

# A Randomized Clinical Trial of Laser Hemorrhoidoplasty vs Milligan and Morgan Hemorrhoidectomy

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## ABSTRACT

**Introduction:** Hemorrhoidectomy is one of the most common surgical procedures, and other treatments such as laser hemorrhoidectomy had been used as an alternative. The aim of this study was to determine the outcome and postoperation complications of treatment by laser compared with open hemorrhoidectomy.

**Materials and methods:** In this randomized clinical trial (RCT), 85 cases with a second or third degree of hemorrhoids were assigned to two groups at random and followed for 6 months. Those patients in the intervention group were treated by laser hemorrhoidoplasty (LHP) and those in the control group underwent Milligan and Morgan hemorrhoidectomy. At the end of follow-up, 80 cases remained in the trial on whom postoperative pain [visual analog scale (VAS)], complications, and quality of life according to the 36-item Short Form Health Survey (SF-36) questionnaire were studied. Data were analyzed using R 3.5.1 software and  $p$  value  $< 0.05$  was considered significant.

**Results:** The most common complaints were bleeding (57%) and pain (41%). Postoperative pain immediately and after 6 months was not significantly different between the two groups ( $p > 0.05$ ). No complications were seen in any groups in follow-up. All eight scales of SF-36 questionnaire, except general health, were significantly different in the two groups. Physical functioning was lower in patients who underwent LHP, whereas the patients' quality of life in other scales was better in the laser group. The total score of SF-36 was  $66.1 \pm 3.6$  and  $56.0 \pm 3.3$  in laser and surgery groups, respectively ( $p < 0.001$ ).

**Conclusion:** Laser hemorrhoidectomy is a safe procedure, not associated with any excessive postoperative complications. It improves patients' quality of life and can be a substitution of other surgical methods.

**Keywords:** Complications, Hemorrhoidectomy, Laser, Quality of life.

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## INTRODUCTION

Hemorrhoid is one of the most common side effects of urbanization. More than 50% of people are affected by this disease over the past 50 years, and the disease has been seen in both sexes and across wide age ranges. As of today, signs of hemorrhoids are seen in 4.4% of the American population.

Hemorrhoid is a familiar cause of admission to surgical clinics and its treatment requires medical and surgical procedures, many of which are performed for hemorrhoids of grades II, III, and IV. One of the most prominent surgical procedures for hemorrhoids is Milligan and Morgan hemorrhoidectomy. Other techniques of hemorrhoid surgery involve using devices such as stapler or procedures such as laser therapy.<sup>1</sup>

Using lasers was primarily recognized by Maymen in 1960 upon the construction of the ruby laser. In the following years, various types of lasers were designed and built, and with the discovery of laser, a remarkable revolution was created in industrial, military, and medical world.

The laser was first used in medicine and ophthalmology. Today, laser treatment is not uncommon in the treatment of hemorrhoids for outpatients. During the treatment process, the arterial blood flow of hemorrhoids is halted using Doppler laser coagulation. In another method, laser is projected into the hemorrhoidal packet, causing subsequent fibrosis upon which the hemorrhoidal packet shrinks and sticks to the anal canal wall to prevent its prolapse.

Various types of lasers are of great benefit in the field medicine. Their different wavelengths can exert different effects in the tissues. The most popular lasers are the carbon dioxide laser, argon laser, and neodymium: yttrium–aluminum garnet.

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**Conflict of interest:** None

Using lasers in the treatment of hemorrhoid leads to minimal tissue damage and good hemostasis, and it can also reduce the duration of surgery and hospital stay. However, against all the benefits, specific training and precaution measurements are required to use lasers in therapy. Moreover, to protect their eyes from invisible lights produced by laser, it is a must that the surgeons use goggles.<sup>2,3</sup>

In this study, the effects of two surgical methods of Milligan and Morgan and the use of lasers in the treatment of hemorrhoids were evaluated in terms of the effectiveness of the treatment, the duration of surgery, and the possible complications caused by such medical methods.

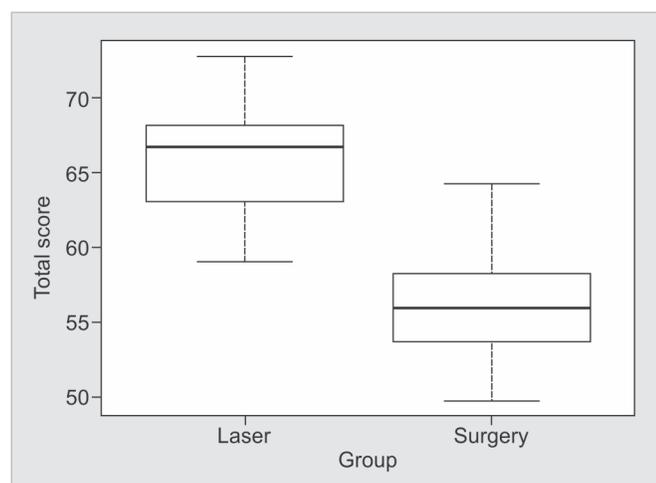
## MATERIALS AND METHODS

This study was a phase 3, randomized open blind trial. It consisted of two parallel groups. Eighty patients were studied between

March 2011 and March 2013 and followed for 6 months at Ghaem and Sina Hospitals in Mashhad, Iran. Inclusion criteria are having been diagnosed with hemorrhoids grade II or III. Those who refused to follow-up were excluded from the study. The estimation of sample size was done using the result of Palper et al., type I error of 5%, power of 90%, and statistical software of PASS version 11.0.4 (Fig. 1).

Based on permuted block randomization with block size of four, patients were randomly assigned to two groups with an allocation ratio of 1. The intervention patient groups underwent LHP and those in control group were treated with Milligan and Morgan hemorrhoidectomy by the same surgeon (Flowchart 1).

In LHP, Diode Laser 1470 (CERALAS model; Biolitec Company) was used. In this method, the patient was first put under general anesthesia. After prep and drep (decrease the number of microorganisms at the operative site), special optical fiber entered the hemorrhoidal packet.



**Fig. 1:** Box plot for total score of 36-item Short Form Health Survey (SF-36) questionnaire for two groups

Then the hemorrhoidal packet was measured from the proximal part to the distal part using the LHP technique. In the next step, hemorrhoidopexy was done with running suture using 2.0 vicryl (absorbable sutures catgut sutures 0–4 Turkey) performed from the proximal to the distal part of the packet. At the end of the procedure, two or three packets were treated at a time. After performing the LHP, cold compression was done by placing ice over each packet for 3 minutes.

In the Milligan and Morgan method, after prep and drep, the patients were under either general or spinal anesthesia. Afterward, they were placed in the lithotomy position. By this method, three hemorrhoid packets with at an angle of about 60° were selected. Then the packet had to be eliminated below the tooth line of the anus while the skin and the mucous bridges between the packets stayed preserved.

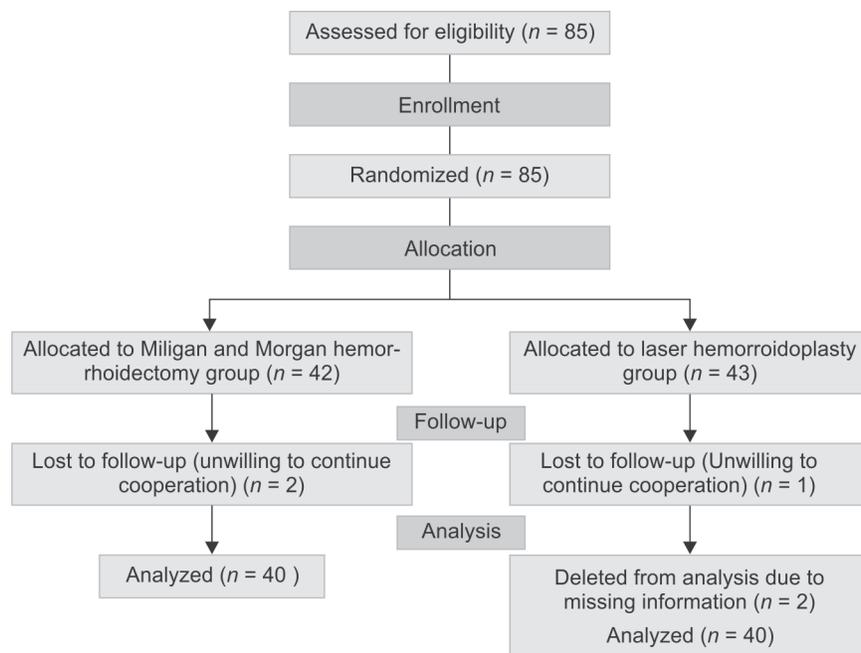
The main outcome variables included pain, delayed bleeding, the presence of urinary retention, painful defecation, fistula, acute infection fissure, anal stenosis, fecal incontinence, and postoperative thrombosis. The length of hospitalization and quality of life of patients 6 months after operation were evaluated using SF-36 questionnaire. The 36-item SF-36 includes several domains of health-related quality of life, namely, general health, limitations of activities, physical health problems, emotional health problems, social activities, pain, and energy and emotions. A higher score indicates a better quality of life. The validity and reliability of the questionnaire were approved in Iranian population.<sup>4</sup>

This study had been approved by the ethics committee and the institutional review board of Mashhad University of Medical Sciences (IR.MUMS.REC.1391.93), and informed consent was obtained before enrollment. Registration ID of this study in the Iranian Registry of Clinical Trial is "IRCT20180204038605N1."

### Statistical Analysis

Data were analyzed by R software version 3.5.1. The differences among groups in terms of ordinal or scale variables were analyzed using the Mann–Whitney nonparametric test or independent *t* test.

**Flowchart 1:** CONSORT flow diagram: laser hemorrhoidoplasty vs Milligan and Morgan hemorrhoidectomy



The Chi-square or Fisher's exact test was used for comparison of the categorical variables between groups. The  $p$  value  $<0.05$  was considered as statistically significant.

## RESULTS

The mean age of the patients in the laser and the surgery groups was  $38.13 \pm 8.29$  years and  $38.73 \pm 9.53$  years, respectively. Thirty-six (45%) patients were male [18 patients (45.0%) in the surgery group and 18 patients (45.0%) in the laser group]. The main cause of referring to hospital in both groups was bleeding (65% vs 50%) and hemorrhoids of grade II was more common. No significant difference was observed between the two groups regarding sex, grade of hemorrhoid, and cause of referring to hospital (Table 1).

The pain severity based on VAS score immediately after surgery for half of the patients was more than 3 of 10 and for laser group 2 of 10. The median pain in laser and surgery groups was 2 and 3, respectively, which were not statistically different ( $p = 0.198$ ). 6 months after surgery the pain intensity reduced dramatically, resulting in the median pain of 1 of 10 in both the groups, but the mean of pain was  $1.20 \pm 0.40$  in the laser group and  $1.37 \pm 0.58$  in those who underwent Milligan and Morgan surgery (Table 2).

The length of hospitalization after surgery was  $1.70 \pm 0.65$  days for the surgery group and  $1.50 \pm 0.55$  days for the laser group. According to the result, no statistically significant difference was found between the two groups in this regard ( $p = 0.142$ ).

**Table 1:** Demographic characteristics of patients

Variable	Group		p value
	Laser (n = 40)	Milligan and Morgan (n = 40)	
Gender <sup>a</sup>			
Male	18 (45%)	18 (45%)	0.99 <sup>‡</sup>
Age (year) <sup>b</sup>	$38.12 \pm 8.29$	$38.72 \pm 9.52$	0.76 <sup>†</sup>
Cause of referring <sup>b</sup>			
Pain	14 (35%)	19 (47.5%)	0.26 <sup>§</sup>
Bleeding	26 (65%)	20 (50%)	
Itching	0	1 (2.5%)	
Grade of hemorrhoid <sup>b</sup>			
II	29 (72.5%)	25 (62.5%)	0.34 <sup>‡</sup>
III	11 (27.5%)	15 (37.5%)	

<sup>a</sup>Frequency, %

<sup>b</sup>Mean  $\pm$  standard deviation (SD)

<sup>‡</sup>Based on Pearson's Chi-square test

<sup>†</sup>Based on independent  $t$  test

<sup>§</sup>Based on Fisher's exact test

**Table 2:** Visual analog scale (VAS) pain immediately and 6 months after operation

VAS pain <sup>a</sup>	Group		p value <sup>‡</sup>
	Laser (n = 40)	Milligan and Morgan (n = 40)	
Immediately after operation	$2.35 \pm 0.80$ 2 (1–4)	$2.57 \pm 0.93$ 3 (1–5)	0.198
6 months postoperative	$1.20 \pm 0.40$ 1 (1–2)	$1.37 \pm 0.58$ 1 (1–3)	0.174

<sup>a</sup>Mean  $\pm$  standard deviation (SD), median (min–max)

<sup>‡</sup>Based on Mann–Whitney test

In addition, we evaluated the health of patients through the study of emotions and their ability to perform daily tasks by means of SF-36 questionnaire 6 months after operation. In the first step, patients were asked how they feel now and in comparison to the past year. In the laser group, 87.5% answered they are excellent or good now, while 47.5% of patients in the surgery group felt good. Nonetheless, the general health of patients regarding how they feel about 1 year ago and how they seem to be were the same ( $p = 0.094$ ). The total score of role limitations due to physical health scale was higher in those patients who were treated with laser ( $63.4$  vs  $56.9$ ) ( $p = 0.002$ ). In the field of physical health problem, patients evaluated in the terms of having difficulty with their work or other regular daily activities during the 4 last weeks, which was  $84.5 \pm 10.5$  in the surgery group and  $80.2 \pm 4.3$  in the laser group ( $p < 0.001$ ). Moreover, emotional health problems were less in laser group ( $p < 0.001$ ). In the seventh scale of questionnaire, two groups were compared regarding the pain of patients during the past 4 weeks and how much this pain interfered with their normal work, and it was revealed that pain in surgery group was significantly much more than that in the laser group ( $p < 0.001$ ), and two groups were not comparable in the field of energy and emotions ( $p < 0.001$ ). Finally, contrary to all other scales, the mean of physical functioning was higher in the surgery group and this difference was significant ( $p < 0.001$ ) (Table 3).

To sum up, the difference between two groups concerning mental component summary (MCS) was higher than the physical component summary (7.5 and 12.6). However, both were meaningful ( $p < 0.001$ ). The difference in total score of quality of life was  $2.2 \pm 1.0$ , which is in favor of the laser group ( $p = 0.037$ ) (Fig. 1).

## DISCUSSION

An uncomplicated hemorrhoidectomy is desirable for both the patient and the surgeon. Almost all the proposed hemorrhoidectomy techniques are expected to reduce postoperative pain, bleeding,

**Table 3:** Comparison of patient's quality of life 6 months after operation

Scale <sup>a</sup>	Group		p value <sup>‡</sup>
	Laser (n = 40)	Milligan and Morgan (n = 40)	
Physical functioning	$80.2 \pm 4.3$ 80 (70–87)	$84.5 \pm 10.5$ 86.7 (47–93)	$<0.001$
Role limitations due to physical health	$63.4 \pm 9.1$ 62.5 (50–75)	$56.9 \pm 9.4$ 50 (50–75)	0.002
Role limitations due to mental health	$81.2 \pm 14.2$ 83 (50–100)	$57.9 \pm 8.4$ 50 (50–67)	$<0.001$
Energy/fatigue	$57.5 \pm 10.6$ 58 (37–97)	$47.9 \pm 5.2$ 50 (37–67)	$<0.001$
Emotional well-being	$57.7 \pm 10.4$ 60 (40–77)	$48.3 \pm 5.5$ 47 (40–63)	$<0.001$
Social functioning	$72.5 \pm 10.8$ 70 (50–90)	$64.5 \pm 10.1$ 60 (40–80)	0.002
Pain	$57.5 \pm 11.2$ 59 (27–82)	$31.6 \pm 10.3$ 27 (18–54)	$<0.001$
General health	$58.7 \pm 6.6$ 58 (43–73)	$56.7 \pm 3.1$ 57 (50–63)	0.094

<sup>a</sup>Mean  $\pm$  standard deviation (SD), median (min–max)

<sup>‡</sup>Based on Mann–Whitney test

and length of stay and facilitate the timely return of the patient to daily activities and, thus, enhance the quality of life for the patients after surgery. Since the complications of such surgeries might be quite destructive and cause severe bleeding, using these techniques requires high proficiency and training. While selecting the surgical procedure, the skills and experiences of the surgeon need to be taken into account, so that the results of the surgery could be satisfactory and healthful.<sup>5</sup> In addition, the most common problem among patients after the surgery of hemorrhoidectomy is the acute pain during the first and second days after surgery. It is likely for the pain to trouble the patient for some days and this can be a matter of concern for the patient.<sup>6</sup>

Pain is a major cause that puts off patients from undergoing a hemorrhoidectomy. Beside the fact that pain itself is annoying, it is likely to cause certain problems such as urinary retention and fecal compaction. On the other hand, because postoperative pain is a very common side effect of hemorrhoidectomy, not many patients consider it as a surgical complication, but they see it as a predictable consequence of the surgery.<sup>7,8</sup>

We evaluated the postoperative pain in two time points which were immediately and 6 months after surgery based on VAS. The mean VAS score in patients who were treated with laser was 0.22 and 0.17 after surgery and in the 6 months follow-up, respectively. Moreover, these differences were not considered statistically significant.

Similar to our result, Arbman et al. claimed no significant differences between the two groups in terms of VAS.<sup>9</sup> Also in the study by Walfisch, no differences with regard to postoperative pain were observed between the laser-based method and hemorrhoidectomy or any other nonlaser methods.<sup>10</sup> In another experiment by Zahir on 50 patients treated with laser-based techniques, the pain alleviation frequency was reported to be as much as up to 65% compared to the control group.<sup>11</sup> However, in the study by Sankar, postoperative pain was significantly lower than that of other surgical procedures such as open surgery.<sup>12</sup> In another study by Masson, hemorrhoidectomy with lasers is known to cause less postoperative pain compared to other surgical methods such as open hemorrhoidectomy.<sup>13</sup> Besides in the study by Plapler, the mean pain severity has been reported as 1.13 (of 10) that was significantly lower than that in the control group who underwent Milligan and Morgan method or cold scalpel method.<sup>14</sup>

In our study, the length of hospitalization after surgery in the patients was  $1.70 \pm 0.65$  days for the surgery group and  $1.5 \pm 0.55$  for the laser group, and the two groups were not significantly different in terms of the time they were hospitalized. Nonetheless, in the study by Sankar, the lower length of hospitalization in the laser group was significant.<sup>12</sup> Also in the study by Masson, it was concluded that hemorrhoidectomy patients treated with laser-based methods had none or minimal need for hospitalization and lower costs, and they made a faster return to daily tasks.<sup>13</sup>

Our finding revealed that the quality of life in the LHP group in terms of both physical and MCS was relatively better ( $p < 0.05$ ). These results were similar to other studies.<sup>5,15</sup> Erdoğan et al. also evaluated the quality of life after stapler hemorrhoidectomy by using SF-36 questionnaire. They demonstrated that physical health (physical functioning, physical role restriction, and bodily pain) scores significantly improved after surgery.<sup>16</sup> Bouchard et al. in a multicenter trial followed patients who underwent hemorrhoidectomy for 1 year and reported that all physical and mental domains of quality of life significantly improved, and 88% of patients were satisfied or very satisfied by the surgery.<sup>15-18</sup>

The common postoperative complications in laser surgeries include delayed bleeding, presence of urinary retention, painful defecation, fistula, acute infection fissure, anal stenosis, fecal incontinence, and postoperative thrombosis. None of mentioned complications were observed in any of our patients within 6 months after surgery. Many studies support our findings. Sowula reports no cases of postoperative bleeding during the follow-up. He states that the patients who were treated with laser therapy had a much more facilitated postoperative period and that the complications of these methods were very rare.<sup>17</sup> Also Leff claimed that wound healing was observed in all cases, and it was inferred that hemorrhoidectomy with lasers did not promote any adverse effects of surgery on the patients.<sup>15</sup> In another experiment performed by Zahir on 50 patients treated by laser therapy, pain alleviation was reported to be up to 65%.<sup>11</sup> On the contrary, the result of some RCTs demonstrated the lower frequency of well treated by laser. As an example, in the study by Arbman, 86% of the hemorrhoidectomy patients who were treated with lasers had complete healing of their wounds within a follow-up of 3 weeks and no one developed symptoms of any sorts of infection. Of those patients who had a surgery with Milligan and Morgan method, only 18% had complete healing of wounds and symptoms of delayed improvement were detected in several cases. One of their patients had a minor wound infection, and even after 1 year, more than 10% of the hemorrhoid patients still showed symptoms of the disease.<sup>9</sup> In addition, Plapler counts a number of side effects for laser-based therapy. For instance, burning lesions and residual plicoma (skin tag) were detected in five patients under treatment with lasers due to the impairment of the laser system. However, even in this study practical and complete improvements were reported within a short period compared to hemorrhoidectomy.<sup>14</sup>

In the present study, redoing the operation was not required in any of patients in either group during the 6-month follow-up. Moreover, there was no recurrence of the disease during the 6 months and a complete remission was observed in all cases. However, Skobelkin pointed out that the recurrence was two times more in open surgery of Milligan and Morgan.<sup>18</sup>

Clearly, those patients in the laser group had an easier recovery. Similar to our study, in the study by Sankar, postoperative recovery period was significantly lower than other surgical procedures such as open surgery.<sup>12</sup>

## CONCLUSION

Hemorrhoidectomy through laser-based methods does not aggrandize the side effects of surgery in the patients. Furthermore, due to the ease of implementation and not imposing any additional risks to the patient at the time of performing and because of the possibility of performing it as outpatient surgery, these methods can be greatly beneficial and practical. They can be an alternative to the usual hemorrhoidectomy. Lasers are effective and safe in case of anal lesions and are comparable with other conventional methods of surgery. Effective methods with lasers, along with other available treatments, could expand new horizons in the treatment of anorectal diseases like hemorrhoidectomy. Nonetheless, further studies in this field are to be done.<sup>19</sup>

## COMPLIANCE WITH ETHICAL STANDARDS

### Informed Consent

Informed consent was obtained from all individual participants included in the study.

## Ethical Approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of ethics Committee of Mashhad University of Medical Sciences, Mashhad, Iran.

## THIS PILOT CASE

This study was a phase 3, randomized open blind trial. It consisted of two parallel groups. Eighty patients were studied between March 2011 and March 2013 and followed for 6 months on Ghaem and Sina Hospitals in Mashhad, Iran, and approved by the ethics committee and the institutional review board of Mashhad University of Medical Science (IR.MUMS.REC.1391.93) and informed consent was obtained before enrollment. Registration ID of this study in Iranian Registry of Clinical Trial is "IRCT20180204038605N1."

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