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# Comprehensive Analysis of Different Laser Devices Treating Lower Extremity Varicose Veins at the Same Power and LEED Value

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**Abstract:** *Objective*: To compare the clinical efficacy and complication rate of Biolitec laser and Halo laser for the treatment of lower extremity great saphenous vein (GSV) and small saphenous vein (SSV) under the same LEED value. *Methods*: A total of 70 cases of GSV and 30 cases of SSV treated with laser in our hospital from May 2022 to May 2023 were selected and treated with Biolitec and Halo laser equipment, respectively. The working mode was continuous mode. The patients were divided into the Biolitec group (35 patients with GSV and 15 patients with SSV) and the Halo group (35 patients with GSV and 15 patients with SSV) according to different laser equipment. The days of returning to normal activity, closure rate, and changes in venous clinical severity score (VCSS) were evaluated. Safety endpoints were deep vein thrombosis (DVT), heat-induced thrombosis (EHIT), surgical site ecchymosis, postoperative paresthesia (numbness), postoperative edema, burns, superficial phlebitis, and other adverse events. *Results*: There were no significant differences in the days of postoperative recovery, the closure rate of varicose veins, the change of VCSS, and the incidence of postoperative complications between the two groups. *Conclusions*: The Biolitec and the Halo laser have the same efficacy and safety in treating the GSV and SSV under the same power and LEED.

**Keywords:** Laser equipment; Great saphenous vein; Small saphenous vein; VCSS

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## 1. Introduction

Varicose veins of the lower extremities is a common vascular disease, with an incidence of 20% in general surgery [1–2]. The early clinical symptoms of patients with lower extremity varicose veins are limb edema, heavy fatigue, and superficial vein dilatation [2–4]. Due to venous stasis, traditional treatment methods such as high ligation and stripping of the great saphenous vein (GSV) are effective, but there are some disadvantages such as surgical injury, delayed recovery, and other complications [5–7]. With the development of medical technology, minimally invasive treatment has gradually become the current trend. Intravenous laser ablation therapy (EVLA),

as a new minimally invasive treatment method, provides a new option for the treatment of lower extremity varicose veins [8–9]. The aim of this study was to compare the clinical effectiveness and complication rates of Biolitec and Halo, two common laser devices, for the treatment of lower extremity GSV and small saphenous veins (SSV) with the same power and LEED.

## 2. Materials and methods

### 2.1. General information

From May 2022 to May 2023, patients with lower extremity GSV and SSV varicose treated with laser in our hospital were selected. Among them, 70 patients with varicose GSV of lower extremity were randomly divided into an observation group and a control group, with 35 cases in each group. The observation group was treated with Halo laser equipment, including 20 males and 15 females. The control group was treated with Biolitec laser equipment, including 18 males and 17 females. A total of 30 patients with SSV varicose of lower limbs were randomly divided into the observation group and the control group, with 15 cases in each group. The observation group was treated with Halo laser equipment, including 8 males and 7 females. The control group was treated with Biolitec laser equipment, including 7 males and 8 females.

Inclusion criteria: (1) patients aged 20–75 years old; (2) complete medical records; (3) all patients were diagnosed by clinical symptoms, signs, and imaging examination showing that the deep veins of the lower limbs were unobstructed and the GSV had venous reflux. Primary varicose vein of lower extremity was diagnosed by imaging examination. (4) The patient was in normal consciousness and could cooperate with the operation, and the related indicators were tested, and there was no serious mental disease or other contraindications. (5) Clinical etiology anatomy pathophysiology (CEAP) grades C1-2 to C4. (6) All patients had signed the informed consent.

Exclusion criteria: (1) Complicated with serious diseases of vital organs; (2) iliac vein compression; (3) post-thrombotic syndrome; (4) severe allergic constitution; (5) pregnant or lactating women; (6) patients with surgical contraindications; (7) lost in follow-up.

There was no statistically significant difference in the general data between the two groups ($P > 0.05$), as shown in **Tables 1** and **2**.

**Table 1.** Comparison of general data between the two groups of patients with varicose great saphenous vein of lower extremities [$n = 35$, (Mean ± SD)]

| Groups | Age (Years) | Duration of disease (Years) | Gender (Cases) | Affected sides | | | CEAP classification | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | Male/ Female | Left side | Right side | Bilateral | Lv.C1–C2 | Lv.C3 | Lv.C4a | Lv.C4b |
| Observation group | 56.23 ± 8.09 | 4.31 ± 2.15 | 20/15 | 14 | 13 | 8 | 7 | 14 | 8 | 6 |
| Control group | 55.83 ± 9.30 | 4.23 ± 2.30 | 18/17 | 15 | 11 | 9 | 8 | 12 | 9 | 6 |
| $t/\chi^2$ | 0.192 | 0.161 | 0.227 | | 0.260 | | | 0.279 | | |
| $P$ | 0.848 | 0.873 | 0.634 | | 0.0608 | | | 0.0630 | | |

**Table 2.** Comparison of general data between two groups of patients with varicose small saphenous vein of lower extremity

| Groups | Age (Years) | Duration of disease (Years) | Gender (Cases) | Affected sides | | | CEAP classification | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | Male/ Female | Left side | Right side | Bilateral | Lv.C1–C2 | Lv.C3 | Lv.C4a | Lv.C4b |
| Observation group | 56.13 ± 6.77 | 4.13 ± 1.64 | 8/7 | 6 | 6 | 3 | 2 | 5 | 5 | 3 |
| Control group | 55.93 ± 6.30 | 4.07 ± 1.22 | 7/8 | 7 | 5 | 3 | 1 | 6 | 4 | 4 |
| $t/x^2$ | 0.084 | 0.126 | 0.129 | 0.168 | | | 0.493 | | | |
| $P$ | 0.934 | 0.900 | 0.719 | 0.919 | | | 0.782 | | | |

## 2.2. Treatment methods

### 2.2.1. Instruments and consumables

Observation group: Halo Diode Laser System (Micro-Energy Medical Technology Co., Ltd), using the same company fiber, Halo-R-0.40-2.5, Halo-R-0.60-2.5.

Control group: Ceralas E Laser System (Biolitec AG, CeramOptecCeramOptec GmbH), using the same company fiber, ELVeS Radial 400 μm, 600 μm.

### 2.2.2. Procedures

The patients' medical history was collected and confirmed. On the day of treatment, the patients were examined physically and underwent imaging examination to determine the venous position, reflux, and surface markers. The patient was placed in the supine position, and local injection anesthesia was used. Tumescent anesthesia solution was prepared by mixing 500 ml of Hartmann's solution with 20 ml of 2% lidocaine, and perivenous infiltration injection was performed under intraoperative ultrasound guidance, ensuring that the vein was at least 10 mm away from the skin after injection. A vascular sheath was used to obtain access, and a laser fiber connected to a laser therapeutic system was inserted into the GSV/SSV through the vascular sheath for ablation. Treatment parameters were set according to the requirements of the Guidelines for Diagnosis and Treatment of Common Venous Diseases (2022 Edition) [6]. The GSV in the observation group was treated with Halo-R-0.60-2.5 fiber, and the GSV in the control group was treated with ELVeS Radial 600 μm fiber. Other parameters were set in continuous mode, laser power was set at 6 to 8w, and LEED was 50 J/cm. The SSV in the observation group was treated with Halo-R-0.40-2.5 fiber, and the SSV in the control group was treated with ELVeS Radial 400 μm fiber. The other parameters were set in continuous mode, the laser power was set to 4–5 W, and the LEED was 40 J/cm. For GSV treatment, ablation was initiated 2 cm distal to the saphenofemoral junction (SFJ) but did not extend below the knee joint region. SSV ablation was performed by puncture in the lower leg, and the ablation site was started 2 cm distal to the saphenous popliteal junction. During the laser ablation, the patient was kept in a 30-degree head-down position. After the whole ablation procedure, the lower limbs were then wrapped with elastic bandages.

### 2.2.3. Postoperative management

Passive mobilization of the affected limb was performed immediately after operation to prevent deep vein thrombosis (DVT) of the lower extremity. Clinical observation of the blood supply of the affected limb and the condition of the dorsalis pedis artery were performed. The patients were encouraged to walk independently off the bed 6 hours after

operation. Aescuven forte was given orally twice a day (2 tablets each time) for at least 3 months after surgery. The elastic bandage was replaced by medical elastic stockings (long-legged above the knee, second-level pressure) 2 days after operation and continued to be used for 3 months or more. If the Carprini score was ≥5, prophylactic anticoagulation therapy was performed by subcutaneous injection of enoxaparin 4000U, once every 24 hours for 7 days.

### 2.3. Observation indicators

The time required for patients to return to normal activities after surgery and the short-term (0 time, 1 month, 3 months) and long-term (12 months) venous closure rate after surgery were compared between the two groups. The changes of the venous clinical severity score (VCSS) before and after treatment were compared between the two groups.

The incidence of postoperative DVT, heat-induced thrombosis (EHIT), surgical site ecchymosis, postoperative paresthesia (numbness), postoperative edema, burns, superficial phlebitis, and other adverse events were observed.

### 2.4. Statistical methods

Statistical software was used for data analysis. Measurement data were expressed as (Mean ± SD), and a *t* test was used for comparison between groups. Count data were expressed as rate (%), and an $x^2$ test was used for comparison between groups. $P < 0.05$ was considered statistically significant.

## 3. Results

### 3.1. Short-term and long-term postoperative closure rate

At 0 time after operation, the vein closure rate of the two groups was 100%. At 1 month, 3 months, and 12 months, the closure rates of the two groups decreased, but there was no significant difference between the two groups ($P > 0.05$), as shown in **Tables 3** and **4**.

**Table 3.** Comparison of surgical closure rate between two groups of great saphenous vein varices of lower extremity [$n = 35$, n/(%)]

| Groups | At 0 time* | 1 month* | 3 month* | 12 month* |
|---|---|---|---|---|
| Observation group | 35 (100%) | 35 (100%) | 35 (100%) | 34 (97.14%) |
| Control group | 35 (100%) | 35 (100%) | 35 (100%) | 33 (94.28%) |
| $x^2$ | | | | 0.011 |
| P | | | | >0.999 |

Notes: *Indicates the time after surgery

**Table 4.** Comparison of surgical closure rate between two groups of small saphenous vein varices of lower extremity [$n = 15$, n/(%)]

| Groups | At 0 time* | 1 month* | 3 month* | 12 month* |
|---|---|---|---|---|
| Observation group | 15 (100%) | 15 (100%) | 15 (100%) | 14 (93.33%) |
| Control group | 15 (100%) | 15 (100%) | 15 (100%) | 13 (86.67%) |
| $x^2$ | | | | 0.028 |
| *P* | | | | 0.999 |

Notes: *Indicates the time after surgery

## 3.2. Days of postoperative return to activity

In the GSV flexural surgery of the lower limbs, the average days of returning to normal activities were 2.71 ± 1.22 days in the observation group and 2.80 ± 1.28 days in the control group, and there was no significant difference between the two groups ($P > 0.05$), as shown in **Table 5**.

**Table 5.** Comparison of the days of return to normal activities after surgery between the two groups for varicose great saphenous veins of the lower extremities [$n = 35$, (Mean ± SD)]

| Groups | Cases | Days of return to activity after surgery |
|---|---|---|
| Observation group | 35 | 2.71 ± 1.22 |
| Control group | 35 | 2.80 ± 1.28 |
| *t* | | 0.289 |
| *P* | | 0.773 |

The mean days of recovery after surgery for lower extremity saphenous vein flexion were 2.80 ± 1.08 days in the Halo laser group and 2.93 ± 0.79 days in the Biolitec laser group, with no statistical significance between the groups ($P > 0.05$), as shown in **Table 6**.

**Table 6.** Comparison of the days of return to normal activities after surgery between the two groups for small saphenous varicose veins of the lower extremities [$n = 15$, (Mean ± SD)]

| Groups | Cases | Days of return to activity after surgery |
|---|---|---|
| Observation group | 15 | 2.80 ± 1.08 |
| Control group | 15 | 2.93 ± 0.79 |
| *t* | | 0.384 |
| *P* | | 0.704 |

## 3.3. VCSS score

Before operation, there was no significant difference in VCSS scores between the two groups of patients with lower extremity GSV varices ($t = 0.082$, $P > 0.05$), and there was no significant difference in VCSS scores between the two groups of patients with lower extremity SSV varices ($t = 1.269$, $P > 0.05$). Comparison between the observation group and the control group shows that the VCSS scores of both groups were significantly improved at 12 months after treatment, but there was no significant difference between the two groups (GSV varices $t = 0.548$, $P > 0.05$; SSV varicose $t = 0.770$, $P > 0.05$).

Comparison between the short-term (1 month, 3 months) and long-term (12 months) of the observation group show that the VCSS scores of the patients with GSV and SSV in the two groups were significantly lower than those before operation ($P < 0.05$) and slightly increased at 12 months after operation. Comparison of short-term (1 month, 3 months) and long-term (12 months) in the control group: the VCSS scores of patients with saphenous varicose veins in the GSV and SSV groups had the same phenomenon as those in the observation group.

There was no significant difference between the observation group and the control group ($P > 0.05$), and there was no statistical difference between the observation group and the control group ($P > 0.05$), and there was no statistical difference between the SSV group ($P > 0.05$), as shown in **Tables 7** and **8**.

**Table 7.** Surgical VCSS scores for varicose great saphenous veins of the lower extremities in both groups [$n$ = 35, (Mean ± SD)]

| Groups | Pre-operation | 1 month* | 3 month* | 12 month* | *t* | *P* |
|---|---|---|---|---|---|---|
| Observation group | 10.65 ± 5.28 | 1.62 ± 0.77 | 1.91 ± 0.78 | 4.14 ± 1.53 | 7.008 | <0.0001 |
| Control group | 10.23 ± 4.88 | 1.69 ± 0.76 | 2.00 ± 0.84 | 4.25 ± 1.52 | 6.917 | <0.0001 |
| *t* | 0.353 | 0.313 | 0.442 | 0.313 | | |
| *P* | 0.725 | 0.755 | 0.660 | 0.755 | | |

Notes: *Indicates the time after surgery

**Table 8.** Surgical VCSS scores for varicose small saphenous veins of the lower extremities in both groups [$n$ = 15, (Mean ± SD)]

| Groups | Pre-operation | 1 month* | 3 month* | 12 month* | *t* | *P* |
|---|---|---|---|---|---|---|
| Observation group | 11.13 ± 4.15 | 1.73 ± 0.88 | 2.00 ± 0.84 | 4.33 ± 1.63 | 5.899 | <0.0001 |
| Control group | 11.53 ± 4.08 | 1.80 ± 0.77 | 2.06 ± 0.88 | 4.40 ± 1.50 | 6.346 | <0.0001 |
| *t* | 0.266 | 0.220 | 0.211 | 0.116 | | |
| *P* | 0.792 | 0.828 | 0.834 | 0.908 | | |

Notes: *Indicates the time after surgery

## 3.4. Incidence of complications

There was no significant difference in the incidence of DVT, EHIT, surgical site ecchymosis, postoperative paresthesia (numbness), postoperative edema, burn, and superficial phlebitis between the two groups of patients with great saphenous vein varices and small saphenous vein varices ($P > 0.05$), as shown in **Table 9** and **10**.

**Table 9.** Comparison of the incidence of surgical complications between the two groups for varicose veins of the great saphenous vein of the lower extremities [$n$ = 35, n/(%)]

| Groups | DVT | EHIT | Ecchymosis at the surgical site | Postoperative paresthesia (numbness) | Postoperative edema | Burn | Superficial phlebitis |
|---|---|---|---|---|---|---|---|
| Observation group | 0 | 0 | 5 (14.28%) | 1 (2.86%) | 1 (2.86%) | 0 | 0 |
| Control group | 0 | 0 | 6 (17.14%) | 2 (5.71%) | 1 (2.86%) | 0 | 0 |
| $x^2$ | | | | | | | 0.177 |
| *P* | | | | | | | 0.915 |

**Table 10**. Comparison of the incidence of surgical complications between the two groups for varicose veins of the small saphenous vein of the lower extremities [n = 15, n/(%)]

| Groups | DVT | EHIT | Ecchymosis at the surgical site | Postoperative paresthesia (numbness) | Postoperative edema | Burn | Superficial phlebitis |
|---|---|---|---|---|---|---|---|
| Observation group | 0 | 0 | 2 (13.33%) | 1 (6.87%) | 0 | 0 | 0 |
| Control group | 0 | 0 | 3 (20.00%) | 1 (6.87%) | 0 | 0 | 0 |
| $x^2$ | | | | | | | 0.050 |
| *P* | | | | | | | 0.823 |

## 4. Discussion

Chronic venous disease (CVD) of lower limbs is a syndrome of poor venous blood return and high venous pressure due to abnormal structure or function of veins, which leads to a series of symptoms and signs, mainly manifested as varicose, heavy, fatigue, distension and pain of saphenous veins of lower limbs [1–2, 8]. Edema, intermittent claudication, skin ulcer, and so on. In China, the prevalence of CVD was 8.89%, mainly for GSV varices, and 19% for SSA varices [10]. The treatment of varicose veins mainly includes surgical and non-surgical treatments. In the early stages of the disease, non-surgical procedures can be performed by paying attention to diet, changing lifestyle habits, and using elastic socks [11–12]. However, when the disease progresses to the advanced stage or more serious cases, it needs to be treated by surgery. There are various surgical methods, such as traditional high ligation, but with the development of endovenous treatment theories and techniques, the treatment of varicose veins of the lower extremities gradually develops to open, minimally invasive and non-invasive, and varicose vein dissection is developed successively, as well as the emerging endovenous ablation, EVLA, endovenous radiofrequency ablation (RFA), and so on [9, 13]. EVLA has the characteristics of less trauma, less psychological burden, faster recovery, less intraoperative blood loss, etc., and has been more and more widely used in the treatment of lower limb varicose veins [11–13].

In the previous study, the results show that the Biolitec and Halo laser devices have good clinical effectiveness in the treatment of the lower extremity great saphenous vein and small saphenous vein during EVLA treatment at the same power and LEED value, which is consistent with previous studies [12]. The closure rate was 100% in both groups at time 0 after surgery, and although the closure rate decreased over time, there was no significant difference between the two groups. The two groups also performed similarly in terms of the number of days back to activity after surgery and improvement in VCSS scores. In terms of safety, the incidence of adverse events was low and did not differ significantly between the two devices. This indicates that the safety of the two devices during treatment is comparable.

## 5. Limitations

However, this study also has some limitations. The sample size was relatively small and the follow-up time was limited, which may have some impact on the accuracy of the study results. Further studies with large sample size, multi-center and long-term follow-up are needed to evaluate the efficacy and safety of these two laser devices more comprehensively in the future.

## 6. Conclusions

In conclusion, both Biolitec and Halo laser devices were safe and effective for the treatment of lower extremity great and small saphenous veins at the same power and LEED, with no statistically significant differences in closure rates, days to return to normal activities after surgery, improvement in VCSS scores, and incidence of adverse events. Hence, clinicians can choose according to the patient's situation.

## Disclosure statement

The author declares no conflict of interest.

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