

# A New Rigid Fistulectomy Set for Minimally Invasive “Core-Out” Excision of High Anal Fistulas

Siamak Najarian, Meysam Esmaeili, Mohsen Towliat Kashani

**Abstract**—In this article, we propose a new surgical device for circumferentially excision of high anal fistulas in a minimally invasive manner. The new apparatus works on the basis of axially rotating and moving a tubular blade along a fistulous tract straightened using a rigid straight guidewire. As the blade moves along the tract, its sharp circular cutting edge circumferentially separates approximately 2.25 mm thickness of tract encircling the rigid guidewire. We used the new set to excise two anal fistulas in a 62-year-old male patient, an extrasphincteric type and a long tract with no internal opening. With regard to the results of this test, the new device can be considered as a sphincter preserving mechanism for treatment of high anal fistulas. Consequently, a major reduction in the risk of fecal incontinence, recurrence rate, convalescence period and patient morbidity may be achieved using the new device for treatment of fistula-in-ano.

**Keywords**—Fecal Incontinence, Fistulectomy, High Anal Fistula, Minimally Invasive.

## I. INTRODUCTION

THE goals in the treatment of fistula-in-ano are 1) to eliminate the septic foci and any associated epithelialized tracts, and 2) to do so with the least amount of functional derangement [1]-[4]. Simple low fistulas may be treated by laying open or fistulotomy with a minimal risk of fecal continence [2]. Surgical management of high anal fistula is still a serious problem. Many treatment modalities such as staged fistulotomy, core-out, seton applications, mucosal advancement flaps, re-routing of fistula tract, fibrin glue have all been alternatively used in the treatment of complex and high anal fistulas with various success rates depending on the experience of the surgeon and the type of fistula [5].

Core fistulectomy with endorectal advancement flap repair is reported as a safe and effective technique for treatment of high anal fistulas with good results in terms of recurrence and continence [6], [7]. Developing a new device to do core fistulectomy as a minimally invasive surgery (MIS) enhances

The authors thank the Iran National Science Foundation (INSF) for providing the financial support for this project.

S. Najarian is with the Faculty of Biomedical Engineering, Amirkabir University of Technology, Tehran, Iran (corresponding author phone: +982164542378; fax: +982166468186; e-mail: najarian@aut.ac.ir).

M. Esmaeili is with the Faculty of Biomedical Engineering, Amirkabir University of Technology, Tehran, Iran (e-mail: m.esmaeili@aut.ac.ir).

M. Towliat Kashani is with the Department of Surgery, Baqiyatallah University of Medical Sciences, Tehran, Iran (e-mail: m.towliat@bmsu.ac.ir).

the advantages of this useful technique. MIS is now being widely used as one of the most preferred choices for various types of operations [8], [9]. Review of the relevant literature revealed rigid and flexible devices designed for minimally invasive fistulectomy of fistula-in-ano [2], [5], [10], [11]. Although, our fabricated apparatus is similar to the previous rigid device in principle of work, they have different designs and structures, and our design has proved its practicability under a clinical test.

In this article, the basic structure of our new fistulectomy set and its principle of work are described and minimally invasive removal of two anal fistulas by means of the new set is reported.

## II. MATERIALS AND METHODS

### A. New Fistulectomy Set

Fig. 1 shows the new fistulectomy set components and connections. The new apparatus consists of a rigid bar with a length of 19 cm and a diameter of 4.5 mm, a special rigid guidewire with a total length of 16.5 cm and a diameter of 2.5 mm, a cylindrical stabilizer with a length of 2 cm and a diameter of 6.95 mm, a tubular blade with a length of 18 cm and an internal diameter of 7 mm and an external diameter of 8 mm, two handles with 4.55-milimeter-diameter central holes, and a connecting bolt.

As shown in Fig. 1, the rear end of the rigid bar is connected to the aft handle by the connecting bolt and its front end is coaxially fixed to the rigid guidewire by means of the cylindrical stabilizer. This bar plays the role of a straight rail for conducting the blade in correct cutting path and is the foundation of the device. The front handle which is fixed to the tubular blade, can slide along the bar and rotate around its longitudinal axis. The set of bar, stabilizer, and front handle keeps the blade coaxial with the guidewire. So, the radial space between guidewire and internal surface of the tubular blade remains constant while the blade slides along the rigid bar. Introducing the rigid guidewire through the fistula straightens the lumen then by rotating the blade and sliding it along the guidewire towards the internal opening of tract, the fistula is circumferentially separated by the blade circular cutting edge. With regard to 2.5-milimeter-diameter of the guidewire and the 7-milimeter-diameter of the blade circular cutting edge, the radial thickness of the annularly separated tissue is 2.25 mm.

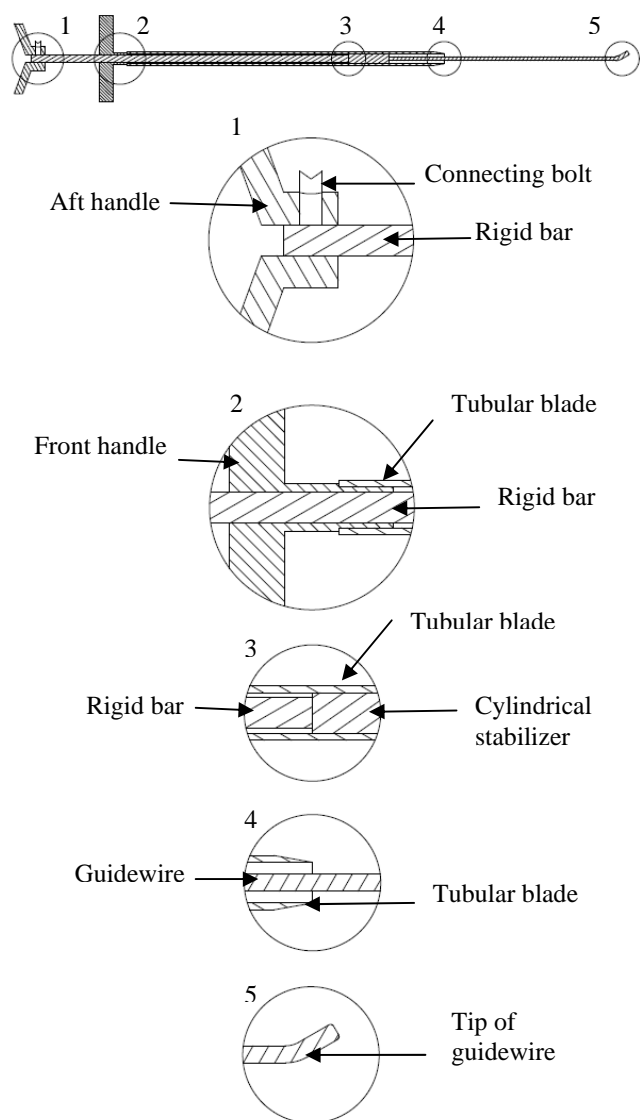


Fig. 1. Structure of the new fistulectomy set

This thickness is sufficient for minimally invasive fistulectomy of anal fistulas as stated in [5].

As shown in Fig. 1, the tip of the guidewire has a bend angle of 30 degrees relative to its axis. Rotating the guidewire in the fistulous tract helps its inclined tip align with the direction of the tract so facilitates its forward motion in the lumen and reduces the risk of damage to surrounding healthy tissues.

At the end of the separation procedure, the front handle comes in contact with the stabilizer and its forward motion stops. This design prevents the abruptly exit of blade from the internal orifice of the fistulectomy lumen and keeps the blade cutting edge at the back of the guidewire tip in all conditions. So, the risk of injury to the rectum wall caused by the sudden impact of the blade cutting edge is minimized.

Selecting a suitable material for fabrication of the new apparatus components was an important issue. The material

should be biocompatible with the ability of easily being sterilized and suitable for creating sharp cutting edges at the blade forward end. Regarding the above criteria, all device components were fabricated of stainless steel 316.

### B. Surgical Technique

Fistulography was performed to delineate the shape of the primary fistulous tracts and/or any secondary tracts and to determine the location of the internal and external openings. After identifying the internal orifices, the following 4 steps as shown in Fig. 2 were performed sequentially to excise fistulas whereas the patient was in lithotomy position.

Step 1. The rigid guidewire was introduced through the external opening of the tract and progressed toward the internal opening. This step is shown in Fig. 2 (a). Rotating the guidewire facilitates its forward motion along the tract and minimizes the risk of damage to surrounding tissues. Inserting the guidewire in the tract changes it into a straight lumen and prepares it for separation by the straight tubular blade.

Step 2. The tip of the wire protruding from the internal orifice was fixed in the rectum by a suitable gripper. This step is shown in Fig. 2 (b). Fixing the tip of the guidewire prevents its free motion in rectum and minimizes the risk of damage to rectum wall.

Step 3. By keeping the aft handle in its position and gently rotating and sliding the front handle along the rigid bar, the blade circular cutting edge circumferentially separated 2.25 mm thickness of the tract. This step is shown in Fig. 2 (c). This step should be continued until the blade cutting edge reaches the internal opening of the tract showing separation of the whole tract from the peripheral tissues. This separated tissue accommodates in the cylindrical space between tubular blade and straight guidewire after passing through the circular cutting edge of blade.

Step 4. Removing the device by gently rotating the handles and pulling them backward. After removing the device a lumen with a small diameter approximately equal to 8 mm remained in patient body. This step is shown in Fig. 2 (d).

### C. Patients

To show the practicability of our design, we used the new fistulectomy set for excising peri-anal fistulas in a 62-year-old male patient. The patient had 2 anal fistula tracts, an extrasphincteric type and another tract with no internal opening, each of them with a length about 8 cm.

## III. RESULTS

Using the new fistulectomy set, we could excise approximately 2.25 mm thickness of two anal fistulas with no need to create any extra cut in peri-anal tissues. Fig. 3 (a) shows the extrasphincteric fistulous tract excised from the patient body, tubular in shape with a length approximately equal to 8 cm. Fig. 3 (b) also shows the new fistulectomy set to represent the length of excised tissue in comparison to the 16-centimeter-long tubular blade.

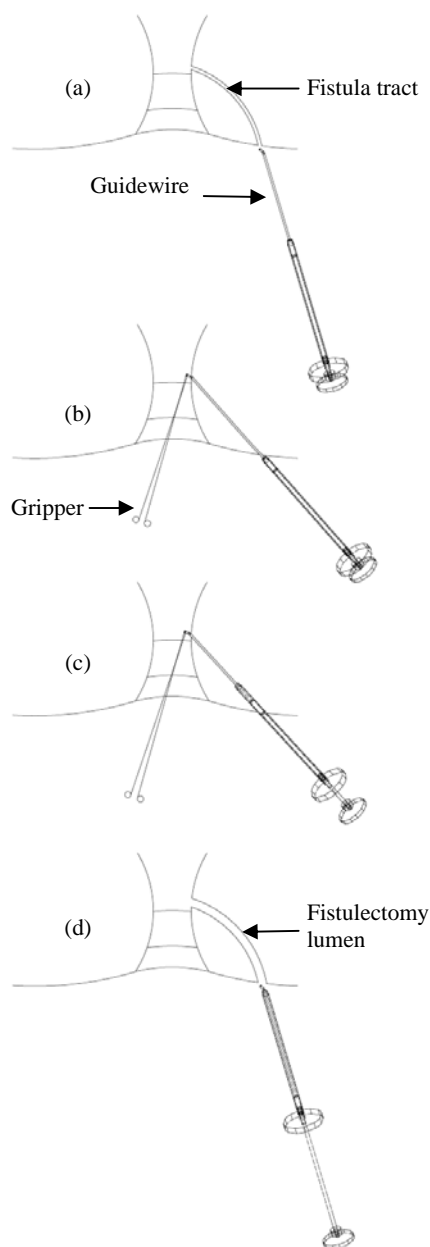


Fig. 2. Representation of the minimally invasive core-out excision by the new fistulectomy set. (a) Inserting the rigid guidewire into the fistulous tract. (b) Fixing the tip of the guidewire in the rectum. (c) Excising the fistulous tract by rotating and sliding the front handle along the rigid bar. (d) Removing the device from patient body.



Fig. 3. (a) New fistulectomy set. (b) Excised tissue from the patient body.

After removing the device, a lumen with a small diameter approximately equal to 8 mm remained in patient body. This test showed that the new device is successfully capable of

circumferentially excising of fistulous tracts with minimum damage to peripheral healthy tissues.

#### IV. DISCUSSION

In simple anal fistulas, a little amount of anal muscles is encompassed by fistulous tract and the conventional surgical treatment is to lay open or completely excise the tract [5]. Using this technique for treatment of high anal fistulas, fecal incontinence is inevitable because of the need for deep incisions to access the tract. In these types of anal fistulas a number of sphincter-preserving surgical techniques such as fistulectomy [4], [6], [7], endo-rectal advancement flap [6], [12], [13], seton sutures [14], [15], fibrin glue injection [16]-[19] and bioprosthesis plug [19], [20] have been used with various results in terms of recurrence and continence disturbance.

“Core-out” fistulectomy is considered a safe and effective surgical technique for treatment of complex anal fistulas in many papers [6], [7]. The principle of this technique is to circumferentially separate the abnormal fibrous tract whilst tracing a probe which is already inserted in the tract. In high anal fistulas (extrasphincteric, suprasphincteric, and high transsphincteric) tracing the tract in deep peri-anal tissues is very difficult and may cause harmful damages to these tissues. Depending on the experience of the surgeon, the thickness of the separated healthy tissues surrounding the tract and the damage to sphincter muscles change. To eliminate these problems, there is a need for an efficient instrument capable of easily removal of inaccessible portions of the tract with minimum invasion. Review of the relevant literature revealed rigid and flexible devices specially designed for this purpose. In 1997, Al-Tameem presented some rigid devices for fistulectomy of anal fistulas but there is not any published document showing the practicability and efficiency of the designs [10], [11]. Although our apparatus is similar to the previously rigid devices in principle of work, they have different designs and structures, and our device practicability is proved with regards to our test results. Relevant flexible fistulectomy devices were presented by Tasci in 2002 and Lasheen in 2004 with excellent results in terms of recurrence and continence disturbance [2], [5]. These devices have completely different designs and principle of work in comparison to our mechanism.

The proposed surgical device in this study is fabricated with the goal of “core-out” fistulectomy idealization which can be achieved by avoiding extra cuts and minimizing the thickness of excised healthy tissue. By excising the fistula tract with minimum invasion to peripheral tissues, the advantages of MIS (reducing trauma, alleviating pain, requiring smaller incisions, faster recovery time, and reducing post-operation complications) can be achieved [21]. Our newly designed fistulectomy set facilitates the excision of fistulous tract with confidence and noticeably reduces the diameter of the fistulectomy lumen in comparison to the conventional technique. Consequently, the injuries to anal

sphincters will be diminished, and a major reduction in the risk of fecal incontinence, recurrence rate and convalescence period may be achieved.

#### REFERENCES

- [1] M. H. Whiteford, J. Kilkenny III, N. Hyman, W. Donald Buie, J. Dohen, C. Orsay, *et al.* "Practice parameters for the treatment of perianal abscess and fistula-in-ano (revised)," *Dis. Colon Rectum*, vol. 48, pp. 1337-1342, 2005.
- [2] A. E. Lasheen, "Partial fistulectomy and fistular wall flap for the treatment of high perianal fistulas," *Surg. Today*, vol. 34, pp. 977-980, 2004.
- [3] J. Garcia-Aguilar, C. Belmonte, D. W. Wong, S. M. Goldberg, R. D. Madoff, "Anal fistula surgery: factors associated with recurrence and incontinence," *Dis. Colon Rectum*, vol. 39, pp. 723-729, 1996.
- [4] T. Toyonaga, M. Matsushima, Y. Tanaka, K. Suzuki, N. Sogawa, H. Kanyama, *et al.* "Non-sphincter splitting fistulectomy vs conventional fistulotomy for high trans-sphincteric fistula-in-ano: a prospective functional and manometric study," *Int. J. Colorectal Dis.*, vol. 22, pp. 1097-1102, 2007.
- [5] I. Tasci, "The fistulectome: a new device for treatment of complex anal fistulas by "core-out" fistulectomy," *Dis. Colon Rectum*, vol. 46, pp. 1566-1571, 2003.
- [6] T. Sonoda, T. Hull T, M. R. Piedmonte, V. W. Fazio, "Outcomes of primary repair of anorectal and rectovaginal fistulas using the endorectal advancement flap," *Dis. Colon Rectum*, vol. 45, pp. 1622-1628, 2002.
- [7] H. Ortiz, J. Marzo, "Endorectal flap advancement repair and fistulectomy for high trans-sphincteric and suprasphincteric fistulas," *Br. J. Surg.*, vol. 87, pp. 1680-1683, 2000.
- [8] S. Najarian, J. Dargahi, A. Abouei Mehrizi, *Artificial tactile sensing in biomedical engineering*. USA: McGraw-Hill, 2009, pp. 182-192.
- [9] J. Dargahi, S. Najarian, B. Liu, "Sensitivity analysis of a novel tactile probe for measurement of tissue softness with applications in biomedical robotics," *J. Mater. Process. Technol.*, vol. 183, pp. 176-182, 2007.
- [10] Al-Tameem, Moshin. "Device for excision of a fistula." Patent 5,643,305. 1 July 1997.
- [11] Al-Tameem, Moshin. "Method of using a device for excision of a fistula." Patent 5,628,762. 13 May 1997.
- [12] S. H. Jun, G. S. Choi, "Anocutaneous advancement flap closure of high anal fistulas," *Br. J. Surg.*, vol. 86, pp. 490-492, 1998.
- [13] N. Uribe, M. Millán, M. Minguez, C. Ballester, F. Asencio, V. Sanchiz, *et al.* "Clinical and manometric results of endorectal advancement flaps for complex anal fistula," *Int. J. Colorectal Dis.*, vol. 22, pp. 259-264, 2007.
- [14] C. Vatansev, Ö. Alabaz, A. Tekin, F. Aksoy, H. Yilmaz, T. Kücükartallar, *et al.* "A new seton type for the treatment of anal fistula," *Dig. Dis. Sci.*, vol. 52, pp. 1920-1923, 2007.
- [15] A. P. Zbar, J. Ramesh, M. Beer-Gabel, R. Salazar, M. Pescatori, "Conventional cutting vs. internal anal sphincter-preserving seton for high trans-sphincteric fistula: a prospective randomized manometric and clinical trial," *Tech. Coloproctol.*, vol. 7, pp. 89-94, 2003.
- [16] R. Loungnarath, D. W. Dietz, M. G. Mutch, E. H. Birnbaum, I. J. Kodner, J. W. Fleshman, "Fibrin glue treatment of complex anal fistulas has low success rate," *Dis. Colon Rectum*, vol. 47, pp. 432-436, 2004.
- [17] S. M. Sentovich, "Fibrin glue for anal fistulas: long-term results," *Dis. Colon Rectum*, vol. 46, pp. 498-502, 2003.
- [18] G. N. Buchanan, C. I. Bartram, R. K. S. Phillips, S. W. T. Gould, S. Halligan, T. A. Rockall, *et al.* "Efficacy of fibrin sealant in the management of complex anal fistula: a prospective trial," *Dis. Colon Rectum*, vol. 46, pp. 1167-1174, 2003.
- [19] E. K. Johnson EK, J. U. Gaw, D. N. Armstrong, "Efficacy of anal fistula plug vs. fibrin glue in closure of anorectal fistulas," *Dis. Colon Rectum*, vol. 49, pp. 371-376, 2006.
- [20] B. J. Champagne, L. M. O'Connor, M. Ferguson, G. R. Orangio, M. E. Schertzer, D. N. Armstrong, "Efficacy of anal fistula plug in closure of cryptoglandular fistulas: long-term follow-up," *Dis. Colon Rectum*, vol. 49, pp. 1817-1821, 2006.
- [21] S. Najarian, J. Dargahi, X. Z. Zheng, "A novel method in measuring the stiffness of sensed objects with applications for biomedical robotic systems," *Int. J. Med. Robotics Comput. Assist. Surg.*, vol. 2, pp. 84-90, 2006.