

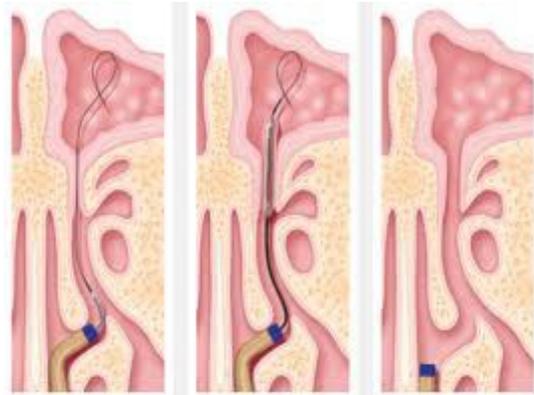


Carolina Ear, Nose & Throat Head and Neck Surgery Center

BALLOON SINUPLASTY

Balloon sinuplasty is a minimally invasive procedure used to treat chronic and recurrent acute rhinosinusitis that is causing persistent symptoms despite prolonged medical treatment. This FDA-approved technology has been available for use in the operating room since 2005, and this procedure has been performed in over 300,000 patients nationwide and counting. This procedure can be performed in the operating room under general anesthesia, but may also be an option for select patients to have this treatment under local anesthesia in the office. The procedure is less invasive than traditional sinus surgery, and equally effective at relieving symptoms of chronic sinusitis. Unlike conventional sinus surgery, it does not include removal of bone or tissue from the nose.

When performed in the office, it is similar to a dental procedure. Topical and local anesthetics are applied in a relaxed environment. The sinuses are visualized with an endoscope and camera, while a lighted guide-wire is positioned atraumatically into the sinus to be dilated. The physician then inserts a small balloon, similar to those used for cardiac angioplasty, along the wire inside the catheter. Once the balloon is properly positioned, the doctor inflates it and dilates the sinus opening. As the deflated balloon is removed, the sinus drains. The patient feels a decrease in pain and pressure, and the procedure is over. If necessary, the sinus can simultaneously be washed out. There is no removal of tissue, so bleeding is minimal. The procedure is very well tolerated, especially in properly selected patients.



The procedure is also very safe, with very low risk for complications. Return to normal activities is typical 24 hours later. Patients return for a follow-up visit so the dilated sinus openings can be visualized. Post-operative sinus cleanings or debridements are generally unnecessary.

Advantages of this procedure include minimal invasiveness with no tissue removal, reduced bleeding, quick recovery and less pain, no nasal packing, no general anesthesia or operating room and the associated costs, and preservation of future treatment options if needed.

While there continues to be controversy regarding proper use and efficacy regarding balloon sinuplasty, the majority of studies to date done with this procedure have been favorable. Studies have shown symptom improvement for 85% of patients at 2 years post-op with no serious adverse events. The American Rhinologic Society.

In Office Balloon Sinuplasty (IOBSP) Information for Patients

1. This procedure is being performed in an attempt to open up your sinuses under local anesthesia. If, for some reason, we are unsuccessful in this attempt, you still have the option of having conventional sinus surgery performed in the operating room.
2. You will be given a prescription for Ativan (an anti-anxiety pill) that you must get filled and bring to the office with you on the day of the procedure. You should take one Ativan 1 hour before your appointment time and bring the other pill to your appointment. You will need someone to come with you to the appointment; you **cannot** drive yourself.
3. You also need to bring a bottle of oxymetazoline (Afrin) nasal spray with you to the appointment. Generic form is suitable. 1 hour before your appointment time begin spraying 2 sprays in each nostril—5 minutes apart—3 times.
4. Do Not eat for 2 hours prior to your procedure time.
5. Please remove all piercings prior to coming in for your procedure.
6. If we do not already have your sinus CT films in the office, you will need to bring them to the office on the day of your procedure day.
7. Plan to be in the office about 2 hours for this procedure. It takes up to 60 minutes to adequately anesthetize the nose and about 30 minutes for the procedure.
8. During the procedure, the lights will be off in the room. This enables the physician to see the guide light as it enters your sinuses. You may want to consider bringing an iPod or other music device to listen to during the procedure.

9. The local medication that is put in your nose to numb it will most likely also make your teeth and throat numb and it has a bad taste. The numbness wears off in about 1-2 hours.

10. It is NORMAL to hear a cracking sound and have brief tooth pain when the balloon is inflated in your sinuses.

11. It is NORMAL to have some sinus pain or pressure after the procedure – you can treat this with OTC medications (Ibuprofen, acetaminophen) or the prescribed painkiller, if needed.

12. You will need to rinse your sinuses with saline twice a day starting the day of the procedure. You will continue this until the physician tells you that it is OK to stop. Alternatively you may be prescribed a form of aerosolized (nebulized) medication which should be started the day of the procedure.

13. Alcohol is a potent vessel dilator and can promote edema or swelling and even bleeding. It is best to abstain from heavy drinking for 1 week prior to surgery and to avoid any alcohol intake the week after surgery.

Smoking can severely affect the outcome of your sinus surgery. Smoking causes increased scar tissue and poor healing that can lead to poor outcome of surgery. We will usually ask you to stop smoking 3-4 weeks before surgery and to avoid smoking for an additional month after surgery.

Carolina Ear, Nose & Throat
Head and Neck Surgery Center, P.A.
CONSENT FOR BALLOON SINUPLASTY

Patient: _____ Chart # _____

I (we) understand that the specific risks associated with the proposed procedure are:

- a) Infection
- b) Chronic dryness and crusting in the nose
- c) Bleeding
- d) Cerebral spinal fluid leak with potential infection requiring intervention
- e) Temporary or permanent visual change and injury to eye muscles
- f) Recurrence of sinus disease requiring additional medical or surgical therapy

I (we) understand that the practical alternatives to the procedure are:

- a) Continued use of decongestants and antibiotics
- b) Sinus irrigations
- c) Allergy testing and immunotherapy if indicated

I (we) understand that if the procedure is rejected, the likely prognosis is:

- a) Spread of infection with possible orbital or brain complications
- b) Chronic or recurrent main drug resistant sinus disease

I (we) have read this consent document. I (we) understand the nature, expected benefits and risks of the surgical procedures described to me, as well as alternative treatment options. All of my (our) questions have been answered to my (our) satisfaction, and I (we) understand that there are no guarantees to surgical outcome.

Signature of Patient/Parent/Legal Guardian

Date

Witness