



XEN Gel Implant

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What is the XEN Gel Implant?

The XEN Gel Implant is a very small tube made of soft porcine gelatin, which is used to treat glaucoma. Glaucoma is a disease in which the pressure within the eye builds up and damages the eye nerve. Treatment of glaucoma involves lowering the eye pressure.

The XEN Gel Implant is 6 mm in length and almost as thin as a strand of human hair (Figure 1). It is well accepted by the human body and creates a permanent pathway to drain fluid from the eye to a small pocket of fluid (bleb) under the most superficial layer of the eye (conjunctiva) (Figure 2). This reduces the pressure in the eye hence slows down glaucoma progression and preserves the vision.

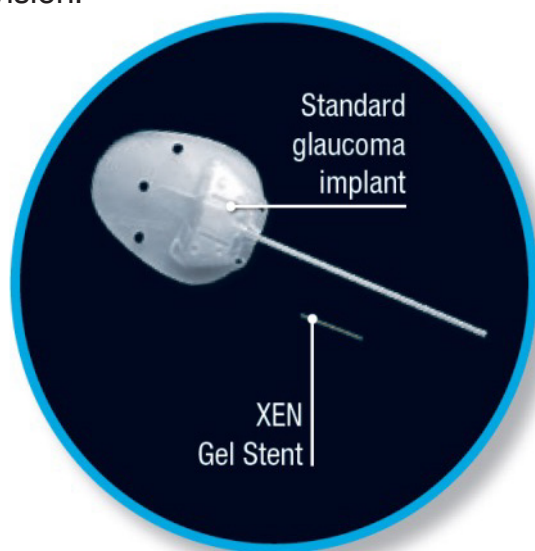


Figure 1.

The size of a XEN Gel Implant compared to a conventional glaucoma tube shunt implant. (Courtesy of Allergan plc, Dublin, Ireland)

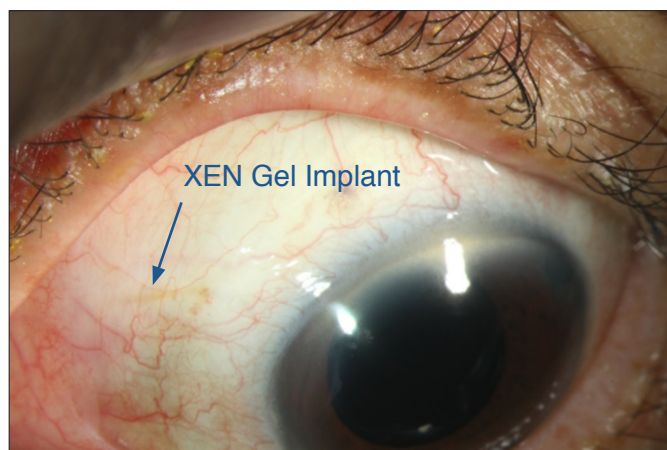


Figure 2.

Photograph showing a XEN Gel Implant draining fluid from the eye to a bleb. (Courtesy of Chelvin Sng)

The XEN Gel Implant is most often used in patients with mild and moderate open angle glaucoma whose eye pressure is not sufficiently reduced by eye drops or laser. Patients who do not use glaucoma medications as regularly as they should, experience side effects from the medications or are allergic to them may also choose to have the XEN Gel Implant inserted by itself or in combination with cataract surgery, so as to reduce the number of glaucoma medications required. If you have very advanced glaucoma, the XEN Gel Implant may not be appropriate for you.

The XEN Gel Implant will not reverse any damage already caused by glaucoma, improve your vision or cure your glaucoma.

What are the advantages of the XEN Gel Implant?

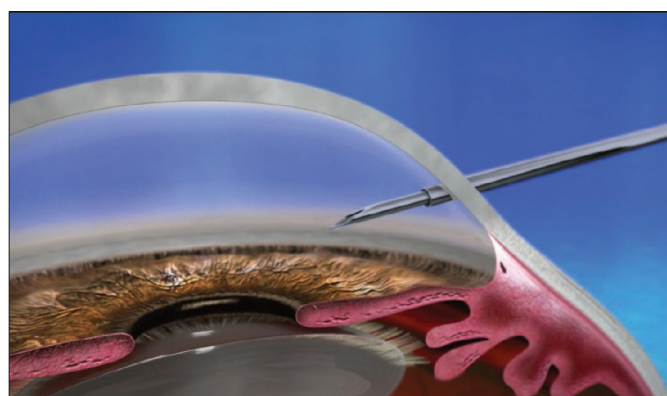
The XEN Gel Implant is less invasive compared to other conventional glaucoma surgeries (such as trabeculectomy or tube shunt implants). Only a very small cut in the eye is required to insert the XEN Gel Implant and unlike conventional glaucoma surgeries, no stitches are required. Hence, the surgery is faster with a quicker recovery time. Unlike conventional glaucoma surgeries, the XEN Gel Implant is unlikely to have much effect on your spectacles power. In previous clinical studies, the XEN Gel Implant was associated with a reduction in eye pressure and the number of glaucoma medications.¹⁻³

How is the XEN Gel Implant inserted into the eye?

The XEN Gel Implant can be inserted into the eye either by itself or in combination with cataract surgery. A medication called mitomycin C is given to your eye before inserting the XEN Gel implant, which reduces scarring and increases the long-term success of your surgery. Eyedrops are used to make the eye numb and some surgeons may also give an injection around the eye so that you won't feel pain or discomfort during the procedure. In some hospitals, you may also receive light sedation during the surgery so that you will feel more relaxed and comfortable. You will be awake during the procedure and should not feel any pain during the surgery.

Only a very small cut in the eye is required to insert the XEN Gel Implant, which does not require stitches (Figure 3). The procedure usually takes approximately 10 minutes. At the end of the procedure, the operated eye is covered with an eye shield and may also be padded. You will usually be able to go home the same day as your operation.

A.



B.

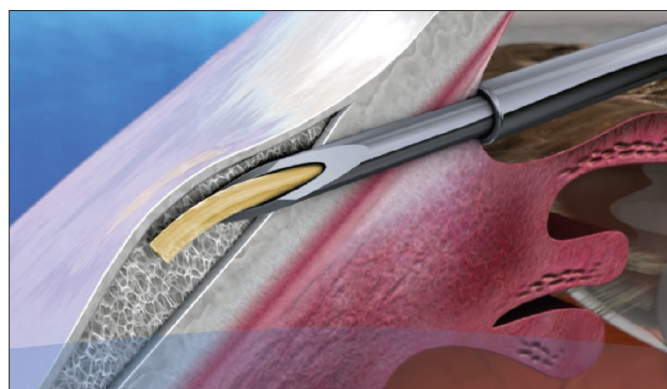


Figure 3.

- A. The XEN Gel Implant is introduced into the eye through a very small cut.
 - B. The XEN Gel Implant is injected under the conjunctiva (the most superficial layer of the eye) to drain fluid from the eye to a bleb.
- (Courtesy of Allergan plc, Dublin, Ireland)*

What precautions should I take after undergoing XEN Gel Implant surgery?

You should avoid strenuous activities for the first month, including swimming, jogging, contact sports and vigorous exercises. It would be advisable to cover the operated eye with an eye shield at night for a few weeks after the surgery, so as to avoid accidental injury to the eye while you are sleeping. Eye make-up should be avoided for about 4 weeks after the surgery. Reading or watching the television will not harm your eye and you may continue with these activities as usual. Your doctor will prescribe you with antibiotic eyedrops to prevent infection, and anti-inflammatory eyedrops to minimize scarring and increase the long-term success of the surgery. It is important to use these eyedrops as instructed by your eye doctor. The anti-inflammatory eyedrop may need to be continued for several months after the surgery, and only stop it if your eye doctor has explicitly asked you to do so. Immediately after the surgery, you will be asked to stop using the glaucoma eyedrops in the operated eye as the XEN Gel Implant works immediately to lower your eye pressure. If your other eye requires glaucoma eyedrops as well, they will still need to be continued as usual after the surgery.

The nature of your work will determine the length of time you would need to take off work after the surgery, though most people take two to three weeks off.

What are the risks associated with the XEN Gel Implant?

Studies have shown that the XEN Gel Implant has a good safety profile. However, there are still potential complications associated with the surgery:

During the Surgery

There is a small risk of damage to the other structures in the eye during the surgery, such as the iris (the structure made of muscle which controls the size of your pupil and is in front of the lens). If you are not undergoing cataract surgery at the same time, there is also a potential risk of the surgery damaging your lens and causing a cataract. Bleeding in the front of your eye may occur during the surgery, which usually resolves on its own within two weeks after the surgery. If there is bleeding inside your eye, your vision may be blurred for a few weeks.

After the surgery

Bleeding can occur in the front of your eye after the surgery, which usually resolves on its own within two weeks after the surgery. There is also a small risk of the eye pressure being too low for a couple of weeks after XEN Gel Implant surgery, and this resolves within a few weeks in the vast majority of cases. Your vision may be blurred when the eye pressure is low, but it usually improves to baseline if the eye pressure increases within a few weeks. Low eye pressure can lead to an accumulation of fluid in the wall of the eye (choroidal detachment) but this usually resolves spontaneously when the eye pressure increases. Occasionally, if the eye pressure is low for a prolonged period

of time or if the front section of your eye is flat in association with low eye pressure, you may require an injection of a jelly-like substance (called viscoelastic) into the front section of your eye. This is usually performed in the clinic. Rarely, you may require another surgery to address the low eye pressure.

The XEN Gel Implant is soft and very small, and occasionally can break after the surgery. However, even if it should break, this is usually not associated with adverse effects on the eye. Unlike conventional tube implant surgery, the soft material of the XEN Gel Implant has not been associated with damage to the cornea (the transparent structure in front of the eye), though this is still potentially possible.

If scarring occurs around the XEN Gel Implant, fluid will not flow well from the implant. Additional procedures may be required to break the scar tissue after the implant, which are usually performed in the clinic but may require another surgery. Very rarely, the XEN Gel Implant may also be blocked by iris, and additional laser or surgical procedures may be necessary to relieve this blockage. If your eye pressure is still not low enough after XEN Gel Implant surgery, your glaucoma may progress and you may need to re-start your glaucoma medications or further surgeries may be required to control your eye pressure.

Rarely, a small number of patients may experience increased eye dryness or discomfort due to the presence of the bleb. Most of the time, these symptoms are

relieved by lubricating eyedrops. However, if the discomfort persists, additional steps may need to be taken to make the bleb more comfortable. As with conventional glaucoma surgery, it is also possible that the eyelids may become more droopy after XEN Gel Implant surgery. If your cataract has not been removed, the cataract may become worse after XEN Gel Implant surgery, resulting in a decrease in vision. If this occurs, you may require subsequent cataract surgery.

Serious complications after XEN Gel Implant surgery (e.g. vision loss, major bleeds at the back of the eye, infection, detachment of the retina [light-sensitive tissue lining the back of the eye]) are fortunately extremely rare. However, every time you undergo an eye surgery, these serious complications can potentially occur, though the risk of these occurring with the XEN Gel Implant is likely to be less than that associated with conventional glaucoma surgeries.²⁻³ All surgeries which create blebs have a potential life-long risk of infection.

What are the alternatives to the XEN Gel Implant?

Glaucoma can be treated with medications to lower the pressure in the eye. However, many patients do not use glaucoma medications as regularly as they should, experience side effects from the medications or are allergic to them. The medications may also not reduce the eye pressure sufficiently, and surgical procedures may be required to control the eye pressure and prevent further vision loss from glaucoma.

A laser procedure called selective laser trabeculoplasty may be appropriate for some patients with open angle glaucoma, though in other patients it may not reduce the eye pressure sufficiently or may need to be repeated. Conventional glaucoma surgeries include trabeculectomy or tube shunt implants, which are effective in lowering

the eye pressure but are associated with potentially serious complications. Besides the XEN Gel Implant, other minimally invasive glaucoma surgery devices are also available. Please consult your eye doctor regarding the most appropriate surgery or glaucoma device for you.

References

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