IRB Approved Retrospective Observational Study Assesing the Effectiveness of a Nylon Hook-Array Fabric Device For Diagnostic Tangential Shave Biopsy

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Hooked Kylon® Fabric-Based Tangential Biopsy Device

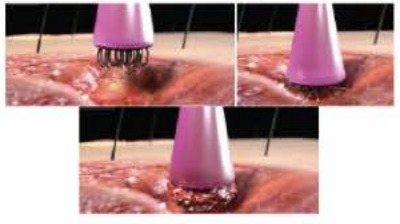
Introduction:

Tangential biopsy has a clinical utility in dermatopathology. By shaving and collecting skin lesions a clinician can obtain a surgical specimen, albeit accepting it will obtain the depth from surface to the base, and sacrifice analyzing intact epidermal-dermal architecture. Chronic wounds are commonly laden with necrotic tissue and slough. Visualization of potential pathology on the base requires debridement or cleaning of the surface necrosis to properly target, shave, and collect tangential biopsies for histopathology or for organism identification via culture or molecular means (Schultz). There are some pathologies such as r/o melanoma where punch biopsy is preferred for needed architecture, and tangential biopsy avoided.

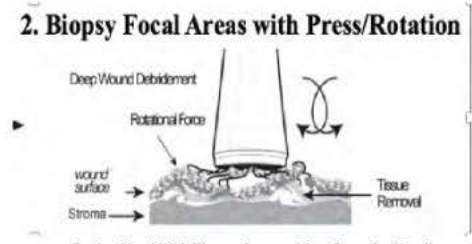
Methods:

This study was reviewed and deemed exempt from IRB approval. This was a retrospective observational study of multiple advanced practice nurses and a physician who were licensed to perform chronic wound and skin surgical biopsies. They used a novel hooked micro-curette biopsy brush that excavates and traps biopsy samples for lab transport (SoftBiopsy®, Histologics LLC, Anaheim, CA). The clinicianswere unaware of future audit and had available the instructions for use, and decided sites to biopsy. The investigators reviewed the reports and confirmed them as "diagnostic tissue" if non-necrotic epithelial, dermal, subcutaneous tissue, muscle, or bone was identified and a histopathologic diagnosis was rendered. We sought to evaluate the diagnostic capability of brush tangential biopsy of chronic wounds.

1. Target
2. Press and Twist
3. Capture Tissue



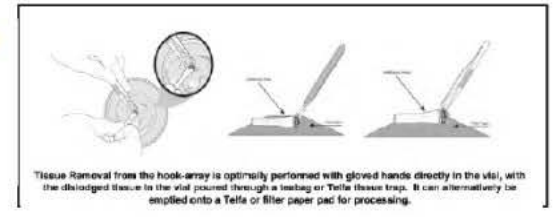
Hooked Frictional Fabric Biopsy



Device Head With Tissue Snapped free from the Handle

inspect/Assure Biopsy Specimen to be Detached for Lab

SofBiopsy ® device head in vial



Tissue Removed from Hooked Fabric Tip

Results:

We reviewed a series of redacted HIPAA compliant pathology reports from the two histopathology labs that received tangential biopsies carried by the hooked nylon fabric biopsy brush. Twenty Five cases (13 female, 12 male, mean age 71) who had the hooked brush used for tangential biopsies were identified. One case had tissue in gross inspection on the brush but lost in processing per the report description. Nine cases were devoid of viable tissue and showed necrosis or fibrinopurulent material. Fifteen cases met the criteria as diagnostic (See Wound Histopathology Results).

Photomicrographs:

Ulcerated Skin — Bowens Disease (CIS)

Two examples of Histopathologic diagoses from brush biopsy sampling of suspected pathology from disrupted skin (wounds).

Wound Histopathology Results

Biopsy Sites	Diagnoses	Non-Diagnostic Findings
Lower Extremity (14)	Benign, Inflamed or Ulcerated Skin	Ulcer, granulation w/ no viable tissue
Foot or Anke (4)	Bowens Disease (Sq Ca in Situ)	Necro-inflammatory debris
Upper Leg/Thigh (1)	Verrucous Keratosis or wart	fibrosis, hemorrhage, cocci
Buttock/Pelvic (4)	Benign Cartilage	no tissue identified
Abdomen (1)	Angioproliferation tissue	
Chest (1)	Skin with Granulation Tissue	

References

1. Gregory Schultz, PhD1; et al;c Consensus guidelines for the identification and treatment of biofilms in chronic nonhealing wounds, Wound Rep Reg (2017) 25 744–757. Wound Healing Society.
2. Urmila N, Nischal KC, Uday K. Techniques of Skin Biopsy and Practical Considerations. J Cutan Aesthet Surg. 2008 Jul-Dec; 1(2): 107–111.
3. Winter M et al. Fabric-based exocervical and endocervical biopsy in comparison with punch biopsy and sharp curettage J Low Genit Tract Dis. 2012 Apr;16(2):80-7.

Acknowledgement:
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Discussion:

To date over one million consistently diagnostic cases with hooked-brush biopsy of mucosal cervix tissue with similar methodology; utilizing the devices under study have been documented and proven in a randomized clinical trial (Winter). Although capable of obtaining tangential shave biopsies for diagnosis in 15 of 25 casses, the histopathology review appears to show that biopsy is compromised as non-diagostic by necrosis and slough, and one case with tissue lost in processing. As per the instructions provided to clinicians, debridement to visualize the viable lesion in the target wound base is imperative to obtaining diagnostic wound base biopsies. This may have been the cause of the non-diagnostic cases. Squamous cell cancer in-situ was diagnosable with hooked brush-curette tangential biopsy.

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