Washington University in St. Louis
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A Novel Bandage System

Progress Report

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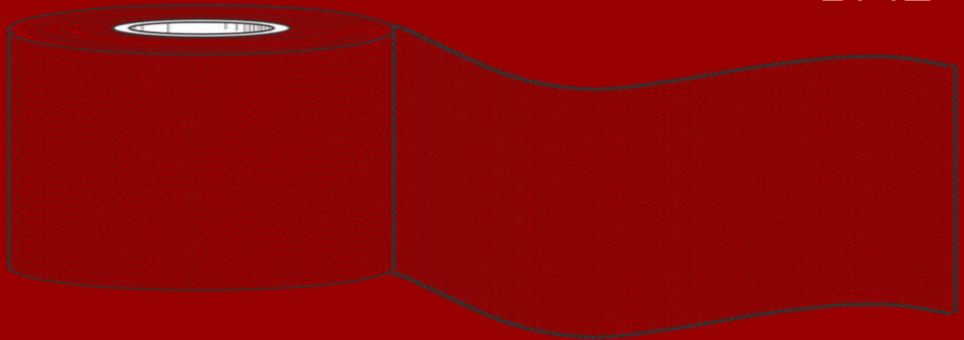
Group 15
BME 401A



Needs Statement - Initial

There is a need for a wound analysis and care system by clinicians to capture chronic stage 2-3 wound morphology and generate in a timely manner waste-reducing custom bandages to **promote healing**.

Needs Statement - Modifications

There is a need for a wound analysis and care system by clinicians to capture chronic stage 2-3 wound morphology and generate in a timely manner waste-reducing custom bandages.

Project Scope - Initial

The group proposes to deliver a prototype of a system that can be easily used by clinicians for analyzing chronic stage 2-3 wounds and producing waste-reducing custom bandage templates. Clinicians currently tend to only use a fraction of larger bandages for wound care, and they would benefit from an optimized process reducing bandage waste when treating wounds of various profiles and complex contours. The first step of the process will require a portable imaging device that can be connected to a computer to record and save images of the wound in a digital file. Software will also be developed to analyze the wound from the images, quantify and model the interior surface of the wound, and **create a custom bandage**.

Project Scope - Modifications

The group proposes to deliver a prototype of a system that can be easily used by clinicians for analyzing chronic stage 2-3 wounds and producing waste-reducing custom bandage templates. Clinicians currently tend to only use a fraction of larger bandages for wound care, and they would benefit from an optimized process reducing bandage waste when treating wounds of various profiles and complex contours. The first step of the process will require a portable imaging device that can be connected to a computer to record and save images of the wound in a digital file. Software will also be developed to analyze the wound from the images, quantify and model the interior surface of the wound, and **create a physical product embodying the size and shape of a custom bandage**.

Design Specifications - Modifications

Sterility
The bandage must be sterile and meet current U.S. medical standards of sterility. The final generated bandage should have an equivalent or better bioburden level compared to current commercially-available bandages used for wound care.

→

Sterility
The process of producing the custom bandage template must meet current U.S. medical standards of sterility.

Team Responsibilities - Modifications

Software

Yushin

Extract topographic information

Yushin

Construct bandage template based on wound analysis

Hannah

Interface between template and production method software

Victoria

Design Schedule - Modifications

- Complete Makerspace training by January
- Confirm with appropriate contact persons regarding utilization of needed equipment for prototyping and testing

As the objective of the project is to develop an optimized system for wound analysis and custom bandage template generation, potential solutions were considered for each component.

Design Alternatives - Wound Documentation

Phone Camera

- Similar functions across brands
  - Adjust focus
  - Record video
- Wireless connection
- Voice commands
  - Increase ease-of-use
- Minimal training
- May be vulnerable to HIPAA violations
- Standard wall power sufficient
  - Requires charging often
- Pricing varies
  - $384 on average

Digital Trends (2019), GfK (2019)

Design Alternatives - Wound Documentation

Point-and-Shoot Digital Camera

- Similar functions across brands
  - Automatically adjust for optimal results
  - Record video
- Wireless connection
  - Direct upload to computer
- Rechargeable (standard wall power)
- One-handed use
- Minimal training
- 18 MP resolution
  - >$40
- HIPAA adherence may be easier

Amazon (2019), PCMag (2019)

Design Alternatives - Wound Documentation

Digital Single-Lens Reflex (DSLR) Camera

- Faster reflex mirror so view actual final image rather than an approximation
- Faster shutter speed
- Larger than point-and-shoot cameras
- Wireless connection
    - Direct upload to computer
- Greater cost
    - 24 MP resolution DSLR camera valued at >$90
- Rechargeable (standard wall power)
- HIPAA adherence may be easier

Amazon (2019), Nikon (2019)

Design Alternatives - Wound Documentation

Optical Coherence Tomography (OCT)

- Near-infrared light produces 2D image of optical scattering
  - Essentially a high-resolution ultrasound
- Structural information of wound
- Usually non-contact system
- Requires advanced training
- Expensive
  - $35000-$150000
- Standard wall power sufficient
- HIPAA compliance may be easier

Jayachandran et al. (2015), Gefvert (2017), Nidek Intl. (2019)

Design Alternatives - Wound Documentation

3D Camera

- Range camera
  - Distance between each point and reference point → range map
- Stereo camera
  - Uses 2 or more lenses → 3D images
- ZED Mini 3D camera *(Stereolabs)*
  - MATLAB compatible
  - Depth range: 0.15-12m
- Price varies
  - $200-$10000
- Rechargeable (standard wall power)
- HIPAA compliance may be easier

Jain (2016), Stereolabs (2019)

Pugh Chart

Criteria	*Weight*	Phone Camera	Point-and-Shoot Camera	DSLR Camera	Optical Coherence Tomography	3D Camera
Cost	*8*	8	8	6	3	4
Size and Ease of Use	*8*	8	7	6	5	5
Skill Level to Use	*7*	8	7	5	3	5
Output Quality	*9*	8	8	8	7	5
HIPAA Compliance	*7*	5	7	7	7	6
Power Source	*5*	7	8	8	8	8
		326	**330**	**292**	**237**	**234**

Design Alternatives - Wound Analysis

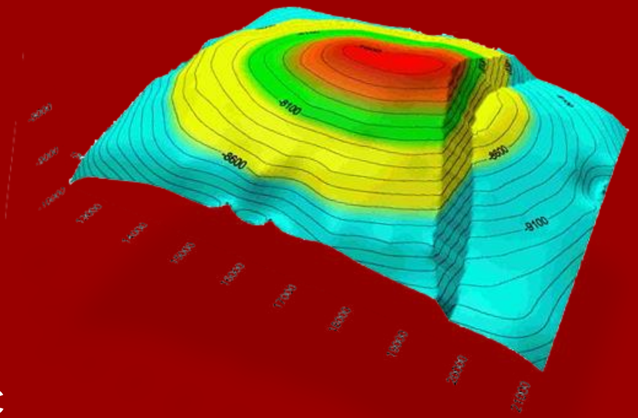
Surface Mapping

- Translates 3D surface into 2D map

- Dimension reduction methods
  - Represent 3D surface on multiple planar grids
  - Map 3D data in 2D space

- Maintains spatial features and relationships between data points

- Impossible to equally preserve geometric relationship of all surface points



Yang et al. (2012), Civil Engineering Software Database (2019)

Design Alternatives - Wound Analysis

Edge Detection

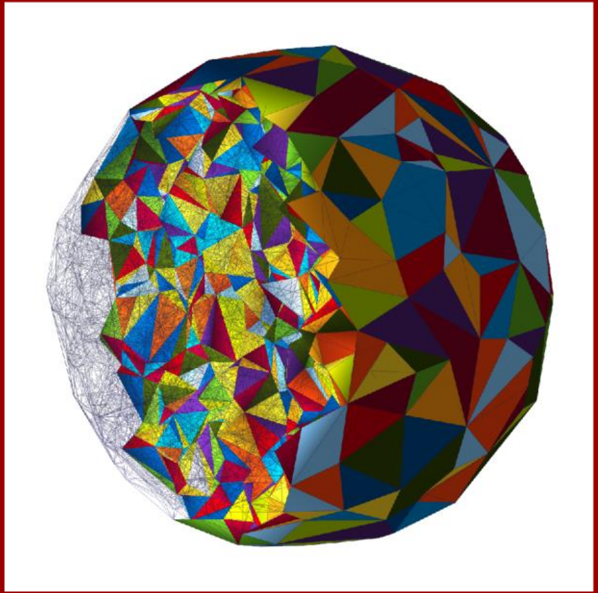
- Determines object boundaries
  - Detects discontinuities in image detection
- Depth edge detection
  - Detects discontinuities in depth
- High-resolution analysis
- Noise
  - Reduced by filtering
  - Filter application reduces edge strength
- Conventional → grayscale
- Color edge detection
  - Segments image based on color difference
  - More effectively eliminates image noise in similar color regions

MathWorks (2019), Zhuo et al. (2016), George and Lakshmi (2013)

Design Alternatives - Wound Analysis

Image Triangulation

- Segments image into triangles and applies linear color gradient
- Reproduces color, shape, and depth
- Requires multiple viewpoints
- Analysis becomes more complex as triangulation increases
    - Approximation improves with increased triangulation
- Video triangulation
    - Considers each frame independently
    - Temporal instability



Lawonn and Günther (2018), National University of Singapore (2014)

Design Alternatives - Wound Analysis

Photometric Stereo

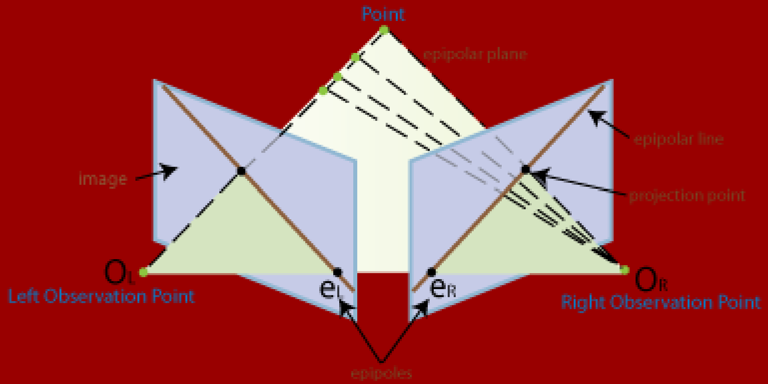
- Integrates over surface pixel orientation
- Estimates surface geometry and depth
- Requires multiple images from same viewing angle with varying lighting
- No correspondence determination step
- Requires lighting calibration

Queau et al. (2107), Hold-Geoffroy et al. (2015)

Design Alternatives - Wound Analysis

Structure from Motion (SfM) Analysis

- High resolution 3D reconstruction from 2D images
- Uses overlapping 2D images from multiple perspectives
- Automatically determines camera position and orientation
- Reference object needed to accurately determine sizing
- High accuracy
  - 1-5% surface area and volume relative error



Westoby et al. (2012), Yee et al. (2017), MathWorks (2019)

Pugh Chart

Criteria	*Weight*	Surface Mapping	Edge Detection	Image Triangulation	Photometric Stereo	Structure from Motion
Simplicity	*6*	6	9	6	6	6
Surface Area Accuracy	*9*	6	5	7	7	8
Depth Accuracy	*8*	5	3	7	7	8
		130	**123**	**155**	**155**	**172**

Design Alternatives - Production Methods

Laser Cutting

- Focus laser beam to increase heat density at area of focus
- Cuts variety of material
  - E.g. cotton, nylon, metal
- Accurate
  - +/- 0.254mm
- Seals fabric edges
- Fast
- Variable amount of excess material
- 2'x3' industrial laser cutter valued at $16000

Epilog Laser (2019), Boss Laser (2019)

Design Alternatives - Production Methods

3D-Printing

- Produces model one layer at a time
- Fuses layers using adhesive or UV light
- Prints variety of materials
  - E.g. Plastic, nylon, polymer fiber
- Accuracy and tolerance vary
- Limited waste
- Slow
- Industrial 3D printers valued >$20000

Form Labs (2019), Computer Aided Technology (2019), Redbrick3D (2019)

Design Alternatives - Production Methods

Manual Cutting

- Need disposable ruler
- Reference points are highly subjective
  - Likely non-repeatable
- 44% error
- Leads to waste
- Fast
- Inexpensive
  - Scissors
    - $9
  - Rulers
    - $2.50

Yee et al. (2017), Amazon (2019), Southwest Regional Wound Care Program (2019)

Design Alternatives - Production Methods

3D Textile Production

- 3D-weaving or 3D-knitting
- Modifiable
  - Fiber size
  - Fiber orientation
  - Porosity
- Accurate
- Reduces waste
- Slow
- Expensive
  - 3D-knitting system
    - $13000
  - 3D-weaving system
    - $15000

Akbari et al. (2016), Kniterate (2019), Alibaba (2019), Shapeways (2019), Lindauer DORNIER GmbH (2019)

Pugh Chart

Criteria	*Weight*	Laser Cutting	3D Printing	Manual Cutting	3D Textile Production
Cost	*9*	7	6	10	8
Accuracy	*8*	9	9	2	9
Time	*7*	8	4	9	4
Waste Reduction	*9*	7	9	3	9
Material Compatibility with Existing Materials	*7*	9	5	9	5
Power Source	*5*	8	8	10	8
		357	**310**	**309**	**328**

Design Alternatives - Sterilization

UV Germicidal Irradiation Lamps

- Ultraviolet C energy
  - Destroys or inactivates pathogens
- Disinfectant system
- Limitations
  - Penetration power
  - Extended exposure time
- Personal protective equipment required
- May damage materials
- Inexpensive
  - $16/lamp

Centers for Disease Control, University of Colorado Boulder, Amazon (2019), University Corporation for Atmospheric Research Center

Design Alternatives - Sterilization

Wet Heat (Steam)

- Autoclave
- Sterilization system
  - Coagulates and denatures proteins
- Fast
  - Exposure time of minutes
- Widely used
- May damage materials
- Non-toxic
- Inexpensive
- May cause burns

Centers for Disease Control, Amazon (2019)

Design Alternatives - Sterilization

Dry Heat

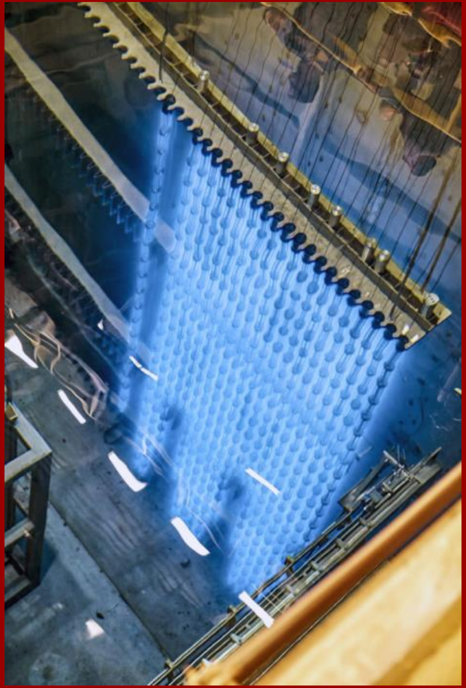
- Oxidizes cell components
  - Disrupts protein structure and function
- Sterilization system
- Slow
  - Exposure time of hours
- May damage materials
- Non-toxic
- Inexpensive to install and maintain
- May cause burns

Centers for Disease Control, University of Colorado Boulder, Amazon (2019), Duraline Systems

Design Alternatives - Sterilization

Ionizing Radiation

- Cobalt-60 gamma rays, electron beams, X-rays
- Sterilization system
  - Mutagenic effects
- Extensive training required
- Expensive
  - Shielding equipment
  - Production and storage requirements (cobalt-60)
- Large-scale use
- Low temperature
- May damage material



Centers for Disease Control, Amazon (2019), Bruce Power

Design Alternatives - Sterilization

Ethylene Oxide (EtO) Gas

- Gaseous sterilization system
  - Interrupts metabolic and reproductive processes to kill microbes
- Slow cycle
- Reduces damage to materials
  - Radiation
  - Heat
  - Moisture
- Flammable
- Carcinogen
- Expensive
  - Must maintain EtO supply

Centers for Disease Control, 3M (2015)

Design Alternatives - Sterilization

Hydrogen Peroxide Gas Plasma (HPGP)

- Sterilization system
  - Disrupts biomolecules to inhibit metabolic and life functions
- Reduces damage to materials
  - Radiation
  - Heat
- Non-toxic by-products
- May cause irritation

Centers for Disease Control, University of Rochester Medical Center, Bionics Scientific Technologies

Pugh Chart

Criteria	*Weight*	UV Germicidal Irradiation Lamps	Ionizing Radiation	Wet Heat (Steam)	Dry Heat	Ethylene Oxide Gas	Hydrogen Peroxide Gas Plasma
Cost	*7*	9	3	5	8	4	5
Efficacy	*10*	5	9	9	7	9	9
Safety	*8*	7	4	8	7	4	8
Cycle or Exposure Time	*5*	4	8	8	5	4	7
Material Compatibility	*7*	8	5	5	5	9	9
Ease of Implementation	*5*	8	4	6	7	4	4
		285	**238**	**294**	**277**	**253**	**307**

Chosen Solution

Pugh chart analyses were conducted to select the most viable option for each solution component:

- Point-and-shoot camera
- Structure from motion analysis (SfM)
- Laser cutting
- Hydrogen peroxide gas plasma sterilization (HPGP)

Chosen Solution - Overview

Point-and-Shoot Camera

- Multiple photos will be taken at different perspectives
  - Minimum of 3 photos
- Ruler
  - To provide reference dimensions when visually documenting wound

Structure from Motion (SfM) Analysis

- Analyze visual documentation of wound in MATLAB
- Provide 3 bandage templates

Chosen Solution - Overview

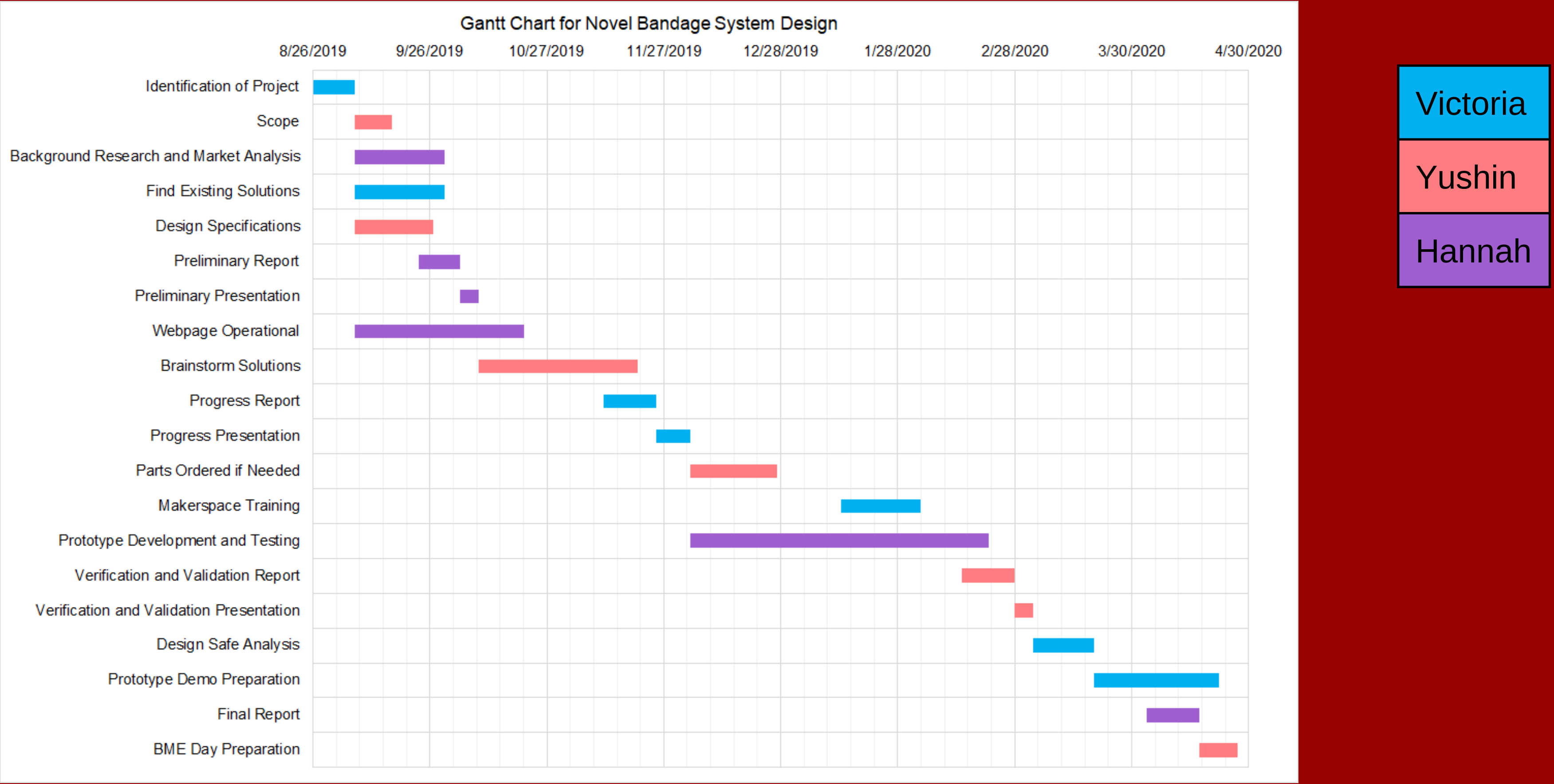
Laser Cutting

- Processed SfM data will interface with appropriate software to direct laser cutter
- Produce desired bandage shape
- 100% cotton cut in place of bandage material for proof-of-concept

Hydrogen Peroxide Gas Plasma (HPGP) Sterilization

- Incorporate into production process
- Observe clinical sterility standards

Updated Design Schedule with Gantt Chart



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Questions?