formatk

Case Study: Unwanted Bikini Area Hair Removal in German Female Patients Treated with the ALPHA / Spark Pro System Using an 808nm Diode Laser

Dr. Nadav Pam, Clinical Director at FormaTK | Medical Aesthetic Device R&D | Global Training & Innovation in Energy-Based Systems

Agnessa Schindler, Manager & Certified Experienced Cosmetician, Germany

www.forma-tk.com

Case Study - Unwanted Bikini Area Hair Removal in German Female Patients Treated with the ALPHA / Spark Pro System Using an 808nm Diode Laser

Dr. Nadav Pam MD[1] – Clinical Director | Medical Aesthetic Device R&D | Global Training & Innovation in Energy-Based Systems.

Agnessa Schindler[2], Manager and certified experienced cosmetician at KRASOTA

[1]FormaTK Systems Ltd, Medical equipment manufacturer in Tirat Carmel - Yozma St 3, Tirat Carmel– Clinical Department.

[2]KRASOTA Ästhetik & Kosmetik Clinic. Address: Engelbertstraße 4, 45663 Recklinghausen, Germany

Background

Unwanted hair growth in the bikini and intimate region is a common physiological feature that varies across the female lifespan and is influenced by genetic background, hormonal sensitivity, age, and ethnicity. Hair in this area typically transitions to terminal growth during puberty under normal androgenic influence and represents a standard secondary sexual characteristic rather than a pathological condition. With time, gradual increases in hair density, thickness, and pigmentation may occur, particularly during hormonal fluctuations associated with pregnancy, the postpartum period, and peri- or post-menopause.

In the vast majority of women, hair growth in the bikini area reflects localized follicular responsiveness to androgens within the groin and inguinal regions, without evidence of systemic endocrine abnormality. Inter-individual variability is substantial and strongly influenced by ethnic background; women of Mediterranean, Middle Eastern, South Asian, and Latin ancestry commonly exhibit denser, coarser, and more pigmented hair in this region compared with women of Northern European or East Asian descent. Such differences fall entirely within normal physiological limits.

Despite its benign nature, unwanted hair in the bikini area may have meaningful aesthetic, hygienic, and quality-of-life implications. Frequently reported concerns include visibility in swimwear or intimate apparel, discomfort during physical or sexual activity, recurrent folliculitis or pseudofolliculitis, ingrown hairs, and post-inflammatory hyperpigmentation associated with repeated shaving or waxing.

Anatomical features of the bikini region - including relatively thin skin, higher baseline pigmentation, friction, occlusion, and increased moisture, may further predispose this area to irritation and inflammatory sequelae when conventional hair-removal methods are used.

Among available professional treatment modalities, the 808nm diode laser is widely regarded as a safe and effective option for long-term hair reduction in the bikini and intimate region. Its mechanism is based on selective photothermolysis, in which laser energy is preferentially absorbed by melanin within the hair shaft and follicle, converted to heat, and used to selectively damage follicular growth structures while preserving surrounding epidermal and dermal tissue. The 808nm wavelength provides a favourable balance between dermal penetration and controlled epidermal absorption, supporting effective treatment of coarse terminal hair with an acceptable safety profile across Fitzpatrick skin types I–VI when treatment parameters are appropriately individualized.

The Alpha / Spark Pro System LLD 808nm diode applicator incorporates Golden Touch™ Adaptive Contact Cooling Technology using a sapphire-glass tip that maintains a stable surface temperature of approximately 5 °C. Continuous contact cooling is particularly relevant in the bikini area due to heightened skin sensitivity and an increased risk of post-inflammatory pigmentary changes. This integrated cooling approach supports epidermal protection, improves patient comfort, and facilitates consistent energy delivery throughout treatment. When delivered in Single-Stamping Mode, laser pulses are applied with precise spatial control, uniform fluence, and minimal overlap. This technique limits cumulative thermal exposure, promotes homogeneous follicular targeting, and may reduce the likelihood of adverse effects such as excessive erythema, blistering, or post-inflammatory hyperpigmentation - important considerations when treating anatomically sensitive and often more pigmented skin regions.

In routine clinical practice, optimal safety and outcomes are supported by pre-treatment melanin assessment for individualized parameter selection, patch testing, the use of Parker coupling gel to enhance optical contact and cooling efficiency, and strict adherence to laser safety standards, including appropriate protective eyewear for both the patient and the operator. Conservative fluence initiation with gradual escalation and careful anatomical mapping are commonly employed, particularly during early sessions and in patients with higher skin phototypes.

Despite widespread clinical application, published diode laser literature specifically evaluating hair removal in patient-defined bikini or intimate treatment areas remains limited, with these regions often grouped under broader anatomical terms such as the groin or inguinal areas rather than analysed as distinct clinical zones.

Aims

The primary endpoint was to assess the effectiveness of 808nm diode laser hair removal in the bikini area, following a standardized treatment protocol consisting of at least four treatment sessions per patient, each separated by a minimum interval of 4 weeks, delivered in Single-Stamping Mode. Effectiveness was evaluated by the reduction in visible terminal hair at follow-up compared with baseline. The requirement for a minimum of four sessions was defined a priori, reflecting the earliest clinically meaningful time point at which sustained terminal hair reduction can be reliably assessed.

Secondary endpoints included patient-reported outcomes using a Visual Analog Scale (VAS) to assess satisfaction and perceived improvement, as well as the systematic observation and documentation of treatment-related side effects, including erythema, edema, pigmentary changes, or other adverse skin reactions throughout the treatment period and follow-up.

Methods

This single-center, retrospective observational case study was conducted at KRASOTA Ästhetik & Kosmetik Clinic, Engelbertstraße 4, 45663 Recklinghausen, Germany, between January 2025 and December 2025. The clinic has been in continuous operation for approximately five years and provides routine aesthetic medical services to the local community.

The first Alpha / Spark Pro system was installed in May 2023 and has been in routine clinical use since then. In subsequent years, two Alpha/Spark Pro systems have been operated concurrently, reflecting sustained real-world use of this platform in everyday clinical practice. No comparative claims regarding device performance or preference relative to other technologies are implied.

The study was conducted under the direction of Ms. Agnessa Schindler, a certified and experienced cosmetologist and clinic manager with specialized expertise in laser hair removal, together with her clinical team. The center routinely employs a range of aesthetic technologies for multiple cosmetic indications as part of standard clinical practice.

The clinic serves a demographically diverse patient population representative of the surrounding community. Clinical consultations and patient communication are supported by multilingual staff fluent in German, Russian, Turkish, Albanian, and Romanian, facilitating informed consent, treatment counselling, and follow-up within routine care. No stratification or subgroup analyses by ethnicity or language were planned or performed, and all patients were treated according to a standardized clinical protocol.

As part of routine clinical activity, the center has performed laser hair removal in more than 7,000 patients using the Alpha / Spark Pro system. Approximately 2,000 of these patients underwent bikini area hair removal, demonstrating long-term clinical use, workflow integration, and substantial operator expertise with the Alpha / Spark Pro systems.

Figure 1, 2 - Ms. Agnessa Schindler and her team at KRASOTA Ästhetik & Kosmetik Clinic Germany.

Case Study Population

The clinic routinely treats both male and female patients for the removal of unwanted hair across multiple body areas. The present investigation focused exclusively on female patients undergoing laser hair removal of the bikini area. A total of three healthy adult female volunteers, aged 29–41 years, were enrolled. All participants were classified as Fitzpatrick skin types II–III.

Pre-Treatment Preparation and Safety Measures

Hair in the treatment area was shaved 24–48 hours before treatment. No topical anaesthetics were used. Melanin assessment was performed in all participants using a melanin meter, and patch testing was conducted before treatment initiation. Parker coupling gel was applied during all procedures.

Both the operator and all participants wore protective eyewear rated for 808m diode laser exposure throughout each session, in accordance with established laser safety standards. Written informed consent was obtained from all participants before study enrolment, including consent for treatment and the use of standardized clinical photographs.

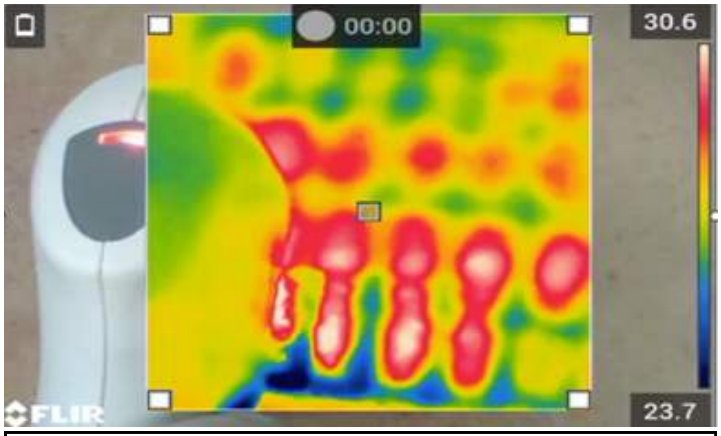


Figure 3 - LLD applicator 1st generation Single-mode ("stamping") hair removal mode 15cmX10cm box thermal photos taken with FLIR N95 camera. Courtesy of Formatk System Ltd.

Device and Treatment Parameters

Treatments were performed using the Alpha / Spark Pro System (manufactured by FormaTK Systems Ltd.), a medical laser platform holding CE certification, EU Medical Device Regulation (MDR) compliance, and U.S. FDA clearance for laser hair removal. The system was equipped with an 808nm Large Laser Diode (LLD) applicator featuring a 15 × 30 mm (4.5 cm^2) treatment window. The applicator was operated in first-generation Single-Stamping Mode, delivering uniform fluence with approximately 10% overlap to ensure consistent coverage and homogeneous follicular heating.

Figure 4 - Female Bikini area hair removal treatment - Melanin check using FormaTK's Milo - digital melanin meter. Photo courtesy of KRASOTA Ästhetik & Kosmetik Clinic.

Treatment parameters were individualized, beginning with a fluence of roughly 18 J/cm^2, adjusted according to skin type, and progressively increased over successive treatment sessions (not within the same session) to a maximum of 25 J/cm^2. A fixed pulse duration of 40–45 ms was applied in all sessions, delivered at a repetition rate of 1 Hz. All procedures utilized Golden Touch™ Adaptive Contact Cooling Technology, incorporating a sapphire-glass contact tip that maintained a stable surface temperature of approximately 5 °C, providing epidermal protection during treatment.

Diode Laser 808nm Treatment Mechanism

The treatment mechanism was based on selective photothermolysis, whereby the 808nm wavelength targets melanin chromophores within anagen-phase hair follicles. Absorbed optical energy is converted into heat, elevating follicular temperature to approximately 70 °C for ~1 millisecond, sufficient to induce thermal denaturation of follicular stem cells and the germinative matrix within the bulge and bulb regions.

The short pulse duration confines thermal injury primarily to the pigmented follicle, limiting thermal diffusion to surrounding epidermal and dermal tissues.

Diode Laser 808nm Treatment Mechanism

The treatment mechanism was based on selective photothermolysis, whereby the 808nm wavelength targets melanin chromophores within anagen-phase hair follicles. Absorbed optical energy is converted into heat, elevating follicular temperature to approximately 70 °C for ~1 millisecond, sufficient to induce thermal denaturation of follicular stem cells and the germinative matrix within the bulge and bulb regions.

The short pulse duration confines thermal injury primarily to the pigmented follicle, limiting thermal diffusion to surrounding epidermal and dermal tissues.

Post-Treatment Care

Immediately after treatment, participants were instructed to avoid direct sun exposure and heat-inducing activities (including saunas, hot showers, and vigorous exercise) for 48–72 hours to minimize the risk of erythema, edema, or post-inflammatory hyperpigmentation (PIH). The use of a soothing, fragrance-free post-laser gel or thermal-water spray was recommended. Participants were advised to apply a broad-spectrum SPF 50+ sunscreen daily for at least two weeks, with reapplication every 2–3 hours when outdoors.

Between sessions, participants were instructed not to pluck, wax, or epilate treated hairs to preserve follicular integrity; gentle shaving was permitted if necessary. Mild perifollicular erythema or edema, when present, typically resolved within 24 hours and was managed conservatively. The use of topical retinoids, exfoliating acids, or chemical peels was discouraged for 5–7 days following treatment. Participants were informed that treated hairs would gradually loosen and shed over 5–14 days, representing normal follicular ejection rather than regrowth.

Figure 5 - Female Bikini area hair removal treatment using Alpha/Spark Pro LLD applicator.
Photo courtesy of KRASOTA Ästhetik & Kosmetik Clinic.

Photographic Documentation and Outcome Review

Standardized high-resolution photographs were obtained by trained clinical personnel before the first treatment session and at the final follow-up. A methodological limitation related to baseline photographic documentation was identified. Due to personal, cultural, and aesthetic considerations, participants declined to be photographed with fully grown, unshaved hair in the treatment area.

Consequently, all baseline (“before”) photographs were obtained after shaving but before the first diode laser session. While this approach ensured participant comfort and ethical compliance, it limited visual documentation of baseline hair density; however, it did not affect treatment delivery, clinical safety, or outcome assessment. The authors appropriately analyzed only patients who reached the predefined treatment threshold necessary to evaluate efficacy. All clinical outcomes and photographic documentation were independently reviewed and assessed by Dr. Nadav Pam, Clinical Director at FormaTK Systems Ltd.

Inclusion criteria

- Healthy females aged between 18 and 70 years with unwanted bikini-area hair.
- All participants had refrained from exposure to sun or solarium (solar lamps) during the study period, in accordance with routine clinical instructions.
- All patients had been informed about the treatment objectives, procedural details, potential benefits, and possible adverse effects as part of standard clinical practice.
- All participants had provided written informed consent before treatment, including consent for the retrospective use of anonymized clinical data and photographs.

Exclusion criteria

- Drug-induced photosensitivity (e.g., Isotretinoin, Retin A)
- Pregnancy and breastfeeding
- Cancer
- Epilepsy
- Severe diseases
- Autoimmune diseases
- Frequent episodes of labial Herpes Simplex in the case of the face
- Immunosuppressive pharmacologic therapy
- Any other medical condition is considered contraindicated for the treatment by the investigator. Any other hair removal treatments, such as drugs, topical creams/lotions, or other phototherapy medical devices.

Results

A total of 3 healthy adult female participants were successfully treated for unwanted hair in the bikini area. Participants were 25–41 years old and classified as Fitzpatrick skin types II–III. Each treatment area received 4-6 laser sessions, and no adverse events or side effects were observed or reported throughout the study period.

Patient #	Age	Gender	Fitzpatrick skin type	Anatomical area treated
1	29	Female	3	Bikini
2	25	Female	2	Bikini
3	41	Female	2	Bikini

Patient #	Avg. time for each session	Total treatments	Overall, 4 point Scale Improvement	Side Effects
1	15min	6	92%	None
2	15min	4	87%	None
3	15min	5	89%	None

Discussion

The primary aim of this retrospective observational case study was to evaluate the effectiveness of 808nm diode laser hair removal in the bikini area, following a standardized treatment protocol using Single-Stamping Mode, with effectiveness defined as a reduction in visible terminal hair after a minimum of 4 treatment sessions. All enrolled participants demonstrated substantial visible hair reduction at follow-up, with improvement scores ranging from approximately 87% to 92%, thereby meeting the primary endpoint in all cases. Notably, these outcomes were achieved with a relatively limited number of treatment sessions and an average session duration of approximately 15 minutes, supporting a clinically efficient approach in this anatomically sensitive region.

The observed effectiveness is consistent with established principles of selective photothermolysis at 808nm, which enable adequate penetration into target melanin-rich anagen hair follicles while maintaining controlled epidermal absorption. The use of Single-Stamping Mode with individualized fluence escalation between sessions likely contributed to uniform follicular targeting and progressive suppression of hair regrowth. Although the small sample size precludes formal statistical

analysis, the consistency of response across enrolled participants supports attainment of the primary objective under the applied treatment conditions.

Secondary aims included assessing patient-reported outcomes using a Visual Analog Scale (VAS) and systematically monitoring treatment-related side effects. Patient-reported satisfaction and perceived improvement were uniformly high, aligning with objective clinical observations. From a safety standpoint, no adverse events or clinically relevant treatment-related side effects - including prolonged erythema, edema, blistering, or pigmentary alterations, were observed or reported, indicating that the secondary safety endpoint was met.

The absence of adverse events is particularly notable given the anatomical and physiological characteristics of the bikini area, including dense follicular distribution, rich sensory innervation, higher baseline pigmentation, friction, and occlusion. In addition, it should be recognized that the bikini area does not constitute a rigid anatomical boundary but rather a patient-defined treatment region influenced by individual preferences, cultural norms, lifestyle considerations, and clothing habits. Despite this inherent variability, adequate epidermal protection and patient comfort were consistently achieved without the use of topical anesthetics, suggesting that the sapphire-based contact cooling system provided sufficient thermal mitigation during treatment.

Importantly, the limited number of participants enrolled in this case study does not reflect limited clinical experience with bikini-area laser hair removal at the study center. As part of routine clinical practice, approximately 2,000 of more than 7,000 laser hair removal patients treated at this center have undergone bikini-area procedures using the same device platform and treatment principles. However, due to the intimate nature of the treatment area, only a small subset of patients consented to the use and publication of anonymized before-and-after clinical photographs and treatment data. Consequently, only three patients were enrolled in this observational case study despite extensive underlying clinical experience.

The favorable tolerability profile observed in this study likely reflects the combined effect of continuous adaptive contact cooling, conservative initiation of fluence with gradual escalation between sessions, melanin-guided parameter selection, and precise energy delivery using Single-Stamping Mode. Together, these measures appear to have limited cumulative thermal stress while preserving treatment efficacy.

A methodological limitation relevant to both primary and secondary endpoints relates to baseline photographic documentation. Due to personal, cultural, and aesthetic considerations, participants declined to have their hair photographed in its fully grown, unshaved state; therefore, baseline images were obtained after shaving but before the first laser session. At the same time, this limited visual documentation of untreated hair density did not affect treatment delivery, safety monitoring, or outcome assessment, which relied on follow-up evaluation, patient-reported outcomes, and systematic observation of adverse effects.

Additional limitations include the small number of enrolled participants and restriction to Fitzpatrick skin types II–III, which limit generalizability. Accordingly, the findings should be interpreted as descriptive and hypothesis-generating. Larger studies incorporating objective hair-count measurements, broader skin-type representation, longer follow-up, and comparative designs would be valuable for further substantiating these observations.

In conclusion, this case study demonstrates that 808nm diode laser hair removal using the Alpha System achieved the primary endpoint of visible terminal hair reduction in the bikini area with a relatively low number of treatment sessions and short per-session treatment times, while also meeting secondary endpoints related to patient satisfaction and safety. The absence of adverse events and the ability to perform treatment without topical anesthesia, even in a densely innervated, follicle-rich patient-defined anatomical region, support the clinical feasibility and tolerability of the described protocol. The findings should be interpreted in the context of extensive routine clinical use, while acknowledging the ethical and privacy constraints inherent to research involving intimate treatment areas.

Conclusion

This single-center, retrospective observational case study demonstrates that 808nm diode laser hair removal using the Alpha / Spark Pro System achieved effective reduction of visible terminal hair in the bikini area of adult female patients with Fitzpatrick skin types II–III, thereby fulfilling the predefined primary endpoint. Clinically meaningful improvement was consistently observed following a relatively limited number of treatment sessions, with an average session duration of approximately 15 minutes, supporting both clinical effectiveness and procedural efficiency in this anatomically sensitive treatment region.

Secondary endpoints related to patient-reported satisfaction and safety were also met. High levels of perceived improvement were reported, and no treatment-related adverse events or clinically significant side effects were observed throughout the treatment course or follow-up period. Notably, adequate epidermal protection and patient comfort were maintained without topical anesthesia, despite treatment of a densely innervated, follicle-rich area, indicating that adaptive sapphire-tip contact cooling provided sufficient thermal mitigation under the applied parameters.

Although only three patients were formally enrolled in this case study due to ethical and privacy considerations associated with the intimate nature of the bikini region, these findings should be interpreted within the context of extensive routine clinical experience. At the study center, approximately 2,000 of more than 7,000 laser hair removal patients have undergone bikini-area treatments using the same device platform and treatment principles. The limited study cohort, therefore, reflects informed consent constraints rather than limited clinical exposure, underscoring the importance of patient autonomy and data protection in research involving intimate anatomical areas.

Taken together, these findings support the clinical feasibility, tolerability, and effectiveness of individualized 808nm diode laser protocols for bikini-area hair removal. While the results are descriptive and hypothesis-generating, they provide a robust foundation for future, larger-scale, controlled investigations incorporating objective outcome measures, broader representation of skin types, and extended follow-up further to define optimal treatment strategies across diverse patient populations.

Key Take-Home Messages

- **Effective bikini-area hair reduction**
  The 808nm diode laser protocol achieved consistent, clinically meaningful reductions in unwanted bikini-area hair in adult female patients.

- **Efficient treatment workflow**
  Bikini-area treatments were completed in approximately 15 minutes per session, supporting high clinical efficiency without compromising
  outcomes.

- **Fewer sessions, meaningful results**
  Substantial improvement was observed after a relatively limited number of treatment sessions, facilitating practical treatment planning.

- **High tolerability in a sensitive region**
  Treatments were well tolerated in a densely innervated, follicle-rich anatomical area, with no reported adverse events.

- **No topical anesthesia required**
  Adequate patient comfort and epidermal protection were achieved without topical anesthetics, highlighting the effectiveness of integrated sapphire-tip contact cooling.

- **Strong safety profile**
  No treatment-related erythema, blistering, pigmentary changes, or other clinically significant adverse effects were observed.

- **Patient-defined treatment area**
  The bikini region represents a personalized treatment zone, influenced by individual preference, cultural norms, and lifestyle choices; consistent outcomes were achieved despite this variability.

- **Extensive real-world clinical experience**
  Although only three patients were enrolled due to informed consent and privacy considerations, the findings reflect protocols routinely applied to approximately 2,000 bikini-area treatments performed at the study center.

- **Regulatory-cleared technology**
  Treatments were performed using a CE, MDR, and FDA-cleared 808nm diode laser system, supporting regulatory confidence.

References

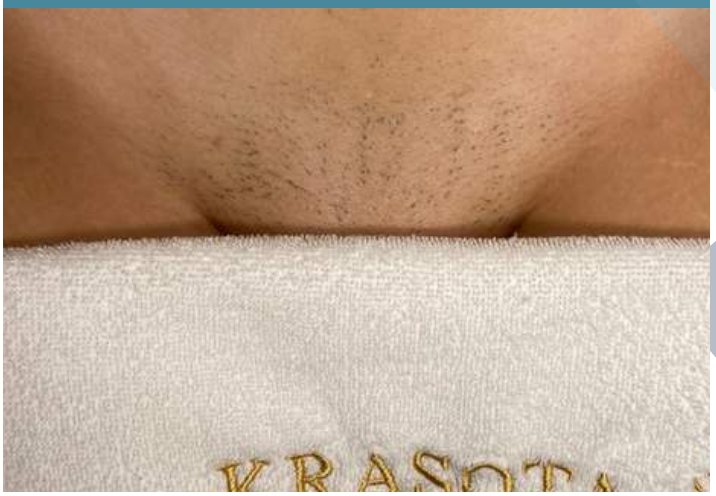
1] Guidelines on photoepilation: techniques for intimate body areas. Open Access Surgery & Aesthetic Knowledge (OASK) Publishers. Available at: https://oaskpublishers.com/assets/article-pdf/guidelines-on-photoepilation-techniques-for-intimate-body-areas.pdf Accessed [16 Dec 2025].
2] Blume-Peytavi U. An overview of unwanted female hair. Br J Dermatol. 2011 Dec;165 Suppl 3:19-23. Doi: 10.1111/j.1365-2133.2011.10632.x. PMID: 22171681
3] Anderson, R. R., & Parrish, J. A. (1983). Selective photothermolysis: Precise microsurgery by selective absorption of pulsed radiation. Science, 220(4596), 524–527.
4] Puri N. Comparative Study of Diode Laser Versus Neodymium-Yttrium Aluminum: Garnet Laser Versus Intense Pulsed Light for the Treatment of Hirsutism. J Cutan Aesthet Surg. 2015 Apr-Jun;8(2):97-101.
5] Lumezi BG, Berisha VL, Pupovci HL, Goçi A, Hajrushi AB. Grading of hirsutism based on the Ferriman-Gallwey scoring system in Kosovar women. Postepy Dermatol Alergol. 2018 Dec;35(6):631-635.

Before & After Results

Patient #1

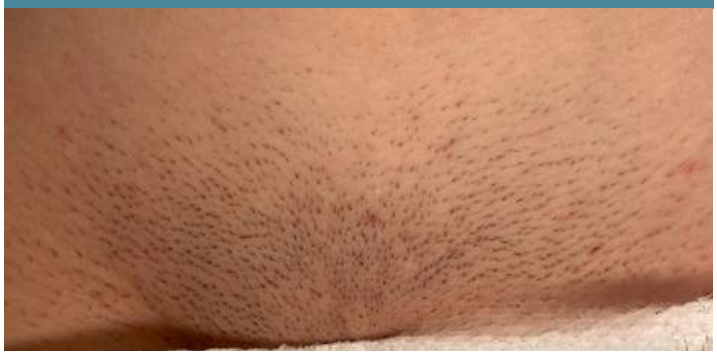
BEFORE

AFTER 6TX

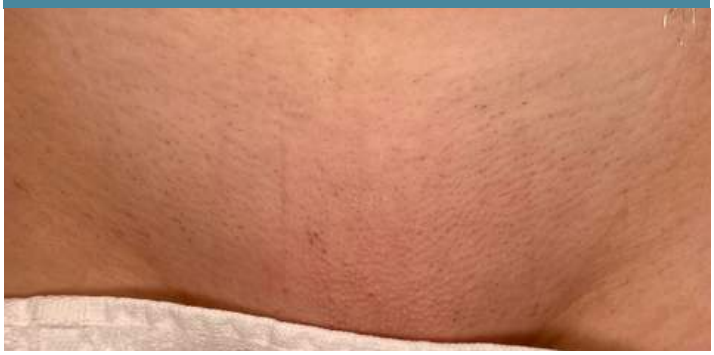


Patient #2

BEFORE

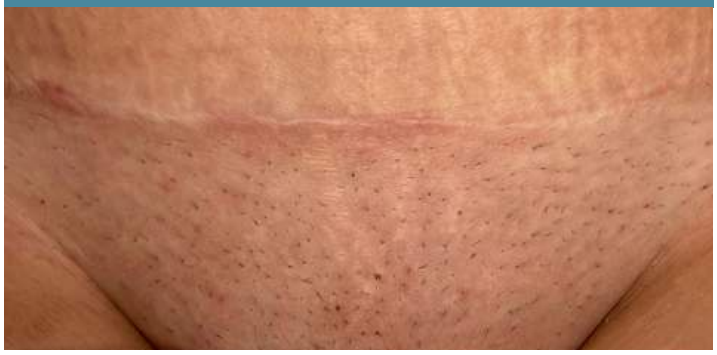


AFTER 4TX

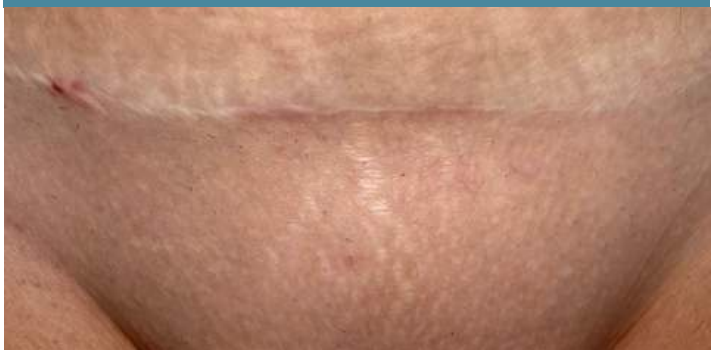


Patient #3

BEFORE



AFTER 5TX



formatk

Taking care of you