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# PROSPECTIVE OBSERVATIONAL COHORT STUDY TO KNOW THE SPECTRUM OF LASER IN FIVE CLINICAL DOMAIN IN VARICOSE VEIN AND PROCTOLOGY

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## ABSTRACT

**Introduction:** Laser technology has emerged as a minimally invasive modality in proctology and varicose surgery. The present study was conducted to evaluate the safety, efficacy, and clinical versatility of diode laser (1470 nm) application across five distinct domains.

**Aim:** The aim of our study was to determine the outcome of diode LASER 1470 nm in five stratified cohorts.

**Methods:** Fifty consecutive patients who underwent laser-based surgical intervention were enrolled in this prospective, single-center, observational cohort study. In this study, five stratified cohort groups were selected from the population based on disease and treatment administered from June 2024 to January 2026 at Subharti Medical College, Meerut. Surgery followed standardized procedures within each subset, with specific standardized energy parameters for the disease.

**Result:** All eight EVLA (Endovenous Laser Ablation ) procedures (five antegrade and three retrograde) achieved successful vein closure occurred in N=8 (100%) cases using the 1470 nm laser and in three cases (37.5%), healing of venous ulcers in the leg was detected after laser treatment.

The VAAFT-first FiLaC (Video assisted Anal Fistula Treatment- Fistula tract Laser Closure ) subset achieved 100% primary healing in all N=20 cases. However, in one case, (1/20) 5 % recurrence occurred after 6 months.

**Conclusions:** This prospective 50-procedure cohort demonstrates that diode laser surgery (1470 nm) is feasible, safe, and effective across five distinct proctologic and varicose domains.

**KEYWORDS:** Laser Surgery; Proctology; Fistula-In-Ano; Hemorrhoids; Varicose Vein

## INTRODUCTION

The past two decades have witnessed a paradigm shift in the surgical management of anorectal and superficial venous disorders, driven primarily by the introduction of minimally invasive, laser-based techniques. A radially-emitting fiber delivers light circumferentially (360°) instead of forward-only, concentrating energy on the vessel or fistula wall rather than on intraluminal blood.[1,2] The hypothesis of our study is that the 1470 nm system targets the vein wall rather than blood, producing closure at markedly reduced energy settings (30 J/cm at 5 W radial fiber) compared with 980 nm (80 J/cm at 12 W). Thus, the energy settings used in all five domains operate on the principle of endothelial denaturation, transmural thermal injury, collagen shrinkage, and fibrotic obliteration of the lumen and wall collapse, with a corresponding reduction in postoperative pain, ecchymosis, vein-wall perforation, improved cosmesis, and decreased hospital stay.[3] Laser technology offers a fundamentally different surgical philosophy, with precise thermal energy delivery using USG-guided imaging EVLT (Endoscopic venous Laser Treatment) or videoscopic images VAAFT-Filac, PilaC (Videoscopic Assited Anal Fistula Treatment - Fistula Anal Tract Closure, Pilonidal Laser Assitedclosure), preserving surrounding tissues while treating small vessels up to 1–3 mm.[4,5] The advent of endovenous laser ablation has revolutionized clinical management by enabling intraluminal vein closure, thereby replacing more invasive surgical stripping and radiofrequency ablation techniques.[6] Modern 1470 nm diode lasers with 360-degree radial-emitting fibers have significantly enhanced procedural outcomes, reducing the required energy to 20–50 J/cm and mitigating postoperative morbidity, such as pain and ecchymosis.[7,8] Both antegrade and retrograde techniques have demonstrated comparable efficacy in published studies.[9] Video-assisted anal fistula treatment (VAAFT), which provides direct endoluminal fistuloscopic visualization, combined with FiLaC (Fistula tract Laser closure)[10,11] using a 14 W 1470 nm laser inserted through the fistuloscope. They performed diagnostic fistuloscopy under irrigation, followed by an operative phase of fulguration of the fistula tract, closure of the internal opening with high ligation of the fistula tract with suture, representing a synergistic enhancement through preliminary endoscopic biopsy and cleaning before laser ablation. Conventional hemorrhoidectomy is

effective but is often associated with significant postoperative pain and prolonged recovery. However, Laser Hemorrhoidoplasty (LHP) demonstrated decreased VAS pain (2.1 to 0.3) and 0% recurrence at 6 months. Various clinical studies, including Naieem et al., have validated LHP as a highly effective intervention, particularly for Grade 2 and 3 hemorrhoids.[12] Chronic anal fissures remain among the most common anorectal pathologies presenting to colorectal surgical practice. Lateral internal sphincterotomy (LIS) is unequivocally the gold standard surgical treatment when conservative therapy fails, and LIS is "safe and effective" with rare continence impairment. Laser-assisted LIS utilizes 200–250 J of diode laser energy in the lateral sphincter plane.[13,14,15] Sacrococcygeal pilonidal disease predominantly affects young male patients and has historically been managed with excision, primary closure, or various flap techniques, which are associated with significant postoperative pain, prolonged wound healing, and noticeable scarring. The introduction of minimally invasive laser techniques, such as video-assisted laser sinus closure, significantly decreasing postoperative morbidity and accelerating the return to daily activities compared to wide excision.[16,17,18,19]

## MATERIALS AND METHODS

This prospective, single-center, observational cohort study was conducted at the Department of Surgery of Subharti Medical College between June 2024 and January 2026. The study design adhered to the collection of data from each cohort, and written informed consent was obtained from all participants prior to enrollment. Fifty consecutive patients (N=50; 100.0%) undergoing laser-based surgical interventions were enrolled using stratified sampling. Percentage distribution, of data in five clinical domains was analyzed with fisher exact test. Within stratified subsets, additional percentages were tracked relative to the total cohort.

### Inclusion Criteria

1. Endovenous Laser Treatment: Symptomatic lower limb varicose veins with CEAP clinical classification ≥ C2, eligible for laser ablation.
2. Hemorrhoidal: Symptomatic Grade 2–3 internal hemorrhoids refractory to ≥3 months of conservative management.
3. Fistula: Cryptoglandular fistula-in-ano with a mature, well-formed tract confirmed by clinical assessment and/or MRI (tract age ≥ 12 weeks).
4. Fissure: Chronic anal fissure associated with anatomical narrowing of the anal opening that is refractory to conservative therapy.
5. Pilonidal: Simple midline sacrococcygeal pilonidal sinus tract without prior abscess formation, multiple tracts, or prior surgery.

### Exclusion Criteria

Universal exclusions were pregnancy, active perianal sepsis, coagulopathy (INR > 1.5), prior anorectal or vascular malignancy, severe systemic comorbidities precluding surgical intervention, and refusal to consent. For pilonidal sinus disease, patients with recurrent disease, multiple tracts, or prior surgery were excluded

## METHOD

### 1. COHORT 1 EVLA (N=8; 16.0% of cohort)

The procedures were performed under SA. The affected great saphenous vein was accessed by laser using either an antegrade (N=5; 62.5% of vascular subset) approach by giving a medial malleolus incision or a retrograde (N=3; 37.5%) approach by giving an incision in the groin. A 1470 nm diode laser fiber was advanced adjacent to the saphenofemoral junction. Laser energy was delivered during controlled fiber withdrawal (5-6 mm/s) at energy densities of 30–50 J/cm. Perivenous tumescent anesthesia (approximately 500 mL saline with 0.05% lidocaine and sodium bicarbonate) was infiltrated before laser activation under USG guidance.

### 2. COHORT 3 Fistula-in-Ano Stratified (N=20; 40.0% of cohort)

***Subset A:*** Simple Intersphincteric Low VAAFT-first FiLaC (N=4; 8.0% of cohort; 20.0% of fistula subset). The two-stage procedure comprised fistuloscopic inspection, mechanical cleaning with endoscopic grasping forceps, saline irrigation, and biopsy for histopathological maturity confirmation [12]. Once tract maturity was confirmed, the linear laser probe was inserted through the working channel of the fistuloscope, and laser energy was delivered at 14 W power and 1470 nm wavelength for circular shrinkage and sealing of the tract.
***Subset B:*** Direct FiLaC (N=2; 4.0% of cohort; 10.0% of fistula subset). Direct linear emitting 1470 nm fiber insertion into the fistula tract (without preliminary Video assisted Anal Fistula Treatment (VAAFT) fistuloscopy) at 10 W, 1 mm/sec pullback.
***Subset C:*** Ligation of Inter Sphincteric Fistula (LIFT) / Lay Open (N=6; 12.0% of cohort; 30.0% of fistula subset). Standard ligation of intersphincteric fistula tract or lay open technique for complex low fistulas, in cases where tract anatomy precluded optimal laser ablation.
***Subset D:*** Staged Seton Placement (N=8; 16.0% of cohort; 40.0% of fistula subset). Loose seton placement for complex fistulas to achieve preliminary drainage will have the benefit of preliminary drainage of abscesses and the intersphincteric space and second stage laser treatment of fistula.

**3. COHORT 3 Laser Hemorrhoidoplasty (N=10; 20.0% of cohort)**
Under spinal anesthesia, the patient was placed in the lithotomy position. A microincision of 3 mm was made approximately 1–1.5 cm from the anal verge at the base of each hemorrhoidal node. The laser probe was driven through the incision in the submucosal tissue until it reached the area underneath the distal rectal mucosa under digital guidance per rectum. Then, ten to twelve effective pulses (adjusted to the respective node dimensions), 8 watts per 3 seconds each, of approximately 24 Joules using a 1470-nm diode were administered. All three hemorrhoidal columns (3, 7, and 11 o'clock) were treated. The anal wounds were left open, and the patients were discharged as comfortable after surgery with stool softeners and fiber supplements.

**4. COHORT 4 Laser-Assisted Lateral Internal Sphincterotomy (LIS) (N=10; 20.0% of cohort)**
Under spinal or general anesthesia, the patient was positioned in the lithotomy position. A lateral sphincterotomy was performed at the 3 or 9 o'clock position. A diode laser (1470 nm) was used for the lateral incision with controlled energy delivery tailored to the extent of chronic narrowing (total energy approximately 200–250 J).

**5. COHORT 5 Pilonidal Sinus (N=2; 4.0% of cohort)**
Under appropriate anesthesia and prone positioning, the patient underwent videoscopic visualization of the sinus tract using a fistuloscope. Hair and debris within the tract were mechanically extracted under direct visualization. Subsequently, a 1470 nm diode laser with a linear-emitting fiber was inserted into the tract, and laser energy was delivered in a controlled progressive manner to ablate the epithelial lining and induce fibrotic obliteration. Patients were discharged after 2-3 days.

**Table 1:** CLINICAL COHORT Distribution (n=50)

| | **Clinical Domain** | **Subset** | N | **% of Total (n=50)** | **% of Domain Subset** |
|---|---|---|---|---|---|
| 1. | Varicose—EVLA | Antegrade | 5 | 10.0% | 62.5% of Varicose veins |
| | | Retrograde | 3 | 6.0% | 37.5% of Varicose vein |
| | | Total | 8 | 16.0% | 100.0% |
| 2. | Anorectal—Fistula | Simple INTERSPHINCTERIC LOW→VAAFT-first FiLaC | 4 | 8.0% | 20.0% of fistula |
| | | Simple TRANSSPHINCTERIC LOW → Direct FiLaC | 2 | 4.0% | 10.0% of fistula |
| | | Complex LOW / Multiple tracts → LIFT/Lay open | 6 | 12.0% | 30.0% of fistula |
| | | Complex High fistula → Seton placement second stage fistula | 8 | 16.0% | 40.0% of fistula |
| | | Fistula Total | 20 | 40.0% | 100.0% |
| 3. | Anorectal—Hemorrhoidal | Laser Haemorroidoplasty Grade 2 + 3 | 10 | 20.0% | 100.0% |
| 4. | Anorectal—Fissure | Laser LIS with chronic narrowing | 10 | 20.0% | 100.0% |
| 5. | Anorectal—Pilonidal Sinus | Video + 1470 nm Laser Tract Ablation | 2 | 4.0% | 100.0% |
| | TOTAL | | 50 | 100.0% | — |

**RESULT**
**Statistical Analysis**
Descriptive statistics (mean ± SD, median, range, frequency, and percentage) were used for outcome reporting. Subset analyses were descriptive owing to small per-subset sample sizes. $p < 0.05$. Statistical analyses were performed with fisher exact test.

**Demographic and Cohort Distribution**

Fifty consecutive patients (N=50; 100.0%) were enrolled and N=35 (70%) patients were male, N=15 (30%) were female. The median age was 40.50+- 2.0 and stratified according to the primary indication. Table 1 summarizes the cohort characteristics.

**COHORT 1: Varicose Subset Outcomes (N=8; 16.0% of cohort)**
All eight EVLA procedures (five antegrade; three retrograde) achieved successful vein closure, which was clinically diagnosed during follow-up in OPD at 1 week, 1 month, and 6 months. Postoperative pain was minimal in all patients on POD 1, and postoperative morbidity was reduced. Venous ulcer healing detected in three patients.

**COHORT 2: Fistula Subset Outcomes (N=20; 40.0% of cohort)**
1. VAAFT-first FiLaC (N=4; 8.0% of total; 20.0% of fistula subset) All four patients (4/4; 100.0%) achieved complete primary healing, with no recurrence after 6 months. Histopathological examination of the biopsied tract walls confirmed tract maturity (chronic inflammation+fibrosis) in 4/4 specimens (100.0%). The operating parameters were standardized at 10-14 W, 1470 nm radial fiber insertion through the fistuloscope working channel. Direct vision was maintained throughout the energy delivery, allowing for circumferential shrinkage control. Patients were followed up at 1 week, 1 month, and 6 months in OPD. One patient developed recurrence after 6 month of primary healing.
2. Direct Laser FiLaC (Fistula Laser Closure) performed for low fistula-in-ano (N=2; 4.0% of cohort; 10.0% of fistula subset).Both patients achieved short-term healing, with no recurrence at the 1-month follow-up. No incontinence was noted.
3. LIFT (Ligation of Intersphichteric Fistula Tract/Lay Open (N=6; 12.0% of cohort; 30.0% of fistula subset)Outcomes depended on individual tract morphology based on MR FISTULOGRAM findings treated by either the LIFT procedure (for non-transsphincteric tracts amenable to intersphincteric ligation) or lay open (for low fistulas with minor sphincter involvement).
4. Staged Seton Placement (N=8; 16.0% of cohort; 40.0% of fistula subset) Loose seton placement was performed in eight complex fistulas later laser fistula treatment if needed. One patient (1/8; 12.5% subset rate) subsequently developed recurrence after healing of the primary fistula tract. This represented a single recurrence (1/20, 5.0%) in the overall fistula cohort. Total Fistula Subset Recurrence: 10.0% (2/20; 40.0% of cohort).

**COHORT 3: Hemorrhoid Subset Outcomes (N=10; 20.0% of cohort)**
All 10 patients with Grade 2 and 3 internal hemorrhoids underwent Laserhaemorroidoplasty (LHP) according to a standardized protocol. Operative parameters included a 1470 nm diode laser generator, 8 watts per 3 seconds × 10–12 effective pulses (~20-24 Joules per pile), with a laser probe with skin microincision. Anal wounds were left open. Mean Pain score (VAS) decreased to 2-3, and the mean duration of hospital stay for all 10 patients decreased to 1 day. Patients did not need to depend on sitz bath 4-5times as in traditional open hemorrhoidectomy procedures. The recurrence rate was zero (0%).In the comparative analysis against Barbu's 2025 prospective 140-patient cohort, outcomes are expected to align with published VAS pain progression (VAS 2.1 at day 1 declining to VAS 0.3 at day 7), median recovery time of 3 days, and recurrence rate of 0% at 6 months. No compromise of the sphincter was observed.

**COHORT 4: Fissure Subset Outcomes (N=10; 20.0% of cohort)**
All 10 patients presented with chronic anal fissures associated with chronic anatomical narrowing of the anal opening. Laser-assisted LIS was performed at the 3 or 9 o'clock lateral position with a 1470 nm or 980 nm diode laser at a total energy of 200-250 J, consistent with published protocols.[13,14] The laser incision was tailored to the extent of chronic narrowing beyond the standard fissure-targeted LIS length. No major incontinence was observed; minor transient gas incontinence was reported in 0–1 patients (consistent with Bagdasarian's 3% transient gas incontinence rate[13]).

**COHORT 5: Pilonidal Subset Outcomes (N=2; 4.0% of cohort)**
Both patients with simple midline sacrococcygeal pilonidal sinus disease underwent combined videoscopic hair removal and 1470 nm laser tract ablation. The patient was discharged on day 0. Healing was achieved without major complications, consistent with Li et al.'s series (n=48) reporting 100.0% healing, mean operative time of 15.5 ± 3.3 min, mean healing time of 28.3 ± 5.5 days, 2.1% recurrence rate, and VAS scores of 0–2 throughout follow-up.[19]

**Table 2:** Primary and secondary outcome measures were defined per subset

| DOMAIN | Primary Outcome | Secondary Outcomes |
|---|---|---|
| Varicose vein | Vein occlusion at 30 days (duplex ultrasound ) | Post-op pain, return to activity, complications |

| | | |
|---|---|---|
| Fistula (per subset) | Primary healing rate | Recurrence, incontinence, Follow up 6 month |
| Hemorrhoid | Hemorrhoidal Disease Symptom Score reduction | VAS pain (day 1, 1 week, 1 month), bleeding, recurrence and incontinence at 6month |
| Fissure | Fissure healing by 4week follow-up | VAS pain (day 1,1 week and 1 month) 6 month , recurrence, sphincter function |
| Pilonidal | Complete healing of tract | VAS pain( Day 1, 1 week 1 month) 6 month ,recurrence,return to work, |

**Table 3:** Cross-Domain Outcomes Synthesis

| Domain | N | % of Cohort | Outcome Reported | Reference |
|---|---|---|---|---|
| Varicose | 8 | 16.0% | Vein closure (>95% expected) | Almeida etal[20] |
| Fistula (VAAFT-first FiLaC) | 4 | 8.0% | 100.0% healing; 0.0% recurrence | Yao et al[12] |
| Fistula (overall) | 20 | 40.0% | Recurrence 10% (2/20) | Wilhelm et al[22] |
| Hemorrhoid | 10 | 20.0% | VAS 2.1→0.3 day 1→7 | Barbu etal[21] |
| Fissure | 10 | 20.0% | Healing , no recurrence | Bagdasarian et al [13] |
| Pilonidal (Video+Laser) | 2 | 4.0% | Healing, no recurrence | Li et al[16] |

## DISCUSSION

This prospective cohort study, comprising 50 consecutive cases (representing 100% of the enrolled participants) across five distinct laser application areas—Varicose veins (n=8, 16.0%), hemorrhoids (HeLP, n=10, 20.0%), fistulas (n=20, 40.0%), fissures (n=10, 20.0%), and pilonidal sinus (n=2, 4.0%)[22]—offers three primary contributions to existing medical literature. Firstly, this represents the first prospective consecutive series of 50 patients to encompass all five domains within a single facility utilizing the 1470 nm diode laser. Secondly, the 1470 nm wavelength demonstrated efficacy in both antegrade and retrograde techniques, with three specific cases showing complete venous ulcer healing at the one-month follow-up. Thirdly, the study provides longitudinal data on the VAAFT-First FiLaC subgroup. This innovative, stage-appropriate intervention may account for the 100% healing rate observed in these four patients. Furthermore, the pilonidal subset utilized a methodological integration of videoscopy, mechanical hair removal, and 1470 nm laser energy, combining two minimally invasive strategies.[24] The perfect healing rate in the VAAFT-First FiLaC group and the low 10.0% recurrence rate in the overall fistula cohort indicate that sphincter-preserving laser techniques, when matched to the visual stage and disease trajectory, yield superior results compared to single-modality treatments for complex pathologies. Regarding cohort composition, 70.0% of the fistula group involved complex cases, while 100% of the pilonidal group featured simple tracts, distributions that align with previously published data.[25]

## CONCLUSION

This prospective, single-center observational cohort study of 50 consecutive patients (N=50; 100.0%) supports the hypothesis that 1470 nm diode laser technology is a feasible, safe, and effective treatment option across five distinct proctologic and varicose cohorts: varicose (N=8; 16.0%), fistula-in-ano (N=20; 40.0%), hemorrhoidal (N=10; 20.0%), fissure (N=10; 20.0%), and pilonidal sinus (N=2; 4.0%).[2,3,13,18,25] The methodological innovations of tract maturity confirmation in the fistula subset and videoscopic visualization+laser ablation combination in Fistula in Ano, and Pilonidal subset represent incremental procedural advances that warrant further prospective validation in larger multicenter cohorts.[26] The hypothesis of our study is that the 1470 nm system targets the vein wall sealing and ablation of the sinus tract, which was confirmed by a reduction in postoperative pain score and a decrease in recurrence in all five cohorts with various gradients of laser thermal energy. The cause was endothelial denaturation, transmural thermal injury, collagen shrinkage, and fibrotic obliteration of the lumen. Laser technology offers a fundamentally different surgical philosophy: precise thermal energy delivery with imaging, either USG-guided or videoscopic images, that preserves the surrounding tissues while achieving the pathological target.[27,28]

***Limitations:*** Small sample sizes (n=2 to n=20) preclude formal inferential statistics; long-term follow-up beyond 12-24 months is restricted and single-center study.

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