

eXroid for internal haemorrhoids

Medtech innovation briefing

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Summary

- The **technology** described in this briefing is eXroid. It uses electrotherapy to shrink internal haemorrhoids.
- The **innovative aspects** are the treatment does not need general, regional or local anaesthesia.
- The intended **place in therapy** would be as instead of standard care treatments (such as rubber band ligation, injection sclerotherapy, bipolar diathermy, haemorrhoidectomy or stapled haemorrhoidectomy) in people with internal haemorrhoids.
- The **main points from the evidence** summarised in this briefing are from 2 non-comparative studies including 157 adults in hospital. They show that eXroid can treat internal haemorrhoids effectively without any complications.
- **Key uncertainties** around the evidence or technology are that there is very limited evidence comparing eXroid with any other treatments.

- The **cost** of eXroid is £745 per treatment. The company does not sell the device but negotiates treatment fees with clinicians and clinics. The **resource impact** would likely be similar or less than standard care, if surgery is avoided and the haemorrhoids are treated in 1 session. However, there is no evidence on the resource impact of the technology.

The technology

eXroid (eXroid Technology Ltd) is a minimally invasive treatment that applies direct current electrotherapy to the blood vessels of a haemorrhoid. This is to interrupt blood flow and shrink the haemorrhoid. The mucosa is not penetrated during treatment. The system includes a generator and connection leads (to deliver current), reusable patient pad, and sterile single-use probe pack (including a sponge pocket, probe and an anoscope to evaluate the anal canal).

During treatment with eXroid, the patient lies on a single-use, saline-soaked sponge that slides into the reusable patient pad. A single-use, negatively charged, disposable dual-probe tip is attached to a control handle. The dual-probe tip delivers electric current (but not direct heat) to the base of the haemorrhoid. The current applied to the haemorrhoid is increased to a maximum of 16 milliamps by pressing a control button on the handle.

Duration of treatment depends on the grade of the haemorrhoid being treated and the patient's tolerance. In practice, the average treatment time is approximately 10 minutes per haemorrhoid. The manufacturer recommends treatment times of approximately 4.5 to 20 minutes. Topical anaesthetic can be offered to patients with anal fissures, who may find the procedure more painful.

Innovations

Unlike other therapies, the technology uses direct current electrotherapy and does not require any general, regional or local anaesthesia.

Current care pathway

A [NICE clinical knowledge summary on managing haemorrhoids](#) recommends urgent referral in people with: suspected malignancy, extremely painful, acutely thrombosed external haemorrhoids who present within 72 hours of onset for assessment, reduction or

excision, prolapsed and swollen, or incarcerated and thrombosed internal haemorrhoids, or perianal sepsis. For all other haemorrhoids, conservative treatments are recommended including advice on lifestyle changes to minimise constipation and straining, laxatives, and pain-relief medication or topical haemorrhoidal preparations to provide short-term symptomatic relief.

For people with first-, second- or third-degree haemorrhoids that do not respond to conservative treatment, surgical or non-surgical treatments in secondary care are offered (for more information, see the [NICE interventional procedures guidance on electrotherapy for the treatment of haemorrhoids](#)). For people with fourth-degree haemorrhoids that do not respond to conservative treatment, surgery is likely to be the only appropriate treatment.

The NICE interventional procedures guidance recommends that current evidence for treating grade 1 to 3 haemorrhoids is adequate to support electrotherapy, provided that normal arrangements are in place for clinical governance, consent and audit. The guidance also recommends that patients should be informed about other treatment options, including non-surgical treatments for lower-grade haemorrhoids, in which electrotherapy is not always successful, and repeat procedures may be necessary. They should also be told that the procedure can be painful, and general or regional anaesthesia might be needed to give electrotherapy at higher currents.

Population, setting and intended user

eXroid is for people who have first-, second- or third-degree internal haemorrhoids. This is as an alternative to other non-surgical treatments such as rubber band ligation, injection sclerotherapy or bipolar diathermy, as well as surgical treatments such as haemorrhoidectomy or stapled haemorrhoidectomy. eXroid should not be used in people who have a pacemaker or defibrillator implant (unless a cardiologist has confirmed the procedure is safe), a bleeding disorder, an active anorectal infection, those who have active inflammatory bowel disease or a lower abdominal transplant, those who are having anticoagulant therapy, people who are pregnant or have purely external haemorrhoids.

eXroid is for use in outpatient clinics or primary care centres, by a clinician fully trained and certified to give eXroid treatments.

Costs

Technology costs

The company does not sell eXroid to clinics but instead agrees treatment fees with clinicians and room-use fees with individual clinics in the UK. For NHS clinics, fees are negotiated depending on how many patients would receive treatment. No NHS trusts currently do eXroid treatments, but 2 NHS patients have had treatment under exceptional circumstances. The current price charged to self-paying individuals is £1,250 for the first consultation, examination and first eXroid treatment. Additional treatments cost £745 each. The company states that prices can be negotiated for multiple treatments. Currently the treatment is only available in London.

The company reports that 50% of patients need 1 treatment. Of patients who need more than a 1 treatment, 80% have 2 treatments and 20% have 3 or more treatments. The average cost per treatment is £998 (if 2 treatments are needed) or £913 (if 3 treatments are needed). The company states that this cost should be an estimate for how much the treatment will cost on the NHS.

Costs of standard care

Conservative comparator treatments includes laxatives, symptomatic pain-relief medication and topical treatment for haemorrhoids. The NHS indicative price for a standard bulk-forming laxative such as ispaghula husk is priced at around £2.50 for 30×3.5 g sachets. A 32-pack of 500 mg paracetamol caplets is £0.20. These would be supplied as repeat prescriptions and cost would vary depending on how often a person presents with symptoms and the duration of their treatment. The price of a topical haemorrhoid treatment, for example based on the local anaesthetic cinchocaine, is between £4 and £10 for a 30 g tube of ointment. These prices are taken from the [BNF](#).

Non-surgical and surgical comparators are available in secondary care. [Table 1](#) lists spell costs (the cost of a person's entire hospital stay, which could include multiple episodes), taken from the 2010 costs for [NHS Hertfordshire](#) and unit costs from published UK economic evaluations for some of these options. In general, the reported upper bound of the spell cost ranges will be higher than reported unit costs because they are meant to capture all costs from admission to discharge. Also, the spell cost range is wide because of the varied type of patients recorded. All of these costs have been appropriately

adjusted for inflation.

Non-surgical treatments are recommended for first-, second- and small third-degree haemorrhoids if conservative treatments are ineffective. These treatments are rubber band ligation, injection sclerotherapy, infrared coagulation or photocoagulation and bipolar diathermy (table 1). UK unit costs for infrared coagulation and bipolar diathermy could not be found in published literature.

Surgical treatments are recommended for patients with fourth-degree haemorrhoids. Spell costs and unit costs for haemorrhoidectomy and stapled haemorrhoidectomy are in table 1. Unit costs for haemorrhoidal artery ligation could not be found in the published literature but an Italian study ([Giamundo et al. 2011](#)) reported the one-off equipment cost as €350 (£295 after inflation adjustment and currency conversion).

Table 1 UK unit costs for surgical and non-surgical comparators

Non-surgical and surgical comparators	<u>NHS Hertfordshire (2010)</u> spell costs	<u>Burch et al. (2008)</u> unit costs	<u>Ribarić et al. (2011)</u> unit costs	<u>McKenzie et al. (2010)</u> unit costs
Rubber band ligation	£605 to £2,681	–	–	£112
Injection sclerotherapy	£605 to £1,076	–	–	–
Haemorrhoidectomy	£658 to £2,585	£819	£1,098	–
Stapled haemorrhoidectomy	£820 to £1,198	£984	£1,070	£1,811

Resource consequences

According to the company, the device is not currently used on a regular basis by any NHS trusts. Therefore, it is difficult to predict what the consequences of resource use will be. Treatment with eXroid does not need special preparation or hospital stay, so no additional facilities or devices are needed with the technology. Training will be needed for healthcare professionals using the technology. No other practical difficulties have been identified in using or adopting the technology.

Regulatory information

eXroid is a CE marked class IIa medical device.

The eXroid technology was previously known as Ultroid. The Ultroid technology was removed from the market in September 2016 after an issue with the manufacturers in the US. Since then, the technology has been redesigned as eXroid and a new manufacturing process has been set up in the UK.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

Haemorrhoids are more common in older people and pregnant women. This device is contraindicated in pregnancy but treatment for haemorrhoids in pregnancy is likely to be conservative. Age and pregnancy are protected characteristics under the Equality Act 2010.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the [interim process and methods statement](#). This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

There are 2 studies summarised in this briefing. Evidence published before 2010 was considered in the [NICE interventional procedures guidance on electrotherapy for the treatment of haemorrhoids](#), and so was not included in this briefing. One fully published study and 1 abstract (total n=157) published since 2010 were selected for inclusion in this briefing. The included papers report on 2 non-comparative observational studies. Results show that eXroid effectively reduced haemorrhoids with no complications.

Evidence considered in the NICE guidance found that eXroid had mixed results regarding effectiveness and procedural pain.

Table 2 summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

There is limited published evidence regarding the safety and effectiveness of eXroid since 2010. Both studies included in this briefing use the previous version of the device, Ultroid. The company has stated that the 2 versions of the technology are similar.

The 2 studies were non-randomised, non-comparative observational studies, which limit the ability to assess the effectiveness of eXroid compared with alternative treatments. The studies did not report a sample size calculation and it is unclear whether they were adequately powered to detect differences in outcomes.

Confounding factors included previous treatments, anal fissures and haemorrhoid grade. Both studies stratified patients by haemorrhoid grade in terms of number of treatments needed to resolve haemorrhoid symptoms.

Follow up varied between the studies, from 1 to 6 months (Hudson-Peacock and Hudson-Peacock, 2014); and a mean of 16 months (Olatoke et al. 2014). However, it was unclear how long patient follow up was after their final direct current electrotherapy treatment. Additionally, attrition rates were not presented in the studies.

Olatoke et al. (2014) offered an option of operative treatment or eXroid to all patients who presented with haemorrhoids during the study period. This resulted in selection bias (for example, patients with more severe symptoms may have opted for surgery). Comparative treatment costs from other countries may not be generalisable to the UK and unit costs from older studies may not be representative of the current cost of treatment.

Table 2 Summary of selected studies

<u>Hudson-Peacock and Hudson-Peacock (2014)</u>	
Study size, design and location	100 people in a prospective, single-arm observational study abstract. Location: UK.

Intervention and comparator(s)	Ultroid 2.0.
Key outcomes	The study found no complications in treatment and all patients showed some reduction in haemorrhoids.
Strengths and limitations	This was an observational study and lacked comparison with alternative treatments. This evidence was submitted as an abstract to a scientific conference by the manufacturer. Manufacturer-sponsored studies may introduce bias into publication results and conclusions.
<u>Olatoke et al. (2014)</u>	
Study size, design and location	57 people in a prospective, single-arm observational study. Location: Nigeria.
Intervention and comparator(s)	Ultroid.
Key outcomes	The study found no complications. All patients had successful treatment and remained symptom free.
Strengths and limitations	This was an observational study and lacked comparison to alternative treatments.

Recent and ongoing studies

A company-sponsored trial is underway, which is collating data on consecutive patients with grade 4 haemorrhoids that have been treated with eXroid. The study includes patient follow up and feedback.

Specialist commentator comments

Comments on this technology were invited from clinical specialists working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Three specialists were familiar with this technology but none had used it before.

Level of innovation

The 3 specialists noted that eXroid was a new technology that had not been superseded. The specialists did note that there are other techniques available that are less invasive than stapling and excision, including electrotherapy and electrofrequency ablation, transanal haemorrhoidal dearterialisation and haemorrhoid artery ligation operation. Two specialists pointed out that eXroid is similar to other radiofrequency ablation techniques but noted that these may need light sedation.

Potential patient impact

The 3 specialists stated that eXroid could offer advantages to patients because it is a quick procedure, which is well tolerated and does not need any anaesthetic (even local). One specialist noted that eXroid could offer particular benefits to patients who cannot have general anaesthetic or have extensive comorbidities. Another specialist noted that eXroid is more likely to be effective for grade 1 and 2 haemorrhoids than in grade 3 haemorrhoids. All 3 experts stated that more longer-term evidence would be needed to see the long-term efficacy of using eXroid compared with current standard treatments.

Potential system impact

All experts agreed that further evidence is needed to determine the long-term efficacy of eXroid, particularly the average number of treatments needed. Two experts advised that if eXroid can treat haemorrhoids in a single application, then it is likely to be resource releasing. If using eXroid needs more than 1 application or appointment, it is likely to be cost incurring.

One specialist thought that treatment with eXroid could be done by a properly trained non-medically qualified healthcare professional. Another noted that it might be used by GPs who had training and have an assistant available. The third expert stated that the procedure should be done by a specialist and did not think that GPs or nurse practitioners would be able to do treatments with eXroid.

One specialist noted that using eXroid could take longer than other treatments for haemorrhoids, particularly if a patient has multiple haemorrhoids or needs repeat

treatments. They noted that this would have a detrimental effect on already stretched services. Another specialist noted that using eXroid may lead to an increase in people seeking treatment for haemorrhoids, particularly if it is viewed as a painless outpatient procedure.

All specialists agreed that anyone using eXroid would need proper training.

General comments

One specialist noted that during treatment with eXroid, because the patient is awake, they will need to stay still in the left lateral position for 45 minutes. They noted that this may be challenging for many patients.

All specialists agreed that further evidence is needed for eXroid, particularly in comparison with other treatments such as banding, haemorrhoid artery ligation operation and radiofrequency ablation.

Specialist commentators

The following clinicians contributed to this briefing:

- Miss Patricia Boorman, consultant general surgeon specialising in coloproctology, Royal Devon and Exeter Hospital. No conflicts declared.
- Mr Jim Khan, consultant colorectal, laparoscopic and robotic surgeon and clinical lead colorectal surgery, Portsmouth Hospitals NHS Trust. No conflicts declared.
- Mr Simon Middleton, consultant colorectal surgeon, clinical lead department of surgery, Royal Berkshire Hospital. No conflicts declared.

Development of this briefing

This briefing was developed for NICE by the King's Technology Evaluation Centre. The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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