DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS

6 MAY 2016

MEMORANDUM FOR ST
ATTN: CAPT RENFORD CINDASS

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled **A Novel Bioresorbable, Biointegratable, and Biocompatible Dressing for NPWT** presented at/published to **Association of Surgeons Great Britain and Ireland 11-13 May 2016** with MDWI 41-108, and has been assigned local file #**16193.**

2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.

3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are 59 MDW staff member, we can forward your request for funds to the designated wing POC.

4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

Linda Steel-Goodwin

LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

INSTRUCTIONS

USE ONLY THE MOST CURRENT 59 MDW FORM 3039 LOCATED ON AF E-PUBLISHING

1. The author must complete page two of this form:
   a. In Section 2, add the funding source for your study [e.g., 59 MDW CRD Graduate Health Sciences Education (GHSE) (SG5 O&M); SG5 R&D; Tri-Service Nursing Research Program (TSNRP); Defense Medical Research & Development Program (DMRDP); NIH; Congressionally Directed Medical Research Program (CDMRP) ; Grants; etc.]

   b. In Section 2, there may be funding available for journal costs, if your department is not paying for figures, tables or photographs for your publication. Please state "YES" or "NO" in Section 2 of the form, if you need publication funding support.

2. Print your name, rank/grade, sign and date the form in the author's signature block or use an electronic signature.

3. Attach a copy of the 59 MDW IRB or IACUC approval letter for the research related study. If this is a technical publication/presentation, state the type (e.g. case report, QA/QI study, program evaluation study, informational report/briefing, etc.) in the "Protocol Title" box.

4. Attach a copy of your abstract, paper, poster and other supporting documentation.

5. Save and forward, via email, the processing form and all supporting documentation to your unit commander, program director or immediate supervisor for review/approval.

6. On page 2, have either your unit commander, program director or immediate supervisor:
   a. Print their name, rank/grade, title; sign and date the form in the approving authority's signature block or use an electronic signature.

7. Submit your completed form and all supporting documentation to the CRD for processing (59crdpubspres@us.af.mil). If you have any questions or concerns, please contact the 59 CRD/ Publications and Presentations Section at 292-7141 for assistance.

8. The 59 CRD/Publications and Presentations Section will route the request form to clinical investigations, 502 ISG/JAC (Ethics Review) and Public Affairs (59 MDW/PA) for review and then forward you a final letter of approval or disapproval.

9. Once your manuscript, poster or presentation has been approved for a one-time public release, you may proceed with your publication or presentation submission activities, as stated on this form. **Note:** For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.

10. If your manuscript is accepted for scientific publication, please contact the 59 CRD/Publications and Presentations Section at 292-7141. This information is reported to the 59 MDW/CC. All medical research or technical information publications/presentations must be reported to the Defense Technical Information Center (DITC). See 59 MDWI 41-108, *Presentation and Publication of Medical and Technical Papers*, for additional information.

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement:
"The views expressed are those of the [author(s)] [presenter(s)] and do not reflect the official views or policy of the Department of Defense or its Components"

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving humans:
"The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DODI 3216.02_AFI 40-402."

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving animals, as required by AFMAN 40-401_IP :
"The experiments reported herein were conducted according to the principles set forth in the National Institute of Health Publication No. 80-23, Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act of 1966, as amended."

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1. TO: CLINICAL RESEARCH	2. FROM: (Author's Name, Rank, Grade, Office Symbol)	3. GME/GHSE STUDENT:	4. PROTOCOL NUMBER:
	Renford Cindass, O-3	☒ YES ☐ NO	NAVY15-04

5. PROTOCOL TITLE: (**NOTE:** For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.)

Evaluation of a Novel Bioabsorbable/Biointegratable Negative Pressure Wound Dressing Sponge in a Porcine Model (Sus scrofa domestica)

6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED:

A Novel Bioresorbable, Biointegratable, and Biocompatible Dressing for NPWT

7. FUNDING RECEIVED FOR THIS STUDY? ☒ YES ☐ NO FUNDING SOURCE: AFMSA/ 59MDW ST

8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: ☐ YES ☒ NO

9. IS THIS MATERIAL CLASSIFIED? ☐ YES ☒ NO

10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.?
☐ YES ☒ NO **NOTE:** If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.

11. MATERIAL IS FOR: ☐ DOMESTIC RELEASE ☒ FOREIGN RELEASE
CHECK APPROPRIATE BOX OR BOXES FOR APPROVAL WITH THIS REQUEST. ATTACH COPY OF MATERIAL TO BE PUBLISHED/PRESENTED.

☐ 11a. PUBLICATION/JOURNAL (List intended publication/journal.)

☐ 11b. PUBLISHED ABSTRACT (List intended journal.)

☐ 11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.)

☐ 11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, state, and date of meting.)
Association of Surgeons of Great Britain and Ireland/ 11-13 May 2016

☐ 11e. OTHER (Describe: name of meeting, city, state, and date of meeting.)

12. EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC
NOTE: All publications/presentations are required to be placed in the Defense Technical Information Center (DTIC).

DATE: May 10, 2016

13. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email)	14. DUTY PHONE/PAGER NUMBER
Corpus Raul S, raul.s.corpus.ctr@mail.mil	2105394404

15. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript.

LAST NAME, FIRST NAME AND M.I.	GRADE/RANK	SQUADRON/GROUP/OFFICE SYMBOL	INSTITUTION (If not 59 MDW)
a. Primary/Corresponding Author Renford Cindass	O-3	59MDW ST RESTOR	
b. Kevin Wu	CTR	59MDW ST RESTOR	
c. Sharon Lawson	CTR	59MDW ST RESTOR	
d. Vijay Gorantla			UPitt
e. Michael Davis	O-5	59MDW ST RESTOR	
f.			

I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401_IP, AND 59 MDWI 41-108. I HAVE READ THE FINAL VERSION OF THE ATTACHED MATERIAL AND CERTIFY THAT IT IS AN ACCURATE MANUSCRIPT FOR PUBLICATION AND/OR PRESENTATION.

16. AUTHOR'S PRINTED NAME, RANK, GRADE	17. AUTHOR'S SIGNATURE	18. DATE
Renford Cindass, O-3		April 26, 2016
19. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE	**20. APPROVING AUTHORITY'S SIGNATURE**	**21. DATE**
Michael R Davis, Lt Col, Director-RESTOR, Deputy Commander		April 26, 2016

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1st ENDORSEMENT (59 MDW/SGVU Use Only)

TO: Clinical Research Division 59 MDW/CRD Contact 292-7141 for email instructions.	22. DATE RECEIVED 4/26/2016	23. ASSIGNED PROCESSING REQUEST FILE NUMBER 16193
24. DATE REVIEWED 29 Apr 2016		25. DATE FORWARDED TO 502 ISG/JAC

26. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES: ☒ NO ☐ YES If yes, give date. _____ ☐ N/A

27. COMMENTS ☒ APPROVED ☐ DISAPPROVED

The presentation is approved. This should receive a legal ethics review since it will be presented to a foreign audience.

28. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	29. REVIEWER SIGNATURE	30. DATE
Rocky Calcote, PhD, Clinical Res. Administrator	CALCOTE.ROCKY.D.1178245844 Digitally signed by CALCOTE.ROCKY.D.1178245844 DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USAF, cn=CALCOTE.ROCKY.D.1178245844 Date: 2016.04.29 06:48:08 -05'00'	

2nd ENDORSEMENT (502 ISG/JAC Use Only)

31. DATE RECEIVED	32. DATE FORWARDED TO 59 MDW/PA

33. COMMENTS ☐ APPROVED (In compliance with security and policy review directives.) ☐ DISAPPROVED

34. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	35. REVIEWER SIGNATURE	36. DATE

3rd ENDORSEMENT (59 MDW/PA Use Only)

37. DATE RECEIVED	38. DATE FORWARDED TO 59 MDW/SGVU
6 May 2016	6 May 2016

39. COMMENTS ☑ APPROVED (In compliance with security and policy review directives.) ☐ DISAPPROVED

40. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	41. REVIEWER SIGNATURE	42. DATE
Christopher Carwile, TSgt/E-6, NCOIC, PA	CARWILE.CHRISTOPHER.STEWART.1280477229 Digitally signed by CARWILE.CHRISTOPHER.STEWART.1280477229 DN: c=US, o=U.S. Government, ou=DoD, ou=PKI, ou=USAF, cn=CARWILE.CHRISTOPHER.STEWART.1280477229 Date: 2016.05.06 11:10:22 -05'00'	6 May 2016

4th ENDORSEMENT (59 MDW/SGVU Use Only)

43. DATE RECEIVED	44. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL ☐ YES ☐ NO ☐ COULD NOT BE REACHED ☐ LEFT MESSAGE

45. COMMENTS ☐ APPROVED ☐ DISAPPROVED

46. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	47. REVIEWER SIGNATURE	48. DATE

A Novel Bioresorbable, Biointegratable, and Biocompatible Dressing for NPWT

CPT Renford Cindass Jr., MD
General Surgery Resident, San Antonio Military Medical Center,
RESTOR Program, 59th Medical Wing ST

Lt Col Michael R. Davis, MD, FACS
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Deputy Commander, USA Institute of Surgical Research
59MDW Science and Technology

Disclaimer

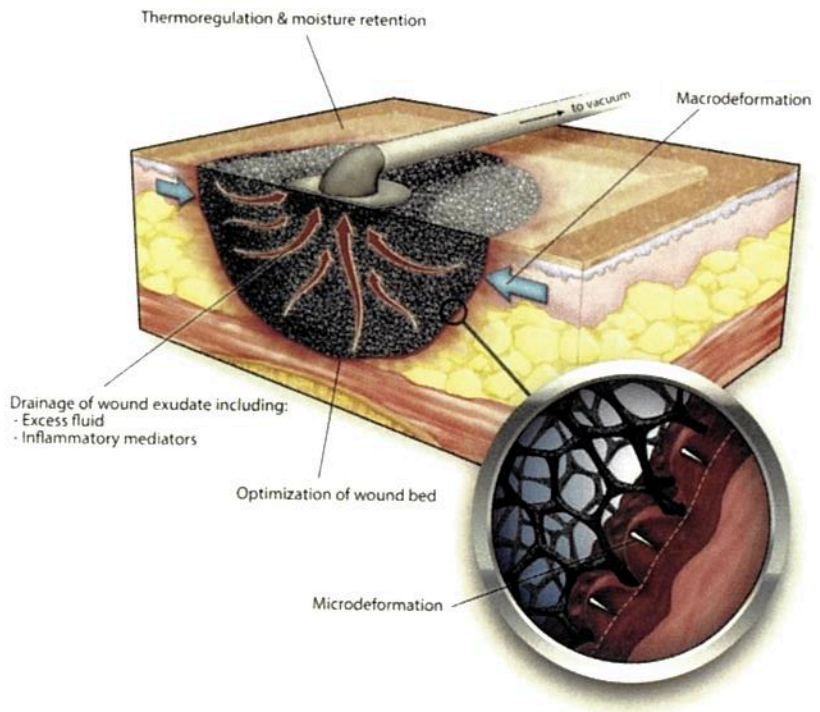
The views expressed are those of the authors and do not reflect the official view or policy of the Department of Defense, Department of the Army, Department of the Air Force or its Components.

The experiments reported herein were conducted according to the principles set forth in the National Institute of Health Publication 80 23, Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act of 1966, as amended.

Project was funded through the US Air Force Medical Support Agency, coordinated through and managed by the 59MDW Office of Wing Chief Scientist, Science and Technology.

Negative Pressure Wound Therapy

- Developed in 1997
- Mechanisms
  - Thermoregulation and moisture retention
  - Drainage of exudate and inflammatory mediators
  - Optimization of the wound bed
  - Microdeformation
  - Macrodeformation



Huang C *et al*. Current Problems in Surgery 51 (2014) 301-331

Limitations of Polyurethane Sponge

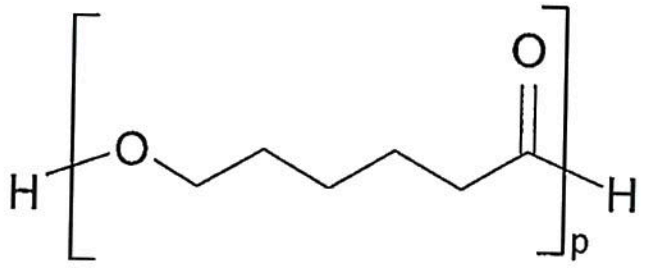
- Dressing changes every 2-3 days
- Occasionally painful for the patient
- Macrodeformation causes wound contraction

Goals for the Ideal Sponge

- Bioabsorbable to prevent dressing changes
- Provides a scaffold to fill the defect
- Minimize wound contraction
- Accelerate granulation tissue formation

Our Sponges

- **Bioresorbable, biointegratable, and biocompatible sponge**
  - Polycaprolactone (PCL)
    - A biodegradable polyester
    - Used in Monocryl™ suture (Ethicon)
  - 2 different manufacturing processes
    - Synthesized from a 25%/75% PCL/chloroform solution
    - 3D printed scaffold
  - PCL is inherently hydrophobic
    - Treated with different agents to make the sponge hydrophilic
      - Sodium hydroxide
      - Polydopamine
      - Polydextrose



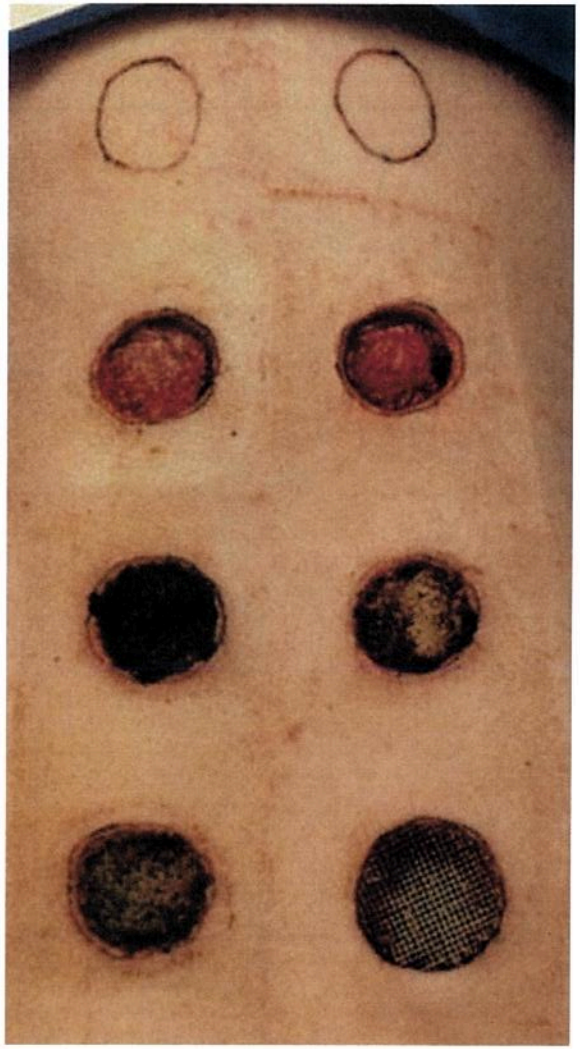
Pilot Study Design

Growth Control

Wet-to-Dry Dressing

Untreated PCL Sponge

PCL Polydopamine Sponge



Growth Control

Polyurethane Sponge

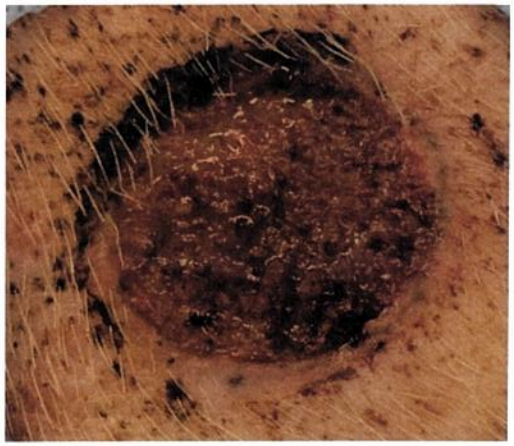
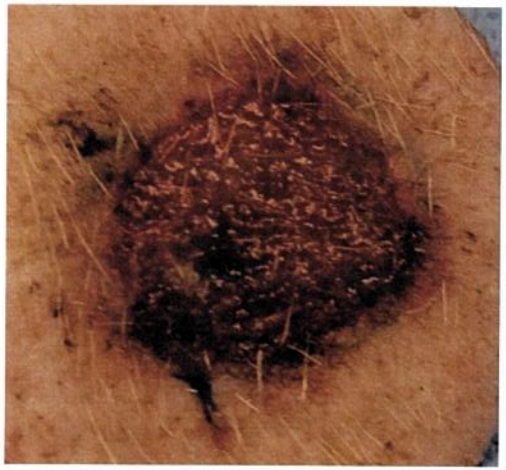
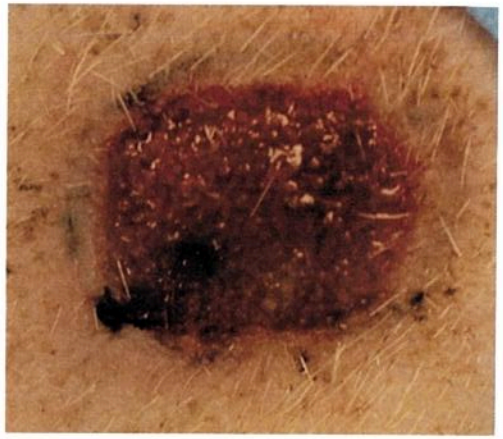
PCL NaOH Sponge

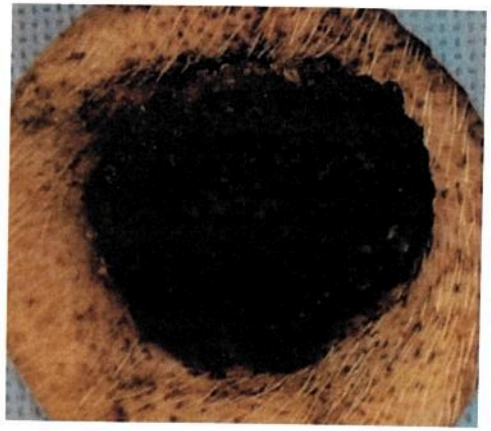
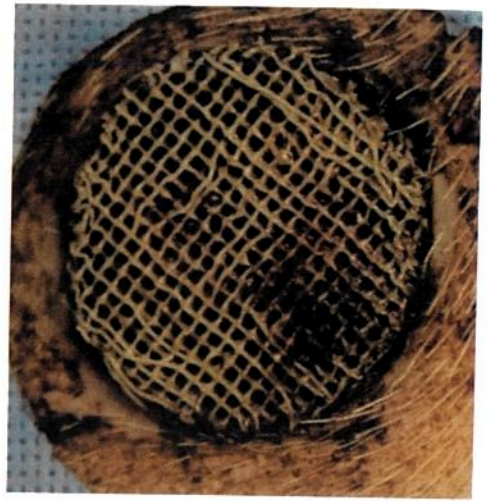
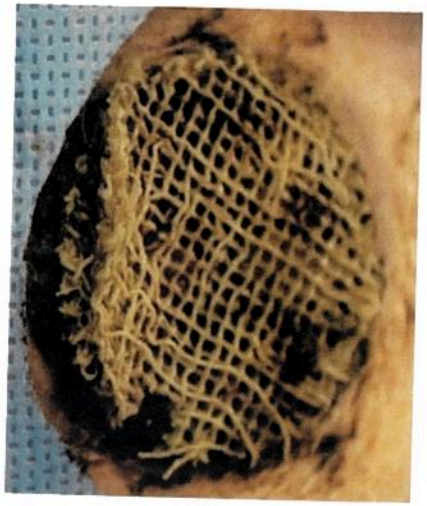
3D Printed
PCL Polydextrose Scaffold

Controls

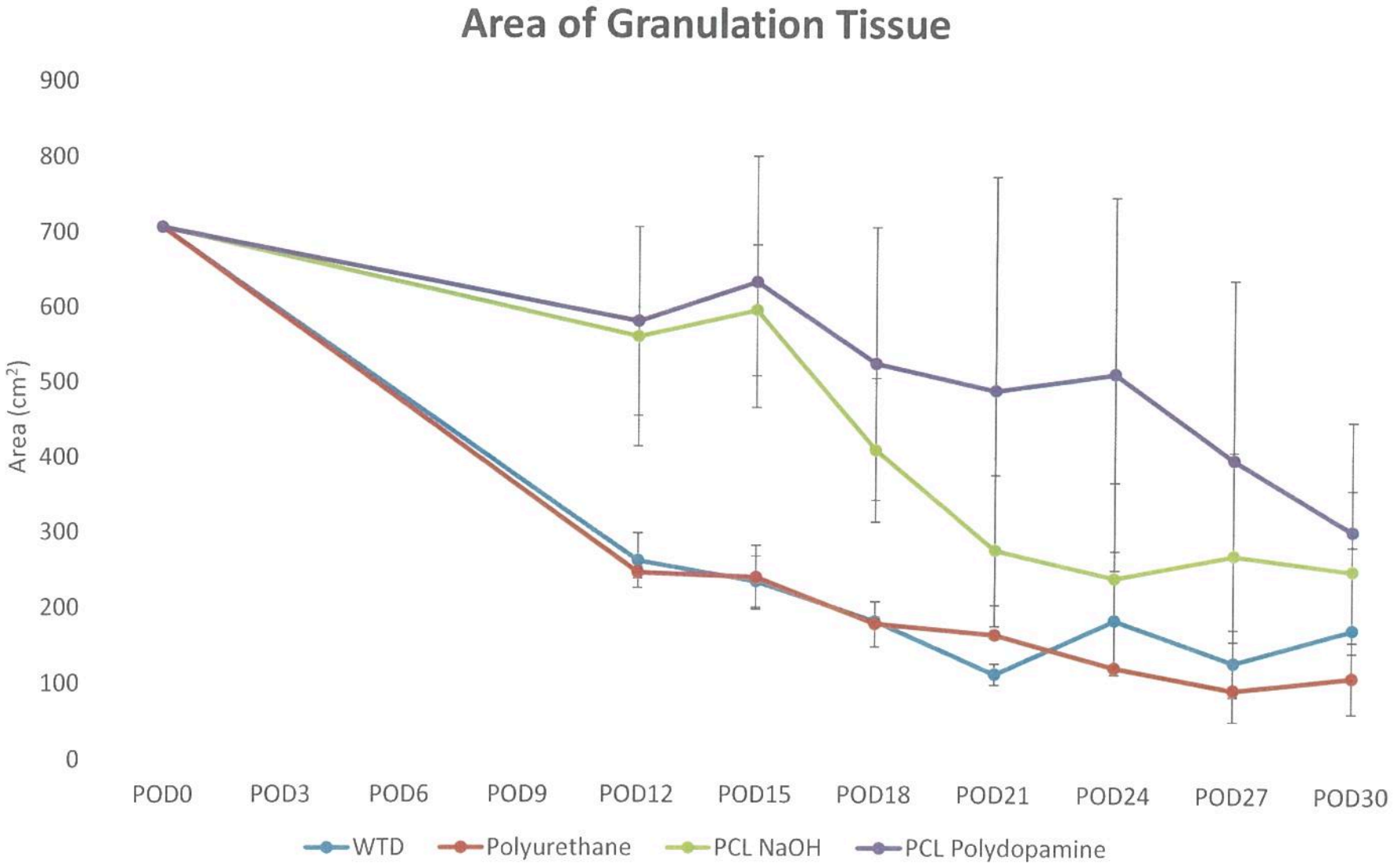
	POD 12	POD 15	POD 18
Wet-to-dry			
Polyurethane			

Hydrophilic Sponges

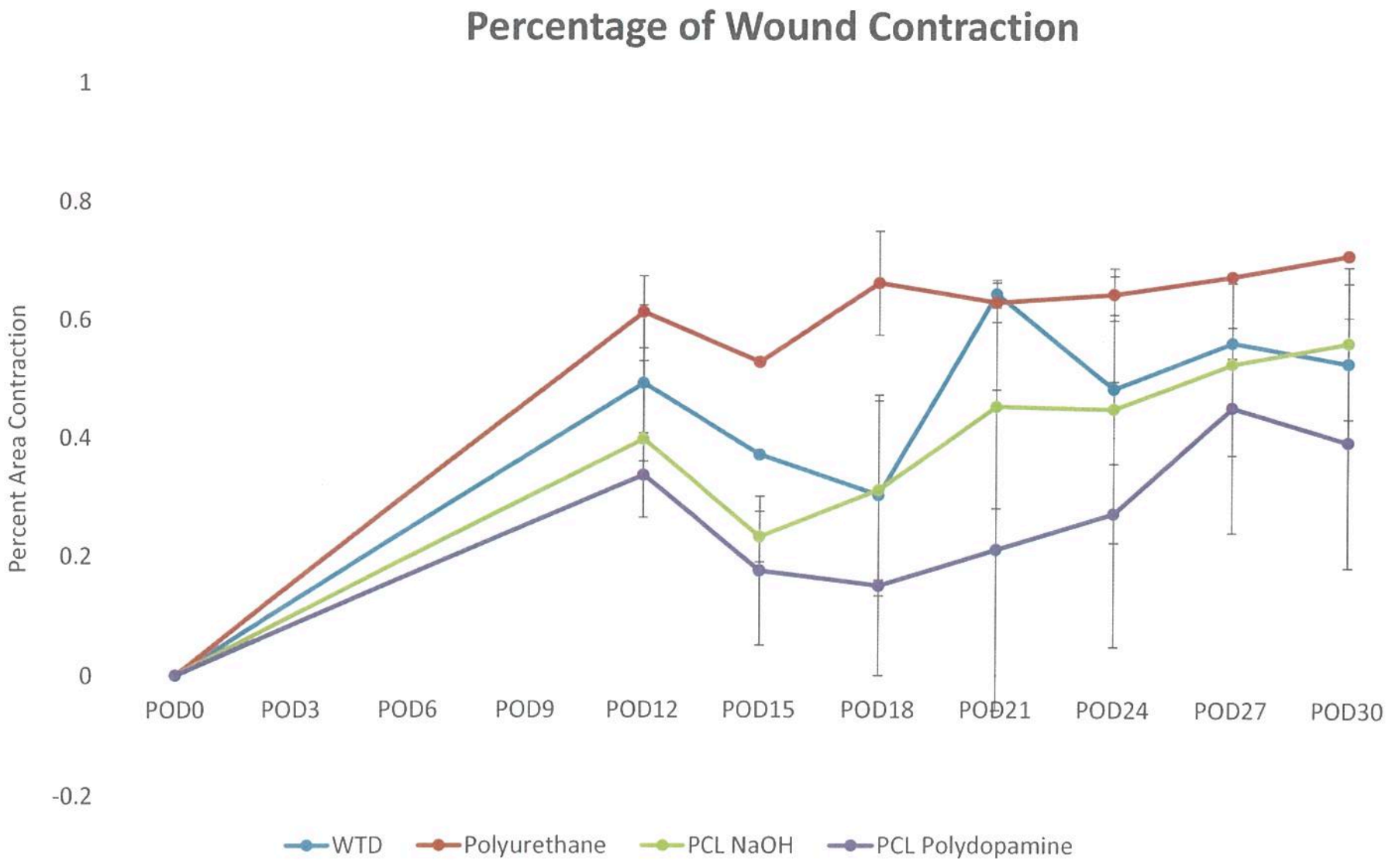
	POD 12	POD 15	POD 18
PCL NaOH			
PCL Polydopamine			

	POD 12	POD 15	POD 18
Untreated PCL			
3D Printed PCL Polydextrose			

Results


Area of Granulation Tissue
900
800
700
600
500
400
300
200
100
0
Area (cm²)
POD0
POD3
POD6
POD9
POD12
POD15
POD18
POD21
POD24
POD27
POD30
WTD
Polyurethane
PCL NaOH
PCL Polydopamine

Results


Percentage of Wound Contraction
Percent Area Contraction
1
0.8
0.6
0.4
0.2
0
-0.2
POD0
POD3
POD6
POD9
POD12
POD15
POD18
POD21
POD24
POD27
POD30
WTD
Polyurethane
PCL NaOH
PCL Polydopamine

Conclusions

- A bioresorbable, biointegratable, and biocompatible sponges
  - Potentially obviate the need for dressing changes by providing a scaffold for cellular ingrowth
  - Minimize wound contraction

Future direction

- Expand the study to assess the PCL sponges treated with NaOH and polydopamine
- Pathology assessment with immunohistochemical staining
- Larger wounds

Thank you

USAISR
Lt Col Michael Davis
Dr Shari Lawson
Dr Kevin Wu
Mr Raul Corpus

University of Pittsburgh Medical Center
Dr Vijay Gorontla

NAMRU, San Antonio
Dr James Johnson
Ms Carrie Crane
Ms Candice Angueira

Southwest Research Institute
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