DR. MURIEL M. SCHORNACK: Hello, I'm Dr. Muriel short back from the ophthalmology department at the Mayo Clinic in Rochester, Minnesota. We're going to spend the next several minutes talking about scleral lenses. So I thought I'd start with a definition of exactly what a scleral lens is. It's a large diameter, rigid gas permeable contact lens that actually rests on the sclera, or the white part of the eye, and traps a layer of fluid between the back of the lens and the front of the cornea. This gives it some unique fitting characteristics as well as some unique optical characteristics that we'll discuss as we move further along.

So how are scleral lenses different than other contact lenses? Well, you can see that obviously a square lens, which you see on the right, is considerably larger than a corneal rigid gas permeable lens. That's the first major difference. The second major difference is where it lands. It doesn't land on the cornea at all. It lands on the sclera instead. So for patients with compromised corneas or patients with very irregular corneas, one doesn't have to worry about compromising that cornea further with the application of a scleral lens.

One might also think that being so much larger than a corneal lens, it would be more uncomfortable than a corneal lens. Surprisingly, most patients actually report that scleral lenses are more comfortable than corneal rigid gas permeable lenses because they land on the conjunctival tissue overlying the square which is less densely innervated than corneal tissue. Another question that I'm frequently asked is whether or not scleral lenses are new technology.

In fact, they're not. Scleral lenses were first described in the late 1880s by three researchers in Germany working simultaneously but independently on blown glass shells for the treatment of various ocular conditions. Scleral lenses never went away entirely, but there were some problems with the earlier lenses. First of all, glass is completely impermeable to oxygen, so the cornea became quite hypoxic after a short period of wear.

Secondly, blown glass shells were very difficult to manufacture and were not particularly reproducible. In the early 1900s, impression molding and creation of a poly methyl methacrylate shell over top of that mold kept scleral lenses alive, and the picture you're seeing here is a pair of those molded scleral lenses from the early 1900s But again, poly methyl methacrylate is not permeable to oxygen, so it was very difficult to wear these lenses long term. The other issue, of course, as you could well imagine, is that a lens that's created from an impression mold of the front surface of the eye would not be terrifically reproducible. So if the patient did happen to get a lens that fit extremely well, it would be virtually impossible to replicate that.

In the 1980s several researchers again working simultaneously but independently came up with the idea of making scleral lenses out of rigid gas permeable contact lens materials. This solved several problems. First of all, lens materials that were gas permeable allowed oxygen to the cornea and kept the cornea from becoming hypoxic. Secondly, the lenses could be manufactured with lathes that would allow for the production of reproducible devices.

Currently, scleral lenses are primarily used for corneal irregularities, ocular surface disease, and management of very high refractive air. Let's talk a little bit more about each of these indications. Corneal irregularity comprises both primary corneal ectasia, such as keratoconus, pellucid marginal degeneration, even things like Salzmann's dystrophy.

Corneal irregularity could also include things like ocular trauma, ocular surgery, as is the case here where you can see that a patient has had not one, but several corneal transplants, or ocular disease. Sometimes a corneal infection will leave a patient with a scar that creates some irregularity on the front surface of the eye. In cases like this, scleral lenses really do function as prosthetic ocular surfaces. The definition of prosthesis, of course, is replacing the function of a tissue, and in this case, we are replacing the function of the smooth corneal surface that allows for good vision. So in the management of corneal irregularity, the primary benefit of scleral lens wear is, in fact, improved visual acuity.

Scleral lenses are also used in the management of ocular surface disease. And by ocular surface disease, I'm referring to any disorder of the tear film or abnormality in the eyelid structure or function that could result in compromise to the ocular surface. The patients that I have demonstrated in the photos here from left to right include a patient with graft versus host disease, a patient with neurpotrophic keratopathy or persistent epithelial defect, and finally a patient with cranial nerve seven palsy, who is unable to blink.

These represent just several of the many manifestations of ocular surface disease that can be effectively treated with scleral lenses. Patients with high refractive error can also wear scleral lenses if they have failed other forms of correction. At Mayo, we tend not to use scleral lenses for the correction of uncomplicated refractive error, but in patients who have either extreme myopia, extreme hyperopia, or considerable astigmatic refractive error, we have been successful in fitting patients with scleral lenses and giving them very good vision.

So how are scleral lenses currently fit? At present, the use of diagnostic lenses is essential. We did a study here several years ago that discovered that topography is not really particularly useful in fitting scleral lenses, and that's not surprising.

Topography gives us an outline of the shape of the cornea, which is fabulous if you are actually going to rest a lens on the cornea. But since scleral lenses measurably vault the cornea, the exact curvature of the cornea is not particularly helpful in fitting lenses. So we actually simply apply a diagnostic lens to an eye, we evaluate the alignment of the landing zone or flange of the lens on the conjunctival tissue overlying the sclera, and then we assess the amount of clearance or vault behind the lens and in front of the cornea.

What we're actually looking for with scleral lenses is a bit of space between the back of the lens and the front surface of the eye. Taking a look at the images here, the image farthest on the left is of a scleral lens on an eye with dry eye syndrome. And you'll notice that there is a tiny bit of fluorescine stain in that post lens fluid reservoir that's giving the fluid reservoir just a little bit of a green appearance. The second image is from a pentacam, and if you look closely, you'll see that the scleral lens is actually measurably vaulting the cornea. The third image is not using fluorescine, but you can see the reflection off of the front surface of the lens, the reflection of the back surface of the lens, a small space, and then the cornea.

So our goals are as follows-- we want that lens to be completely supported by the sclera. We want the lens to completely and measurably vault the cornea and limbus, and we want that lens to create an even baring zone on conjunctival tissue that results in neither compression of blood vessels or actual lens lift off. The picture on the upper left shows a scleral lens on the eye with multiple corneal transplants shown earlier in the presentation. The picture on the lower left shows a scleral lens in place on the eye with an even fluorescine pattern behind that lends. And the picture on the lower right shows proper alignment of the landing zone or flange on the conjunctival tissue.

As you can imagine, diagnostically fitting scleral lenses can be a time consuming process, with the application and removal of many lenses in quick succession before I can find one that provides an adequate fitting relationship. But there is some new technology in the works that would accurately map the shape of the sclera well beyond the cornea that would give us an idea of how to fit the landing zone or flange of the lens. There's also a company that creates lenses that are based upon an impression mold of the front surface of the eye.

When might one considers scleral lenses? Where does one place them within a therapeutic regimen? We tend to be rather conservative here at Mayo and we'll try a lot of things before we will go to scleral lenses.

On the left side of the slide, you will see some of the interventions that could be attempted in the management of ocular surface disease. Obviously, we would try over-the-counter lubricant drops or artificial tears before we would proceed with anything more invasive. We'll actually frequently prescribe topical medications such as ciclosporin, or perhaps a topical steroid as well before we would try scleral lenses.

Punctual occlusion is another thing that we frequently do before we consider the use of scleral lenses. Systemic therapy in the form of oral antibiotics or oral anti-inflammatories is necessary in some patients. We tend to place sclerals immediately before we would consider doing a surgery such as a conjunctival flap, tarsorraphy, or amniotic membrane.

On the right hand side, you'll see the management strategy for folks with corneal irregularities. Obviously, if somebody sees well with glasses, we need not go any farther than that. Hydrogel lenses are certainly available in a wide variety of parameters at this stage in the game. So we would certainly try those before we try anything more specialized.

Corneal rigid gas permeable lenses work very well for a number of patients as do any number of specialty lenses, including hybrid lenses, custom soft lenses, or any number of other possibilities. My personal comfort zone for scleral lenses is again immediately before surgery, and I do consider scleral lenses as a bit of a bridge. I don't necessarily believe that they will completely eliminate the surgery, but they can buy the patient some time to consider what surgical options may be best for them or to wait for the development of an improved technique.

So the Mayo Clinic scleral lens program was initiated in 2006, and since that time, we've completed fits in over 500 eyes. There are currently two providers, myself and Dr. Sheri [INAUDIBLE], who are active in fitting scleral lenses here at Mayo, and we are both actively participating in academic and educational scleral lens community. So what are some of the questions that we are asking about scleral lenses right now? Well, a big one is the complications that may be associated with scleral lenses. They are made of the same materials that rigid gas permeable corneal lenses are made from.

However, the fitting characteristics are considerably different, and that may lead to a different set of complications with scleral lenses compared to corneal lenses. As scleral lenses become more popular, a number of companies are marketing devices that are meant to correct refractive error in healthy eyes. And as we move towards that indication for scleral lens wear, we're going to want to make sure that we have a very firm grasp of what those complications may be. And we're also going to want to know what the risk factors for scleral lens complications are. Again, these may be somewhat different than the risk factors for the complications in corneal lenses.

We also want to know whether or not scleral lenses affect anterior segment metabolic processes. Do scleral lenses cause unhealthy levels of corneal hypoxia? Do scleral lenses cause compression of Schlemm's canal and could they be associated with increased risk of forms of glaucoma? Once again, these are things that we need to answer as we move from a population which scleral lenses represent the last option before surgery into a population of relatively healthy individuals.

We also need to study the mechanical effects of scleral lenses on the ocular surface. We know that conjunctival tissue can be compressed by scleral lenses, but we don't know whether or not that compression has negative ramifications with long term scleral lens wear. We know that the fluid reservoir can cause some changes or almost a waterlogged appearance of the corneal epithelium, but again, we don't know if that causes any long term problems.

We also need to take a look at the fitting process for scleral lenses, and we need to find ways to make that more convenient for patients, a little bit more streamlined through the use of emerging technology. And finally, how can we improve patient experience with scleral lens wear? The lens are large in diameter.

Placing them on the front surface of the eye removing them requires some special plungers. Some patients find that they have difficulties getting themselves into the posture necessary in order to apply a scleral lens. Many patients find that their scleral lens experience is most successful if they are able to remove the lens after four or five hours of wear, clean it, refill it with fresh saline, and reapply it. And we need to address some of those issues in order to improve the patient experience with scleral lens wear.

Since the inception of the Mayo Clinic scleral lens program, I have been privileged to see how these devices can change lives of patients who have few other options. It gives them hope. It gives them vision.

It gives them ocular comfort that they could only dream of prior to wearing scleral lenses. If you have a patient that you think may benefit from these devices, I would be more than happy to consult with you or to see the patient here at Mayo and Rochester. Once again, I'm Doctor Muriel Schornack from the Mayo Clinic in Rochester, Minnesota. Thank you for spending this time with me.