



SUBURBAN
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Balloon Sinuplasty Surgical Informed Consent and Education

General Information: The paranasal sinuses, commonly known as 'sinuses', are bony outpouchings from our nose that extend into several regions of our skull. We typically have 4 paired sinuses: frontal, sphenoid, maxillary and ethmoid. There is variation in the size of the sinuses, and about 10% of us won't have even developed one or both of our frontal sinuses. Interestingly, we still do not know exactly why we have sinuses. Some theories exist: they lighten our skull, offer protection to our eyes and brains in the event of head trauma, add resonance to our voice, and others.

"Sinusitis" is a term frequently applied to a variety of symptoms, but specifically refers to inflammation or infection of the sinus lining in one or more of the affected sinuses. Recurrent acute bacterial sinusitis or chronic sinusitis are two of the common conditions that balloon sinuplasty may offer improvement. It is estimated by the CDC that 32 million people suffer with chronic sinusitis. Chronic sinusitis is defined as sinus problems that last more than 3 months and have not been cured with antibiotics, nasal steroid sprays, and other medical therapies.

Standard sinus surgery has evolved. In the 1980s it was a procedure involving incisions on the face and in the mouth to treat the sinuses. In the last 25 years fiberoptic telescopes and tools have evolved so now most of the procedures can be accomplished through the nostrils, with no visible incisions. 200,000 to 350,000 people undergo sinus procedures every year. Many of these patients will have significant improvement in their daily symptoms and quality of life. While not a cure for all sinus problems, the surgery may be very helpful for many patients.

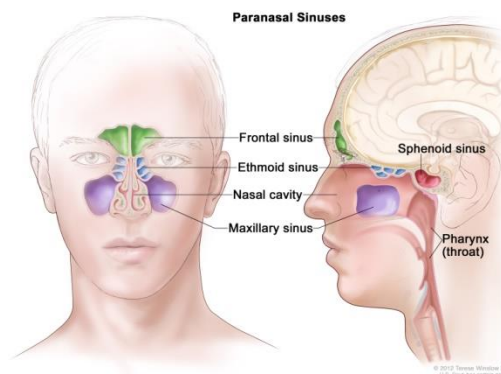
It is important to understand that chronic sinusitis generally cannot be cured, even with surgery. Our goal is to improve the condition, decrease your symptoms and make you feel better. Surgery is not a cure-all but is just one mode of therapy. Additional medical and allergy treatment is often necessary.

Balloon dilation sinus surgery or "balloon sinuplasty" is considered to be a less invasive alternative to traditional functional endoscopic sinus surgery (FESS). Traditional sinus surgery removes tissue and bone, whereas balloon sinuplasty uses small balloons, similar to those used in blood vessel procedures like cardiac angioplasty, to dilate tissue and bone without leaving raw surfaces to heal. Balloon sinuplasty is done in the office under local anesthesia. Often you will also be prescribed medicine to reduce pain and anxiety prior to beginning of the procedure. You can expect to be in our office for 1 to 2 hours for this procedure. The recovery is generally easy and unremarkable. There is typically minimal pain and minimal bleeding. Most people can resume normal activities the following day or two.

Outcomes: Balloon sinuplasty, similar to traditional endoscopic sinus surgery does not work for everyone. The balloon technique can be used in many of the sinuses, but not all.

Risks: As with any surgical procedure, risks exist.

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- Failure to eradicate facial pain and headaches.
- Failure to decrease the frequency of sinus infections.
- Failure to eradicate the signs and symptoms of chronic sinusitis.
- Nosebleeds.
- Poor scarring necessitating traditional sinus surgery.
- Loss or change of smell sensation. The nerves that carry smell up to our brain are located at the top of the nasal cavity. This surgery should not impact those nerves but there is a very rare association of any form of intranasal surgery resulting in a loss or a change in the sense of smell.
 - Injury to the brain or the covering of the brain (the meninges) resulting in brain injury or brain fluid (CSF) leakage. This is exceedingly rare in balloon sinuplasty.
 - Injury to the eye socket tissues or the eyeball itself causing double vision or loss of vision. Also exceedingly rare in balloon sinuplasty.
 - Inability to perform the procedure. In a small percentage of patients because of anatomic variations, it may be impossible to insert the balloon into the sinuses and the procedure would have to be aborted.

Alternatives: Balloon sinuplasty is an elective procedure. Your alternative is to not have the procedure performed. You can continue medical therapy for your sinus inflammatory disease. You can also opt for more aggressive traditional sinus surgery.

At Suburban ear, Nose and Throat Associates Ltd., we go to great lengths to try to help you understand your plan of care. If at any time you have questions or concerns please call us at (847)-259-2530.

Instructions: You will need someone to take you to the appointment and take you home also. If any pre-procedure medicines have been prescribed, please be sure to sign this consent form and have it witnessed *before* you take the medicines. You cannot drive the remainder of the day, or for 24 hours after taking any narcotic pain medicine, if it is needed. Typically there is not excessive discomfort after the procedure.

I have been given an opportunity to ask questions about my condition, alternative forms of therapy, risks of non-treatment, the procedure and risks and hazards involved. I have sufficient information to give this informed consent. I understand every effort will be made to provide a positive outcome, but there are no guarantees.

Patient PRINTED Name: _____

Patient SIGNATURE: _____

Date: _____ Time: _____

Witness: _____ Date: _____