so no air bubbles appear in the solution
4) 1 hour UV curing (365 nm) in glass mold with 1 mm silicone buffer.
5) laser cut with laser printer (Epilog Zing 24) in predesigned shape.

CHITOSAN OSTOMY BONDING SOLUTION (COBS & COBSEN)

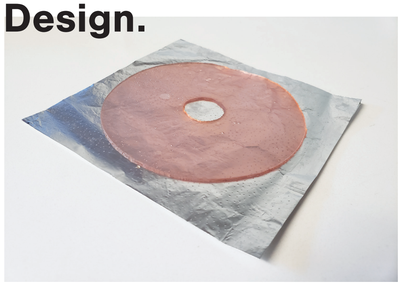


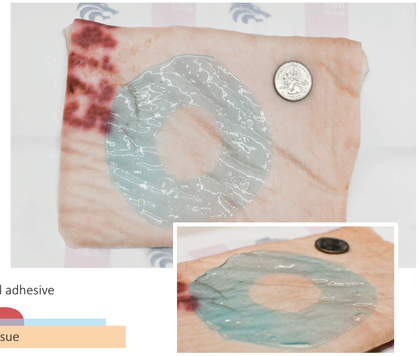
1) Chitosan was dissolved in 0.1 M MES hydrate for 1 hour.
(Chitosan ostomy bonding solution EDC-NHS (COBSEN) was an alternative solution for stronger adhesion used in the adhesion tests. N-Hydroxysuccinimide *(NHS) and 1-Ethyl-3-(3-dimethylaminopropyl)carbodiimide (EDC) were added into COBS.)*
2) Solution was evenly spread on the skin prior to adhesion. HOA applied for a minimum of 5 minutes for bonding to occur.



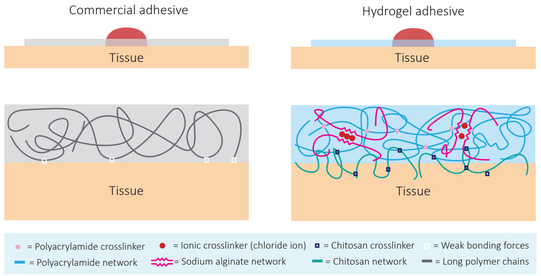
Additional information about the creation of the device and other mechanical tests can be found in Materials and Methods and Supplementary Information.

Design.



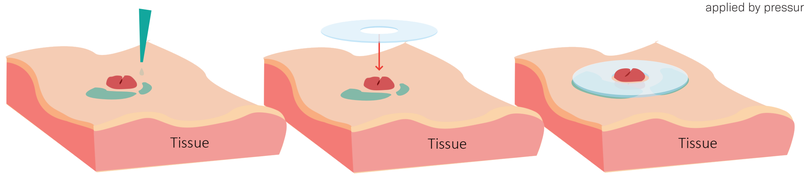


▲ Ex vivo porcine skin test on the hydrogel ostomy adhesive.

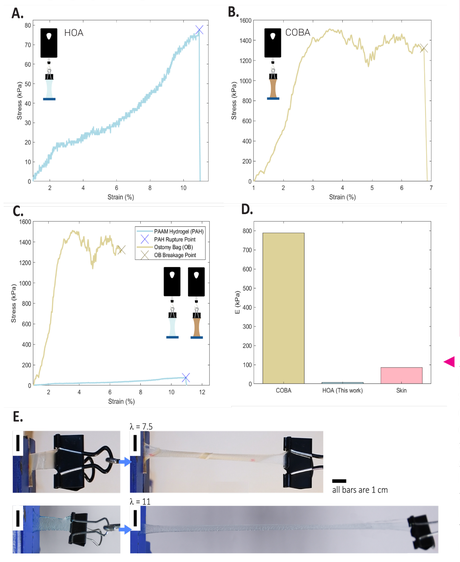


◀ Conventional adhesive methods use weak forces like van der Waal interactions and dipole-dipole interactions. This work uses a polymer network of chitosan that cross the two substrates by diffusion to create strong but flexible bonding. As well, the double polymer network of polyacrylamide and sodium alginate creates high strength and elasticity for more effective coverage of the skin.

▼ Steps of adhesion of the device on skin. COBS or COBSEN is added on the skin and the device is then applied by pressure.



Results.



◀ **A.** Stress-stretch curve of the HOA's material, polyacrylamide alginate hydrogel, until rupture. Nominal stress is the force applied over the original measured cross sectional area. **B.** Stress-stretch curve of the current ostomy bag material, a hydrocolloid with pectin and various other carbohydrates. **C.** Stress-stretch curves of **A.** and **B.** in comparison with the stress-stretch curves of human skin. **D.** When comparing the stiffness of each of the materials, the hydrogel of the HOA outperforms COBA materials as it is closer to the Young's Modulus of skin. **E.** Time-lapse images of the COBA (top) and HOA (bottom) materials exposed to maximum stretch force.

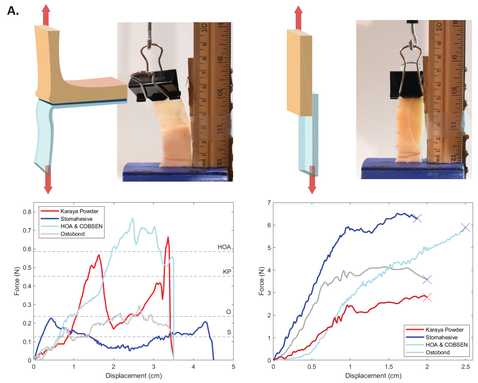
Mechanical softness and strength of the hydrogel ostomy adhesive.

- Skin has a modulus of around 85 kpa [4], and the HOA has a modulus of 6.66 kPa, allowing for softness, stretchiness, and strength that matches that of skin.
- Current ostomy bag adhesives (COBA) on the other hand have a modulus of around 7.89 x 10^2 kPa, possessing stiffer properties that not match that of skin.
- The HOA material has a high stretch factor, allowing for better coverage of the skin.

Results (cont).

Robust adhesion in ex vivo porcine models of the hydrogel ostomy adhesive. ▶

- The HOA with COBSEN provides high adhesive strength with an interfacial toughness of 58.5 J m^{-2} and a shear strength of 9.822 kPa.
- This device does better than most commercial ostomy pastes and powders like Karaya Powder, Stomahesive, and Ostobond.

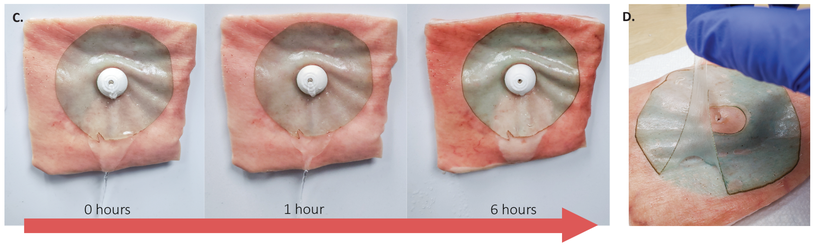


A. A 180° degree peel test was to determine the interfacial toughness of each of the different solutions (left). A lap shear test was used to determine shear strength of the each of the different solutions (right). **B.** The HOA with the COBSEN exceeds in adhesion compared to convetional ostomy pastes and powders in terms of interfacial toughness and shear strength.

High wear endurance of the hydrogel ostomy adhesive. ▼

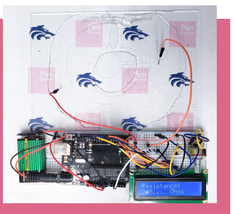
The HOA can hold 4.9 N of shear force even after 12 hours of wear, as shown by hanging a 500 g mass on the device.

▼ **C.** Time-lapse images of mock ostomy endurance flow tests over 6 hours. The HOA exhibits barely any change to its adhesive and mechanical strength. **D.** After 12 hours of continuous water flow to simulate ostomy conditions, the HOA still had strong adhesion.



Future Directions.

- ***Drug Delivery:*** to administer medication to reduce inflammation after a leak.
- ***Leak Detection:*** to detect ion flow under the device before a leak occurs. (shown on the right).
- ***Improvement:*** The HOA can be improved by adding a layer of polydimethylsiloxane (PDMS) to prevent drying, similar to the methods in Yuk et al. 2016 [5]



Conclusions. This work presents the HOA, a stronger, biocompatible, and smart adhesive device that is made of hydrogels, along with the COBS, a tough interconnected polymer network with the skin that creates adhesion for up to 24 hours. The HOA can allow for ostomy patients to live with ease and live truer to who they want to be.

References.

[1] Steinhagen, E., Colwell, J. & Cannon, L. M. Intestinal Stomas—Postoperative Stoma Care and Peristomal Skin Complications. Clin Colon Rectal Surg 30, 184–192 (2017). **[2]** Cressey, B. D. et al. Stoma care products represent a common and previously underreported source of peristomal contact dermatitis. Contact Dermatitis 76, 27–33 (2017). **[3]** Leong, A. P. K., Londono-Schimmer, E. E. & Phillips, R. K. S. Life-table analysis of stomal complications following ileostomy. Br. J. Surg. 81, 727–729 (1994). **[4]** McKee, C. T., Last, J. A., Russell, P. & Murphy, C. J. Indentation versus tensile measurements of Young's modulus for soft biological tissues. Tissue Eng Part B Rev 17, 155–164 (2011). **[5]** Yuk, H., Zhang, T., Parada, G. A., Liu, X. & Zhao, X. Skin-inspired hydrogel–elastomer hybrids with robust interfaces and functional microstructures. Nat Commun 7, 12028 (2016).

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Research Paper

Supplementary Materials

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