Innovations in Balloon Catheter Technology in Rhinology

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KEYWORDS

• Balloon catheter technology • Balloon sinus dilation • Chronic sinus disease
• Endoscopic sinus surgery

KEY POINTS

- Balloon catheter technology (BCT) continues to expand as innovations in lighted guidewires, compatibility with surgical navigation, and ergonomics help to increase the scope of utilization.
- "Hybrid" balloon catheter dilation procedures are becoming more common, and there is high-quality literature supporting their use in improving outcomes.
- Indications for BCT have been bolstered by randomized controlled clinical trials showing durable improvement in quality of life and radiological outcomes in appropriately selected patients.
- Further prospective clinical trials are needed comparing stand-alone BCT with traditional endoscopic sinus surgery to help determine the specific patient populations that would benefit.

INTRODUCTION

The use of balloon catheter technology (BCT) is one of the more recent advances in the treatment of chronic rhinosinusitis (CRS). In 2015, the US market exploded, and the fastest growing segment of ear, nose, throat (ENT) endoscopic devices was balloon technologies.[1] Fueled by the demand for minimally invasive technologies and expanded insurance coverage, the marketplace for BCT was estimated to increase in value from approximately $50 million in 2012 to more than $200 million in 2015.

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Otolaryngol Clin N Am ■ (2017) ■–■
http://dx.doi.org/10.1016/j.otc.2017.01.008
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The technology was first introduced as a treatment of chronic sinusitis in 2005 with US Food and Drug Administration approval of the Balloon Sinuplasty device (Acclarent, Inc, Menlo Park, CA, USA).

BCT has been present in other fields within medicine for decades. It was not until the early twenty-first century that experiments began with its use in dilating sinus ostia.[2,3] The initial devices were modifications of cardiac stenting balloons that provided a nonconforming balloon appliance fed over a flexible guidewire.[2]

Over the last 10 years, there have been many innovations in BCT as a therapy for paranasal sinus disease. The devices now permit multisinus applications using just one device and are equipped with suction and irrigation capabilities. They have also improved in ergonomics, and the methods of localization have expanded. Initial BCT localization was via fluoroscopy with the inherent risks of exposure to radiation. Today, recent advances include the utilization of transillumination and real-time 3-dimensional image guidance. The goals of this article are to explore these innovations and focus on the specific details of the technologies and utilities involved. This comprehensive review also examines the indications and limitations of BCT as evidenced in the contemporary literature.

INNOVATIONS IN SPECIFIC BALLOON CATHETER TECHNOLOGIES

BCTs have seen many generations developed from several companies over the years. They were initially conceived in the early portion of the twenty-first century as a distinct minimally invasive procedure that could serve as another tool in the treatment of CRS. In 2004, Acclarent Inc was the first company to begin development of BCT in treatment of sinus disease.[4] Multiple US patents have been obtained on the system, which uses a guidewire over which a sheath is passed to introduce the balloon into the targeted sinus (**Fig. 1**).

Entellus Medical, Inc (Maple Grove, MN, USA) was founded in 2006 as a company developing sinus-specific balloon technology. Their initial product was the Functional Infundibular Endoscopic Sinus System that proceeded through a transantral route. In 2010, Entellus developed a device using a transnasal route for dilation, irrigation, and suctioning of the frontal, sphenoid, or maxillary sinus ostia. It functions by using a flexible and malleable distal cannula along with an overlying balloon catheter to directly palpate and cannulate an ostium (**Fig. 2**). The more invasive transantral technique of approaching the maxillary sinus ostium from inside out via canine puncture has been largely abandoned.

More recently, Medtronic Inc (Minneapolis, MN, USA) has become involved in BCT with the release of their balloon platform, which can be readily coupled with their (EM) surgical navigation system. In 2014, Medtronic began offering a product called the NuVent EM Balloon sinus dilation system (**Fig. 3**), which offers a "plug and play" ability to track the tip of the balloon instrument obviating calibration.

Fig. 1. Acclarent Relieva spin plus balloon sinuplasty system. (*Courtesy of* Acclarent Inc, Menlo Park, CA; with permission.)