



Validation of Placental Preservation for Pathologic Examination Using the TissueSAFE® Formalin-Free Vacuum-Sealing System (2092)

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Abstract

Background: Placentas are the unloved specimens of Labor and Delivery (L&D) and Pathology. Most are normal and not seen in Pathology but require safe systems for storage and disposal. Placentas that require pathologic evaluation present numerous challenges of non-standardized ex vivo time, tissue preservation conditions, timed exposure to formalin-fixation, consumption of high volumes of formalin for proper fixation and expensive disposal of the specimen and associated bucket of bloody formalin as hazardous waste. To address these issues, we have validated a vacuum-sealed, formalin-free tissue handling system designed to originate from L&D with intent to control placenta preservation and transport to Pathology for histologic examination.

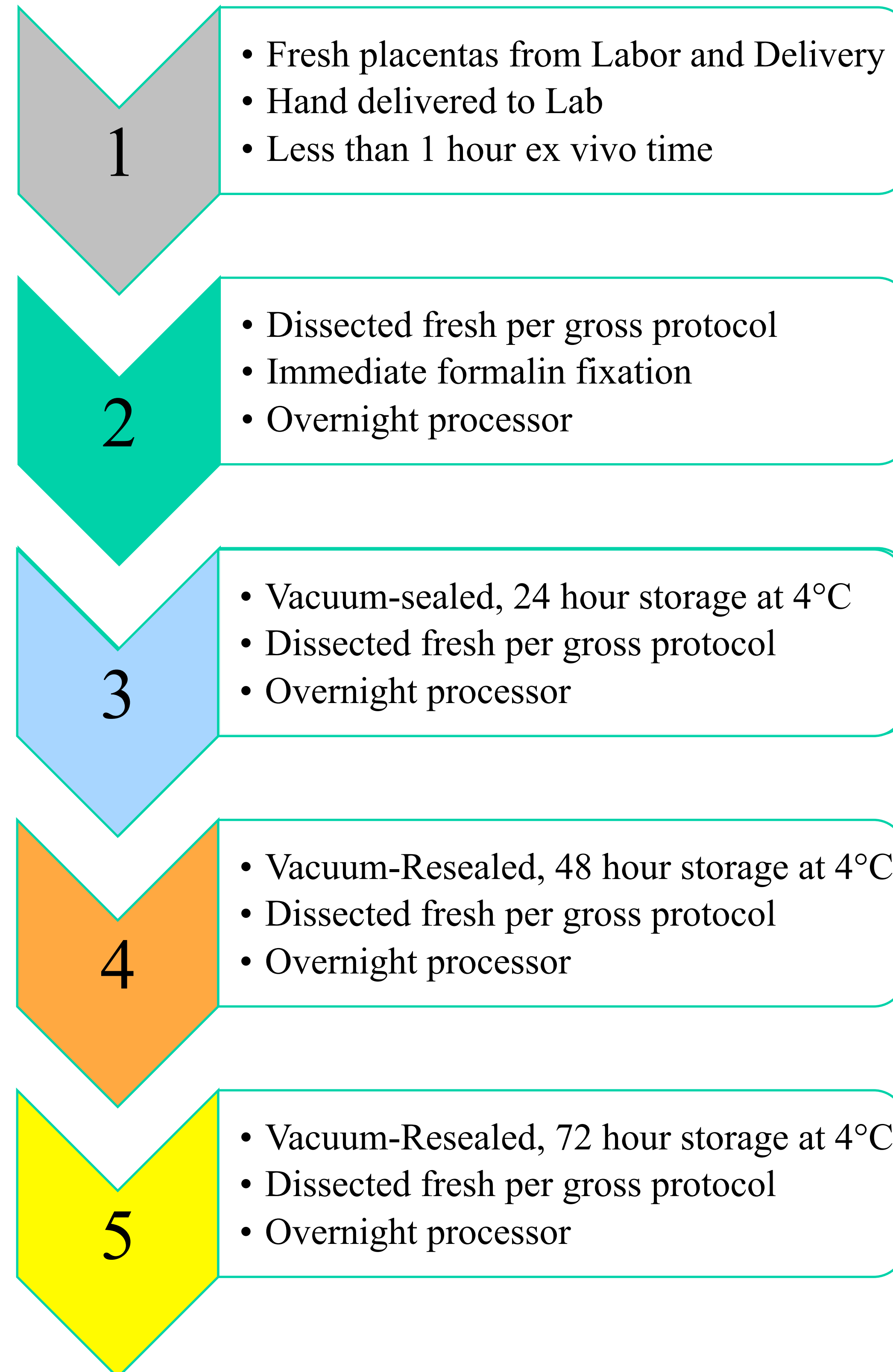
Design: 8 placentas were transported fresh from L&D to Henry Ford Hospital Pathology. Each was dissected according to protocol with 3 standard sections for immediate formalin fixation. Placentas were then sealed under low vacuum with the TissueSAFE® system (Milestone Medical, Kalamazoo, MI) and retrieved for dissection and formalin fixation after storage in vacuum-sealed bags at 4°C for 24 hours (8 cases), 48 hours (4 cases) and 72 hours (4 cases). H&E stained slides were independently assessed by 2 placental pathologists using a 3 part scheme of: 1) Adequate, 2) Less than optimal, or 3) Inadequate for histologic evaluation. This study was IRB-exempt.

Results: All 102 H&E slides were assessed adequate for histologic evaluation. No degradation of histologic detail was noted between fresh, formalin fixed to delayed fixation after 72 hours of vacuum-sealed cold storage.

Conclusions: This histologic validation of vacuum-sealed human placentas allows consideration of differently designed processes for tissue handling by caregivers and pathologists. Potential advantages are controlled preanalytic placenta preservation up to 3 days at refrigerator temperature. Controlled fixation of fresh sections from each preserved placenta markedly reduces the amount of formalin (approximately 1 gallon/placenta) ordinarily used to fix the entire placenta before gross examination. Reduction of formalin at the front-end process of initial fixation translates to reduced back-end disposal of formalin as expensive hazardous waste. Both reductions translate to financial savings to the healthcare system. In L&D practices, this may eliminate formalin from the unit. Additionally, most placentas require disposal and vacuum-sealing of individual specimens provides for a safe isolation and disposal avoiding a fetid waste receptacle in L&D.

(The authors declare no conflicts of interest)

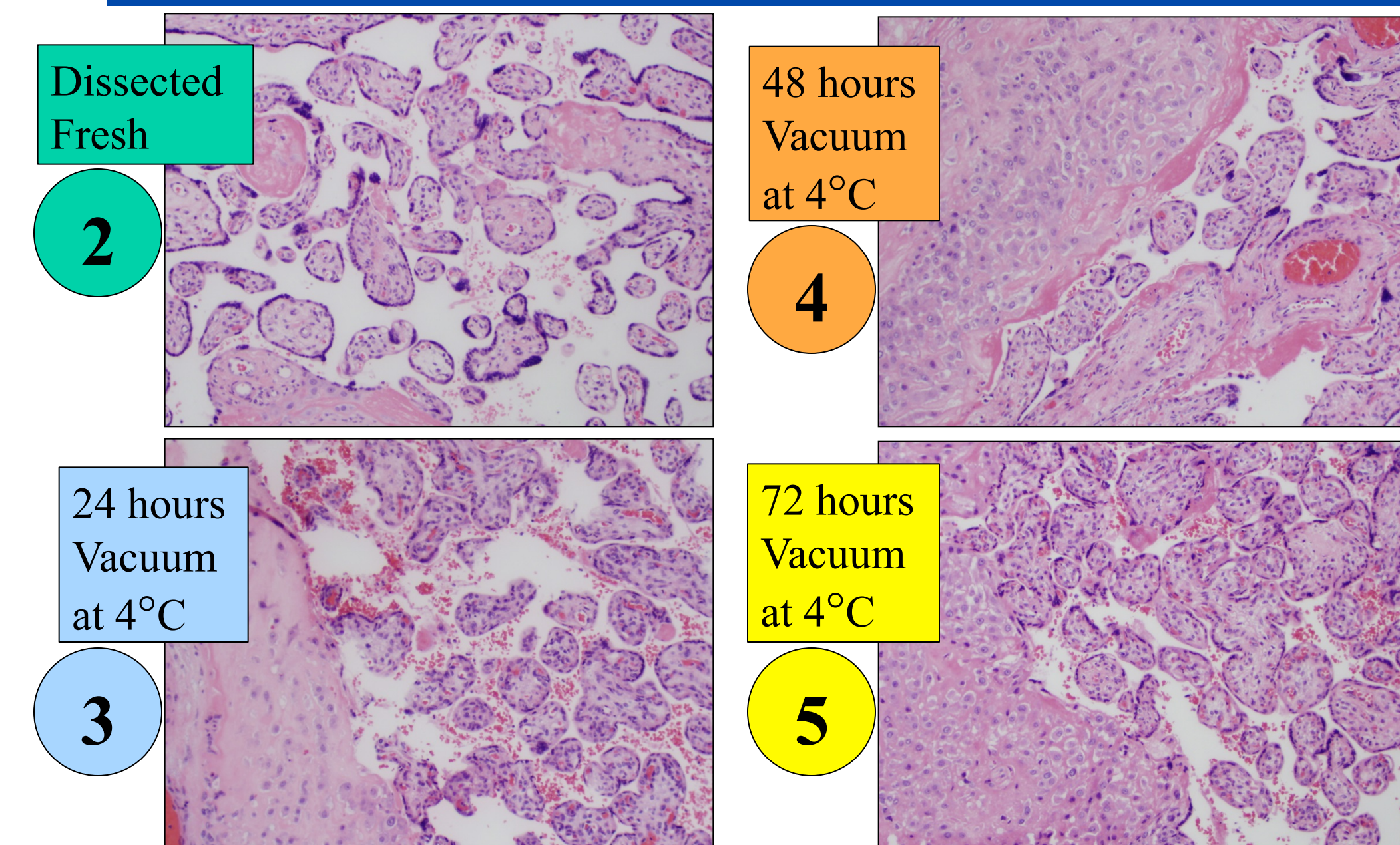
Design



Results

- 102 H&E slides evaluated independently by 2 placental pathologists
- 3 part assessment scheme
 - Adequate for histologic evaluation
 - Less than optimal
 - Inadequate for histologic evaluation
- All samples were evaluated to be **Adequate for histologic evaluation**

Representative Images



Conclusions

- Vacuum-sealing and cold preservation of human placentas in Labor and Delivery is a disruptive technology that advances 3 improvement opportunities:
 1. Safety
 1. No formalin in L&D required to transport placentas to Lab
 2. Safe isolation of remaining placentas in sealed bags for waste disposal or return to patient (if requested)
 3. Minimal use and disposal of formalin in Pathology Gross Lab
 2. Quality
 1. Controlled pre-analytic specimen preservation variables
 2. Controlled formalin fixation times in Lab
 3. Cost
 1. Avoidance of formalin disposal as expensive hazardous waste