

**Prospective, Randomized Controlled Trial of Starion™ versus  
Ligasure™ Hemorrhoidectomy for Prolapsed Hemorrhoids**

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**Short running head:** Starion™ vs. Ligasure™ hemorrhoidectomy

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## ABSTRACT

**PURPOSE:** The aim of this study was to evaluate the efficacy and outcome between the Starion™ and Ligasure™ vessel sealing systems for sutureless hemorrhoidectomy.

**METHOD:** Sixty-four patients with grades III and IV hemorrhoids were randomized into two groups: 1) Starion™ hemorrhoidectomy (32 patients), and 2) Ligasure™ hemorrhoidectomy (32 patients). The patient demographics, operative details, numbers of parenteral analgesic injections, post-operative pain scores (assessed by an independent assessor), operating time, intra-operative blood loss, hospital stay, early and delayed complications, and time off from work or normal activity were recorded. The patients were regularly followed-up at 1, 2, 4, 6, 8 and 12 weeks after surgery.

**RESULTS:** The mean blood loss, mean operating time, duration of hospital stay and time off from work or normal activity were not significantly different between the two methods (all  $P > 0.05$ ), except for a lower pain score ( $P = 0.032$ ) and reduced numbers of parenteral analgesic injections ( $P < 0.001$ ) in Starion™ hemorrhoidectomy. In addition, there were no differences in the early and delayed post-operative complications between the two methods (all  $P > 0.05$ ). Unfortunately, 2 patients with symptomatic anal stenosis requiring treatment were encountered by Ligasure™ hemorrhoidectomy, but none by Starion™ hemorrhoidectomy.

**CONCLUSIONS:** Starion™ hemorrhoidectomy with submucosal dissection is a safe

and effective procedure, comparable to Ligasure™ hemorrhoidectomy. Patients derive a short-term benefit of less pain and reduced parenteral analgesic use by Starion™ hemorrhoidectomy. The superiority of no cases complicated with symptomatic anal stenosis requiring treatment by Starion™ hemorrhoidectomy seems to offer a better therapeutic alternative for prolapsed hemorrhoids.

**Key words:** Hemorrhoid, Starion™, Ligasure™, Submucosal dissection

## INTRODUCTION

Hemorrhoidectomy is superior to any proposed conservative procedure, including rubber band ligation, sclerotherapy, photocoagulation, and cryotherapy for treating symptomatic grades III and IV hemorrhoids.<sup>1</sup> Unfortunately, it is usually associated with significant post-operative complications, including pain, bleeding, and anal stricture, which can result in a protracted period of convalescence.<sup>2</sup> Therefore, this has stimulated continuing efforts to develop new techniques and modifications which promise a less painful course and faster recovery.

Recent advances in instrumental technology including the bipolar electrothermal device<sup>3</sup>, ultrasonic scalpel<sup>4</sup>, and circular stapler<sup>5</sup> are gaining popularity as effective alternatives in hemorrhoidectomy. Of these instruments, theoretically, the Ligasure™ vessel sealing system (Valleylab, Boulder, CO) is an ideal instrument for hemorrhoidectomy as its limited tissue injury may reduce wound sepsis, facilitate wound healing, and decrease post-operative pain. Several randomized trials have been performed to compare Ligasure™ hemorrhoidectomy with conventional hemorrhoidectomy<sup>3,6-12</sup>, and it is suggested that Ligasure™ hemorrhoidectomy is a safe and effective method to improve surgical outcomes. Likewise, we have demonstrated the Ligasure™ vessel sealing system is an ideal instrument for hemorrhoidectomy, as it enables short-term benefit of reduced intra-operative blood

loss, operative time, and post-operative pain, as well as earlier resumption of work or normal activity.<sup>6</sup> However, at three-month follow-up of these 42 patients treated by Ligasure<sup>TM</sup> hemorrhoidectomy with submucosal dissection, two patients (6.3 percent) developed symptomatic anal stenosis requiring anal dilation with St. Mark's dilators. Significant heat production generated by the larger surface area of jaws leading to a scalding effect may be responsible for this complication<sup>7,13</sup>.

Another novel vessel sealing system - Starion<sup>TM</sup> TLS<sup>2</sup> (Starion Instruments Corp., Saratoga, CA) uses the "tissue welding technology" to simultaneously fuse vessels and tissue structures closed, and is designed for a number of surgical applications including gastric bypass, Nissen fundoplication and hemorrhoidectomy procedures. Because tissue-welding technology uses minimum energy as a mode of operation at temperature less than 100°C, it thereby produces less heat and minimizes collateral tissue damage for improved patient outcomes. Up to the present, no information about Starion<sup>TM</sup> surgical devices for the management of prolapsed hemorrhoids has been reported.

In this randomized controlled study, we proposed Starion<sup>TM</sup> hemorrhoidectomy with submucosal dissection, to ensure the intact underlying sphincter and complete removal of hemorrhoid bundles. The operative outcomes between Starion<sup>TM</sup> and Ligasure<sup>TM</sup> hemorrhoidectomy are compared to determine the efficacy and safety

between the two vessel sealing devices.

## **PATIENTS AND METHODS**

This prospective study included 64 consecutive patients with symptomatic grade III or IV hemorrhoid operated on at the Department of Surgery, Kaohsiung Medical University Hospital between December 2005 and June 2006. This study has been approved by the institutional review board of Kaohsiung Medical University Hospital, and is not supported by any commercial company. Written informed consent was obtained from all of the subjects and/or guardians after full explanation of the procedure. The exclusion criteria included patients on anticoagulants, with hematological disorder, with concomitant anal disease, or a previous history of anorectal surgery. The recruited patients were randomly allocated to undergo either a Starion<sup>TM</sup> hemorrhoidectomy with submucosal dissection (32 patients) or Ligasure<sup>TM</sup> hemorrhoidectomy with submucosal dissection (32 patients). The submucosal dissection technique was used in both arms, and the only difference in the technique was the energy source.

The operative procedures for hemorrhoidectomy were standardized in each case by the same team of surgeons. Randomization was performed at the time of anesthesia by drawing sealed envelopes of receiving either Starion<sup>TM</sup> or Ligasure<sup>TM</sup> hemorrhoidectomy. The operation was performed under general or epidural anesthesia at the discretion of the anesthetist. The patients were placed in the prone jackknife

position and a Ferguson retractor was used to expose the hemorrhoids. Starion<sup>TM</sup> hemorrhoidectomy with submucosal dissection was performed initially with a skin incision at the junction of the hemorrhoid and the flat peri-anal skin by a scalpel, followed by the dissection of the hemorrhoid bundles off the underlying sphincter (Fig. 1). Starion<sup>TM</sup> handset was applied to the dissected hemorrhoids to the pedicles, taking care to avoid incorporating the underlying sphincter, and the device was activated to seal mucosal edges on each side (Fig. 2). Finally, the hemorrhoidal pedicle was sealed and divided by Starion<sup>TM</sup> handset (Fig. 3). Figure 4 depicted the result of complete hemorrhoidectomy. Again, Ligasure<sup>TM</sup> hemorrhoidectomy was performed according to our previous description.<sup>6</sup> In both Starion<sup>TM</sup> and Ligasure<sup>TM</sup> groups, hemostasis was ensured and a haemostatic sponge was inserted into the anal canal.

For post-operative pain relief, oral acetaminophen (500 mg) was prescribed for all of the patients at the dose of one tablet, four times a day. Additional parenteral analgesics would be administered when patients complained of pain intolerance. The independent assessor evaluated the pain score by means of the visual analog score (0-10) at 24 hours post-operatively. The patient demographics, duration of symptoms, operative details, operating time, intra-operative blood loss, and hospital stay were documented. Follow-up was performed at one, two, four, six, eight, and twelve weeks

to detect post-operative complications and time off work or normal activity in all 64 patients by an independent blind assessor.

Initial power calculation suggested that a minimum of 30 patients would be required to achieve statistical significance in postoperative pain with a power of 80 percent at the 5 percent significance level. All of the data were analyzed using the Statistical Package for the Social Sciences Version 11.5 software (SPSS Inc., Chicago, IL). Results were expressed as mean  $\pm$  standard deviation. The two-sided Pearson  $\chi^2$  test and the student t-test were used to compare the variables between the two groups. A *P* value less than 0.05 was considered statistically significant.

## RESULTS

The characteristics of 64 symptomatic grade III and IV hemorrhoid patients are summarized in Table 1. There were 15 males and 17 females treated by Starion™ hemorrhoidectomy, and 16 males and 16 females treated by Ligasure™ hemorrhoidectomy ( $P = 0.802$ ). The mean age was  $46.9 \pm 2.4$  and  $47.8 \pm 2.3$  years for the Starion™ and Ligasure™ hemorrhoidectomies respectively ( $P = 0.638$ ). In addition, there was no statistical difference in the duration of symptoms ( $P = 0.857$ ), and the severity of hemorrhoids ( $P = 0.777$ ) between the two groups.

Table 2 shows the operative details and outcomes between the two groups. The numbers of hemorrhoids resected, the mean operating time, the mean intra-operative blood loss, the hospital stay, and the return to normal activity were not significantly different between the two groups (all  $P > 0.05$ ). However, lower pain scores ( $P = 0.032$ ) and numbers of parenteral analgesic injections ( $P < 0.001$ ) during admission were observed in the Starion™ hemorrhoidectomy than in the Ligasure™ hemorrhoidectomy.

As regards early post-operative complications, two (6.3 percent), one (3.1 percent), and one (3.1 percent) patient developed constipation, urine retention, and hemorrhage respectively, in the Starion™ hemorrhoidectomy, while two (6.3 percent), two (6.3 percent), and one (3.1 percent) patient developed the corresponding

complications in the Ligasure™ hemorrhoidectomy (all  $P > 0.05$ ). The incidence of post-operative hemorrhage was the same in each group (3.1 percent), which happened to one patient with underlying chronic renal failure receiving hemodialysis, and to another one with underlying liver cirrhosis. Both patients hemorrhaged 2 weeks after surgery.

The incidence of delayed post-operative complications, such as poor wound healing (not completely healed at 4 weeks postoperatively) and symptomatic anal stenosis (improvement of anal stenosis by cathartics, anal dilation or surgical intervention is mandatory), did not show any significant difference between the two groups (both  $P > 0.05$ ). Complete wound healing was achieved in three patients who were found to have poor wound healing at the four-week follow-up, after six weeks in both groups. Unfortunately, two patients (6.25 percent) developed subsequent anal stenosis requiring anal dilation at the outpatient department in the Ligasure™ hemorrhoidectomy; whereas no symptomatic anal stenotic patients were found in the Starion™ hemorrhoidectomy at the three-month follow-up.

Finally, the return to work or normal activity was not considerably different between Starion™ hemorrhoidectomy ( $7.4 \pm 0.3$  days) and Ligasure™ hemorrhoidectomy ( $7.6 \pm 0.3$  days) ( $P = 0.787$ ).

## DISCUSSION

Hemorrhoidectomy has been well established as the most effective and definitive treatment of choice for prolapsed hemorrhoids. However, although it is considered a minor procedure, the post-operative course is protracted, and the post-operative complications are not negligible. The resulting pain-related complications after conventional hemorrhoidectomy are often the major factors that prolong hospital stay and delayed recovery. Recently various new treatment modalities have been developed with the aim of overcoming post-operative pain, such as Harmonic scalpel™, Ligasure™, and Starion™ sealing devices. The Starion™ Thermal Welding system, a new type of surgical instrument, has been developed which uses thermal energy and pressure to simultaneously coagulate, as well as divide blood vessels and other tissue. The device offers the surgeon an alternative to existing technologies including the bipolar and ultrasonic coagulating and sealing instruments in the management of prolapsed hemorrhoids.

Recently we have demonstrated that Ligasure™ hemorrhoidectomy with submucosal dissection is a fast, safe, and excellent surgical modality for achieving bloodless dissection of the hemorrhoidal cushions with a limited complication rate.<sup>6</sup> Compared to Ferguson hemorrhoidectomy, the Ligasure™ method of dissection prominently reduces post-operative pain and numbers of parenteral analgesic

injections, which illustrates that the minimal collateral thermal spread, limited tissue charring and absence of sutures might lead to less post-operative pain. Consequently, the Ligasure™ system would facilitate earlier hospital discharge and return to normal work or activities.<sup>8-13</sup> In addition, Harmonic Scalpel™ (UltraCision® 10-mm Coagulating Shears, Ethicon Endo-Surgery, Inc., Cincinnati, OH) is also a new tissue sealing instrument that makes use of a different energy source, of which has been reported that Harmonic Scalpel™ is superior to bipolar scissors because of less postoperative pain.<sup>14</sup> Kwok *et al.* have also demonstrated that Ligasure™ hemorrhoidectomy reduces the postoperative pain and operating time compared to the Harmonic scalpel hemorrhoidectomy.<sup>15</sup>

In the current investigation, we have demonstrated that Starion™ hemorrhoidectomy has the short-term benefits of even less post-operative pain and parenteral analgesic requirement than Ligasure™ hemorrhoidectomy. However, the pain during the first 24 hours after surgery is often the most critical point, because it is during that time period that severe pain may exacerbate urinary retention, especially in male patients. The same advantages of shorter operating time and little blood loss were detected in both methods. In both methods, with the concomitant use of submucosal dissection, the hemorrhoidal plexuses can be readily elevated off the underlying anal sphincter, allowing safe application of the diathermy forceps and no

clinical sphincter injury. Consequently, with the preservation of sphincters, no flatus or stool incontinence was noted in both groups. By Ligasure<sup>TM</sup> hemorrhoidectomy symptomatic anal stenosis was noted, which is similar to observation from Ramcharan and Hunt<sup>7</sup>, whereas no anal stenosis was discovered by Starion<sup>TM</sup> hemorrhoidectomy. This may be entirely due to minimal thermal spread to collateral tissue by Starion's thermal welding technology, leading to no charring of tissue.

The early and delayed complication rates of both methods are similar, and no serious complications were observed. After conservative management, all of the patients recovered uneventfully without subsequent surgical intervention. One of 32 patients (3.1 percent) in each group developed post-operative hemorrhage: one patient with an underlying disease of uremia, and the other with an underlying disease of liver cirrhosis. Poor wound healing with the coexisting medical illness may be the major reason for this complication. Therefore, for treating these patients, a longer close-up observation period is highly recommended.

As usual, stapled hemorrhoidectomy is suggested to be used primarily in patients with third-degree hemorrhoids. Indeed, circular stapling devices are unsatisfactory in dealing with external hemorrhoidal components and skin tags.<sup>16</sup> In practice, Ligasure<sup>TM</sup> hemorrhoidectomy is now used increasingly for more severe hemorrhoidal diseases, such as grade IV piles, rather than considering a more radical

operation.<sup>17,18</sup> Alternatively, from our preliminary results, using Starion™ hemorrhoidectomy with submucosal dissection, concomitant external hemorrhoid components and skin tags can be dealt with, and the complete removal of the hemorrhoid tissues can be ensured while keeping the underlying sphincter intact. No symptomatic anal stenosis at a three-month follow-up, despite no statically significant difference, is a very attractive reason for surgeons to choose Starion™ devices among various tissue sealing instruments.

In conclusion, both methods were found to be surprisingly equivalent in all major aspects analyzed. Starion™ hemorrhoidectomy with submucosal dissection can provide a safe, fast, bloodless, and low-morbidity surgical alternative to hemorrhoidal surgery. However, long-term follow-up with a larger series is warranted for its definite role in treating this disease.

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### FIGURE LEGENDS

**Figure 1.** Dissection of the hemorrhoidal complex off the underlying sphincters using a mosquito clamp.

**Figure 2.** Starion™ handset was applied beneath dissected hemorrhoids.

**Figure 3.** Complete excision and sealing of the hemorrhoidal pedicle by Starion™ device.

**Figure 4.** Completed sutureless hemorrhoidectomy.