Chronic sinusitis is one of the most common diseases. In USA, it affects 31 million people annually.\(^1\) Its deleterious effect on the quality of life has also been found to be worse than other common chronic diseases like diabetes and heart failure.\(^2\) Chronic sinusitis that does not respond to maximal medical therapy is treated with surgery.

The current gold standard in the surgical treatment of chronic sinusitis is endoscopic sinus surgery (ESS) using rigid instruments. These rigid instruments remove diseased or obstructing mucosa, and bone. The aim of surgery is to relieve the sinuses of obstruction, thereby allowing normal ventilation and physiology to return.

A new technology called "balloon sinuplasty" was first unveiled to the field of sinus surgery in 2006. The procedure follows the concept of cardiac balloon angioplasty in that it dilates the obstructed sinus outflow tracts to achieve the same aim as surgery with traditional rigid instruments, while minimising collateral damage to surrounding mucosa and structures more effectively and safely.

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The Technique

The balloon sinuplasty system consists of three key components: guide wire, guide catheter and balloon.

First, the guide wire is passed into the obstructed/diseased sinus with the help of an angled guide catheter [Figure 1]. Successful and proper cannulation of the sinus is then confirmed with either fluoroscopy/XR [Figure 2a] or by transillumination using a lighted guide wire [Figure 2b]. The balloon is then railroaded over the guide wire to sit across the obstructed sinus outflow tract and inflated to dilate it [Figure 3]. Irrigation of the sinus may be followed, before the entire system is removed [Figure 4].

Advantage over Current Rigid Instrumentation

The key advantage of using this device is that it is minimally
traumatic, especially to the surrounding mucosa. Thus, the risk of collateral damage, post-operative adhesions and scarring is significantly reduced, as well as the amount of the post-operative bleeding and pain that patients experience.

In the event of unsatisfactory treatment with this device, the surgeon still has the option of endoscopic sinus surgery with traditional rigid instruments to fall back on.

**Clinical efficacy**

To date, there have been two large scale case series studies on the use of this device, evaluating a total of 1101 patients. It was found that symptom improvement was achieved in 85-95.2% of patients, with a revision rate of 2.4-9.2%.

Published data on surgery with traditional rigid instruments, on the other hand, report symptom improvement in 75-95% of patients, with revision rates of 10-15%. Unfortunately, there is no direct head-to-head comparative data yet.

**Safety**

Major complications from sinus surgery with rigid instruments, like orbital injury and cerebrospinal fluid (CSF) leak, are rare (up to 1.5%), and result from penetration of the protective bony barrier of the orbit and base of skull. Minor complications occur in 1.1-20.8% of cases.

In the two large scale studies, there were no major complications encountered, and minor complications like post-operative sinusitis occurred in 8.3% of patients and significant epistaxis in <1%.

However, as of March 2010, there have been four reported cases to the US FDA of CSF leak and orbital wall penetration, a timely reminder that though this device is minimally traumatic, it is not completely atraumatic, and familiarisation and training in the use of this device would not only improve surgical outcomes, but also improve patient safety.

**Role in Current Surgical Management of Sinus Disease**

As with any new device, the exact role of this technology in the surgical algorithm for chronic sinusitis is still evolving as more experience and data is collected. Based on available literature
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and clinical experience thus far, balloon sinuplasty appears to be particularly suitable for patients who have mild-to-moderate chronic sinusitis [Figure 5] who have not been operated on before. Sinusitis involving the frontal sinus would be particularly amenable to balloon sinuplasty as the frontal sinus is the most challenging to operate on due to its difficult anatomy and its increased propensity for scarring and stenosis, leading to higher failure and revision rates. Other indications for balloon sinuplasty include patients suffering from barometric pressure or coagulopathy.

Balloon sinuplasty is not suitable for extensive nasal polyposis or sino-nasal tumours (as it does not remove tissue), or when wider exposure is required (eg, large fungus balls within the sinuses).

Criticisms
Each balloon sinuplasty system is a single use, disposable set, and is not cheap. The surgeon will need to discuss the cost-benefit of using this device with the patient.

If fluoroscopy/XR is employed to confirm correct placement of the balloon sinuplasty guide wire during the procedure, there is radiation exposure to both patient and surgeon. This amount of radiation has however been determined to be well within safe levels.7 To completely avoid this concern, many surgeons now use a lighted guideline instead [Figure 2b].

There has been real concern expressed over the possible formation of mucocoeles as a result of inadvertent obstruction of the adjacent sinus air cells when a sinus outflow tract is dilated and displaced by the balloon sinuplasty balloon. This complication takes many years to manifest and we will therefore need several years to see whether this problem does indeed develop.

Summary
Balloon sinuplasty is a new tool for sinus surgery. Its main advantage is that it is minimally traumatic compared to conventional rigid instruments. Currently, the main indication for its use is primary surgery for mild-to-moderate chronic sinusitis (especially frontal sinusitis). Published data suggests that it has clinical efficacy at least comparable to traditional rigid instruments, but with probably a better safety profile. However, cost is a consideration that needs to be discussed with the patient.

References