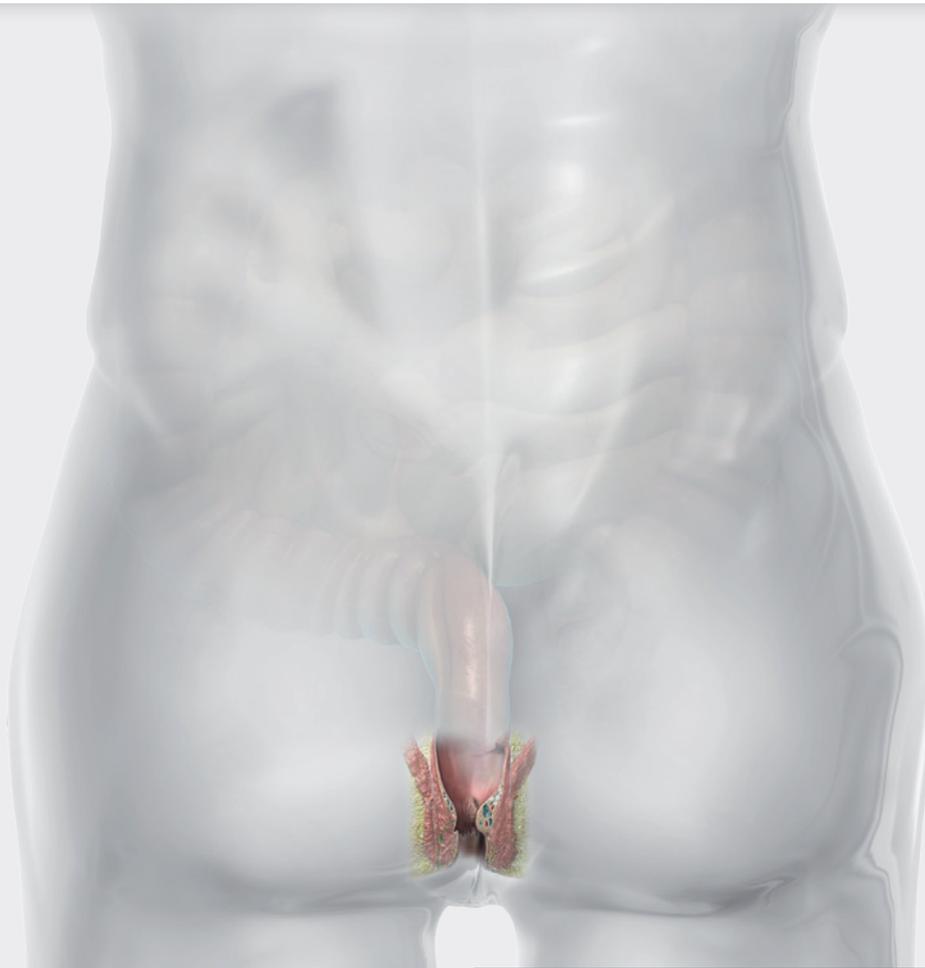


LHP[®] FiLaC[®]

Minimally invasive laser therapy
of hemorrhoids and fistulas



- Painless
- Controlled hemorrhoidal shrinkage
- Very good hemostasis
- Maximized preservation of continence



Our laser solutions in coloproctology

LHP[®]

(LaserHemorrhoidoPlasty) – for hemorrhoids

This approach is used for the treatment of advanced hemorrhoids under appropriate anesthesia. The energy of the laser is inserted centrally into the hemorrhoidal node. By this technique the hemorrhoid can be treated according to its size without causing any damage to the anoderm or mucosa.

FiLaC[®]

(Fistula-tract Laser Closure) – for anal fistulas

The aim is to gently remove the fistula tract without damaging the sphincter. Thus, any parts of the muscle are preserved to a maximum and incontinence is avoided. Furthermore the FiLaC procedure offers a minimally invasive approach for the treatment of sinus pilonidalis whereas the subcutaneous tract as well as the pits are addressed by laser energy

Other possible proctological applications of the biolitec[®] laser and fibers

- Skin tags
- Removal of polyps
- Condyloma
- Fissures

Literature LHP®

Patients and methods

Since 2006, Laser Hemorrhoidoplasty (LHP®) has been available as additional minimally-invasive alternative treatment of advanced hemorrhoid problems. The 1470-nm diode laser made by biolitec® serves to submucosally denaturize hypertrophic hemorrhoidal tissue and thus make it smaller. We describe our experiences made by 225 patients from 2010 to 2013. First we provide a small skin incision in about 1 to 1.5 cm distance from the anal edge concentrically for about 4 millimeters and have the perianal skin/anodermis tunneled with the scissors to the edge of the internus. The pointed laser probe is then quickly driven subanodermally/submucosally until it has reached the area underneath the distal rectal mucosa. This is followed by about six pulses (adjusted to respective dimensions of the piles) of approx. 30 Joule per node; half of which highly submucosal, the other half high intra-nodal. The tissue's response can be clearly discerned by the light reduction: contraction is occasionally observed immediately.

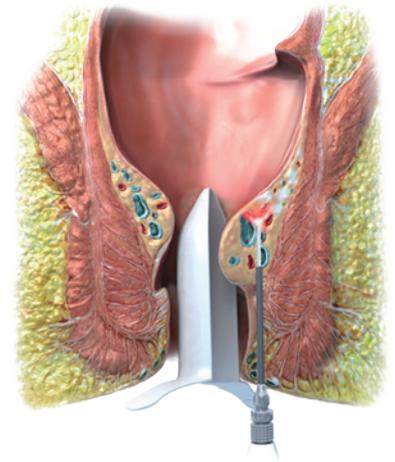
Results

On average, the surgical procedure extended over 14 minutes. Averagely 2.6 nodes of category 2.6 were being treated. Each patient was exposed to averagely 446 J applied. The impression of post-surgical pain (scale: 0 = "pain free" to 2 "heavy pain") was on the day surgery took place rated at 0.5. On the first post-surgical day it was at 1.2, on the second at 0.6. Two weeks later only individual patients still suffered from pain. 99 % of the patients in follow up experienced general improvement. The symptom relevance was at 92 percent (280 of 305 described symptoms). 96 percent of them would advise others to undergo the same procedure and undergo it again personally.

Conclusion

Laser Hemorrhoidoplasty is a nearly pain-free, minimally-invasive procedure of high long-term symptom relevance and patient satisfaction. With respect to reposition and tissue reduction, the functional effects of Laser Hemorrhoidoplasty are comparable to reconstructions according to Parks. Among our patient stock, LHP® is characterized by high long-term symptom relevance and patient satisfaction. An interesting aspect in terms of health-economics is the chance to perform this procedure on the growing number of patients suffering from coagulation disorders, whereas the frequency of specific complications does not experience any increase.

Laser-Hemorrhoido-Plasty (LHP®)



If reduction of the hemorrhoidal cushion is indicated (no matter if it is segmental or circular), this therapy will provide you with an improved patient outcome especially regarding pain and recovery compared to conventional surgical proceeding for 2nd and 3rd degree hemorrhoids. Under proper local or general anesthesia, the controlled laser energy deposition obliterates the nodes from the inside and preserves the mucosa and sphincter structures to an extremely high degree. The homogenous laser emission from the LHP® fiber required for this procedure results in:

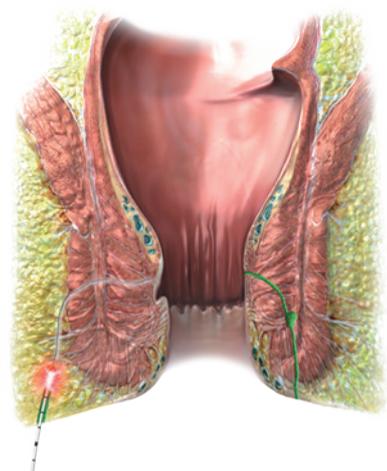
- Tissue reduction in the hemorrhoidal node
- Closure of the arteries entering the CCR feeding the hemorrhoidal cushion
- Maximum preservation of muscle, anal canal lining and mucosa
- Restoration of the natural anatomical structure

Use of the LaserHemorrhoidoplasty-Kit enables the endoluminal laser coagulation of both segmental and circular hemorrhoidal nodes.

The controlled emission of laser energy, which is applied submucosally, causes the hemorrhoidal mass to shrink. In addition, fibrotic reconstruction generates new connective tissue, which ensures that the mucosa adheres to the underlying tissue. This also prevents the occurrence or recurrence of a prolapse. No foreign materials (clamps) need to be inserted and, unlike other procedures, LHP® is not associated with any risk of stenosis. Healing is excellent because, unlike conventional surgeries, there are no incisions or stitches. Access into the hemorrhoid is achieved by entering through a small perianal port. By this approach no wounds are generated in the area of the anoderm or mucosa. As a result, the patient experiences less post-operative pain and can return to normal activities within a shorter space of time.

- No incisions
- No excisions
- No open wounds

Fistula-tract Laser Closure (FiLaC[®])



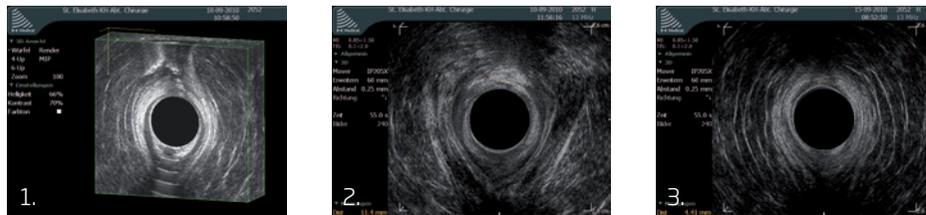
In order to eliminate the fistula tract as gently as possible, the flexible, radially emitting laser fiber is inserted from the outside and positioned exactly by using the pilot beam. Defined energy is being emitted radially into the fistula. The epithelialized tissue is being destroyed in a controlled way and the fistula tract collapses to a very high degree. This also supports and accelerates the healing process.

- Good control
- No excision or splitting
- Independent on the length of the fistula tract
- Flexible fiber also allows use in convoluted tract
- Can be executed in only a few minutes
- Can be combined with other forms of therapy for closing the osteum

FiLaC[®] fiber

The FiLaC[®] fiber applies energy to the pathway of the fistula tract. The 360° energy emission ensures homogenous photothermal destruction of the fistula tract, allowing safe closure. Any flap techniques can be performed before or after the laser application. The efficient radiation concept of the FiLaC[®] fiber makes optimal use of the laser energy applied. Optimal monitoring of the fiber tip is possible thanks to its excellent ultrasound visibility (if applied).





1. 3-D ultrasound illustration of a trans-sphincteric anal fistula at 12 o'clock (contrast enhancement via H₂O₂)
2. Ultrasound image directly after advancement flap. In the area of the former inner opening in the musculus sphinkter ani internus strong echo-reactions can be seen due to the applied laser energy. The protecting flap can be seen as isoechoic zone beneath.
3. Ultrasound image 5 days post-op. In the treated area the hyperechoic regions are vanished and form a hypoechoic district. The dimensions correlate to the original fistula tract and display the entrance depth of the laser. It also shows the safe application of the laser and short term wound healing.

by courtesy of Dr. med. A. Wilhelm

Literature FiLaC®

Patients and methods

This study assesses a cohort of high anal fistulae (cases where conventional surgery potentially placed continence function at risk) managed with laserablation plus definitive flap closure of the internal fistula opening over a long-term follow up. Factors governing primary healing success and secondary healing success were determined.

Results

The study analyzed 117 patients over a median follow-up period of 25.4 months (range, 6-60 months) with 13 patients (11.1%) having Crohn's-related fistulae. No major faecal incontinence was reported with minor incontinence observed in 2 cases (1.7%) and a late abscess treated in one case (0.8%). The primary healing success rate was 64.1% overall with a secondary healing success rate of 88.0% overall. A significantly higher primary success rates were observed for intersphincteric-type fistulae with no effect on primary or secondary outcome of age, gender, the number of prior surgeries, the type of flap designed to close the internal fistula opening, the time interval between prior and definitive surgery or the presence of Crohn's disease.

Conclusions

There is a moderate primary success rate and a high secondary success rate for all anal fistula types using first-up FilaC™ treatment, regardless of the number of prior surgeries or the presence of Crohn's disease. The minimally invasive FiLaC™ approach may therefore represent a sensible first line treatment option for anal fistula repair

Dr. med. Arne Wilhelm, Techniques in Coloproctology, 2016 (accepted publication)



LEONARDO®



Model	LEONARDO® Mini 1470 nm	LEONARDO® Mini Dual	LEONARDO® DUAL 45
REF	SL1470nm8W	SL980+1470nm14W	SL980+1470nm45W
Wavelength	1470 nm	980 nm and 1470 nm	980 nm and 1470 nm
Power	8 W (1470 nm)	10 W (980 nm) / 4 W (1470 nm)	max. 45 Watt (1470 nm / 15 Watt + 980 nm / 30 Watt) separately adjustable
Fiber diameter	≥ 360 µm	≥ 360 µm	≥ 360 µm
Aiming beam	635 nm, max. 4 mW	635 nm, max. 4 mW	532 nm and 635 nm, green 1 mW, red 4 mW, user controlled intensity
Treatment mode	CW, Pulse Mode (optional), ELVeS® Signal	CW, Pulse Mode (optional)	CW, Pulse Mode, ELVeS® Signal, ELVeS® Segment, Derma Mode
Pulse duration/-break	0.01 – 60 sec. / 0.01 – 60 sec.	0.01 – 60 sec. / 0.01 – 60 sec.	0.01 – 60 sec / 0.01 – 60 sec
Power supply	110 - 240 VAC, 50 - 60 Hz (7.2 VDC @ 36 W)	110 - 240 VAC, 50 - 60 Hz (7.2 VDC @ 36 W)	110 - 240 VAC, 50 / 60 Hz, 450 VA
Batteries	Li-ion batteries	Li-ion batteries	-
Dimensions (H × W × D)	6.0 cm × 9.0 cm × 21.5 cm	6.0 cm × 9.0 cm × 21.5 cm	approx. 28 cm × 37 cm × 9 cm
Weight	900 g	900 g	approx. 8.5 kg

All laser sets incl. 3 safety goggles, foot switch, interlock connector, power cord and manual in a carrying case.

Fibers

REF	Product	PU [Packaging unit]	length [m]	ø fiber [mm]
503100250	FiLaC® Fistula Probe, IC	2	2.6	1.85
503200740	Bare Fiber 600 µm, Flat Tip, IC	5	2.6	0.96
503400505	HeLP® Bare Fiber 1000 µm, Flat Tip, with handpiece, IC	5	2.6	1.5

Kits

503100220	LHP® Procedure Kit, IC	2	2.6	1.85
503400520	HeLP® Procedure Kit biolitec®, IC	2	2.6	1.5

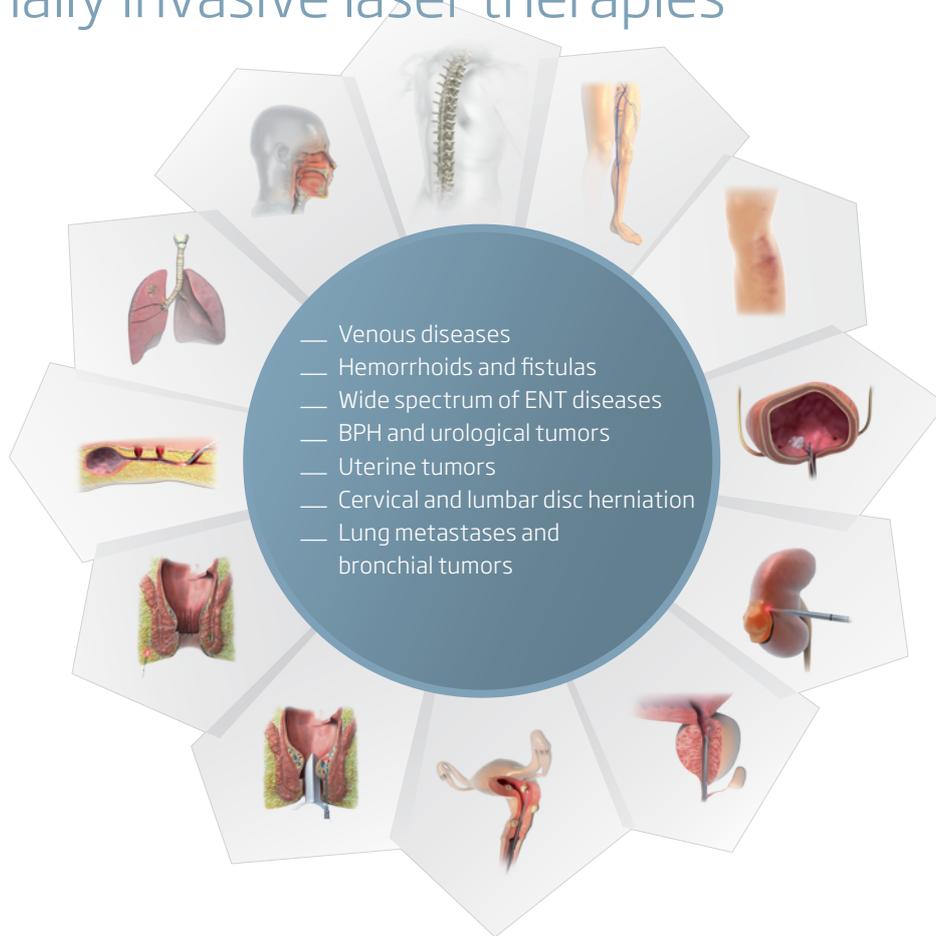
Accessories

REF	Product	PU [Packaging unit]
400100100	Universal Dual Luer Handpiece	1
LA1371	Laser Safety goggles 950 – 1010 L4 + 1470 L2 (FULL), transparent	1
AB2530	HeLP® Doppler Transceiver	1
AB2532	HeLP® Doppler Transceiver Reusable	1
AB2535	HeLP® Doppler Probe reusable	1



Contact us

to learn more about a whole new world
of minimally invasive laser therapies



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and DEHP. Our fibers are single use products
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sterile for immediate use.