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What should I be looking for?

It is important that your remaining corneal tissue remains intact. If you begin to lose the remaining corneal tissue, the AlphaCor may not remain secure and further problems such as infection can occur. **This is why you must follow all post-operative instructions and immediately inform your doctor of the following events:**

- If you notice the appearance of a bright white section in the eye that looks like a “fingernail”.
- If you experience discomfort or stickiness in the eye.
- If you notice a deterioration in vision or any other changes to the eye.

These symptoms may indicate that the tissue is not healing properly with the device. This complication is serious but can usually be managed by “patching” if treated early. Patching involves covering the affected area with tissue from the patient, or from a donor cornea. Sometimes it is necessary to remove the device and replace it with a donor cornea if patching is not successful.

What else should I be doing?

The AlphaCor is made of a material also used in soft contact lenses. It is susceptible to some of the things that can damage soft contact lenses. The AlphaCor could be damaged by:

- Scratching.
- Deposits from proteins, minerals, medication and eye drops.
- Breakdown from medications, eye drops and other substances such as pool chlorine.
- Infections.
- Clouding from smoke exposure.
- Other substances not yet known.

To minimize the risk of your AlphaCor becoming damaged or spoiled:

- Use only medications and eye drops approved by your specialist doctor. All eye drops should be preservative-free and ideally labeled as suitable for soft contact lenses.
- Use all medications as directed. It is very important that you continue using the eye ointment that protects the AlphaCor from damage and infection.
- Do not touch, rub or scratch the eye.
- Avoid people who have conjunctivitis (eye infections).
- Wear protective glasses when gardening, in your work place or any other area where your eye could be damaged.
- Do not smoke and avoid smoky environments.
- Avoid contact sports and discuss the safety of water sports with your doctor.
- Report any change in the appearance of your AlphaCor, or any new sensation or discomfort, to your doctor as early as possible to avoid complications.
- If you are unable to contact your regular doctor, take your patient identity card and this Information Sheet to the doctor that you see, they would be able to contact Argus for advice by:

  E-mail: argusconnect@argusbiomedical.com
  Phone: +61 8 9381 0857
  Fax: +61 8 9381 0759
This Information guide outlines questions frequently asked about AlphaCor™ and the follow-up care that is required following AlphaCor surgery. The content of this guide should be discussed in depth with your surgeon.

What is the cornea?
The cornea is the clear window at the front of the eye that provides physical protection to the eye and part of the eye’s focusing power required for sight.

Why may the cornea need to be replaced?
When the cornea is damaged by injury or disease, scarring and inflammation can reduce the passage of light and prevent vision. In many cases, it is necessary to replace the cornea in order to restore sight. This is usually achieved by transplanting a donated human cornea.

What is the AlphaCor artificial cornea?
The AlphaCor artificial cornea is a small, flexible plastic disc. The central part of an AlphaCor is clear and acts like a lens, just like the natural cornea. The rim of AlphaCor (the skirt) resembles a sponge and acts to secure the device into place by allowing the patient’s own tissue to grow into it and hold it in place.

Why do we need the AlphaCor?
While donated human grafts can be very successful, there are occasions when they fail. In these cases, the chance of further transplants being successful is reduced. In some cases, the chance of failure is so high that a donor graft would not even be attempted. There are many patients who are currently considered untreatable by means of a conventional corneal transplant. Extensive research and trials over 12 years indicate that the AlphaCor may be suitable for many of these patients. In addition, there are some parts of the world that have donor tissue shortages and some religious denominations discourage the use of donor tissue and the use of an artificial cornea may be of benefit in these countries.

What does AlphaCor surgery involve?
The surgery itself is similar to the implantation of a donor cornea, where part of the cornea is removed and the AlphaCor is put in its place. The technique differs from a normal corneal graft because the rim of the AlphaCor is held within the host tissue and is inserted into place through a small cut at the top of the eye, which is stitched at the end of the operation.
The operation is usually completed by the formation of a flap of tissue from the conjunctiva (the outer layer of the ‘white’ of the eye) that is used to cover the surface of the front of the eye. This means that the eye does not look normal after the operation, but the conjunctival flap is important because it allows the AlphaCor to heal into place under the protection of this natural bandage.
Approximately three months after the initial surgery, a second, smaller operation is performed. At this stage, tissue covering the AlphaCor at the front of the eye is removed to allow light to enter. The coloured part of the eye (iris) may appear
smaller and look blue-gray in colour as some of the existing cornea will be covered by the AlphaCor. The white of the eye may seem to have larger blood vessels than a normal eye.

**What side effects or complications might occur?**

All surgery is associated with the risk of complications. This new operation involves all the usual risks and potential complications of a conventional corneal graft, which include infection, glaucoma (raised pressure of the eye) and retinal detachment (damage to the back of the eye).

In addition, however, there are possible risks associated with a new procedure, such as breakage of the AlphaCor, an adverse tissue reaction to the AlphaCor or a reduction in its clarity due to deposited substances.

It is important that the patient’s remaining corneal tissue remains intact. If the patient begins to lose the remaining corneal tissue, the device may not remain secure and further problems such as infection could occur. Such problems can usually be managed by "patching" if it is done early. Patching involves covering the affected area with tissue from the patient, or from a donor cornea. Sometimes it is necessary to remove the device and replace it with a donor cornea if patching is not successful.

The degree of risk in human patients has not yet been fully determined as the AlphaCor is a relatively new product, but several patients have now retained an AlphaCor successfully for over 2 years.

Your doctor will be able to tell you of recent reports on the AlphaCor from published papers in medical journals.

**How long would it last?**

It is difficult to predict how long an artificial cornea such as AlphaCor would last in a patient. The human body always interacts with implanted materials, and in the long term this might lead to a reduction in strength or to some other alteration in the device’s qualities, such as its clarity or its surface smoothness.

All artificial cornea patients should remain under close review, so that if any sign of implant failure occurred, the device could be removed and replaced. AlphaCor replacement is possible and can be done either with another AlphaCor or with donor corneal tissue.

The protective layer over the front surface of the artificial cornea may get smaller and require to be trimmed open. This is a small procedure performed under local anesthetic.

**How well would I be able to see through it?**

Although AlphaCor is made to act as a clear lens with around the same focusing power as a natural cornea, it is difficult to predict how good vision will be in an individual patient.

Just after the first operation, when the cornea is covered by other tissues to assist healing, little vision is possible. When this tissue is opened three months later to reveal the artificial cornea, vision is restored to some extent.

This should allow most patients sensation of light, dark, movement and colour. The things you see may not be in focus (just as a normal corneal graft can give disappointing vision).

After surgery, vision might be able to be improved by spectacles or other means.
If you have good vision in one eye, it is unlikely that the eye with the AlphaCor would be better. It may however give useful sight. If the other eye is of little use, the eye with the AlphaCor may well become the one you depend upon for vision.

Most of the patients who have received an AlphaCor to date have had outcomes varying from a little improvement in vision to regaining the ability to read. A small percentage of patients have experienced worsening in their sight due to complications. It is important to remember that the visual potential of an eye depends upon the health of all parts of the eye. If you also had glaucoma or retinal problems, for example, your vision might still be limited even if the artificial cornea itself worked perfectly.

**Could I end up “worse off” after having an artificial cornea?**

It is possible to end up worse off following any surgery if complications occur.

The worst possible complications arising from AlphaCor surgery would be an infection or a serious hemorrhage (bleeding) within the eye that did not respond to treatment. In the worst scenario, the eye might have to be removed. In order to minimize risks, you would only be offered surgery after detailed ocular assessment and elimination of any extra risk factors - such as eyelid inflammation - which might increase your risk.

All possible precautions should be taken before, during and after your operation and this vigilance should continue indefinitely. You would have to be prepared to attend regular follow-up appointments, which would be very frequent at first.

**What do I need to do after the operation?**

After the operation, you are required to attend regular follow-up appointments with your surgeon. These occur frequently at first but reduce over time. It is most important to attend all follow-up appointments. Ensure that you understand how frequently you should visit your specialist and ensure appointments are made.

In between appointments, you should ask a relative, or friend, to examine your eye frequently so that you can identify any changes in the appearance of your eye and report them promptly.

You will also be required to administer medications to the eye every day as long as you have an AlphaCor. These medications are very important as they protect the eye from damage and infection. Ask your doctor how best to apply these medications and follow all instructions carefully.

You must ensure that the AlphaCor is not damaged. Things that may damage the AlphaCor are discussed below.