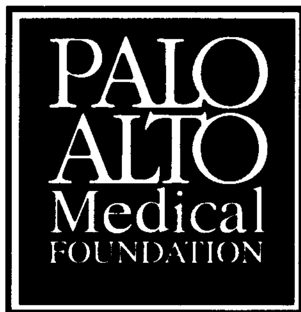

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Information Sheet and Consent For Botox Injection

Michael L. Trollope, M.D., F.A.C.S.

An anal fissure, a split in the skin of the distal anal canal, is a common problem that causes substantial morbidity in people who are otherwise healthy. The incidence of anal fissure is similar in men and women. The majority of fissures occur in the posterior midline of the anal canal and are usually the result of tearing of the skin from hard stool or other physical irritants. Multiple fissures or lateral fissures may have other causes, such a Crohn's disease, ulcerative colitis, tuberculosis, infection with human immunodeficiency virus (HIV), or syphilis.

Spasm of the anal sphincter has been noted in association with anal fissure, and for many years treatment has focused on alleviating spasm of the sphincter. Since 1951, the most common treatment for chronic anal fissure in the United States and Europe has been lateral internal sphincterotomy. This involves cutting the internal sphincter on the right or left mid lateral area to break the circular anatomy of the muscle permanently. Although the technique is simple and effective, the fundamental drawback of this surgery is its potential to cause minor but sometimes permanent alterations in the control of gas, mucus, and occasionally, stool. This can sometimes become a major problem, particularly in elderly patients or those with diarrhea, irritable bowel syndrome, diabetes, or recurrent fissure after previous surgery.

Initial medical management in the office consists of keeping the stools soft to avoid tearing the anal skin, frequent sitz baths to increase local blood flow and relax the sphincter, and topical steroid-anesthetic medications to decrease the inflammatory response and to provide local anesthesia. The goal of medical therapy is to create the effect of a temporary or reversible sphincterotomy, reducing he sphincter pressure only until the fissure has healed.

If this fails after a reasonable treatment duration, the next step has traditionally been surgical intervention with a lateral internal sphincterotomy with or without also removing the fissure itself.

Recently two new medical modalities have been investigated to provide another level of medical therapy before undergoing surgical intervention. Because they have only a temporary effect, they avoid the risk of permanent injury to the internal anal sphincter. A reduction of the anal pressure for three or more months usually allows the fissure to heal and thus eliminates the need for surgery.

The first of these is the topical application of dilute nitroglycerin paste to produce local relaxation of the exposed smooth muscle of the anus. While this does reasonably well in relaxing the sphincter, it does not dramatically produce healing in any large numbers. In addition, it produces incapacitating headaches in many patients. Because of this, it has not turned out to be the new treatment of choice and is of limited value.

The other modality now being reported is the local injection of 20 units of Botulinum Toxin (Botox) into the area of the internal anal sphincter. Botulinum Toxin causes denervation of the internal anal sphincter. The toxin acts rapidly so paralysis occurs within a few hours. Weakening of the muscle is seen clinically for three to four months. This reduction in the resting pressure of the anal muscle produces the equivalent of a surgical lateral internal sphincterotomy and thus allows for healing of the fissure.

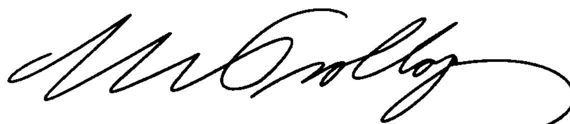
Various healing rates with the toxin injection have been reported to vary from 60 to 90% after two to three months. A second injection is possible.

Complications have been uncommon. Any fecal or mucous leakage has been reported in less than 1% of cases, and it was both minimal and temporary. Pain, infections, or other local problems at the injection site were not recorded.

Although this seems to be a very safe procedure at this time, it may be too early in the world clinical experience yet to really know what the overall rate of healing and complications will be after several years of widespread use. Because of this we do not recommend using the Botox as the initial treatment of a fissure at this time but reserve it for those who fail a reasonable trial of the usual conservative measures.

If you have any questions about this or anything else regarding the procedure, please do not hesitate to ask me.

Thank you,



Michael L. Trollope, M.D., F.A.C.S.

I have read the above, feel that I understand it, and request to proceed:

Patient Signature: ______________________

Witness: ______________________

Date: ______________________

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If you would like to make a donation to the Foundation, please speak to me about it.
Much of my equipment has been donated by generous patients.

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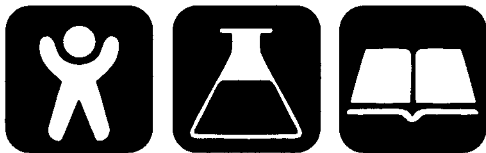

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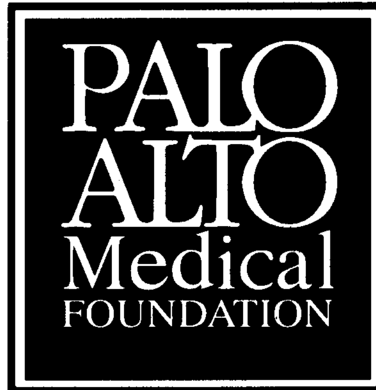
Postoperative Instructions After A Botox Injection



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General Information

Botox injection a new way to treat fissures. Its advantages are that no anesthetic is required, most patients have little pain, and usually no work time is lost. The Botox relaxes the internal anal sphincter to relieve the intense spasm usually associated with the pain of a fissure after a bowel movement. It takes several hours to days for the complete effect to occur. Most patients are unaware of any significant relaxation of the external sphincter so that leakage of stool is rare. Most however are aware that the entire sphincter mechanism is "looser"than it has been and passing gas may be difficult to control. Occasionally some rectal mucous may leak as well. If this happens a stay free pad is usually all that is needed to control the situation. The effect of the Botox is temporary - usually lasting about two months.

Ice Pack

Most patients undergoing Botox will not have enough pain to need an ice pack. However if you do experience severe pain, an ice pack applied to the area will help decrease the pain during the first day or two. Wrap some crushed ice in a wet wash cloth and apply it to the anal area.

Activities

Your may go ahead with your normal activities such as driving a car and working as soon as you are comfortable enough to do so. Avoid active sports for a day or two to let the tissues stabilize.

Bleeding

Expect some intermittent bright red bleeding for at least the first day or two from the injection sites. It should taper off quickly over a period of one to three days. Bleeding the first two or three days may be heavier and frequently follow a bowel movement.

Pain Medication

Pain is usually none to mild for the first day or two. If you are taking more than two pain pills a day you may get constipated and need some help in moving your bowels. An enema is usually too painful at this time. Two to four ounces of Milk of Magnesia or a similar cathartic usually works the best.

Infection

Because the anal area is never sterile, there is always a possibility of developing an infection in the areas of injection. An active infection will show itself by continuing pain in the injection site which is different from the usual fissure pain and is constant rather than coming on just after a bowel movement. Fever and chills may indicate an infection. If you run a temperature greater than 101° F call the office. Pain from the injection should ware off over the first 24 - 48 hours. If you still feel that the injection site is becoming more painful as time goes my call the office.

Diet

No special diet is necessary; however, it is important to keep your stool reasonably soft. A stool softener such as Surfak, Metamucil, or Colace or simply using bran in your diet will decrease pain at the time of bowel movements. Remember that the Botox injection is meant to add to your treatment for the fissure - do not stop the sitz baths, stool softeners, and topical medications.

Early follow up

If the pain persists for more than three or four days, if it goes away then returns, or you experience a fever or chills, please call the office for a checkup. Extremely rare instances of death from infection have occurred in this country. The main symptom of that infection was severe pain. If you are concerned about the amount of bleeding continuing after a week, make an appointment to see me at that time. Although uncommon, sometimes a painful tender hard nodule appears at the anal opening. This is usually an external thrombosis and requires returning to the office for removal of the external clot to relieve the pain.

Late follow up

Otherwise, make an appointment to see me again in six weeks for another exam. It seems at this time that one injection will suffice for most patients however clearly there are some who require a second or even a third injection at two month intervals. The goal with Botox is to relieve pain with bowel movements, the fissure may still take several months to heal even if the pain goes away quickly after the Botox injection.