Dr. Bianchi's Strabismus Surgery Risks Review

Before undergoing eye muscle surgery it is important to understand all the possible risks involved. Dr. Bianchi will have a detailed conversation with you prior to your surgery to obtain your consent. The particular risks will vary somewhat depending on the procedure, but most of the following risks pertain to all strabismus surgeries, whether adult or pediatric. It is useful to review these risks before your pre-operative visit with Dr. Bianchi so you can digest all the information and prepare questions for that visit. To begin, let me quote a short passage from a book on strabismus intended for patients and authored by my esteemed colleague, Dr. Burt Kushner. Dr. Kushner has kindly shared his book for free online (a link to it is available on our website). I think it perfectly sums up the big picture:

Risks of Strabismus Surgery

Fortunately, the actual risks of strabismus surgery are quite small, though not non-existent. The tremendous advances in general anesthesia have now reduced the risk of serious complication (including death) to less than the risk of a 2-hour automobile ride on the freeway. Similarly, serious risk to vision or eyesight is extremely remote. Although an unforeseen infection, hemorrhage, or damage to important parts of the eye can occur and result in vision loss, the likelihood of these happening are also less than the risk of serious injury while crossing a busy street — something people do every day without giving it much thought.

The biggest downside with strabismus surgery is more a limitation than a risk. It relates to the variability or unpredictability of the response. Eye muscle surgery is based on averages. We know that in the average eye, moving a muscle a certain number of millimeters will change its alignment by a given number of degrees. Each individual patient may not experience this same average response. Some eyes may change their alignment more and some less for the same amount of surgery. Consequently some eyes may under-respond to surgery (straightening less than the average amount). If this happens the strabismus would be improved after surgery but still be present to a lesser degree. Alternatively some eyes may occasionally over-respond to surgery. This would result in the eye "going the other way;" an esotropic eye might be exotropic, an exotropic eye might be esotropic after surgery. The bottom line is that a small percentage of patients may need additional surgery to obtain the desired result.

What follows is an exhaustive list of all the various possible risks of strabismus surgery. Please keep in mind that some of the very serious risks that follow occur exceedingly rarely, but I am obligated to warn you about them because they have occurred somewhere, sometime to someone and were reported. Overall, strabismus surgery is very low risk, technically very straightforward and extremely safe as we are operating on the surface of the eye rather than inside the eye. This information is not meant to alarm you, but to inform you.

1 Infection

Infection is a risk of any surgery, but it is very rare in strabismus surgery. One study from 1991 suggested a rate of ~1/1900 cases. The eye has a very rich blood supply which helps to combat infection. The surgical incisions are superficial and open to the air—no eye patches or bandages are used afterwards—which also makes infection less likely. We use topical antibiotics drops and ointment before, during and after the surgery as well to prevent infection. If an infection should occur, it typically happens around 3-5 days after the surgery and presents with increasing redness, pain, swelling and pus around the operated area(s). Antibiotics by mouth would be added in such an event, and usually cure the infection. Extremely rarely an abscess may develop, which would require a second surgery to drain the infectious material.

2 Bleeding

Bleeding is a risk of any surgery in which incisions are made. Some bleeding is unavoidable in eye muscle surgery, but it is very minimal. Most of the bleeding occurs during the very first phase of the surgery when an incision through the conjunctiva is made. The conjunctiva is a thin mucus membrane with lots of small blood vessels, and incisions through it always ooze. Much like a cut inside your mouth or after biting one's tongue, these incisions may ooze traces of blood for up to a week following surgery as they heal. The muscles that have been operated on beneath the conjunctiva may also ooze a little bit following the surgery. It is not unusual to see small pink/red streaks or tiny strands of clot in the tears during the initial post-operative period. (Significant amounts of bright red blood, hemorrhage behind/around the eye or actively bleeding. wounds are virtually unheard of in this kind of surgery.) As a result of this postoperative oozing, the "white" of the eye overlying the operated muscle(s) will appear completely bloodshot. If you've ever seen someone with a broken blood vessel on the surface of their eye, it looks exactly like that. The blood underneath the conjunctiva may shift a bit after surgery as well, due to the movement of our head while sleeping, standing and sitting in the day or two following surgery. This is not due to new bleeding, just the shifting of old blood, and is not cause for concern. The bright red appearance resolves after about 7-10 days as your body slowly resorbs the blood. The white of the eye will then appear slightly pink or "injected" for several weeks, slowly dissipating over time. Usually it is no longer detectable by 3 months after surgery. Children heal

remarkably well and much faster than adults, with the conjunctiva returning to a nearpristine white. Adults heal more slowly as the tissues become more fragile with age, and, even when fully healed, may retain a bit more vascularity in the white of the eye than pre-operatively. Some bleeding into the tissues of the eyelid, giving a "black eye" appearance may very rarely occur as well. This is more common in older adults and when the inferior oblique muscle is being operated. It is completely benign as well, and self-limited, resolving over the course of a week or so.

<u>3</u> Over/Under-Correction

Strabismus surgery is not a perfect science. There is a fair amount of art in addition to the scientific evidence we use in planning surgeries. Even when the surgery goes beautifully, with no complications, there is always the possibility of the eyes not being perfectly straight once the patient is fully healed. The reason is that each patient's response to the same amount of surgery may differ slightly. An under-correction occurs when there is still significant residual crossing or drifting of the eyes after surgery. An over-correction occurs when the problem is reversed or goes "past straight" into the opposite direction. An eye that drifted out now crosses in, for example. The risk of either happening depends very much on the type of strabismus the patient has, the age of onset, the severity of the misalignment, previous treatments, and the patient's underlying quality of binocular function (depth perception). Very large over- or undercorrections are extremely rare. Fortunately, most over- or under-corrections are very slight and usually not even visible to the patient or their family. In fact, the brain can handle very tiny degrees of misalignment after surgery well, even allowing for some degree of "3-D" vision in many cases. For such cases, no further treatment is necessary. If a significant residual strabismus remains, though, a second surgery may be necessary to get the eyes more perfectly straight. Sometimes that is necessary as soon as 8 weeks after surgery, and in other cases it might take 3-4 months to become clear. The risk can range, very generally, from 10%-30% depending on the type strabismus being corrected. There is also a very long-term risk of recurrence associated with many forms of strabismus. Many years after a successful surgery, sometimes decades later, the eyes may become misaligned again, for reasons that are not fully understood. A second surgery can easily be done at that point as well.

<u>4</u> <u>Double Vision ("Diplopia")</u>

In many forms of strabismus double vision is anticipated in the immediate aftermath of surgery. It is very rare in children, and is generally encountered more in adult cases. Surgically correcting exotropia (an outward drift) typically causes a little diplopia for a few days or even weeks after surgery. This is expected and even desirable for exotropia as it generally leads to better long term alignment results. Surgically moving the

muscles on the surface of the eye, tightening some and weakening others, can throw off the brain's eye alignment control center a bit after surgery. The brain has become used to the positions of the misaligned eyes and has to adjust to the new arrangement. Double vision may even occur when the eyes are perfectly straight post-operatively. This is more common in adults than in children. More importantly, the vast majority of these episodes are temporary and resolve on their own. Occasionally we use prism glasses or patching to relieve diplopia until it resolves. Very rarely, if diplopia is persistent and intractable, a second surgery may be performed for relief. Generally, we can predict from pre-operative testing which patients are more likely to experience double vision after surgery and prepare them appropriately. One large study of adult patients found it persisted in only 0.8% of patients, all of whom were identified preoperatively as likely to experience diplopia.

5 Conjunctival Sutures/Surface Changes/Cysts/Allergic Reactions

When we are finished operating on the eye muscles we must close the incision we made in the conjunctiva to reach the muscles. We use a couple of absorbable sutures that are as thin as a hair to close the wound. While these sutures will "melt away" on their own over a few weeks, it is common to feel a sandy, gritty sensation, as if something were in your eye, for the first few days to a week after surgery. If a patient rubs his or her eye very aggressively it is technically possible to break those sutures. If the wound then gapes open very widely it may be necessary to replace a broken stitch. This can be done simply in the office for adults, but would require a trip back to the operating room for young children. Most parents are *extremely* concerned that their child will do this, yet I have only had to go back to the O.R. once thus far in my career for such a problem. In most cases the wound edges remain well apposed and replacement of the broken stitch is not necessary.

Occasionally a small bit of white tissue may be visible or even extend like a small strand through the conjunctival wound right after surgery. This is white connective tissue called "Tenon's capsule" that is normally present just beneath the conjunctiva. It is trimmed during surgery on the muscles but sometimes a small bit can poke through the sutured incision. This is referred to as a prolapse of Tenon's capsule. It is generally of no consequence, usually absorbing on its own over a few weeks. If there is a long strand I may even be able to snip it short in the office (if the patient is old enough to tolerate it). Sometimes we use the post-op eyedrops a bit longer to help speed the absorption.

Very rarely a cyst may develop in or around the wound several weeks to many months after surgery. These are benign and do not affect the alignment. Sometimes this is due to a bit of the conjunctival cells or certain glandular cells getting pulled into the wound during suturing. If it persists or worsens and does not respond to eyedrop therapy, then it can be excised surgically later. This is extremely rare. Most often it is small enough and located out of sight beneath the eyelids that it does not require further treatment. In patients undergoing a second or third muscle surgery, the conjunctiva, even when properly sutured closed, may not heal completely flat due to previous scarring. There can be a slightly lumpy or thickened appearance in the operated area that may persist. Tissue that has been operated on more than once also tends to be a little more vascular or red than untouched tissue, and may always look a little more "pink" than average, even when fully healed. I take great care when handling and closing the conjunctiva in such situations to minimize these effects, but some of this may be unavoidable even with good technique.

Occasionally patients may develop an allergic reaction to the suture material. This becomes evident within a week or so after surgery when a red, inflamed, swollen cyst develops over the suture/surgical site. Some cases present weeks later in a very delayed fashion. A course of topical steroid drops and patience usually resolve this problem as the suture eventually dissolves away. A very rare patient may have an even more pronounced autoimmune reaction that also occurs several weeks after surgery. Topical steroids, and systemic steroids may be necessary in such highly unusual cases.

Scleritis, or an inflammation of the wall of the eye, has been reported extremely rarely following strabismus surgery. There are a handful of such reports in the literature, mostly involving older adult patients with a history of rheumatologic or autoimmune disease. The surgery seems to trigger an immune reaction in their bodies. It presents as a diffuse reddening of the wall of the eye with deep headache/eye pain occurring typically several weeks after surgery. It is treated with steroids by mouth as well as topically. This is an extremely rare occurrence and is unheard of in children. One study suggests a rate of 0.025% in adults.

Patients and family members may also notice some subtle visible changes on the "white of the eye" (sclera) after surgery. Occasionally the insertion site of a muscle that was recessed can remain visible underneath the conjunctiva as a blue-grey vertical line. As surgeons, we try to minimize this possibility with our technique, but it is not always possible to completely avoid it. It generally diminishes with time but may always remain visible to some extent in some patients. It is entirely harmless. The small patch of sclera immediately behind a muscle insertion is thinner than the rest of the eye wall, and has a slightly blue tinge to it, naturally. This may be slightly visible beneath the conjunctiva following surgery, but varies greatly from patient to patient. It tends to be more of an issue in older adults, frankly, than children or young adults.

Some very observant patients and family members may even be able to discern the incision in the conjunctiva when looking very closely at the surface of the eye, perhaps with the aid of a magnifying or "make-up" mirror. After a few months of healing they are very hard to detect, and almost impossible to see with the naked eye at a normal distance from the patient. I try to place most incisions beneath the eyelids so they will never be visible in normal circumstances. Rarely, a subtle irregularity on the surface of

the conjunctiva may persist, but it is usually well-masked by the eyelids. If a significant, cosmetically-unacceptable conjunctival scar persisted it is possible to return to the operating room to revise the conjunctiva, but this is an extremely rare event.

6 Eyelid Changes

When operating on the vertical rectus muscles—the muscles located at 6 and 12 o'clock on the eye, which move the eye up and down—the surgeon must be very careful to disconnect attachments between the muscles and the overlying eyelids. There are ligaments that connect the eye muscles to the muscles that move your eyelids, which are immediately adjacent. We take great care to address these attachments during surgery so that moving the eye muscle doesn't move the eyelid muscle along with it. The eyelid fissure (opening) may narrow or widen if these ligaments are not addressed. There is a small risk that the upper or lower eyelid could be slightly dragged up or down following the procedure being performed on the vertical eye muscle. With proper technique, these changes are minimal and generally not noticeable at all. In fact, it is typically only a concern when performing large weakening or strengthening procedures on these muscles (the superior and inferior rectus muscles). With large procedures, it may not be possible to completely eliminate the eyelid position changes, even with impeccable technique. Even so, significant, cosmetically unacceptable lid position changes are extremely rare. Worst case scenario, they may be addressed a few months later with plastic eye surgery on the eyelids, if necessary.

7 Corneal Abrasion/Dellen

The cornea may inadvertently be scratched during surgery by the instruments we are using. Of course, we take great care to avoid this and it is extremely rare. Any abrasions are usually mild and heal within 1-2 days following surgery. The usual post-operative antibiotic eyedrops are all that is necessary for treatment. An abrasion can feel irritating and painful, depending on the severity. Tylenol or Advil is usually all that is necessary for pain relief.

A dellen is a rare post-operative issue involving the cornea. It is a dry spot that develops on the surface of the cornea, usually near the edge where the cornea meets the conjunctiva. It typically occurs because of the normal post-operative swelling of the conjunctiva immediately adjacent to the cornea. Very puffed-up conjunctiva can prevent the eye's natural tears from spreading across the entire corneal surface. The swollen area of conjunctiva can create a small "valley" on the curved surface of the eye between the corneal edge and the conjunctiva. This can lead to a dry spot on the cornea where tears are not reaching. A small abrasion with thinning can occur in this area, and we call this a dellen. Rarely, such a spot can become infected. These dellen are more common in adult surgeries and complex reoperation cases where lots of old scarring is encountered. Whenever there is more inflammation and swelling postoperatively this is more of a risk. The treatment is aggressive lubrication with lots of artificial tears and ointments. As the swelling subsides the dellen generally heal without any long-term sequelae.

8 Lost Muscle / Ruptured Muscle

When placing a suture through an eye muscle to secure it prior to moving it on the surface of the eye, it is possible for the muscle to fall off the stitch or even tear in two. This is referred to as a lost or ruptured muscle and is extraordinarily rare. Each eye muscle is encased in a thin sleeve of connective tissue called the capsule. If the stitch only captures the capsule and fails to thread through the actual muscle fibers, then the muscle can slide backwards within the capsular sleeve when it is cut off the eye. Several of the eye muscles are fairly elastic and may retract behind the eye when this occurs. It can be very difficult to locate and pull the lost muscle back up to the front of the eye in such cases. Very rarely, a muscle can tear or rupture while it being handled and sutured by the surgeon. The same retraction of the torn muscle can occur in such cases. This kind of rupturing is exceedingly rare and usually occurs in older patients with significant medical diseases and fragile tissues. Thankfully, lost muscles are extraordinarily rare occurrences. Good data on the incidence is not available, but one recent British study reports an occurrence of 0.02% (that's 5 muscles out of 24,000 operated). Every effort is made to find and pull the muscle back up in such circumstances, and many reports in the literature suggest good success in finding the muscle when this complication occurs.

9 Slipped Muscle

A slipped muscle is one that has slid backwards on the wall of the eye from where the surgeon intended to reattach it. It results in an obvious weakness of the muscle's movement in the immediate post-operative period. We think it occurs because a suture knot may weaken, or the muscle may slide within the capsule (as discussed above), but it maintains its attachment to the eye wall. The fix is to return to the operating room and pull the muscle back up to its proper position. Sometimes there can be a very delayed slip that occurs years later, and this appears to be due to a scar forming between the muscle and its new insertion point which slowly stretches out over time. This is also an extremely rare complication-- one study estimated the incidence of this slipped muscles at 0.067%.

10 Deep Needle Pass/Scleral Perforation

When sewing the muscle back on the wall of the eye it is possible to go to deep with the needle. The wall of the eye is paper thin, so we employ special needles and instruments to reduce this risk. Deep needle passes are also rare, though slightly more common than lost or slipped muscles. Multiple studies estimate an incidence ranging from 0.2% to 1%. The concern with a deep needle pass is possible perforation of the wall of the eye with damage to the retina that lies beneath. The good news is that only a very small

fraction of deep needle passes cause a threat to vision. Most often all that happens is a small bit of bleeding underneath the retina with no tear or damage to the retina. The tiny hemorrhage resolves on its own and vision is not threatened. No special treatment is usually required. A small scar may result underneath the retina, but this does not affect vision. Rarely, a tear in the retina can result, which could lead to a retinal detachment. A small tear may be treated and sealed shut in the operating room with the application of a freezing probe (cryotherapy) to the wall of the eye or soon thereafter with a laser procedure by a retina specialist. A detached retina can cause vision loss if not detected and repaired. Whenever the surgeon feels he has made a deep needle pass it is incumbent upon him to dilate the patient's pupil and examine the inside of the eye to ensure no damage to the retina has occurred. If the retina has been torn or detached we would involve a retina surgeon right away to make the appropriate surgical repairs. Data on the incidence of a detached retina occurring in this manner is hard to find, but some estimate it at about 1 in 10,000.

11 Endophthalmitis

Another exceedingly rare risk is infection occurring *inside* the eye following surgery, a condition known as endophthalmitis. This is an extremely serious, vision-threatening complication. Different studies quote rates ranging from 1/18,500 to 1/350,000 cases. Most cases reported in the literature are connected to a deep needle pass that is believed to have introduced bacteria into the inside of the eye, though the exact cause is not definitively known. Vision becomes blurred with new floaters appearing, the eye becomes red and inflamed, the eyelids may swell, and deep pain may develop. The patient may have a fever and become lethargic. It usually happens within the first week after surgery, but some cases have been diagnosed as far as 13 days out. Instead of looking a little bit better each day, these patients get a little worse each day—more red, more swollen, more painful. Endophthalmitis is treated emergently by a retina specialist with injections of antibiotics and occasionally steroids into the inside of the eye. Results are highly variable. These cases are so rare that good data are not available. Some patients experienced a full recovery of vision. In others, if the infection is detected late or does not respond to antibiotics, permanent vision loss occurred.

12 Anterior Segment Ischemia

Detaching the eye muscles from the eye may interfere with the blood supply to the front portion of the eye. This occurs because several very tiny arteries that serve the anterior segment of the eye travel over the surface and across the insertion of the four main eye muscles. When we surgically detach a rectus muscle from the eye we also cut across those arteries. The iris and internal components of the front of the eye can lose their blood supply (become "ischemic") if enough of the arterial blood supply is interrupted. Fortunately, there are other arteries that enter through the back of the eye which offer some redundant circulation. The exact number of severed arteries that it

takes to cause anterior segment ischemia is unknown, and this complication is exceedingly rare. As a general rule, we worry about it mainly when contemplating operating on 3 out of the 4 rectus muscles on the same eye in one surgery – a very rare event. We will sometimes stage surgery in such cases as the risk of anterior segment ischemia declines when the eye has time to develop collateral circulation between surgeries. Good data on the frequency of this complication are hard to find, but one survey-based study suggested a risk of $\sim 1/13,000$ cases (0.007%). When it does happen the eye becomes inflamed, the cornea may become swollen and cloudy, the pupil may change shape, the pressure in the eye may drop or elevate, and vision becomes blurred. Symptoms start within a couple of days of the surgery. Cases may range from very mild to severe. It is treatable with topical steroid and dilating drops, and most cases improve slowly over time. Rarely, systemic steroids and hyperbaric oxygen treatments may be used. In extremely rare cases vision loss and permanent damage to the eye may occur. This complication is literally unheard of in children, with only a few documented cases, most of which involved children with rare medical disorders that complicated their conditions. Advancing age is by far the biggest risk factor. 3 rectus muscles operated at once is the next biggest risk. Other risk factors include diseases like leukemia and thalassemias, diabetes, hypertension, cardiovascular disease and prior retinal detachment surgery.