Semiflex assisted vacuum therapy for perianal abscesses/sinuses and fistula: a pilot study

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With this pilot study we aim to determine the feasibility and efficacy of the novel catheter set, the Semiflex Dome Catheter System, for vacuum therapy of perianal abscesses/sinuses and fistulas. The pilot study will consist of 2 parts. First, 10…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Anal and rectal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON53516

Source
ToetsingOnline

Brief title
The Semiflex Pilot Study

Condition

- Anal and rectal conditions NEC
- Skin and subcutaneous tissue therapeutic procedures

Synonym
fistulous

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Bedrijven: Semiflex Dome System Ltd.

,Semiflex Dome System Ltd.

Intervention

Keyword: abscesses, fistula, perianal, vacuum therapy

Outcome measures

Primary outcome

The primary objective of the first part of the pilot study is to determine if

the Semiflex Dome Catheter System meets the proof of principle with respect to:

a. Smoothness of insertion and changing the semiflex catheters

• Is it feasible to insert the catheter?

• How painful is the changing of the catheters based on the Visual Analoge

Score (VAS)? A VAS >5 is considered too painful.

b. Capability of proper fixation of the catheter

• Will the catheter be fixed during the study period?

c. Capability of maintaining vacuum for more than 48 hours

• Will the vacuum be maintained for more than 48 hours?

d. Compliance to the therapy in terms of pain and discomfort

• How uncomfortable/ painful is the catheter for the patient based on the VAS?

A VAS >5 is considered too painful.

The proof of principle will be met when 50% of the participants per study group

meet all the primary objectives, so point A,B,C and D. These points will be

scored individually and only if one individual meets all of the points, the

participant will be scored as successful. If 50% or more of the participants

per study group are successful, the proof of principle in that corresponding

study group is met. This correspondence with a minimum of 5 participants per study group. When the fistula group and/ or the perianal abscess/sinus group meets the proof of principle, the second part of the pilot study will start. A percentage of 50% has been chosen, so the procedure can be optimized at the Amsterdam UMC, taking a learning curve into account.

The primary objective of the second part of the pilot study is to determine feasibility of the Semiflex Dome Catheter System with respect to:

a. Smoothness of insertion and changing the semiflex catheters

• Is it feasible to insert the catheter?

• How painful is the changing of the catheters based on the Visual Analoge Score (VAS)? A VAS >5 is considered too painful.

b. Capability of proper fixation of the catheter

• Will the catheter be fixed during the study period?

c. Capability of maintaining vacuum for more than 48 hours

• Will the vacuum be maintained for more than 48 hours?

d. Compliance to the therapy in terms of pain and discomfort

• How uncomfortable/ painful is the catheter for the patient based on the VAS? A VAS >5 is considered too painful.

The proposed treatment protocol is considered feasible if at least 70% of the participants per study group meet all the primary objectives. This means that point A, B, C, and D of the primary objectives are met in each individual

participant. This correspondence with 7 participants per study group.

Secondary outcome

Secondary objectives of this study are:

a. Efficacy of drainage of perianal abscess/sinus (e.g. absence of retention)

b. Efficacy of curing the perianal abscess/sinus in terms of complete collapse

of the sinus and disappearance of induration

c. Efficacy of management of perianal fistula in terms of healing after

successive exchanges (first placement is in combination with closure of the

internal opening)

d. Radiological healing defined as complete fibrosis on magnetic resonance

imaging (MRI)

e. Safety of the Semiflex Dome Catheter System in terms of complications which

may occur during treatment

Study description

Background summary

Perianal fistulas are a common, invalidating problem with an estimated incidence of 1.2-2.8 per 10 000 people in Europe.1 Over 90% of the perianal fistulas originate from cryptoglandular sepsis, whereas around 26% of patients with Crohn*s disease will develop one or more perianal fistulas within 20 years after diagnosis.2,3 Treatment of perianal fistulas depends on the underlying pathology, presence of perianal abscesses, the involvement of the external sphincter complex and the fistula characteristics such as the number of internal openings and fistula tracts. Low perianal fistulas crossing less than the lower one-third of the external anal sphincter are easily and mostly successfully treated by fistulotomy. High perianal fistulas are more difficult to eradicate due to a serious risk of sphincter and perianal tissue destruction. Treatment of high perianal fistulas in Crohn*s disease is even more challenging with an increased risk of continence impairment due to the presence of diarrhoea throughout the patient*s life. Permanent closure of

fistulas in patients with Crohn*s disease requires a multidisciplinary approach of combining medical therapy with surgery. Not rarely, multiple surgeries are necessary, especially when septic cavities are present.

In order to prevent recurrent abscess formation treatment of perianal fistulas usually starts with the insertion of a non-cutting seton.4 After appropriate drainage, an attempt at clinical closure can be made in selected fistula which consist mainly of the endorectal advancement flap procedure and the ligation of the intersphincteric fistula tract (LIFT) procedure. However, surgical attempts to close the fistula are technically more difficult in case of multiple internal openings. Overall success rates are reported up to 70% after these procedures for single fistula tracts, but with recurrences in around 22%.5 Thus, a more effective and widely applicable alternative treatment is necessary.

In addition, several conditions exist where there is a large sinus in the pelvis, perianal or after proctectomy. These conditions are very difficult to manage with passive drains and often require major surgery with placement of vital tissue in the tracts. These sinuses or abscesses might benefit from vacuum therapy. Vacuum therapy has become one of the main pillars for management of a wide variety of (chronic) wound healing problems. Vacuum Assisted Closure (VAC) treatment promotes wound healing by reducing tissue oedema, increasing blood flow and by accelerating formation of a granulation tissue, and is therefore widely used for (surgical) wounds.6 After closure of the internal opening, the fistula tract is treated with vacuum therapy. To date, only one cohort study by Hermann et al.7 was published on VAC of perianal fistulas, which showed promising clinical closure rates of 75% using homemade vacuum catheters. The difficulty with the currently available homemade vacuum catheters is that they need to be exchanged under anaesthesia.

A 3D designed and Silicone printed vacuum catheter was developed to enable vacuum therapy in the outpatient setting and exchange of the catheter system without the need of anaesthesia. The presented pilot study tried to determine the feasibility and applicability of the Semiflex catheters.

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2. Parks AG. Pathogenesis and treatment of fistuila-in-ano. Br Med J. 1961;1(5224):463-9.

3. Schwartz DA, Loftus EV, Jr., Tremaine WJ, Panaccione R, Harmsen WS, Zinsmeister AR, et al. The natural history of fistulizing Crohn's disease in Olmsted County, Minnesota. Gastroenterology. 2002;122(4):875-80.

4. Magro F, Gionchetti P, Eliakim R, Ardizzone S, Armuzzi A, Barreiro-de Acosta M, et al. Third European Evidence-based Consensus on Diagnosis and Management

of Ulcerative Colitis. Part 1: Definitions, Diagnosis, Extra-intestinal Manifestations, Pregnancy, Cancer Surveillance, Surgery, and Ileo-anal Pouch Disorders. J Crohns Colitis. 2017;11(6):649-70.

5. Stellingwerf ME, van Praag EM, Tozer PJ, Bemelman WA, Buskens CJ. Systematic review and meta-analysis of endorectal advancement flap and ligation of the intersphincteric fistula tract for cryptoglandular and Crohn's high perianal fistulas. BJS Open. 2019;3(3):231-41.

6. Poteet SJ, Schulz SA, Povoski SP, Chao AH. Negative pressure wound therapy: device design, indications, and the evidence supporting its use. Expert Rev Med Devices. 2021;18(2):151-60.

7. Hermann J, Banasiewicz T, Ko*odziejczak B. Role of Vacuum-Assisted Closure in the Management of Crohn Anal Fistulas. Adv Skin Wound Care. 2019;32(1):35-40.

Study objective

With this pilot study we aim to determine the feasibility and efficacy of the novel catheter set, the Semiflex Dome Catheter System, for vacuum therapy of perianal abscesses/sinuses and fistulas. The pilot study will consist of 2 parts. First, 10 patients in each study group will be included in the study. After inclusion of these 20 patients, it will be assessed per study group whether the catheter meets the proof of principle. This assessment will be done by the DSMB. After a positive result in one or both study groups, the second part of the study will start. 10 patients in each study group will be included in five different hospitals. In total 40 patients will be included.

Objectives study part 1: Pilot in the Amsterdam UMC
Primary Objective:
The primary objective of the first part of the pilot study is to determine if the Semiflex Dome Catheter System meets the proof of principle with respect to:
a. Smoothness of insertion and changing the semiflex catheters
• Is it feasible to insert the catheter?
• How painful is the changing of the catheters based on the Visual Analoge Score (VAS)? A VAS >5 is considered too painful.
b. Capability of proper fixation of the catheter
• Will the catheter be fixed during the study period?
c. Capability of maintaining vacuum for more than 48 hours
• Will the vacuum be maintained for more than 48 hours?
d. Compliance to the therapy in terms of pain and discomfort
• How uncomfortable/ painful is the catheter for the patient based on the VAS? A VAS >5 is considered too painful.

The proof of principle will be met when 50% of the participants per study group meet all the primary objectives, so point A,B,C and D. These points will be

scored individually and only if one individual meets all of the points, the participant will be scored as successful. If 50% or more of the participants per study group are successful, the proof of principle in that corresponding study group is met. This correspondence with a minimum of 5 participants per study group. When the fistula group and/ or the perianal abscess/sinus group meets the proof of principle, the second part of the pilot study will start. A percentage of 50% has been chosen, so the procedure can be optimized at the Amsterdam UMC, taking a learning curve into account.

Objectives study part 2: Participation other centers
Primary Objective:
The primary objective of the second part of the pilot study is to determine feasibility of the Semiflex Dome Catheter System with respect to:
a. Smoothness of insertion and changing the semiflex catheters
• Is it feasible to insert the catheter?
• How painful is the changing of the catheters based on the Visual Analoge Score (VAS)? A VAS >5 is considered too painful.
b. Capability of proper fixation of the catheter
• Will the catheter be fixed during the study period?
c. Capability of maintaining vacuum for more than 48 hours
• Will the vacuum be maintained for more than 48 hours?
d. Compliance to the therapy in terms of pain and discomfort
• How uncomfortable/ painful is the catheter for the patient based on the VAS? A VAS >5 is considered too painful.

The proposed treatment protocol is considered feasible if at least 70% of the participants per study group meet all the primary objectives. This means that point A, B, C, and D of the primary objectives are met in each individual participant. This correspondence with 7 participants per study group.

Secondary Objectives:
Secondary objectives of this study are:
a. Efficacy of drainage of perianal abscess/sinus (e.g. absence of retention)
b. Efficacy of curing the perianal abscess/sinus in terms of complete collapse of the sinus and disappearance of induration
c. Efficacy of management of perianal fistula in terms of healing after successive exchanges (first placement is in combination with closure of the internal opening)
d. Radiological healing defined as complete fibrosis on magnetic resonance imaging (MRI)
e. Safety of the Semiflex Dome Catheter System in terms of complications which may occur during treatment

Study design

The design of the pilot study is a feasibility study with insertion of Semiflex

catheters in patients with a perianal abscess/sinus and fistulas. The pilot study will consist of 2 parts. First, 10 patients in each study group fulfilling the inclusion criteria without any exclusion criteria will be included in the study. This first part of the study will be conducted in the AUMC. After inclusion of these 20 patients, it will be assessed per study group whether the catheter meets the proof of principle. This assessment will be done by the DSMB.
After a positive result in one or both study groups, the second part of the pilot study will start. The second part of the pilot study will be conducted in the Amsterdam UMC, Pozna* University of Medical Sciences, the San Raffaele University Hospital, the Maastricht University Medical Center, the Proctosclinic, and University Hospital Leuven. Patients fulfilling the inclusion criteria without any exclusion criteria will be included in the study. In this second part 10 patients per study group will be included. In total, 40 patients will be included and inclusion is scheduled to take place within 6 months.
Patients will be seen at the outpatient clinic 2-3 days after insertion of the semiflex catheter
by the surgeon where it will be replaced by a smaller sized Semiflex dome catheter. This will be continued until the fistula or perianal abscess/sinus is closed. The therapy is continued for approximately 4 weeks in patients with a perianal fistula and approximately 6 weeks in patients with perianal abscess/sinus, depending on the length of the fistula tract or abscess/sinus. During these contacts outcome parameters will be assessed. Patients will be contacted by telephone after ± 2 weeks and 3 months by the study coordinator to assess complications, additional interventions, re-admissions, duration of hospital stay and visits to the outpatient clinic. After 3 months a MRI will be made to assess the healing of the perianal abscess/sinus and clinical closure of the perianal fistula.
When the results of the study are positive, a conformity study will be started.

Intervention

Patients with a perianal abscess/sinus or (Crohn*s) perianal fistula will be included in the study. This study will evaluate two groups of patients. The first group will consist of patients presenting with a perianal abscess/sinus and the other group will consist of patients with the presence of a (Crohn*s) perianal fistula.

Patients with a perianal abscess/sinus
In patients that present with a perianal abscess/sinus the semiflex dome catheter is inserted under general anesthesia. A small cut is made to drain and irrigate the septic sinus, unless an opening is already present. Before surgery, the size of the perianal abscess/sinus is measured on MRI or CT. If during surgery appears that this is not the appropriate size, a different size catheter can be used. 29 sizes of the Semiflex catheters are available. The

Semiflex dome catheter is inserted with its plate fixed on Renasys Adhesive gel patch (Smith and Nephew). The catheter is connected with a tubing system to a vacuum pomp with an average vacuum pressure of 80 cm H2O. The tube will be taped on the patient. The Semiflex stays in place and will be replaced after every two- three days by a smaller sized Semiflex dome catheter as determined during the outpatient visit. The exchange is meant to be done in the outpatient setting after the administration of 50 mg of parenteral morphine if necessary. The therapy is continued for approximately 6 weeks depending on the length of the abscess/sinus.

Patients with perianal fistula
All patients that will be treated for their perianal fistula have had a seton inserted for at least 6 weeks. Under general anesthesia the seton is removed, the internal opening is excised (de-epithelialized) and the internal opening is closed with a 2-0 Vicryl cross stitch.
Before surgery, the length of the tract is measured on MRI or CT. A Semiflex Catheter with the appropriate length and a diameter between 3.0 and 5.1mm is selected. If during surgery appears that this is not the appropriate size, a different size catheter can be used. 29 sizes of the Semiflex catheters are available. The catheter is fixed on a Renasys Adhesive gel patch (Smith and Nephew). The catheter is connected with a tubing system to a vacuum pomp with an average vacuum pressure of 80 cm H2O. The tube will be taped on the patient. After every two - three days the catheter will be exchanged by a 3-6 mm shorter catheter. The exchange is meant to be done in the outpatient setting after the administration of 50 mg of parenteral morphine if necessary. The therapy is continued for approximately 4 weeks depending on the length of the fistula tract.

Study burden and risks

The Semiflex Dome Catheter may cause the following side effects, adverse effects or discomfort:
- Tissue damage during insertion of the catheter or due to a 'foreign body' reaction against the catheter. However, the chance of this is very low, because the catheter is made entirely of medical grade silicone that has been used in surgery for several decades. The ISO 10933 set includes a set of standards for evaluating medical devices for safe use in humans. One of these ISO standards that applies to the Semiflex catheter is ISO 10993-11. This ISO standard tests the systemic toxicity of a medical device. This ISO standard has not yet been released for the Semiflex Catheter because the production method, namely via the 3D printer, is a new technique. However, tests have been done on the Semiflex Catheter which show it to be non-toxic. The lack of ISO 10993-11 certification is therefore not seen as a risk.
- Tissue damage due to too high vacuum. However, the risk of this is very small if patients adhere to the instructions for use of the vacuum pump. The doctor will set the desired vacuum height per contact moment.
- Tissue damage due to the catheter being suddenly pulled out or breaking off.

The chance of this is minimized by taping the catheter tube to the patient's body during treatment. If the catheter breaks off, there is a chance that it will have to be removed in the operating room under anesthesia. Should the catheter fall out or break off, patients should immediately contact the principal investigator. If this is not available, patients should contact the Amsterdam UMC, location AMC and ask for the surgeon on duty.
- Discomfort of wearing the catheter. The therapy is continued for approximately 4 weeks in patients with a perianal fistula and approximately 6 weeks in patients with perianal abscess/sinus, depending on the length of the fistula tract or abscess/sinus. This means that patients are treated with a catheter connected to a portable vacuum pump during this period. It can be experienced as a considerable burden to have to carry the vacuum pump with you all the time. In addition, patients have to come to the outpatient clinic every 2-3 days to replace the catheter, which can be experienced as a considerable burden.
- The Semiflex Dome Catheter does not work properly and patients develop another abscess or the fistula continues to drain. Patients should immediately contact the Principal Investigator if fever and/or suspected new abscess occurs. If this is not available, patients should contact the Amsterdam UMC, location AMC and ask for the surgeon on duty.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Perianal abscesses/ sinuses or (Crohn*s) perianal fistula
- >= 18 years and < 80 years
- Written informed consent

Exclusion criteria

- Patients with more than 2 external perianal openings
- Rectovaginal fistula
- Life expectancy < 2 years
- Dementia or altered mental status that would prohibit the understanding and giving of informed
consent

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-04-2023
Enrollment:	32
Type:	Actual

Medical products/devices used

Generic name:	Semiflex Dome System
Registration:	No

Ethics review

Approved WMO Date:	06-04-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-05-2024
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL81105.018.22