Published in final edited form as:

Dermatol Surg. 2015 November ; 41(11): 1264–1273. doi:10.1097/DSS.0000000000000530.

Efficacy and Tolerability of a Novel Biopsy Device for Removing Benign Epidermal Skin Lesions

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Abstract

BACKGROUND—The shave biopsy using a razor with an open blade is the current standard of care for sampling superficial skin lesions.

OBJECTIVE—To enhance safety, the authors developed a novel biopsy device with a closed blade design for removing the epidermal layer of skin and evaluated against the open razor blade for tolerability, scarring, and accuracy in histological diagnosis.

MATERIALS AND METHODS—Shave biopsies were performed using the novel device or razor blade on benign epidermal skin lesions in 10 patients on comparable body parts. Digital photography, colorimetry, scar scale evaluations, and questionnaires were used to evaluate the efficacy and tolerability of the devices.

RESULTS—For all patients, accurate histological diagnoses were made regardless of device type. No statistically significant differences were detected between the novel device and razor blade in terms of scar scale assessments, colorimetry, and questionnaire responses. Both patients and the participating dermatologist reported satisfaction with the safety and performance of the novel device. No injuries to the provider occurred with either instrument.

CONCLUSION—The rotating sphere biopsy device is a potential alternative to the razor blade with comparable tolerability, scarring, and accuracy in histological diagnoses, offering improved safety for patients and health care providers.

The shave biopsy is the most commonly used method for sampling skin in a dermatologist's office.^{1–3} Several factors explain the technique's widespread use, including the speed with which the procedure can be performed, lack of suturing, ease of wound care, and good cosmetic results.^{1,4} Typically, an instrument such as a razor blade, scalpel, or a pair of scissors is used.¹ Among the first reports of shave biopsy performed with a razor blade is the 1936 study of epidermal metabolism by Buhmann.⁵ The razor blade has since been modified

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Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the full text and PDF versions of this article on the journal's Web site (www.dermatologicsurgery.org).

only slightly, with the inherent design concept of an exposed blade remaining largely unchanged for the last half-century.⁶ Several disadvantages of the razor blade exist. Owing to the exposed, open blade design, there exists a risk of injury and blood-borne pathogen exposure, especially to the nondominant hand, which is used to stabilize the tissue during the procedure.^{6,7} Furthermore, if not properly disposed, there exists a risk for injury to ancillary staff who handle and dispose the razor blades before and after the procedure. The razor blade biopsy may also require the use of forceps to hold the specimen for counter traction against the blade's movement. This technique renders the specimen vulnerable to crush artifact.^{3,7} In addition, practitioners have found the razor blade unwieldy with user-dependent variability, and the open bladed instrument may appear more intimidating to some patients.⁶

In light of these issues, the authors have developed a novel instrument for conducting a superficial shave biopsy, which addresses several disadvantages of the traditional razor blade shave biopsy. The Department of Dermatology at Johns Hopkins School of Medicine envisioned, designed, and created the device, with collaborators at the Department of Biomedical Engineering at Johns Hopkins University. The entire sharp blade is housed within the cylinder container, such that there is no exposure to an open blade for the practitioner during the biopsy (Figure 1). In the device's starting position, the target lesion is visualized and lined up with a central opening. The specimen is then cut as the upper sphere is rotated. In the final position, the sample is contained within the sphere, ready for retrieval, and the blade remains unexposed. Using the novel biopsy device with no exposed blade design for removing the epidermal layer of skin, the authors compared it against the razor blade for tolerability, scarring, and accuracy in histological diagnosis.

Methods

Study Participants

Participants were recruited from patient populations evaluated in clinic at the Johns Hopkins Department of Dermatology between January 2014 and March 2014. Inclusion criteria were age 18 and above, ability to provide written informed consent, and 2 clinically benign skin lesions with interest in their removal. Exclusion criteria were the following: preexisting skin conditions that may affect clinical evaluation and biopsy; significant medical history which renders study participation unsafe; history of bleeding diathesis; history of pacemaker implantation; history of keloid formation or excessive scarring; pregnant and or nursing status; and known allergy to lidocaine and epinephrine. Skin lesions localized to the head and neck were excluded.

Written informed consent was obtained from all participants. Study protocols were performed at the Johns Hopkins Cutaneous Translational Research Program center. One dermatologist (S.H.Y.) performed all of the biopsies. The Johns Hopkins Institutional Review Board approved the study.

Rotating Sphere Device

The device contains a curved blade to allow for consistent skin thickness at a predetermined depth for sampling. The blade is permanently attached to the interior of the blade holder assembly and is completely confined. The device has a handle that is configured to rotate the blade holder assembly within the inner space of the housing. By turning this handle, the user can sample a skin lesion (Figure 1, and see Supplemental Digital Content 1, Video, <http://links.lww.com/DSS/A30>).

Visit 1 Protocol

Patient demographics and Fitzpatrick skin type were recorded for each participant. Two clinically benign skin lesions located on comparable anatomical regions—either adjacent unilateral or contralateral body parts—were chosen for removal. Baseline digital photographs of the skin lesions to be biopsied were collected using a digital camera and microflash unit (Nikon D300s; Nikon, Tokyo, Japan). The type, location, and dimensions of each target skin lesion were recorded before biopsy. The lesions were randomly assigned to removal through shave biopsy using a razor blade or the novel rotating sphere device. The type of razor blade used was DermaBlade (Personna American Safety Razor Company, Verona, VA), possessing a single-edge and a flexible plastic handle, which is sterilely packaged and single-use. The novel shave device was sterilized by auto-claving at 121°C for 15 minutes after manufacturing and before first use. One percent lidocaine with epinephrine was used for local anesthesia. There was no blinding of either the participant or investigator. Both the novel device and razor blades were discarded after each use.

Visit 2 Protocol

Participants returned after approximately 1 month for evaluation of biopsy scars. Scar dimensions were recorded. Digital photographs of the scar sites were taken. Colorimeter readings were also taken from scar sites using the Konica Minolta CR-400 Chroma Meter (Minolta Corp., Ramsey, NJ) and SpectraMagic NX software. The colorimeter is set to the CIE (Commission Internationale de l'Eclairage) system and was calibrated to a white plate (Model CR-A43; Minolta Corp., Ramsey, NJ) before measuring. The parameters of interest were L* and a*. L* value of 0 is black and 100 is white, corresponding to pigmentation. The parameter a* represents the spectrum from green to red, with more positive values corresponding to increased erythema.^{8,9}

Scar sites were evaluated using previously published scar scales. These include the Observer Scar Assessment Scale, Patient Scar Assessment Scale,¹⁰ and Manchester Scar Scale.¹¹ Adverse events were documented. Participants completed a survey, which included questions addressing impedance to daily activities, discomfort, pain, and effective removal of the unwanted skin lesion.

Visit 3 Protocol

Participants returned approximately 4 months after the date of biopsy for a final visit. The protocol for this visit was identical to that of Visit 2.

Statistical Analysis

The Wilcoxon signed-rank test was applied to compare sizes of lesions and scars, plus scarring severity based on scar scale scores among lesions biopsied with a razor blade versus the rotating sphere device. The Wilcoxon signed-rank test was also applied to compare survey scores and colorimeter data (L^* and a^* values) associated with razor blade versus novel device. A p value of $<.05$ was considered statistically significant, and $.05$ to $.10$ marginally significant.

Results

Patient Characteristics and Outcome

Patient demographics and biopsied lesion characteristics are summarized in Table 1. The mean age of participants was 65.6, with 6 women and 4 men enrolled. Nine participants identified as white, and 1 identified as African American. Two participants had Fitzpatrick skin Type I, 7 had Type II, and 1 had Type V. Four types of lesions were biopsied: cherry angioma, acrochordon, seborrheic keratosis, and intradermal nevus, which had initially been suspected to be an acrochordon. Lesions were of similar sizes, such that the mean dimensions for lesions biopsied by razor blade and by the novel device were 3.4 mm x 3.4 mm and 3.0 mm x 3.0 mm, respectively, with no statistically significant differences ($p = .584$). The duration between Visit 1 and Visit 2 was 29 days on average across all participants. As for the dimensions of biopsy sites on Visit 2, the mean for scars resulting from razor blade was 3.8 mm x 3.8 mm, and the mean for scars resulting from the novel device was 3.3 mm x 3.3 mm, with no statistically significant differences ($p = .208$). No injuries were reported to the provider after the use of either instrument.

Grossly, there were minimal differences in biopsy sites between the novel device and razor blade at Visits 2 and 3 in all patients tested (Figures 2 and 3). In addition, no significant differences were found between scar appearance at Visit 2 based on measured parameters (Table 2), including Manchester Scale score, Observer's Scale score, Patient's Scale score, pigmentation (L^*), and redness (a^*). The scales used for the assessment of scars in this study, the Patient and Observer Scar Assessment Scales and the Manchester Scar Scale, have been previously investigated and found to be valid, robust tools well-suited for scar evaluation.¹⁰⁻¹² The colorimeter has also been demonstrated to be an appropriate instrument for analysis of scar appearance.⁸

Participant survey scores were also compared to assess difference in satisfaction with razor blade versus rotating sphere device. No significant differences were found between scar appearance at Visit 2 based on measured parameters (Table 2). There was a marginally significant ($p = .06$) difference in the pigmentation of scars; scars resulting from razor blade biopsies were more darkly pigmented than scars resulting from the rotating sphere device.

The authors then analyzed longer term outcomes in scar appearance between the razor blade and novel device. Table 3 displays the demographics and biopsy site characteristics for the 4 participants who returned for Visit 3. The remaining participants were lost to follow up. Even at 120 days after the procedures, comparisons of the measured parameters did not yield statistically significant differences (Table 4).

The Dermatology Life Quality Index (DLQI) scoring system, widely used to assess impact on quality of life from dermatological conditions,¹³ was used to assess patients' experiences after skin biopsies. Overall, both the participating dermatologist and patients expressed satisfaction with the novel device (Figures 4, 5, and 6). All 10 patients expressed willingness to undergo a shave biopsy with the rotating sphere device, whereas 9 of 10 patients were willing to undergo the procedure again with the razor blade (Figure 5).

Hundred percent of participants agreed that the rotating sphere biopsy was just as effective as the traditional shave biopsy in removing the skin lesion, and the scar from the rotating sphere biopsy looked and believed similar to the scar from the traditional shave biopsy. All participants expressed willingness to undergo the biopsy procedure again if necessary in the future, with either the razor blade or the rotating sphere device.

Histological Analysis

A dermatopathologist who was blinded to the type of biopsy device used for each sample was able to secure histological diagnoses for all lesions biopsied in the study (Figure 6). Based on histological appearance alone, the dermatopathologist could not distinguish whether a lesion was biopsied using the razor blade or with the rotating sphere device (Figure 7).

Discussion

The shave biopsy with a razor blade, while already a commonplace procedure,¹⁻³ nevertheless has considerable room for improvement and poses a risk for injury to the physician, ancillary staff, and the patient. The authors developed a novel rotating sphere biopsy device to address these deficiencies and compared it against the razor blade in terms of scar appearance and histological outcomes, and also patient and dermatologist satisfaction in removing benign epidermal skin lesions.

There were no visual or statistical differences between scars resulting from the razor blade and scars resulting from the rotating sphere device at both 1 and 4 months after the procedure as measured by multiple scar scales and colorimeter data. Moreover, both patients' and dermatologist's opinions were favorable toward the use of novel shave device regarding their experiences, as demonstrated by the survey responses. Patient satisfaction scores also did not differ significantly between the novel device and razor blade. Moreover, histological interpretations could be performed on all biopsied samples, and the dermatopathologist could not distinguish the type of device used. Taken together, the authors findings demonstrate that the rotating sphere device may be equivalent to the razor blade in important aspects such as scar outcomes, patient satisfaction, user experience, and adequacy for histological diagnosis while providing improved safety for patients and health care providers. It will likely have decreased user-to-user variability, and its use will require less training.

Several limitations characterized this study. Statistical power was restricted by the small sample size of 10. One dermatologist performed all the biopsies, and 1 dermatopathologist reviewed all the slides, such that additional perspectives from different dermatologists and

dermatopathologists were not collected. This pilot study was limited to biopsies of benign epidermal lesions. Furthermore, the device was not tested on nonsmooth, curved skin surfaces such as the ear or nasofacial grooves.

There are many opportunities for further optimization for the novel shave device. By adjusting the size of the open hole on the bottom piece of the shave device (from 2 mm to 20 mm), the desired size of the skin biopsy can be easily adjusted. Furthermore, the depth and thickness of skin biopsy specimens may be adjusted by varying the spherical diameter of the biopsy device. For future studies, the authors are investigating additional ways to improve on the design of the device, including an enclosed formalin container, where the specimen would be automatically deposited immediately after the biopsy, which would eliminate the need for transferring the specimen.

Studies are planned to examine the accuracy and feasibility of using this device on malignant skin lesions, and also melanocytic lesions. A recent study explored the accuracy of sampling by punch and shave biopsy techniques, comparing the histological subtypes of basal cell carcinoma present in the biopsy specimen with the composite subtype found in the biopsy specimen and excision. A total of 18% of the biopsy specimens were inaccurately identified, and occasionally, an aggressive component was missed.¹⁴ Sampling of pigmented lesions with the shave technique has been a controversial issue, due to concerns for melanoma transection. A recent study compared the scoop shave technique, defined as a biopsy into the reticular dermis using a bendable blade, with various other techniques. The authors concluded that the scoop shave technique is safe and effective for diagnosing melanocytic lesions.¹⁵ A similar approach which investigates the rotating sphere device can shed light on the effectiveness of the novel device as a diagnostic tool for non-melanoma skin cancers or pigmented lesions.

Although limited by a small sample size, this pilot study suggests that a novel biopsy device developed here may serve as an alternative to the current standard shave biopsy technique with numerous potential advantages. The ease of using the novel device, and also the ability to achieve a consistent, controlled thickness shave biopsy every time is an advantage, which may especially be of value to dermatologists with disabilities who lack the dexterity to handle open blades. With the novel shave device, there is no exposed open blade, and the nondominant hand or forceps are not needed to provide counter traction, thus reducing the risk for injury or blood-borne pathogen exposure. This novel biopsy device may appeal not only to dermatologists but also to non- dermatologic medical providers including primary care physicians, nurse practitioners, or surgeons who perform skin biopsies. The reduced risk of accidental injury or blood-borne pathogen exposure by eliminating the exposed sharp blade to the operator, clinical staff, and patients is another significant benefit achieved by the novel shave biopsy device.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

The authors thank Max K. Fischer MD for histological analyses and Yifu Dang, Danielle Dorfman, Anish Bhatnagar and Pujan Desai, undergraduate students in the Department of Biomedical Engineering, Johns Hopkins University, for their input on the design and optimization of novel biopsy device.

Supported by a grant from the Department of Biomedical Engineering, Johns Hopkins University, and the Ina R. Drew & Howard J. Drew Innovation Fund in the Department of Dermatology, Johns Hopkins School of Medicine. L. A. Garza received a grant support R01AR064297 from NIAMS/NIH. The study was approved by the Johns Hopkins Institutional Review Board. All patents and intellectual property of the novel biopsy device are owned by the Johns Hopkins University. S. Kang, A. L. Chien, L. A. Garza, and J. M. Taube are coinventors of the device. The other author has indicated no significant interest with commercial supporters.

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Figure 1.

(A) 3D CAD image of the spherical novel shave biopsy device in which the central opening is visible for alignment with the lesion of interest. (B-D) Photographs of the novel shave biopsy device at various positions; the upper sphere is rotated by the handle to cut the specimen of interest. Note that there is no exposure to an open blade at any point during the biopsy. (E) Photograph of the novel biopsy device positioned on the skin; the dotted red circle represents the 5 mm opening where the biopsy will be taken.

Figure 2.

All images are from the same 51-year-old African American patient. (A) Lesion (seborrheic keratosis) to be biopsied by novel device, before biopsy. (B) Novel device scar, 35 days after biopsy. (C) Novel device scar, 150 days after biopsy. (D) Lesion (seborrheic keratosis) to be biopsied by razor blade, before biopsy. (E) Razor blade scar, 35 days after biopsy. (F) Razor blade scar, 150 days after biopsy.

Figure 3.

All images are from the same 76-year-old white patient. (A) Lesion (seborrheic keratosis) to be biopsied by novel device, before biopsy. (B) Novel device scar, 35 days after biopsy. (C) Novel device scar, 116 days after biopsy. (D) Lesion (seborrheic keratosis) to be biopsied by razor blade, before biopsy. (E) Razor blade scar, 35 days after biopsy. (F) Razor blade scar, 116 days after biopsy.

Figure 4.
Visit 1 survey responses collected from the participating dermatologist regarding the use of novel biopsy device on 10 participants.

Figure 5.

Visit 2 survey opinions collected from 10 participants.

Figure 6.
Visit 3 survey opinions collected from 4 participants.

Figure 7. Representative histological sections of sampled lesions, stained by hematoxylin and eosin. Seborrheic keratosis biopsied using the rotating sphere device (A) and razor blade (B). Cherry angiomas biopsied using the rotating sphere device (C) and razor blade (D).

TABLE 1.
Demographics of participants who Completed Visits 1 and 2 and Biopsy Site Characteristics (n = 10)

Age (years)	Race	Fitzpatrick Skin Type	Lesion Removed	Size and Location of Lesion Removed by Razor	Size and Location of Lesion Removed by Novel Device	Days In-Between Visits	Size of Scar Resulting From Razor	Size of Scar Resulting From Novel Device
51	AA	V	Seborrheic keratosis	5 mm x 5 mm right upper back	5 mm x 5 mm left upper back	35	5 mm x 5 mm	5 mm x 5 mm
94	W	I	Cherry angioma	3 mm x 3 mm right upper back	3 mm x 3 mm right upper back	28	3 mm x 3 mm	3 mm x 3 mm
60	W	II	Acrochordon	3 mm x 3 mm left lateral breast	2 mm x 2 mm right lateral breast	28	3 mm x 3 mm	2 mm x 2 mm
53	W	II	Acrochordon	2 mm x 2 mm left axilla	2 mm x 2 mm left axilla	28	2 mm x 2 mm	2 mm x 2 mm
76	W	I	Seborrheic keratosis	6 mm x 5 mm left lateral back	2 mm x 2 mm left shoulder	35	6 mm x 5 mm	2 mm x 2 mm
45	W	II	Intradermal nevus	4 mm x 4 mm mid back	4 mm x 4 mm left lateral back	34	4 mm x 4 mm	4 mm x 4 mm
82	W	II	Seborrheic keratosis	4 mm x 3 mm mid back	4 mm x 4 mm upper mid back	28	4 mm x 3 mm	4 mm x 4 mm
53	W	II	Acrochordon	2 mm x 2 mm left axilla	3 mm x 2 mm right axilla	21	2 mm x 2 mm	3 mm x 2 mm
76	W	II	Cherry angioma	2 mm x 2 mm left abdomen	2 mm x 2 mm left abdomen	28	10 mm x 3 mm	5 mm x 4 mm
66	W	II	Cherry angioma	2 mm x 2 mm right abdomen	2 mm x 2 mm left abdomen	27	2.5 mm x 2.5 mm	2 mm x 2 mm

AA, African American; W, white.

TABLE 2.

Wilcoxon Signed-Rank Test Results From Visit 2 (n = 10)

Compared Parameter	Mean Difference *	Standard Deviation of Differences	Interquartile Range	95% CI of the Mean Difference	z-test Statistic	p *
Manchester Scale score	-0.75	3.13	2.38	-2.99 to 1.49	-0.5704	.2842
Observer's Scale score	-0.2	1.87	0.75	-1.54 to 1.14	0.7842	.7835
Patient's Scale score	0.4	2.17	0	-1.15 to 1.95	0.5613	.7127
Pigmentation	1.92	2.90	3.87	-0.16 to 3.99	-1.5184	.06445
Erythema	-0.66	2.81	2.22	-2.67 to 1.36	-0.3186	.375
Survey satisfaction score	-0.3	3.8	2.5	-3.02 to 2.42	0.2284	.5903

* Differences were obtained by subtracting razor blade data from novel device data.
 CI, confidence intervals.

TABLE 3.

Demographics of Participants Who Completed Visit 3 and Biopsy Site Characteristics (n=4)

Age (years)	Race	Days After Biopsy	Biopsied Lesion Type	Razor Biopsy Scar Location	Razor Biopsy Scar Size	Novel Device Biopsy Location	Novel Device Biopsy Scar Size
51	AA	150	Seborrheic keratosis	Right upper back	5 mm × 5 mm	Left upper back	5 mm × 5 mm
76	W	116	Seborrheickeratosis	Left lateral back	3 mm × 3 mm	Left upper shoulder	2 mm × 2 mm
45	W	116	Intradermalnevus	Midline back	3 mm × 3 mm	Left lateral back	3 mm × 3 mm
66	W	99	Cherryangioma	Left abdomen	2 mm × 2 mm	Right abdomen	2 mm × 2 mm

AA, African American; W, white.

TABLE 4.

Descriptive Statistics of Parameters for Scar Evaluation Measured in Visit 3 (n=4)

Compared Subject	Mean Difference *	Standard Deviation of Differences	Interquartile Range	95% CI of the Mean Difference
Manchester Scale	0.25	3.59	2.75	−5.47 to 5.97
Observer's Scale	−0.5	1.73	1	−3.26 to 2.26
Patient's Scale	0	1.41	1.5	−2.25 to 2.25
Pigmentation	1.84	2.46	1.56	−2.07 to 5.75
Erythema	−2.40	2.35	1.41	−6.14 to 1.35
Survey satisfaction score	0.25	0.5	0.25	−0.55 to 1.05

* Differences were obtained by subtracting razor blade data from novel device data.

CI, confidence intervals.