

FREQUENTLY ASKED QUESTIONS

Q: *Will I ever need to shave again?*

A: **Yes!** After six treatments, you will be asked to resume shaving daily. Not all of your facial hair will be permanently removed. The hairs that remain usually grow back much thinner and finer and no longer cause PFB. The goal of the study is to provide the proper amount of treatments that allows you to resume shaving daily without developing razor bumps.

Q: *Will I be able to grow a beard when I get out of the Military?*

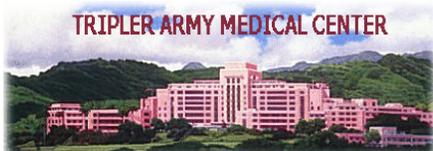
A: Currently there are no long-term studies available to say for sure. Permanent hair reduction is defined by the FDA as elimination of hair growth or an interval greater than six months before hair begins to grow again.



The Dermatology Service at Tripler Army Medical Center is conducting a clinical study for the treatment of Pseudofolliculitis Barbae (PFB) using the CANDELA GentleYAG™ 1064nm Hair Removal Laser.

The study is open to all active duty males who have been diagnosed with PFB.

Enrollment begins
01JULY 2003



WHAT IS PFB ?

Pseudofolliculitis barbae (PFB) is a common condition affecting men and women of African and Hispanic origin who have tightly coiled hair resulting in inflammatory papules, pustules and scarring that is aggravated by shaving daily. PFB is directly related to the structure and direction of hair growth.

Topical medications and modified shaving protocols have consistently demonstrated poor results. The mainstay of treatment has been mostly preventative by the avoidance of shaving. Once thought to be a complete cure, 10% to 20% of affected individuals continue to have inflammatory lesions even after the cessation of shaving.

The only definitive cure for PFB is permanent removal of the hair follicle. Previous treatments for PFB have included electrolysis, waxing, and surgical depilation which are usually impractical, painful, and unsuccessful. Hair removal can be safely achieved with the use of lasers by targeting and destroying the hair follicle with minimal side effects to the surrounding skin.

WHAT IS THE PURPOSE OF THE STUDY ?

The purpose of the study is to establish a successful treatment protocol applicable to active duty male members using the Candela GentleYAG™ Nd-YAG Hair Removal Laser.

All subjects will receive six laser treatments at either three week or six-week intervals. After completing the 6th treatment, subjects will be re-evaluated at the third and sixth month. A total of 54 weeks is needed to complete the study.

WHAT'S INVOLVED ?

The laser used in this study produces an intense light that can selectively destroy or damage hair follicles while minimizing the effects to the surrounding skin. The hair removal laser works by targeting the pigment within the hair follicle. The targeted pigment within the hair follicle is only present when the hair is in a “growth phase” meaning that 30% of the hairs will be unaffected at any given single treatment; therefore multiple treatments are required for optimum results.

The FDA has approved The GentleYAG™ laser for “permanent hair reduction”. Permanent hair reduction is defined as elimination of hair growth or a long interval (greater than six months) before hair begins to grow again.

WHO IS ELIGIBLE ?

Active duty males 18-45 years of age with a diagnosis of moderate to severe (> 21 papules or pustules) PFB to face or neck area.

Documented failure of established PFB protocols requiring a “no shave” profile.

Documented and current “no shave” profile for the last 6 months or longer

You must be available for the entire study period (12 months) and will not be on leave, deployment, or any other form of absence

that will preclude you from completing all of the required treatments and evaluations

You will not be eligible for the study if you have a history of the following:

Photosensitivity

Seizure disorder

Diabetes mellitus and/or collagen vascular disorders.

Immunodeficiency

Herpes simplex to the face or neck areas

Unwillingness to shave after 6th treatment

Previous laser hair removal to face or neck areas

Waxing, tweezing, or electrolysis in the last three months

Use of oral retinoids in the past 12 months

Allergy or sensitivity to topical anesthetics

G6PD deficiency

HOW DO I GET ENROLLED ?

You will first need an evaluation from your primary care provider. Members found to be eligible can then be referred to the TAMC Dermatology Service for consideration.

FURTHER INFORMATION

For additional information, contact the principal investigator assigned to the study:

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