PROTOCOL TITLE:

Ultrasound Evaluation for Baxter VASCU-GUARD Vascular Patches Post-Endarterectomy and Complications Assessment

PRINCIPAL INVESTIGATOR

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SPONSOR / FUNDING AGENCY

Investigator-Initiated Protocol - Funding source for project currently Baxter International

VERSION NUMBER/DATE

Version 1 – Initial Submission

REVISION HISTORY

N/A

Revision #	Version Date	Summary of Changes	Consent Change (Yes/No)

1. Study Summary

Peripheral Arterial Disease (PAD) refers to disorders characterized by progressive stenosis and altered structure and function of non-coronary arteries that supply the brain, visceral organs, and limbs. PAD is most commonly caused by atherosclerosis and plaque buildup.

Endarterectomy is a surgical intervention intended to address the narrowing or blockage of arteries caused by plaque buildup. Its goal is to enhance blood flow in affected areas and relieve associated symptoms. Various types of vascular patches are used during endarterectomies to reinforce vessel walls, repair arterial defects, reduce the risk of restenosis, and improve patient outcomes.

Postoperative surveillance, particularly through non-invasive ultrasound imaging, is essential for monitoring vascular patches' integrity and identifying potential complications. Ultrasound provides high-resolution visualization, enabling clinicians to detect abnormalities such as leaks or thrombosis early on. The non-invasive nature of ultrasound minimizes patient discomfort and allows for timely intervention, ultimately optimizing patient outcomes following vascular procedures.

VASCU-GUARD vascular patches by Baxter International Inc. are commonly used in the operating room. In November 2022, a package change has been made in the USA. Previously, each VASCU-GUARD patch was chemically sterilized and packaged in a jar filled with sterile, non-pyrogenic water containing propylene oxide. With the implementation of the new packaging, the patch is terminally sterilized via gamma irradiation and comes in a double-pouch system (where the contents of the outer pouch are sterile). The inner pouch maintains the bovine pericardium patch’s moisture while packaged, and it doesn’t contain any water or solution.

VASCU-GUARD vascular patches with the new packaging have been available at the Houston Methodist Hospital since January 2023. This study is a retrospective chart review, aiming to compare the performance of Baxter VASCU-GUARD vascular patches implemented during carotid endarterectomies (CEA) prior to January 2023 and after January 2023. This study is one of a kind, as no other comparative retrospective chart review on the performance of VASCU-GUARD vascular patches from the old and new packaging has been published yet.

The project will contribute to the scientific knowledge about long-term outcomes associated with the use of patch material during endarterectomies.

2. Purpose of the Study / Objectives

Primarily focusing on the implementation of VASCU-GUARD vascular patches in carotid endarterectomies (CEA), the study aims to identify VASCU-GUARD patches with old (before January 2023) and new (after January 2023) packaging and compare the results of standard-of-care exams between the two groups.

The objectives of this study include:

Ultrasound evaluation of Baxter VASCU-GUARD vascular patches:
Retrospective review of ultrasound recordings and ultrasound reports at one-month, 3-months, 6-months and 1-year follow-up after endarterectomy – if available, to evaluate patch patency, morphology, integrity, complications, and blood flow dynamics.

Complications assessment:
Analyze complications linked with Baxter Vascular Patches (VASCU-GUARD), including but not limited to thrombosis, stroke, dissection, restenosis, infection, fluid collection, pseudoaneurysm formation, fraying or irregularities in patch material.

Correlation with Clinical Outcomes:
Recognize correlations between ultrasound findings and clinical outcomes. This correlation will complement the understanding of how ultrasound monitoring can predict and influence patient prognosis.

3. Background

Peripheral artery disease (PAD) results in the buildup of plaque in the arteries, leading to a disruption of blood flow to the head, organs, and limbs. In the US, it affects approximately 8.5 million people, predominantly those over the age of 40, and contributes significantly to healthcare costs, amounting to tens of billions of dollars annually.

Endarterectomy is a surgical procedure, during which atherosclerotic plaque from the inner lining of arteries is removed. The objective of endarterectomies is to improve blood flow in affected territories and to alleviate symptoms. The use of vascular patches in these interventions has become standard practice to reinforce vessel walls, repair arterial defects, reduce the risk of restenosis, and improve patient outcomes. Postoperative surveillance, especially through ultrasound imaging, plays a pivotal role in monitoring the efficacy of these vascular patches and identifying potential complications.

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sterilized via gamma irradiation and comes in a double-pouch system (where the contents of the outer pouch are sterile). The inner pouch maintains the bovine pericardium patch's moisture while packaged, and it doesn't contain any water or solution.

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Ultrasound provides high-resolution visualization, enabling clinicians to detect abnormalities such as leaks or thrombosis early on. The non-invasive nature of ultrasound minimizes patient discomfort and allows for timely intervention, ultimately optimizing patient outcomes following vascular procedures.

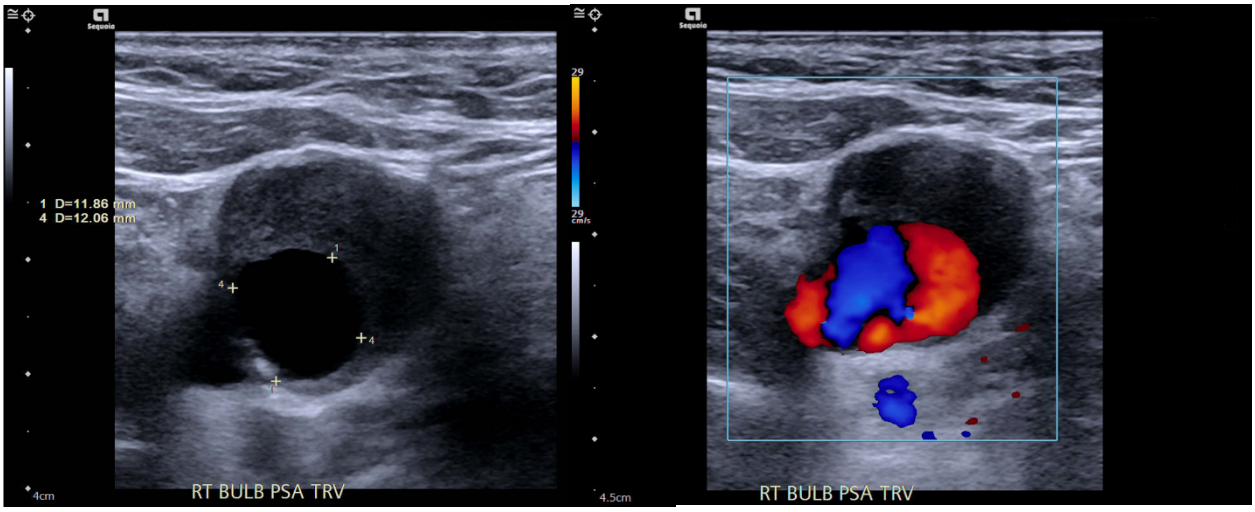

Figure 1. Ultrasound showing pseudoaneurysm formation directly from the patch material. Left – true lumen is measured with yellow crosses. Right – "Pepsi sign" on color Doppler in the context of bidirectional flow from a pseudoaneurysm.

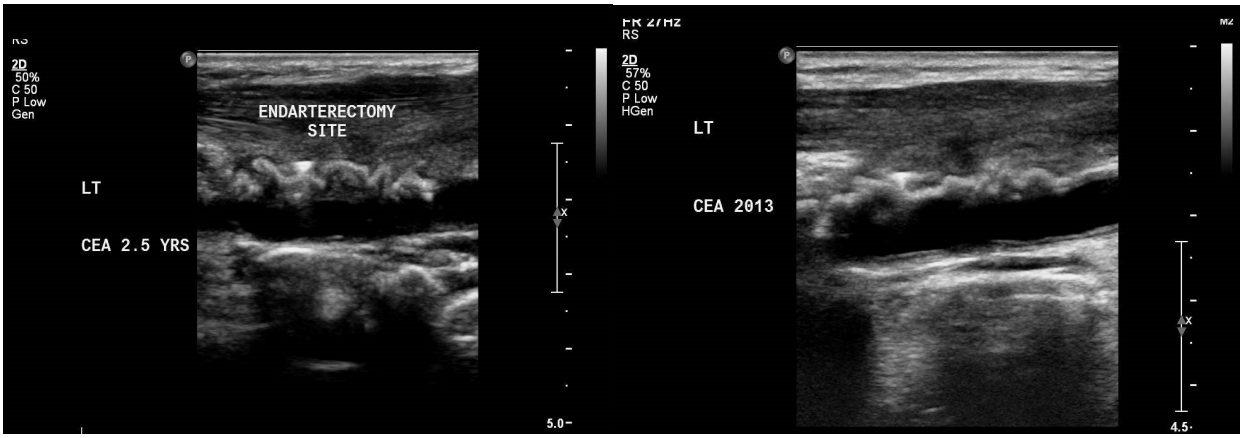

Figure 2. Ultrasound showing irregularities in the patch material due to infection.

4. Study Design

This study is a retrospective chart review. The data is collected from January the 1st 2022 till April the 30th 2024.

Medical Records Review
Baseline information, operative information, and outcomes will be determined via retrospective review of medical records. Data obtained via medical record review will include demographic information (age, gender, ethnicity), baseline clinical information (medical co-morbidities, medications, history of underlying cause of peripheral artery disease, etc.) data on the operation (date of operation/procedure, discharge date, surgeons name, anatomical site, campus where the surgery was performed, type of anesthesia, intraoperative blood pressures, estimated blood loss, intraoperative complications, etc.), results of standard-of-care exams.

Data Processing Procedure
The data collectors will complete the data forms and review all items for accuracy. All information will be entered into an electronic excel database created for the study.

Statistical Analysis
A retrospective chart review will be conducted on a maximum of 500 patients. Analyzing data from 500 patients will provide a robust baseline to conduct a study of differences, similarities, and trends among the patients. All information will be entered into an electronic excel database created for the study and analyzed in STATA statistical program. All subjects meeting eligibility criteria will be enrolled.

The data will be abstracted from Houston Methodist Hospital electronic medical records, DigiView and from the MCVSA office charts by the PI and trained members of his research staff. The required information will be transferred from electronic medical records by the research staff to the study specific electronic Excel data collection forms.

Permission to review medical records will be obtained from the Houston Methodist Hospital Research Institute (TMHRI) Human Subjects Committee via a HIPAA Waiver of Authorization and Waiver of Consent.

Data to be collected:

- Age at surgery, sex, race
- Preoperative risk factors: HTN, DM, TIA, CAD, HLD, previous strokes, previous thromboembolic events, previous surgeries
- Intraoperative data: Type of patch material used, intraoperative complications (if any), MAP, Heart rate, Medications given, Estimated blood loss, Intraoperative antibiotics given, Intraoperative antiplatelet/anticoagulation medication given
- Postoperative outcomes: Stroke/TIA, Postop ICU time, mortality (up to 30 days)
- Follow up neurological evaluation, any symptoms reported by the patient
- Imaging: MRI/CT, MRA, CTA, TCD, vascular duplex ultrasound

Postoperative ultrasound follow-up:

- ultrasound assessment of the vascular patch: patch patency, morphology, integrity, complications, and blood flow dynamics.
- detection of complication: thrombosis, dissection, restenosis, infection, fluid collection, pseudoaneurysm formation, fraying or irregularities in patch material
- repeat ultrasound assessment: morphological changes in the vascular patch, evolution of blood flow dynamics, signs of restenosis or complications
- Data obtained from duplex ultrasound: wall thickness, presence of plaque, lumen diameter, peak systolic velocity (PSV), end-diastolic velocity (EDV), mean flow velocity (MFV), pulsatility index (PI), direction of blood flow, velocities, degree of stenosis

5. Study Intervention

N/A. Retrospective chart review of standard-of-care exams.

6. Drugs, Biologics, Devices

N/A

7. Collaborative / Multi-site Research

N/A – Investigator Initiated Project

8. Data Privacy / Confidentiality

Required for all protocol types including Sponsored trials. Provide local information.

The data will be abstracted from Houston Methodist Hospital electronic medical records by the PI and trained members of his research staff. The required information will be transferred from electronic medical records by the research staff to the study specific data collection forms.

Study data will be registered into an electronic, password protected database located on the TMHS server accessible only by the research team, applicable regulatory personnel and authorities.

Documents requiring an investigator's signature, should any be created, will be promptly signed, and dated in real-time. In accordance with departmental policies, research-specific documents will be retained on-site for 6 years post-study closure.

No images, video recordings, or photographs of patients will be requested for this study. Study will remain minimal risk with provisions to limit the risk of loss of confidentiality, outlined in section 17. Minimal PHI identifiers will be utilized to build the cohort. Identifies will not be utilized for cohort analysis. Sufficient security and data privacy measures will be implemented in terms of data collection, processing, storing, and maintaining the database as per the institutional policies and the regulations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Study site/investigators will not disclose any proprietary information or confidential data.

As applicable, the IRB, FDA, or other relevant health authorities will have the right to review study data at any point in time.

Identifier (or parts of)	Recorded	Disclosed	Comment
Names	Yes	No	This information will be gathered for the chart review and will not be provided or shared with anyone not part of the research team or outside of the institution. Only for the purpose for screening patients of inclusion in cohort.
All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all	Yes	No	This information will be gathered for the chart review and will not be provided or shared with anyone not part of the research team or outside

ages over 89 and elements of dates (including year) indicative of such age			of the institution. Only for the purpose for screening patients of inclusion in cohort.
Medical record numbers	Yes	No	This information will be gathered for the chart review and will not be provided or shared with anyone not part of the research team or outside of the institution. Only for the purpose for screening patients of inclusion in cohort.

9. Data and Specimen Banking

De-identified data pertaining to this investigation will be maintained in encrypted, Houston Methodist provided computers. Only IRB approved study personnel on this study will have access to the study information.

10. Study Population

The study population is patients undergoing carotid endarterectomy (CEA) with the use of Baxter VASCU-GUARD vascular patches in all campuses of the Houston Methodist Hospital.

Inclusion criteria:

- Patients aged 18 years and above.
- Patients undergoing carotid endarterectomy with the use of VASCU-GUARD vascular patches.
- Follow-up ultrasound assessment available.

Exclusion criteria:

- No postoperative ultrasound assessment is available.

11. Screening and Recruitment S R

Subjects will be retrospectively identified through retrospective review of medical records.

12. Withdrawal of Subjects

N/A

13. Provisions to Protect the Privacy Interests of Subjects

N/A

14. Risks to Subjects

This research involves no more than minimal risk because it will involve only a retrospective review of clinical records. All Confidentiality and Data privacy protocols will be strictly adhered to.

15. Potential Benefits

Future participants may receive improved care as the outcome data from this study can influence current practices. However, no direct benefits to participants are anticipated from this research.

16. Financial and Economic Issues

Investigator Initiated project – Funding source for project currently Baxter International

17. Data Safety Plan

The HMRI SOP's will be strictly adhered to in terms of data safety. All information will be kept in excel spreadsheets on locked computers within Houston Methodist Hospital. Information will not be provided outside of the institution. All investigators will be added to the research study via MORTI before assisting in the research study.

18. Waiver of Informed Consent and /or Authorization

Requesting a waiver of informed consent and HIPAA waiver of authorization.

We are requesting a waiver of authorization for the conduct of this research study. As this project only involves the analysis of secondary data in the patient chart, it is deemed minimal risk for participants, and therefore, a waiver of consent can apply. All data being collected are

part of the standard of care, and thus, a waiver should apply as the data being collected is used to understand underlying factors that affect the variables being collected.

Waiver of HIPAA Authorization for Research

Complete this section if you will access identifiable health information in a patient's electronic health record or other record held by Houston Methodist Hospital and you are not obtaining a signed authorization from the patient. This waiver can apply to health information accessed to identify potential research participants or for research involving retrospective chart reviews.

1. Purpose of the Waiver:

☒ Chart review study – collecting retrospective clinically available data that will not have bearing on clinical outcomes.

☐ Partial waiver of authorization to identify, prescreen and contact potential participants.

☐ Alteration of the requirements for a HIPAA Authorization to remove the signature. *

☒ Other Please explain Retrospective Study – clinically available data only

**** Note if the IRB waives the signature requirement, the participant must receive a copy of the HIPAA authorization language.***

2. Provide protocol-specific responses to the following items that describe why the waiver is being requested for the use of PHI in this research.

a. The IRB must find that the use/disclosure of protected health information (PHI) involves no more than minimal risk to the privacy of individuals. Please select the safeguards your team will use to meet this requirement.

☒ Electronic safeguards, such as password protection, data encryption, and institution firewall, will be used to protect PHI

☐ Physical safeguards, such as locked cabinets, locked filing room, secure, locked office area, will be used to protect PHI

☒ The study team will record only anonymous data or coded data that are linked to the participants' identity through a file that is separate from the data.

☒ Administrative safeguards such as polices and procedures, staff education on the HIPAA Privacy Rule.

☐ Other: _____

c. Describe why the research cannot practicably be conducted without the waiver or alteration of patient authorization to use PHI in research

☒ Access to and use of PHI is necessary to obtain information of potential subjects.

☐ The number of screen failures is anticipated to be high for this research and access to

the PHI to confirm potential study eligibility will prevent unnecessary contact with potential participants.

☒ Too many participants will be lost to follow up or will not answer the request for an authorization to conduct the record review study.

☒ Other: _____ **Retrospective Study – clinically available data only**

d. Describe why the research cannot practicably be conducted without access to and use of the PHI:

☐ The study team will access the minimum PHI necessary to contact potential participants to assess their interest and eligibility.

☒ The study team will access the minimum PHI necessary to prescreen for eligibility.

☒ The study team will access the minimal PHI necessary data elements to answer the research question.

Retrospective Chart Review PHI only accessed and recorded locally for the purpose of screening patients for inclusion in cohort. Patients will consent to SOC procedures and surgical consents, which state

3. Identify

List the identifiers you will record by HMRI research team only, not disclosed. Minimal PHI will be accessed

☒ Name

☐ Address (all geographic subdivisions smaller than state, including street address, city county, and zip code)

☒ All elements (except years) of dates related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89)

☐ Telephone number

☐ Fax number

☐ Email addresses

☐ Social Security Number

☒ Medical record number

☐ Health plan beneficiary number

☐ Account number

☐ Certificate or license number

☐ Vehicle identifiers and serial numbers, including license plate numbers

☐ Device identifiers and serial numbers

☐ Web URL

☐ Internet Protocol (IP) Address

☐ Finger or voice print

☐ Photographic image - Photographic images are not limited to images of the face.

☐ Any other characteristic that could uniquely identify the individual

By submitting this request for waiver of patient authorization, I certify:

(1) That the identifiers will be destroyed at the earliest opportunity consistent with the conduct of the research as defined by federal, state, and/or local laws and regulations.

(2)The PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.

19. References

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