



GENERAL
OPEN SURGERY

CLINICAL EVIDENCE FOLDER TST – TISSUE-SELECTING THERAPY STAPLER

SINGLE USE INTERNAL STAPLER FOR
HEMORRHOIDOPEXY AND RECTAL PROPLASE.

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RATIONALE

Circular stapled hemorrhoidopexy has been widely adopted in recent years, because of its minimally invasive nature, combined with a good functional outcome^{1,2}. Circular stapled hemorrhoidopexy (CSH), is characterized by a circular incision of the rectal mucosa, and has been shown to be an effective technique for the treatment of prolapsing hemorrhoids³.

However postoperative complications such as anal stricture, defecatory dysfunction and retrovaginal fistula have been observed. The incidence of postoperative urgency and anal stricture/stenosis were reported to be as high as 40% and up to 22%, respectively^{4,5}. Removal of large areas of the anoderm and hemorrhoidal rectal mucosa, without the sparing of adequate mucocutaneous bridges, can lead to scarring and a progressive stricture^{6,7}. In addition a non-compliant anastomosis might significantly contribute to defecation difficulty in patients⁵. These complications, might be related to the presence of too many staples in the sensitive lower rectum and the nature of the staple line (full circumference)⁵. Therefore, refinement of the of stapler used and a technical modification of the procedure, have the potential to reduce the risk associated with CSH.

Most of the prolapsing hemorrhoids are not circumferential but segmental^{8,9}. Hemorrhoids are most commonly localized in the right anterior, right posterior or /and left lateral position. Therefore, a segmental/partial stapled hemorrhoidopexy has been proposed as a new technique to overcome the limitations and weaknesses of CSH⁵. The partial stapled hemorrhoidopexy is characterized by the use of a dilator anoscope obiturator unit, with one, two or three windows, with which the rectal mucosa above the prolapsing hemorrhoids is partially resected to spare the mucosal bridges between the mucosectomies. Due to the removal of the target tissue and preservation of the normal tissue, partial or segmental stapled hemorrhoidopexy is also called Tissue Selecting Technique (TST). Li et al.⁵ could show that this technique is safe and effective for the treatment of prolapsing hemorrhoids, without increasing the risk of anal stricture or rectovaginal fistula^{5,10}. The TST stapler was introduced in 2008 and according to Lin et al, almost 60.000 TST procedures have been performed so far¹¹.

RATIONALE

Touchstone, Suzhou, China has developed a specialized TST-Kit consisting of a stapler; a single window, a bi-window and a tri-window anoscope and an obturator that can be inserted into the anoscope. The TST deploys 2 staggered rows of titanium staples through a device 33 mm in diameter. The open staple leg length is 3.8 mm and the closed staple height 1.5 mm. The specially designed anoscope includes a hollow body with 2 or 3 apertures that are closed at the distal end with a small opening located at the top. The anoscope is adjusted until its window is aligned with the mucosa above the prolapsing hemorrhoids. If the hemorrhoids are present in the right anterior, right posterior and left lateral position a tri-window anoscope is used. A bi-window anoscope is used when the hemorrhoids are found in two locations.

Giaccaglia et al. compared different circular staplers which are available in the American, European and Asian markets for hemorrhoidal surgery¹². They compared 3 circular single use staplers from different manufacturers, all with a diameter of 33 mm containing two rows of staples, incorporating between 28 and 32 staples each, using pig intestine. In total 50 end-to-end anastomoses were performed with each brand of stapler. To measure the burst pressure achieved by each device, each end of a 30 cm length of intestine was sealed and saline solution was injected. The pressure which lead to a saline leak from the anastomosis was recorded. To measure tensile strength, two layers of a special paper (Tyvek) were stapled together. Each end of the stapled paper was pulled by a machine and the tensile force that could open the "paper anastomosis" was documented. The results showed a comparable anastomotic pressure but a significantly different tensile strength for the staplers which were tested. The highest tensile strength observed was for the TST36 manufactured by Touchstone, Suzhou, China. The authors stated that this result could be due to the different technical characteristics of the tested staplers. They also considered that anastomotic healing in vivo is due to different factors such anastomotic tension, blood tissue supply, tissue approximation and patient clinical conditions and not simply a matter of anastomotic tightness¹².

The available clinical evidence of the single use Tissue – Selecting Technique Stapler (TST33 and TST36) is provided in this folder.

CLINICAL EVIDENCE

CLINICAL EVIDENCE SUMMARY

Naldini et al.¹³ aimed to evaluate the safety, effectiveness and feasibility of a new dedicated device applied for transanal stapled interventions.

The study was designed as a multi-centric, prospective cohort study performed in Italy and China. Patients affected by a III-IV grade hemorrhoidal prolaps or an obstructive defecation syndrome (ODS) with the need of a stapled transanal resection using the TST Stapler of Touchstone were included. The following parameters were analysed: operation time, volume of the resected specimen, length of hospital stay, pain, patient satisfaction and postoperative complications. Patients were examined until 30 days after surgery.

All interventions were performed by experienced surgeons. In total 160 patients were enrolled during a five months recruitment phase in eight participating centers (six centers in Italy and two centres in China). Eighty-four patients were operated due to a hemorrhoidal prolaps and 76 patients suffered of an obstructive defecation syndrome. Average length of hospital stay was 2.2 days. The procedure took 25 min. ranging from 13 to 60 minutes. A perioperative pain score of 1.8 was recorded in the total population which decreased to 0.5 after 30 days after surgery. This trend was found independent of the underlying disease. Patients affected by an obstructive defecation disease reported a significant higher Cleveland Clinic Constipation Score 30 days postoperatively compared to perioperatively; $p < 0.001$. An improvement was also seen regarding the Cleveland Clinic Incontinence Score but the difference was not significant. Most of the patients rated their satisfaction as excellent or good in both subgroups (hemorrhoidal prolaps and ODS). Regarding the feasibility of the device, in all cases the stapler could be used only in seven patients it was reported that the device was difficult to introduce. The following postoperative complications occurred: mild hematoma/edema (4.6%) with no need for treatment; in seven patients postoperative bleeding was observed which was surgically treated in two patients. Postoperative urinary retention was seen in six patients (3.7%) and urgency was reported in 14 cases (8.7%) after 15 days and in one patient 30 days after surgery. No other continence disturbances or major complications occurred within the present study.

Authors concluded that the new TST stapler is a safe and effective device to treat hemorrhoidal prolaps or obstructive defecation syndrome; the open direct view which is provided using this device have the potential to reduce the complication rate, to minimize the recurrence rate and to evolve stapled transanal resections.

The goal of Lin et al.¹¹ was to investigate a modified technique to treat prolapsing hemorrhoids to decrease the anal stricture rate as well as the rectovaginal fistula rate. Within this investigation the TST kit of Touchstone, Suzhou, China was applied to perform segmental stapled hemorrhoidopexy.

A non randomized design was chosen and the Tissue Selecting Technique (TST) was compared to Circular Stapled Technique (CSH). Preliminary results looked very promising because the recurrence rate could be decreased in comparison to the circulated stapled hemorrhoidopexy (2.9% vs. 5.3%). In addition, TST led to less pain, urgency was rarely observed and no anal stricture developed. In a next step the authors planned the conduction of a randomized, multicentric controlled trial comparing TST versus CSH to confirm these initial results.

As mentioned above the partial stapled hemorrhoidopexy was compared to the circular stapled hemorrhoidopexy by Lin et al.⁵ regarding the clinical outcome. The population enrolled underwent the treatment of III-IV grade hemorrhoids. The patients were allocated to two treatment groups in a non-randomized manner. Primary objective of the study was the recurrence rate 2 years postoperatively. Further analysed parameters were postoperative pain, urgency, anal incontinence, anal stenosis, patient satisfaction and costs. Examinations were performed by blinded observers at 1 and 4 weeks, at 2 and 6 months, at 1 and 2 years after surgery.

In total 72 patients were recruited, of these 34 received a partial stapled hemorrhoidopexy (PSH) whereas in 38 patients the circular stapled hemorrhoidopexy (CSH) was applied. PSH was performed using a tri-windows anoscope and a stapler of Touchstone, Suzhou, China. Regarding the demographic both groups were comparable. The time to perform the stapling was similar in both groups. Significant lower pain scores were observed during first defecation in the PSH group, $p = 0.001$ and significant less patients in the PSH group experienced an urgency at 12 hours, one day and 7 days after surgery. In each group four patients developed a hemorrhage without the need for surgical treatment. No anal incontinence were seen in the PSH group, whereas three patients had an anal incontinence in the CSH group (7.9%). An anal stenosis occurred in one patient receiving the CSH treatment whereas no stenosis developed in the partial stapled hemorrhoidopexy. The costs were comparable in both groups. The 2 years follow-up indicated a recurrence rate of 2.9% for PSH and 5.3% for CSH; $p = 1.0$. The patients rated their overall satisfaction as excellent meaning that no symptoms were present (94.1% in the PSH group and 84.2% in CSH group).

In summary partial stapled hemorrhoidopexy is as effective as the circular stapled hemorrhoidopexy for the management of III-IV grade prolapsing hemorrhoids with a slight trend to a lower recurrence rate. PSH seems to be beneficial regarding anal incontinence and anal stenosis compared to CSH, because of its minimal invasive character. A large randomized controlled, multi-centric trial is needed to further clarify the findings of this study.

The first study to assess the safety of a partial stapled hemorrhoidopexy was done by Lin et al.¹¹ in 2011. Recruitment was performed in 2010. Patients with one hemorrhoid were treated using an onewindow anoscope, if two hemorrhoids were present a bi-windows anoscope was applied and three hemorrhoids or circumferential hemorrhoids were operated using a tri-windows anoscope. Devices were manufactured by Touchstone, Suzhou, China. Safety and efficacy parameter were evaluated during a one year follow-up.

CLINICAL EVIDENCE

In total 44 patients were included, of these 2 patients received a treatment with a onewindow anoscope, in 6 patients a bi-windows anoscope was used and in the residual patients a tri-windows anoscope was applied. Hemorrhoids were graded as type III in 35 patients and as grade IV in nine patients. Time to perform the surgery took about 17 minutes in all groups. The volume of blood loss was comparable in all three groups; $p = 0.332$. No intra-operative complications occurred. Also the pain score at first defecation and after different other time points were similar in all three groups without a significant difference. Rate of fecal urgency was 9.1% in the current study and was only seen in the tri-windows anoscope group. Neither an anal incontinence nor an anal stenosis developed in the population. Only one hemorrhage in the tri-windows anoscope treatment group was observed without the need for surgery. Time to return to normal activities and treatment costs were comparable in the three different treatment groups. Authors reported an one year recurrence of 2.3%. Only one patient in the tri-windows anoscope group developed a prolapse. No other complication occurred until 1 year postoperatively and all patients were very satisfied with the applied treatment.

In conclusion, all types of window anoscopes are effective in the management of prolapsing hemorrhoids. This is the first series of patients whose have been treated using this new approach. Further studies are needed to further confirm the results of this promising new technique for hemorrhoidopexy.

Table 1: Publications using TST Stapler

Author	Year	Number of patients	Length of operation [min.]	Pain [VAS]	Urgency [n]	Anal stenosis [n]	Anal incontinence [n]	Costs [EUR]	Recurrence [n]
Naldini et al. ¹³	2014	N = 160	25[13-60]	6h: 1.8 24h: 2.1 15d: 1.8 30d: 0.5	15d: 14 (8.7%) 30d: 1 (0.5%)	NA	NA	NA	NA
Lin et al. ⁵	2012	N = 72		p-value	p-value				
		PSH: 35 CSH: 38	PSH: 17[8-25] CSH: 16[8-25]	12h: 0.286 1d: 0.693 2d: 0.106 3d: 0.570 7d: 0.145 FD: 0.001	12h: 0.025 1d: 0.019 2d: 0.320 3d: 0.173 7d: 0.043	PSH: 0 CSH: 1 2.6%	PSH: 0 CSH: 3 7.9%	PSH: 1.299±147 CSH: 1.311±131	PSH: 1 CSH: 2 (2.3% vs. 5.3%)
Lin et al. ¹⁰	2011	N = 44							
		OW: 2 BW: 6 TW: 36	OW: 17.5±3.5 BW: 17.3±3.0 TW: 17.8±3.5	T: 3[14]12h T: 2[1-4]1d T: 3[2-6]2d T: 1[0-3]3d T: 1[0-2]7d T: 2[2-4]FD	OW: 0 BW: 0 TW: 4 T: 4/44 9.1%	OW: 0 BW: 0 TW: 0	OW: 0 BW: 0 TW: 0	OW: 11.956±213 BW: 11.410±761 TW: 11.174±1.473	OW: 0 BW: 0 TW: 1 T: 1/44 (2.3%)

Legend: OW: onewindow anoscope, BW: bi-windows anoscope, TW: tri-windows anoscope, T: total, FD: first defecation, NA: not applicable

KEY MESSAGES

- The TST stapler is specially designed to treat segmental prolapsing hemorrhoids¹¹.
- TST has the potential to overcome the limitations and the weakness seen with circular stapled hemorrhoidopexy¹¹.
- TST is easy to perform, it shortens operative time, reduces bleeding and can improve the consistency of surgical outcomes, compared to traditional non-stapled hemorrhoidectomy¹¹.
- The use of the TST stapler preserves the normal rectal wall between the mucosectomies, which has the potential to maintain normal rectal compliance¹¹.
- The TST stapler spares the tissue between mucosectomies and therefore protects tissue adjacent to the rectovaginal septum in women, resulting in a reduced risk of rectovaginal fistula and anal stricture¹¹.
- Anastomoses created using the TST stapler have comparable anastomotic pressure resistance to other circular staplers, but have significantly higher tensile strength¹².
- The TST stapler is a safe and effective device, for partial stapled hemorrhoidopexy, without an increase in risk for anal strictures or rectovaginal fistula⁵.
- In comparison to circular stapled hemorrhoidopexy (CSH) the tissue selecting technique (TST) is associated with⁵:
 - less postoperative pain
 - fewer episodes of urgency
 - no postoperative anal incontinence
 - no anal stricture
 - lower recurrence rate
- TST stapler is a safe and effective device to treat hemorrhoidal prolapse or obstructive defecation syndrome; the open direct view which is provided using this device has the potential to reduce complication rates, to minimize the recurrence rate and to evolve stapled transanal resections¹³.
- Single use TST33 stapler is indicated for the treatment of Grade II-IV hemorrhoids.
- Single use TST36 stapler is indicated for the treatment of rectocele, rectal prolapse and grade III-IV hemorrhoids.

ABSTRACTS

Int J Colorectal Dis. 2014 May;29(5):623-9.

Tailored prolapse surgery for the treatment of hemorrhoids and obstructed defecation syndrome with a new dedicated device: TST STARR Plus.

Naldini G, Martellucci J, Rea R, Lucchini S, Schiano di Visconte M, Caviglia A, Menconi C, Ren D, He P, Mascagni D.

OBJECTIVE: The aim of the study was to assess the safety, efficacy and feasibility of stapled transanal procedures performed by a new dedicated device, TST STARR Plus, for tailored transanal stapled surgery.

METHODS: All the consecutive patients admitted to eight referral centres affected by prolapses with III-IV degrees hemorrhoids or obstructed defecation syndrome (ODS) with rectocele and /or rectal intussusception that underwent stapled transanal resection with TST STARR plus were included in the present study. Haemostatic stitches for bleeding of the suture line, specimen volume, operative time, hospital stay and perioperative complications were recorded.

RESULTS: From 1 November 2012 to 31 March 2013, 160 consecutive patients (96 females) were enrolled in the study. In 94 patients, the prolapse was over the half of the circular anal dilator (CAD). The mean duration of the procedure was 25 min. The mean resected volume of the specimen was 13.3 cm³, the mean hospital stay was 2.2 days. In 88 patients (55%), additional stitches on the suture line were needed (mean 2.1). Suture line dehiscence was reported in four cases, with intraoperative reinforcement. Bleeding was reported in seven patients (5%). Urgency after 30 days was reported in one patient. No major complication occurred.

CONCLUSIONS: The new device seems to be safe and effective for a tailored approach to anorectal prolapse due to hemorrhoids or obstructed defecation.

Dis Colon Rectum. 2013 Nov;56(11):1320-4.

The tissue-selecting technique: segmental stapled hemorrhoidopexy.

Lin HC, Lian L, Xie SK, Peng H, Tai JD, Ren DL.

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Department of Coloproctology, the Sixth Affiliated Hospital of Sun Yat-sen University (Gastrointestinal & Anal Hospital), Guangzhou, People's Republic of China 2 Department of Colorectal Surgery, the First Affiliated Hospital of Jilin University, Changchun, People's Republic of China.

We describe a technique for the management of prolapsing hemorrhoids, with the aim to minimize the risk of anal stricture and rectovaginal fistula and to reduce the impact of the stapling technique on rectal compliance. This modified procedure was successfully applied in China, and preliminary data showed promising outcomes (see Video, Supplemental Digital Content 1, <http://links.lww.com/DCR/A117>).

Tech Coloproctol. 2012 Oct;16(5):337-43.

Partial stapled hemorrhoidopexy versus circular stapled hemorrhoidopexy for grade III-IV prolapsing hemorrhoids: a two-year prospective controlled study.

Lin HC, Ren DL, He QL, Peng H, Xie SK, Su D, Wang XX.

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Comment in Tech Coloproctol. 2012 Oct;16(5):345; discussion 347-8.

BACKGROUND: Circular stapled hemorrhoidopexy (CSH) is an effective technique for treating prolapsing hemorrhoids; but urgency and anal stenosis are common postoperative complications. The aim of this study was to assess the efficacy and postoperative outcomes of partial stapled hemorrhoidopexy (PSH), compared with CSH.

METHODS: Seventy-two consecutive patients with grade III and IV hemorrhoids who met the inclusion/exclusion criteria were divided in a non-randomized manner to undergo either PSH (N = 34) or CSH (N = 38). Intraoperative and postoperative parameters in both groups were collected and compared.

RESULTS: The postoperative visual analog score for pain at first defecation was significantly lower in the PSH group than that in the CSH group ($p = 0.001$). Fewer patients in the PSH group experienced postoperative urgency, compared with those in the CSH group at 12 h, 1 day, and 7 days after surgery ($p = 0.025$, $p = 0.019$, and $p = 0.043$, respectively). Gas incontinence occurred in 3 patients (7.9%) in the CSH group, but in none of patients in the PSH group ($p = 0.242$). Postoperative anal stenosis developed in one patient (2.6%) in the CSH group, but in none of the patients in the PSH group ($p = 1.0$). The 2-year recurrence rate was 2.9 and 5.3%, respectively, in the PSH and CSH groups ($p = 1.0$).

ABSTRACTS

CONCLUSIONS: The 2-year recurrence rate is similar in patients with grade III–IV hemorrhoids treated with PSH or CSH. However, PSH is associated with less postoperative pain, fewer episodes of urgency, and no anal incontinence or anal stenosis.

Surg Today. 2012 Sep;42(9):868–75.

Partial stapled hemorrhoidopexy: a minimally invasive technique for hemorrhoids.

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PURPOSE: This study was designed to assess the safety, efficacy, and postoperative outcomes of partial stapled hemorrhoidopexy (PSH).

METHODS: A prospective study was conducted between February and March 2010. PSH was performed with single-window anoscopes for single isolated hemorrhoids, bi-window anoscopes for two isolated hemorrhoids, and tri-window anoscopes for three isolated hemorrhoids or circumferential hemorrhoids. The data pertaining to demographics, preoperative characteristics and postoperative outcomes were collected and analyzed.

RESULTS: Forty-four eligible patients underwent PSH. Single-window anoscopes were used in 2 patients, and bi- and tri-window anoscopes in 6 and 36 patients. The blood loss in patients with single-window, bi-window, and tri-window anoscopes was 6.0 ml (range 5.0–7.0 ml), 5.0 ml (range 5.0–6.5 ml), and 5.0 ml (4.5–14.5 ml) ($p = 0.332$). The mean postoperative visual analog scale score for pain was 3 (range, 1–4), 2 (range 1–4), 3 (range 2–6), 1 (range 0–3), 1 (range 0–2) and 2 (range 2–4) at 12 h, days 1, 2, 3, and 7, and at first defecation. The rate of urgency was 9.1%. No patients developed anal incontinence or stenosis. The 1-year recurrence rate of prolapsing hemorrhoids was 2.3%.

CONCLUSIONS: Partial stapled hemorrhoidopexy appears to be a safe and effective technique for grade III–IV hemorrhoids. Encouragingly, PSH is associated with mild postoperative pain, few urgency episodes, and no stenosis or anal incontinence.

J Mech Behav Biomed Mater. 2016 Jan;53:295–300.

Different characteristics of circular staplers make the difference in anastomotic tensile strength.

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Anastomotic leak after gastrointestinal surgery is a severe complication associated with relevant short and long-term sequelae. Most of the anastomoses are currently performed with a surgical stapler that is required to have appropriate characteristics in order to guarantee good performances. The aim of our study was to evaluate, *ex vivo*, pressure resistance and tensile strength of anastomosis performed with different circular staplers available in the market. We studied 7 circular staplers of 3 different companies, 3 of them used for gastrointestinal anastomosis and 4 staplers for hemorrhoidal prolapse excision. A total of 350 anastomoses, 50 for each of the 7 staplers, were performed using healthy pig fresh intestine, then injected saline solution and recorded the leaking pressure. There were no statistically significant differences between the mean pressure necessary to induce an anastomotic leak in the various instruments ($p > 0.05$). For studying tensile strength, we performed a total of 350 anastomoses with 7 different circular staplers on a special strong paper (Tyvek), and then recorded the maximal tensile force that could open the anastomosis. There were statistically significant differences between one brand stapler vs other 2 companies staplers about the strength necessary to open the staple line ($p < 0.05$). In conclusion, we demonstrated that different circular staplers of three companies available in the

market give comparable anastomotic pressure resistance but different tensile strengths. This is probably due to different technical characteristics.

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NOTES

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