New Razor Technology Improves Appearance and Quality of Life in Men With Pseudofolliculitis Barbae

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PRACTICE POINTS

- Pseudofolliculitis barbae (PFB) is a common follicular inflammatory disorder associated with shaving, most commonly seen in men of African ancestry. It can be distressing and cause a substantial impact on quality of life (QOL).
- Frequent use of a novel razor technology designed specifically for men with PFB was found to improve skin appearance and QOL after 12 weeks vs baseline.
- This razor technology provides an alternative approach to help manage PFB for men who wish to or need to continue shaving.

Pseudofolliculitis barbae (PFB) consists of ingrown hairs leading to papules, pustules, and discomfort. This prospective, 12-week clinical study aimed to assess the appearance of males with razor bumps and shaving irritation when using a new razor technology with 2 blades separated by a bridge feature (SkinGuard [Procter & Gamble]). The impact on participants' shave-related itching, burning, and stinging severity, as well as quality of life (QOL), also was assessed. In men with PFB, shaving with the test razor at least 5 times per week over a 12-week period improved the appearance and QOL of males with razor bumps and shaving irritation compared with baseline.

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seudofolliculitis barbae (PFB)(also known as razor bumps or shaving bumps)¹ is a skin condition that consists of papules resulting from ingrown hairs.² In more severe cases, papules become pustules, then abscesses, which can cause scarring.^{1,2} The condition can be distressing for patients, with considerable negative impact on their daily lives.³ The condition also is associated with shaving-related stinging, burning, pruritus, and cuts on the skin.⁴

Pseudofolliculitis barbae is most common in men of African descent due to the curved nature of the hair follicle,^{2,5,6} with an estimated prevalence in this population of 45% to 83%,^{1,6} but it can affect men of other ethnicities.⁷ A genetic polymorphism in a gene encoding a keratin specific to the hair follicle also has been found to predispose some individuals to PFB.⁵ When hair from a curved or destabilized hair follicle is cut to form a sharp tip, it is susceptible to extrafollicular and/or transfollicular penetration,^{5,6,8} as illustrated in Figure 1.

With extrafollicular or transfollicular penetration, the hair shaft re-enters or retracts into the dermis, triggering an inflammatory response that may be exacerbated by subsequent shaving.² Few studies have been published that aim to identify potential shaving solutions for individuals with PFB who elect to or need to continue shaving.

A new razor technology comprising 2 blades separated by a bridge feature has been designed specifically for men with razor bumps (SkinGuard [Procter & Gamble]). The SkinGuard razor redistributes shaving pressure so that there is less force from the blades on the skin and inflamed lesions than without the bridge, as seen in Figure 2. The razor has been designed to protect the skin from the blades, thereby minimizing the occurrence of new lesions and allowing existing lesions to heal.

The eTables are available in the Appendix online at www.mdedge.com/dermatology.

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Pharmaceuticals; Covance; Eli Lilly and Company; eResearch Technology, Inc; Galderma; Incyte Corporation; Informa Healthcare; Janssen; Johnson & Johnson; Merck & Co, Inc; Pfizer; Procter & Gamble; Revian; UCB; and UpToDate. Dr. De Souza, Mr. Russell, and Ms. Zupkosky report no conflict of interest.

FIGURE 1. Pseudofolliculitis barbae has been associated with shaving. A, In extrafollicular penetration, hair grows out of the follicle, curves, and regrows back toward the skin. The shaved hair tip penetrates the skin. B. In transfollicular penetration, the tip of a regrowing hair pierces through the hair follicle wall before the hair grows out of the skin. (Figures have been scaled to show beard hair diameter [~100 µm] relative to the approximate thickness of the epidermis and dermis of the lower cheek and chin.)





The primary purpose of this study was to assess the appearance of males with razor bumps and shaving irritation when using the new razor technology in a regular shaving routine. The secondary objective was to measure satisfaction of the shaving experience when using the new razor by means of assessing itching, burning, and stinging using the participant global severity assessment (PGSA) and the impact on quality of life (QOL) measures.

Methods

Participants—Eligible participants were male, aged 20 to 60 years, and had clinically diagnosed PFB as well as symptoms of skin irritation from shaving. Participants were recruited from a dermatology clinic and via institutional review board–approved advertising.

Those eligible for inclusion in the study had a shaving routine that comprised shaving at least 3 times a week using a wet-shave, blade-razor technique accompanied by only a shave gel or foam. In addition, eligible participants had mild to moderate symptoms of skin irritation (a minimum of 10 razor bumps) from shaving based on investigator global severity assessment (IGSA) rating scales and were willing to shave at least 5 times a week during the study period. Participants could continue certain topical and systemic interventions for their skin.

Participants were excluded from the study if they had an underlying inflammatory disease that could manifest with a skin rash or were using any of these medications: topical benzoyl peroxide, topical clindamycin, topical retinoids, or oral antibiotics.

Study Design—A prospective, open-label study was conducted over a period of 12 weeks at a single site in the United States. Investigators instructed participants to shave 5 or more times per week with the test razor and to keep a daily shaving journal to track the number of shaves and compliance.

Participants were evaluated at the baseline screening visit, then at 4, 8, and 12 weeks. Evaluations included an investigator lesion count, the IGSA, and the PGSA. The



FIGURE 2. Test razor bridge feature (SkinGuard [Procter & Gamble]) minimizes the force of the razor blades on the skin. Copyright 2022 The Procter & Gamble Company.

PGSA was used to evaluate subjective clinical measurements (ie, indicate how much postshave burning/itching/ stinging the participant was experiencing). The impact of shaving on daily life was evaluated at the baseline screening visit and at 12 weeks with the Participant Quality of Life Questionnaire comprised of 22 QOL statements. eTable 1 summarizes the investigator assessments used in the study, and eTable 2 summarizes the participant self-assessments. Both tables include the scale details and results interpretation for each assessment.

The study was approved by the local institutional review board, and all participants provided written informed consent in accordance with Title 21 of the Code of Federal Regulations, Part 50.

Study Visits—At the baseline screening visit, participants provided written informed consent and completed a prestudy shave questionnaire concerning shaving preparations, techniques, and opinions. Participants also provided a medical history, including prior and concomitant medications, and were evaluated using the inclusion/exclusion criteria. Investigators explained adverse event reporting to the participants. Participants were provided with an adequate supply of test razors for the 12-week period.

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Lesion count	Baseline	4 weeks	8 weeks	12 weeks
Papules				
Mean (SD)	19.1 (10.4)	13.2 (9.1)	6.0 (4.7)	6.0 (6.0)
Estimated mean reduction from baseline, % (95% Cl; <i>P</i> value)		18.9 (-8.2 to 44.9; <i>P</i> =.17)	57.2 (38.2-76.1; <i>P</i> <.0001)	59.6 (38.1-81.2; <i>P</i> <.0001)
Pustules				
Mean (SD) ^a	0.2 (0.5)	0.3 (1.1)	0.1 (0.2)	0.0 (0.0)
Total pustule count (no. of participants)	4 (3)	6 (2)	1 (1)	0 (20)
Participants with ≥ 1 pustule (%)	3 (15)	2 (10)	1 (5)	0 (0)

TABLE 1. Investigator Lesion Counts (N=20)

^aPercentage change from baseline could not be estimated because of the extremely low pustule count at baseline and over the course of the study.



FIGURE 3. Decreasing mean investigator global severity assessment (IGSA) scores (0=clear; 1=almost clear; 2=mild; 3=moderate; 4=severe; 5=very severe) from baseline to 12 weeks. Error bars indicate SD.

Data Analysis—Means and SDs were calculated for the study measures assessed at each visit. Analyses were performed evaluating change from baseline in repeatedmeasures analysis of variance models. These models were adjusted for baseline levels of the outcome measure and visit number. The magnitude of change from baseline was evaluated against a null hypothesis of 0% change. This longitudinal model adjusted for any potential differing baseline levels among participants. Statistical significance was defined as P<.05. SAS version 9.4 (SAS Institute Inc) was used for all analyses.

Results

In total, 21 individuals were enrolled, and 20 completed the study. Participants who completed the study were non-Hispanic Black (n=10); non-Hispanic White (n=8); Asian (n=1); or White, American Indian (n=1). All participants adhered to the protocol and reported shaving at least 5 times a week for 12 weeks using the test razor. One participant was removed after he was found to have a history of sarcoidosis, making him ineligible for the study. No study-related adverse events were reported.

Papules and Pustules—Over the course of the 12-week study, the papule count decreased significantly from baseline. Results from the investigator lesion count (see eTable 1 for key) indicated that by week 12—adjusted for number of papules at baseline—the mean percentage reduction was estimated to be 59.6% (P<.0001). A significant decrease in papule count also was observed between the baseline visit and week 8 (57.2%; P<.0001). A nonsignificant decrease was observed at week 4 (18.9%; P=.17). Only 3 participants presented with pustules at baseline, and the pustule count remained low over the course of the study. No significant change was noted at week 12 vs baseline (P=.98). Notably, there was no increase in pustule count at the end of the study compared with baseline (Table 1).

Skin Appearance—An improvement in the skin's appearance over the course of the study from baseline was consistent with an improvement in the IGSA. The IGSA score significantly improved from a mean (SD) measurement of 2.5 (0.6) (indicating mild to moderate inflammation) at baseline to 1.4 (0.8) at week 8 (P<.0001) and 1.2 (1.1) (indicating mild inflammation to almost clear) at week 12 (P<.0001). The observed decrease in severity of skin condition and skin inflammation is shown in Figure 3.

Significant improvements were observed in every category of the PGSA at week 12 vs baseline ($P \le .0007$) (Table 2). At week 12, there was a significant ($P \le .05$) increase from baseline in participant agreement for all 22 QOL metrics describing positive shave experience, achieving results, skin feel, self-confidence, and social interactions (Figure 4), which supports the positive impact of adopting a shaving regimen with the test razor. Notably, after using the test razor for 12 weeks, men reported that they were more likely to agree with the statements "my skin felt smooth,""my skin felt good to touch," and "I was able to achieve a consistently good shave." Other meaningful increases occurred in "shaving was something I looked forward to doing,""others

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Participant global severity assessment (degree of itching, burning, and stinging)	Baseline	4 weeks	8 weeks	12 weeks	Estimated change from baseline (95% Cl)	P value
How much immediate postshave itching/burning/stinging are you experiencing at this time on a scale of 1 to 5? ^a	2.7	2.3	1.8	1.6	-0.7 (-1.0 to -0.5)	<.0001
How would you rate your current razor irritation condition? ^b	2.9	2.1	1.6	1.2	−1.1 (−1.4 to −0.8)	<.0001
How easy is it to get a smooth shave after shaving? ^c	2.9	2.2	2.2	2.1	-0.7 (-1.0 to -0.4)	<.0001
How easy is it to shave stubborn hairs?°	3.2	2.6	2.5	2.3	-0.6 (-1.0 to -0.3)	.0002
How easy is it to shave against the grain with little irritation?°	3.2	2.5	2.3	2.2	-0.9 (-1.1 to -0.6)	<.0001
How easy is it to shave with the grain with little irritation?°	2.4	2.0	2.0	1.7	-0.5 (-0.7 to -0.2)	.0007
How easy is it to glide comfortably over your skin with the razor blade?°	2.3	1.8	2.2	1.8	-0.5 (-0.7 to -0.3)	<.0001

TABLE 2. Participant Global Severity Assessment Results

a1=none at all; 2=mild or minimal; 3=moderate; 4=severe; 5=very severe.

^b1=completely clear; 2=almost clear; 3=mild; 4=moderate; 5=severe; 6=very severe.

°1=very easy; 2=easy; 3=difficult; 4=very difficult.

thought I looked clean cut," "I looked my best for my family/others/work," and "I felt comfortable/confident getting closer to others." All QOL statements are shown in Figure 4.

Comment

Improvement With Novel Razor Technology-For the first time, frequent use of a novel razor technology designed specifically for men with PFB was found to significantly improve skin appearance, shave satisfaction, and QOL after 12 weeks vs baseline in participants clinically diagnosed with PFB. In men with shave-related skin irritation and razor bumps who typically wet-shaved with a razor at least 3 times a week, use of the test razor with their regular shaving preparation product 5 or more times per week for 12 weeks was associated with significant improvements from baseline in investigator lesion count, IGSA, PGSA, and Participant Quality of Life Questionnaire measurements.

Study strengths included the quantification of the change in the number of lesions and the degree of severity by a trained investigator in a prospective clinical study along with an assessment of the impact on participant QOL. A lack of a control arm could be considered a limitation of the study; however, study end points were evaluated compared with baseline, with each participant serving as their own control. Spontaneous resolution of the condition

with their standard routine was considered highly unlikely in these participants; therefore, in the absence of any other changes, improvements were attributed to regular use of the test product over the course of the study. The results presented here provide strong support for the effectiveness of the new razor technology in improving the appearance of men with razor bumps and shaving irritation.

Hair Removal Tools for the Management of PFB-Although various tools and techniques have been proposed in the past for men with PFB, the current test razor technology provided unique benefits, including improvements in appearance and severity of the condition as well as a positive impact on QOL. In 1979, Conte and Lawrence9 evaluated the effect of using an electric hair clipper and twice-daily use of a skin-cleansing pad on the occurrence of PFB. Participants (n=96) allowed their beards to grow out for 1 month, after which they started shaving with an electric clipper with a triple *O* head. The authors reported a favorable response in 95% (91/96) of cases. However, the electric clippers left 1 mm of beard at the skin level,⁹ which may not be acceptable for those who prefer a clean-shaven appearance.⁶

A prospective survey of 22 men of African descent with PFB found use of a safety razor was preferred over an electric razor.¹⁰ The single-arm study evaluated use of a foil-guarded shaver (single-razor blade) in the management of PFB based on investigator lesion counts and



FIGURE 4. Mean quality of life (QOL) scores at baseline (visit 1) and at week 12 (visit 4). All week 12 scores were significantly higher (P<.05 vs baseline). (See eTable 2 for scale ranges.)

a participant questionnaire. Participants were asked to shave at least every other day and use a specially designed preshave brush. A mean reduction in lesion counts was observed at 2 weeks (29.6%), 4 weeks (38.1%), and 6 weeks (47.1%); statistical significance was not reported. At 6 weeks, 77.3% (17/22) of participants judged the foilguarded shaver to be superior to other shaving devices in controlling their razor bumps, and 90.9% (20/22) indicated they would recommend the shaver to others with PFB. The authors hypothesized that the guard buffered the skin from the blade, which might otherwise facilitate the penetration of ingrowing hairs and cause trauma to existing lesions.

The mean reduction in lesion count from baseline observed at week 4 was greater in the study with the foil-guarded shaver and preshave brush (38% reduction)¹⁰ than in our study (19% reduction in papule count). Different methodologies, use of a preshave brush in the earlier study, and a difference in lesion severity at baseline may have contributed to this difference. The study with the foil-guarded shaver concluded after 6 weeks, and there was a 47.1% reduction in lesion counts vs baseline.¹⁰ In contrast, the current study continued for 12 weeks, and a 59.6% reduction in lesion counts was reported. Participants from both studies reported an improved shaving experience compared with their usual practice,¹⁰ though only the current study explored the

positive impact of the new razor technology on participant QOL.

Preventing Hairs From Being Cut Too Close—The closeness of the shave is believed to be a contributory factor in the development and persistence of PFB^{6,8,11} based on a tendency for the distal portion of tightly curled hair shafts to re-enter the skin after shaving via transfollicular penetration.¹² Inclusion of a buffer in the razor between the sharp blades and the skin has been proposed to prevent hairs from being cut too close and causing transfollicular penetration.¹²

In the test razor used in the current study, the bridge technology acted as the buffer to prevent hairs from being cut too close to the skin and to reduce blade contact with the skin (Figure 2). Having only 2 blades also reduced the closeness of the shave compared with 5-bladed technologies,¹³ as each hair can only be pulled and cut up to a maximum of 2 times per shaving stroke. Notably, this did not impact the participants' QOL scores related to achieving a close shave or skin feeling smooth; both attributes were significantly improved at 12 weeks vs baseline (Figure 4).

By reducing blade contact with the skin, the bridge technology in the test razor was designed to prevent excessive force from being applied to the skin through the blades. Reduced blade loading minimizes contact with and impact on sensitive skin.¹⁴ Additional design features of the test razor to minimize the impact of shaving on the

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skin include treatment of the 2 blades with low-friction coatings, which allows the blades to cut through the beard hair with minimal force, helping to reduce the tugand-pull effect that may otherwise result in irritation and inflammation.^{13,15} Lubrication strips before and after the blades in the test razor reduce friction between the blades and the skin to further protect the skin from the blades.¹⁵

Shaving With Multiblade Razors Does Not Exacerbate PFB—In a 1-week, split-faced, randomized study of 45 Black men, shaving with a manual 3-bladed razor was compared with use of 3 different chemical depilatory formulations.¹⁶ Shaving every other day for 1 week with the manual razor resulted in more papule formation but less irritation than use of the depilatories. The authors concluded that a study with longer duration was needed to explore the impact of shaving on papule formation in participants with a history of PFB.¹⁶

In 2013, an investigator-blinded study of 90 African American men with PFB compared the impact of different shaving regimens on the signs and symptoms of PFB over a 12-week period.⁴ Participants were randomized to 1 of 3 arms: (1) shaving 2 to 3 times per week with a triple-blade razor and standard products (control group); (2) shaving daily with a 5-bladed razor and standard products; and (3) shaving daily with a 5-bladed razor and "advanced" specific pre- and postshave products. The researchers found that the mean papule measurement significantly decreased from baseline in the advanced (P=.01) and control (P=.016) groups. Between-group comparison revealed no significant differences for papule or pustule count among each arm. For the investigator-graded severity, the change from baseline was significant for all 3 groups ($P \le .04$); however, the differences among groups were not significant. Importantly, these data demonstrated that PFB was not exacerbated by multiblade razors used as part of a daily shaving regimen.⁴

The findings of the current study were consistent with those of Daniel et al⁴ in that there was no exacerbation of the signs and symptoms of PFB associated with daily shaving. However, rather than requiring participants to change their entire shaving regimen, the present study only required a change of razor type. Moreover, the use of the new razor technology significantly decreased papule counts at week 12 vs the baseline measurement (P<.0001) and was associated with an improvement in subjective skin severity measurements. The participants in the present study reported significantly less burning, stinging, and itching after using the test product for 12 weeks (P<.0001).

Impact of Treatment on QOL—The current study further expanded on prior findings by combining these clinical end points with the QOL results to assess the test razor's impact on participants' lives. Results showed that over the course of 12 weeks, the new razor technology significantly improved the participants' QOL in all questions related to shaving experience, achieving results, skin feel, selfconfidence, and social interactions. The significant improvement in QOL included statements such as "shaving was a pleasant experience," "I was able to achieve a consistently good shave," and "my skin felt smooth." Participants also reported improvements in meaningful categories such as "my shave made me feel attractive" and "I felt comfortable/confident getting closer to others." As the current study showed, a shave regimen has the potential to change participants' overall assessment of their QOL, a variable that must not be overlooked.

Conclusion

In men with clinically diagnosed PFB, regular shaving with a razor designed to protect the skin was found to significantly decrease lesion counts, increase shave satisfaction, and improve QOL after 12 weeks compared with their usual shaving practice (baseline measures). This razor technology provides another option to help manage PFB for men who wish to or need to continue shaving.

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APPENDIX

eTABLE 1. Investigator Assessment Key: A Summary of All Investigator Assessments Used in the Study

Variable	Dermatologist assessment questions	Scale range	results
Investigator les	sion count		
Lesion count	Number of papules; number of pustules; qualifying lesions were inflammatory papules, follicular papules in the beard area (not including acne), inflammatory pustules, ingrown hairs, hyperpigmentation (including severity), and excoriations	No scale; number of lesions	Decrease indicates improvement in variable
Investigator gl	obal severity assessment		
Severity	1=normal, clear skin with no evidence of skin irritation; 2=rare noninflammatory lesions present, with rare noninflamed papules; 3=some noninflammatory lesions present, with few inflammatory lesions; 4=noninflammatory lesions predominate, with multiple inflammatory lesions evident: several to many papules/pustules, and there may or may not be 1 small nodulocystic lesion; 5=inflammatory lesions more apparent, many papules/pustules, there may or may not be a few nodulocystic lesions; 6=highly inflammatory lesions predominate, many papules/ pustules and many nodulocystic lesions	0=clear; 1=almost clear; 2=mild; 3=moderate; 4=severe; 5=very severe	Decrease indicates improvement in variable

eTABLE 2. Participant Self-assessment Key: A Summary of All Participant Self-assessments Used in the Study

Variable	Self-assessment questions	Scale range	Interpreting results	
Participant global	severity assessment			
Itching, burning, and stinging	Please indicate how much immediate postshave itching/burning/stinging you are experiencing at this time on a scale of 1 to 5	1=none at all; 2=mild or minimal; 3=moderate; 4=severe; 5=very severe	Decrease indicates improvement in variable	
Skin irritation	How would you rate your razor bump condition?	1=completely clear; 2=almost clear; 3=mild; 4=moderate; 5=severe; 6=very severe	Decrease indicates improvement in variable	
Ease of shaving	How easy is it to:	1=very easy; 2=easy; 3=difficult;	Decrease indicates improvement in variable	
	Get a smooth shave after shaving?	4=very difficult		
	• Shave stubborn hairs?			
	 Shave against the grain with little irritation? 			
	• Shave with the grain with little irritation?			
	 Glide comfortably over your skin with the razor blade? 			
Participant Quality	y of Life Questionnaire ^a			
Shave experience	Shaving was a pleasant experience; shaving was worry free; shaving was rewarding; shaving was refreshing; shaving was something I looked forward to doing	1=strongly disagree; 2=moderately disagree; 3=slightly disagree; 4=neither agree nor disagree; 5=slightly agree; 6=moderately agree; 7=strongly agree ^a	Increase indicates improvement in variable	
Achieving results	I felt in control of my shave results; I was able to achieve a consistently good shave; I was able to achieve a close shave		Increase indicates improvement in variable	
Skin feel	My skin felt healthy; my skin felt smooth; my skin felt good to touch		Increase indicates improvement in variable	
Self-confidence	My shave made me feel attractive; my shave made me feel confident; my shave made me feel like I was ready to conquer the day; my shave made me feel energized		Increase indicates improvement in variable	
Social interactions	Others thought I looked clean cut; I looked my best for my family/ others/work; others thought I looked professional; others thought I looked successful; I made a good first impression; I felt comfortable/confident getting closer to others		Increase indicates improvement in variable	

^aScale and result interpretation was inverted to show improvement as an increase and started from 0, where 0=strongly agree and 6=strongly disagree.

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