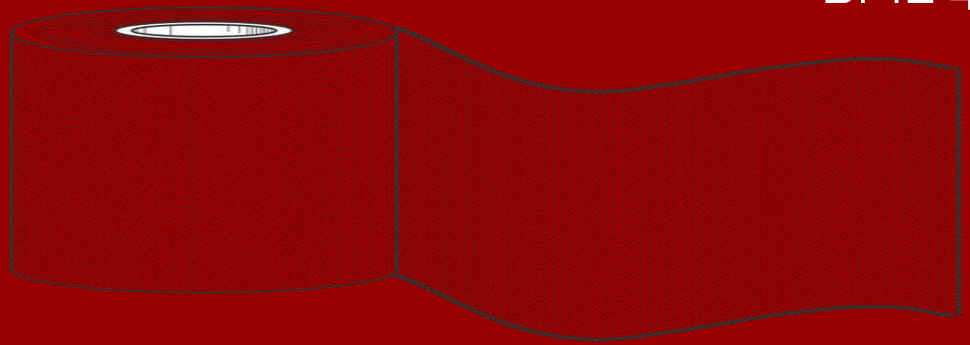
Washington University in St. Louis
James McKelvey School of Engineering

A Novel Bandage System

Preliminary Report

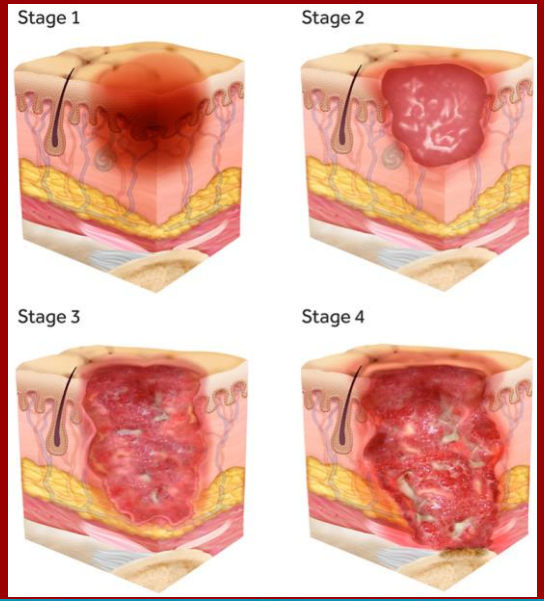
Yushin Lee, Victoria Liu, Hannah Pang
Group 15
BME 401A

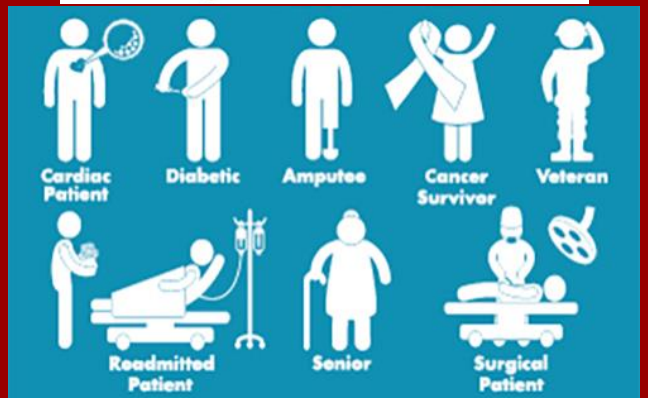


Background – Chronic Wounds

Over 6.5 million people in the U.S. have chronic wounds

- Ulcers: venous, diabetic foot, pressure, arterial insufficiency
- Pressure ulcers categorized into stage 1-4, unstageable, suspected deep tissue injury
- Impaired healing for over 4 weeks
- Costs U.S. healthcare system over $25 billion annually





De Moya et al. (n.d.), Robson and Barbul (2006), Grey et al. (2006), Zulkowski (n.d.)

Background – Wound Care

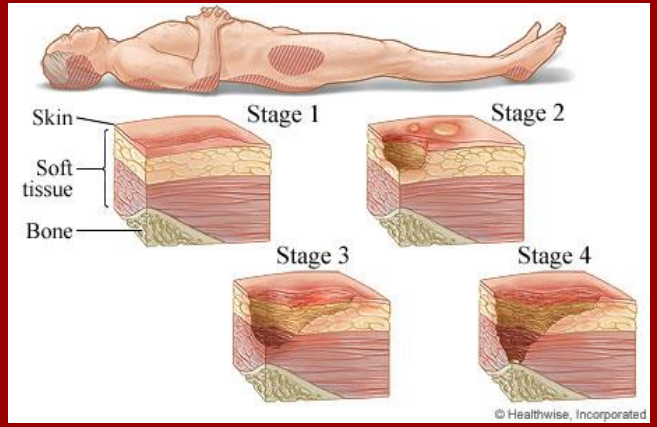
Chronic wound care is wasteful and costly

- 12 weeks follow-up: 30.5% diabetic foot ulcers, 29.6% pressure ulcers, and 44.1% venous ulcers healed
- Care given in outpatient departments, skilled nursing facilities, and home
- Global medical tape and bandage market $7+ billion
- Manual fitting of bandages/dressings leads to wastefulness, imprecision, and sterility concerns

Bauer (2016), Center for Medicare & Medicaid Services, Fife (2018), Grand View Research (2016)

There is a need for a wound analysis and care system that:

- Improves clinicians' ability to treat individual chronic wounds
  - Captures chronic wound morphology
  - Generates in a timely manner waste-reducing custom bandages that promote healing



Project Scope

A system that can be easily used by clinicians for chronic wound care

- Portable imaging device that can be connected to a computer to record and save digital images of wound
- Software that analyzes wound from images, quantifies and models the interior surface of wound, and generates appropriate custom bandage template.
- Software that utilizes the bandage template in a device that will execute design and create custom bandage

By April 2020 the project will be completed with an optimized process that analyzes wound images and creates a schematic for a custom bandage design that can be carried out

Design Specifications – Wound and Imaging

Design Specification	Description and Metric
Size and Ease of Use of Imaging Device	Device should be easily gripped by a person with a 12 cm hand length (“12 cm grip”) or larger and operable with 1 hand
Image Brightness	Wound image being analyzed should have a 200:1 contrast ratio or greater in order to be compatible with the software
Image Resolution	Wound image being analyzed should have a 1 megapixel resolution or greater in order to be compatible with the software
Wound Size	Wound sizes that can be addressed are 1~15cm in length, 1~15cm in width, and 0~5cm in depth
Wound Severity	System applicable to stage 2~3 ulcers

Design Specifications – Wound Analysis

Design Specification	Description and Metric
Measurement Accuracy of Image-to-Model Conversion	Maximum measurement error for conversion of wound image to wound surface model is 10%
Processing Time	Processing time required to develop digital wound template from digital image is within 10~30 minutes
Complexity of Software	Software should be simple enough to use after 30 minutes or fewer of training (not including HIPAA regulations, sterility, or other hospital-specific protocol training)
Skill Level of Software User	No special technical skills required except English proficiency and basic understanding of computer use; all healthcare professionals should be able to use program after training

Design Specifications – Bandage/Dressing

Design Specification	Description and Metric
Template Options	Minimum of 3 different template options are generated by the software for each wound image processed
Production Time	Production time required to make customized bandage from digital template is within 0.5~3 hours
Sterility	Bandage must be sterile and meet current U.S. medical standards of sterility; final generated bandage should have equivalent or better bioburden level compared to current bandages

There are no existing solutions that combine wound analysis with bandage production to create a custom bandage/dressing that requires no further modification, but there are solutions for each component.

Existing Solutions – Wound Analysis

Manual Assessment
- Ruler/tape measure and probe
- Up to 44% error

Wound Works / eKare (*US20160206205A1*)
- Machine learning-based analysis
- Area and volume measurements
- iOS

Tissue Analytics (*WO2016069463A2*)
- Algorithm-based analysis
- 3D reconstruction of 2D surface
- Android and iOS

TISSUEANALYTICS

Grey et al. (2006), Yee et al. (2017), Wu et al. (2015, 2016), Budman et al. (2015, 2016)

Existing Solutions – Wound Analysis

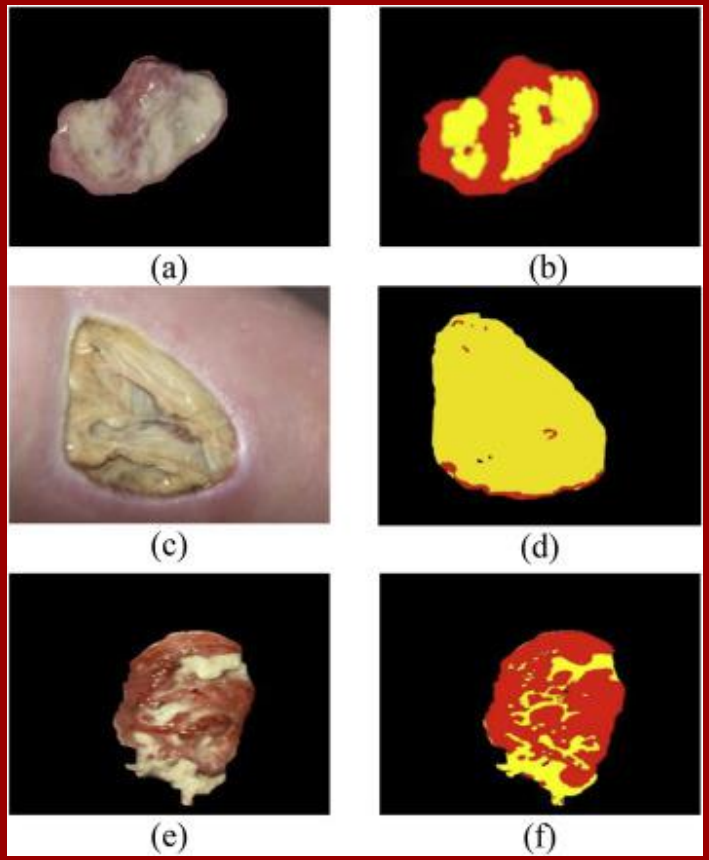
Spectroscopy

- Raman
- Thermal infrared
- Diffuse optical

Fuzzy C-Means Clustering / Color Analysis

- Classify wound types
- Percent composition of different tissues

No solutions directly translate wound characterization into customized bandages/dressings!



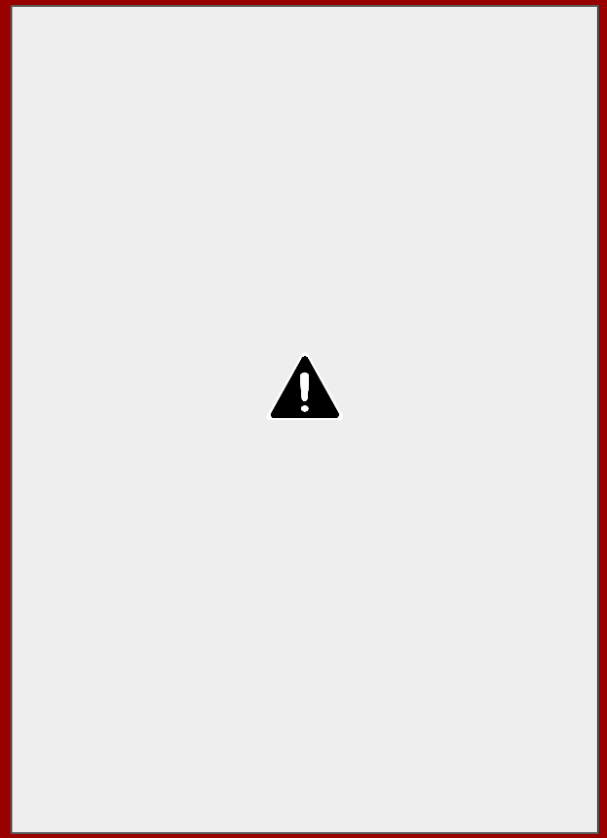
Murphy et al. (2016), Postel (2010), Cuccia et al. (2010), Nizam et al. (2018)

Existing Solutions – Bandages/Dressings

3D-Compressible Dressing (*US8535710B2*)
- Glass fiber-based
- Adjusts surface area to volume ratio

Negative Pressure Therapy Dressing (*WO2014140608A1*)
- Optimized sealant formulations and layers
- Targets irregularly-shaped wounds

These bandages/dressings are versatile for fitting individual wounds, but still require manual modifications to the existing product to fit it to the patient.



Jung et al. (2013),, Collinson et al. (2014)

Existing Solutions – Production Methods

Electrofocused Blow Spinning Device (*WO2017059050A1*)

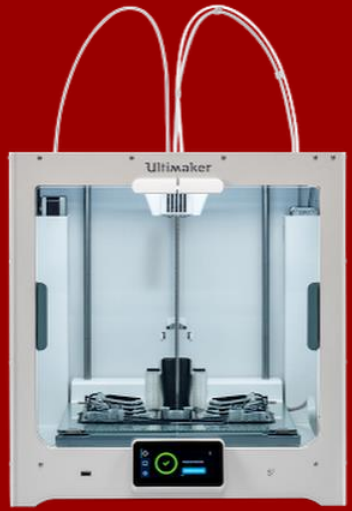
- Spin dressing directly onto wound surface

Elastic Dressing: Lattice or Netting (*US20140081192A1*)

- 3D printing, screen printing, weaving, knitting

3D Printing Repair Construct (*WO2016130953A1*)

- Inject biomaterial in 3D pattern into another material that keeps form intact



Digital Die Cutting (*US6765123B2*)

- Cut multi-layered composite web into shapes

Baharlou et al. (2017), Wenske et al. (2014), Marquez et al. (2016), de Jong et al. (2004)

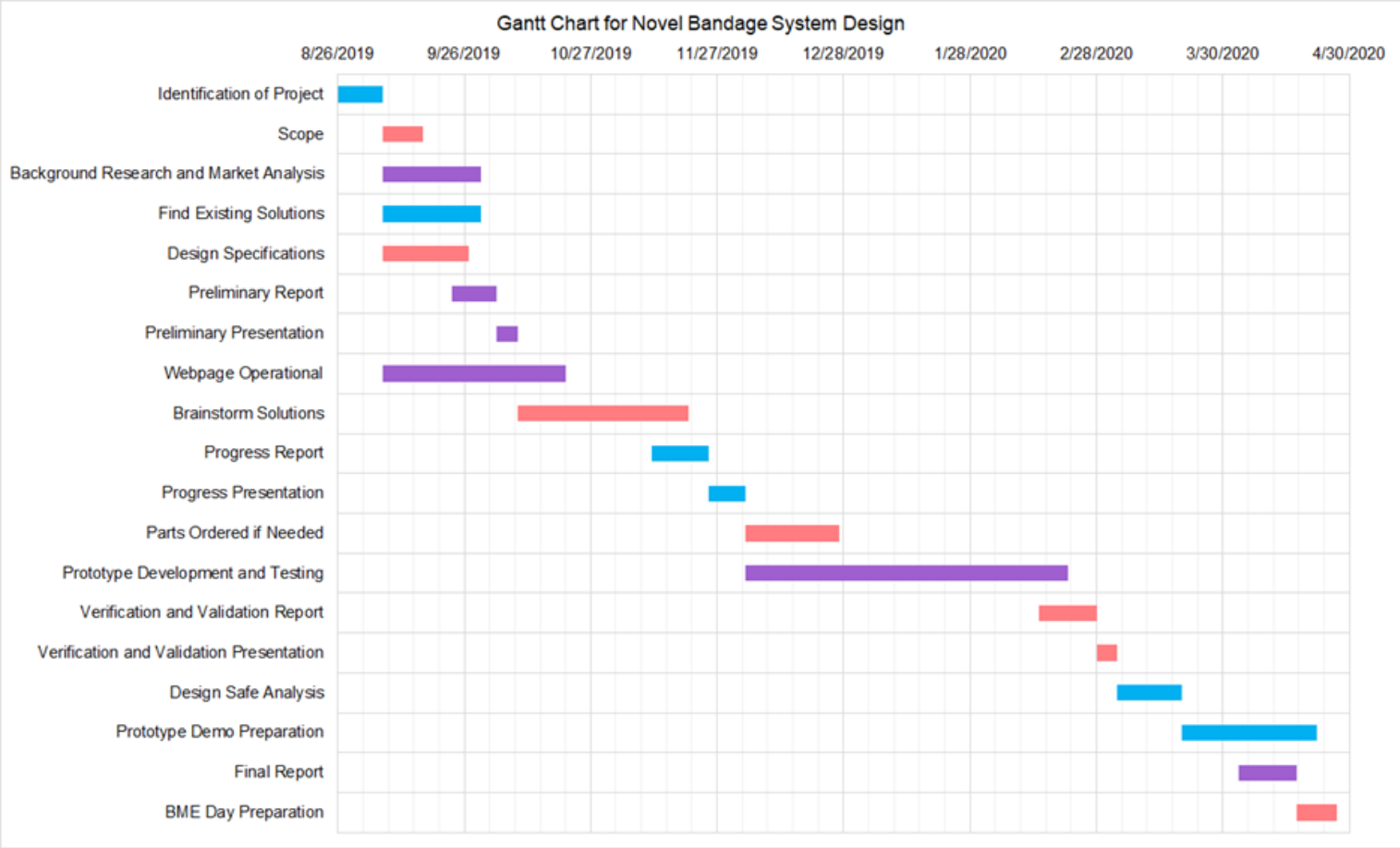
Existing Solutions Recap

Wound characterization and bandage/dressing production are not integrated

- Wound analysis technology
- Maximize adaptability of bandages/dressings
- Advanced bandage/dressing production methods

Automating processes with personalized wound models in a streamlined way will take advantage of advancements in production methods in order to efficiently generate customized dressings to better facilitate healing

Preliminary Design Schedule with Gantt Chart



Victoria

Yushin

Hannah

Team Responsibilities

Victoria

- Circuitry and electronic design
- Communication with clients
- Progress presentation

Yushin

- Coding and software design
- Budget
- V&V presentation

Hannah

- Mechanical design
- Webpage
- Preliminary Presentation

Works Cited

Bauer, Karen et al. “Pressure Ulcers in the United States’ Inpatient Population From 2008 to 2012: Results of a Retrospective Nationwide Study.” *Ostomy Wound Manage* vol. 62,11 (2016): 30-38.

Budman, Joshua et al. “Design of A Smartphone Application for Automated Wound Measurements for Home Care.” *Connected Health Symposium* vol. 1,1 (2015). doi:10.2196/iproc.4703.

“Covered Medical and Other Health Services.” *Medicare Benefit Policy Manual*. Center for Medicare & Medicaid Services. (2019).

Dabiri, Ganary et al. “Choosing a Wound Dressing Based on Common Wound Characteristics.” *Advances in Wound Care* vol. 5,1 (2016): 32-41. doi:10.1089/wound.2014.0586

De Moya, Marc A. et al. *Non-Healing Wounds*. American College of Surgeons Division of Education. (n.d.).

Edsberg, Laura E. et al. “Revised National Pressure Ulcer Advisory Panel Pressure Injury Staging System: Revised Pressure Injury Staging System.” *Journal of Wound, Ostomy, and Continence Nursing: Official Publication of The Wound, Ostomy and Continence Nurses Society* vol. 43,6 (2016): 585-597. doi:10.1097/WON.0000000000000281.

Fife, Caroline E. et al. “Publicly Reported Wound Healing Rates: The Fantasy and the Reality.” *Advances in Wound Care* vol. 7,3 (2018): 77-94. doi:10.1089/wound.2017.0743.

Grey, Joseph E. et al. “Wound Assessment.” *BMJ (Clinical research ed.)* vol. 332,7536 (2006): 285-8. doi:10.1136/bmj.332.7536.285.

Javierre, E. et al. “A mathematical analysis of physiological and morphological aspects of wound closure.” *Journal of Mathematical Biology* vol. 59,5 (2009): 605-630. doi:10.1007/s00285-008-0242-7.

“Medical Tapes & Bandages Market.” *Market Estimates & Trend Analysis*. Grand View Research. (2016).

Nizam, Khajista et al. “Characterization of Tissues in Chronic Wound Images.” *2018 IEEE Student Conference on Research and Development*. (2018). doi:10.1109/SCORED.2018.8710941.

Robson, M. C. and Adrian Barbul. “Guidelines for the best care of chronic wounds.” *Wound Repair and Regeneration* vol. 14,6 (2006): 647-648. doi:10.1111/j.1524-475X.2006.00173.x.

Wu, Kyle L. et al. “Feasibility Of 3D Structure Sensing For Accurate Assessment Of Chronic Wound Dimensions.” *Computer Assisted Radiology and Surgery International Congress*. (2015).

Yee, Adam et al. “Quantitative Monitoring Wound Healing Status Through Three-dimensional Imaging on Mobile Platforms.” *The journal of the American College of Clinical Wound Specialists* vol. 8,1-3 (2017): 21-27. doi:10.1016/j.jccw.2017.11.001.

Zulkowski, Karen. “Wound Classification.” *Agency for Healthcare Research and Quality*. (n.d.). Webinar.

Patents Cited

Baharlou, Sogol M. et al. Portable spinner and methods of use. WO 2017059050 A1, World Intellectual Property Organization, 6 April 2017. *Google Patents*, https://patents.google.com/patent/WO2017059050A1.

Budman, Joshua et al. A system and method for the analysis and transmission of data, images and video relating to mammalian skin damage conditions. WO 2016069463 A2, World Intellectual Property Organization, 6 May 2016. *Google Patents*, https://patents.google.com/patent/WO2016069463A2.

Cavanagh, Peter R. et al. Wound healing system and method of use. US 6720470 B2, United States Patent and Trademark Office, 13 April 2004. *Google Patents*, https://patents.google.com/patent/US6720470B2.

Collinson, Sarah Jenny et al. Wound sealing dressant and use thereof. WO 2014140608 A1, World Intellectual Property Organization, 18 September 2014. *Google Patents*, https://patents.google.com/patent/WO2014140608A1.

Cuccia, David et al. Method for performing qualitative and quantitative analysis of wounds using spatially structured illumination. US 20100210931 A1, United States Patent and Trademark Office, 19 August 2010. *Google Patents*, https://patents.google.com/patent/US20100210931A1.

de Jong, Johannes H.A. et al. Process for the manufacture of multilayered wound dressings. US 6765123 B2, United States Patent and Trademark Office, 20 July 2004. *Google Patents*, https://patents.google.com/patent/US6765123B2.

Jung, Steven B. and Delbert E. Day. Wound care. US 8535710 B2, United States Patent and Trademark Office, 17 September 2013. *Google Patents*, https://patents.google.com/patent/US8535710B2.

Marquez, Samantha M. et al. High speed 3D printing system for wound and tissue replacement. WO 2016130953 A1, World Intellectual Property Organization, 18 August 2016. *Google Patents*, https://patents.google.com/patent/WO2016130953A1.

Murphy, Christopher J. et al. Method of characterizing wounds with raman spectroscopy. US 20160198994 A1, United States Patent and Trademark Office, 14 July 2016. *Google Patents*, https://patents.google.com/patent/US20160198994A1.

Postel, Olivier B. Method for Detecting and/or Monitoring a Wound Using Infrared Thermal Imaging. US 20100041998 A1, United States Patent and Trademark Office, 18 February 2010. *Google Patents*, https://patents.google.com/patent/US20100041998A1.

Wenske, Günther et al. Primary dressing for moist wound healing, and method for producing said primary dressing. US 20140081192 A1, United States Patent and Trademark Office, 20 March 2014. *Google Patents*, https://patents.google.com/patent/US20140081192A1.

Wu, Kyle et al. Method and system for wound assessment management. US 20160206205 A1, United States Patent and Trademark Office, 21 July 2016. *Google Patents*, https://patents.google.com/patent/US20160206205A1.

Questions?