Functional endoscopic sinus surgery (FESS) has become the international standard for the treatment of refractory chronic rhinosinusitis. The most common complication encountered after FESS is the lateralization of the middle turbinate and adhesion formation (synechia) that results in occlusion of the sinus drainage pathway. This can result in recurrent symptoms and subsequent surgical failure. Adhesions form when two non-epithelialised, opposing mucosal surfaces touch. In order to prevent nasal adhesions, it is common practice to place nasal packing material in the operated area. These packing materials have a space-filling ability (bulking) to physically separate mucosal tissues such that adhesions are prevented from forming during the initial healing period of the tissue. However non-resorbable nasal packing has been documented as a major source of pain for patients, especially with regard to dressing removal, and can lead to re-bleeding of the surgical site. 

Over the last few years surgical preference has shifted to using resorbable or degradable packing, including intranasal splints which do not require post-op removal. Similar to nasal packing, intranasal splints have become routine measures for controlling intra-operative bleeding and preventing postoperative adhesion following nasal surgery. Valentine et al. has provided a detailed report on nasal splints and how they have been designed to tamponade mucosal tissues to help control bleeding. 

Figure 1: Photographic and scanning electron microscope (SEM) image of NASASTENT dissolvable dressing, showing the open-cell structure of the dissolvable intranasal splint. NASASTENT dissolvable dressing has pore sizes in the range of 30 to 50µm by visual estimates.
When a nasal dressing is introduced, it fills the nasal or sinus cavity, applies pressure against the mucosa to minimize bleeding and provides a surface against which the blood can clot. The absorbent material of nasal dressings also helps minimize bleeding and edema by absorbing blood and nasal fluid created during surgery.

**NASASTENT® dissolvable nasal dressing**

The NASASTENT nasal dressing is a dissolvable, polysaccharide-based intranasal splint made from plant-based Sodium CarboxyMethyl Cellulose (CMC). NASASTENT nasal dressing is intended to minimize bleeding and edema and to prevent adhesions between the septum and the middle turbinate after surgery or trauma. As NASASTENT nasal dressing absorbs nasal fluids, it turns into a hydrocolloidal gel that naturally drains from the nasal cavity within several days.

CMC is commonly used in pharmaceuticals and medical devices. Medical devices containing CMC, such as Smith & Nephew's (formerly ArthroCare's) RAPID RHINO® epistaxis devices dressings, STAMMBERGER SINU-FOAM® nasal dressing, and Seprafilm Bioreorbable Membrane, have been in clinical use over the last two decades. CMC is also a multipurpose food additive classified by the FDA as 'generally recognized as safe' (GRAS).

In this study the performance characteristics of NASASTENT nasal dressing and a commercial nasal splint, Nasopore Firm (Polyganics BV, Groningen, Holland), were evaluated. Testing was performed using representative *in vitro* models to assess resilience at time of placement, ability to separate and support compromised tissue after placement, fluid uptake (hygroscopic characteristics), and the ability to retain form when exposed to physiological conditions.

**Resilience**

Resilience is the power or ability of a material or structure to return its original form or position after being bent, compressed, or stretched. For ease of placement, the ability to conform to the nasal cavity, and to perform as a mucosal tamponade to help control bleeding, intranasal splints need to be resilient. The robustness or strength of this resilient behavior will determine an intranasal splint's ability to provide a tamponade effect, and determine how reliable it will be in keeping intranasal soft tissue structures in a desired location.
The resilience of the NASASTENT™ nasal dressing and Nasopore Firm was evaluated by measuring a) their compression strength and ability to recover their original dimensions after compression, (Compression Strength & Dimensional Recovery), and b) the force that they generate when placed into gaps of various, clinically-relevant sizes between tissues (Tissue Separation Force).

Compression strength and dimensional recovery

To measure dimensional recovery, the devices were axially compressed to 75% of their initial height using an Instron test machine and then the compressive load was released rapidly (loading and unloading rate of 50mm/min), while recording the cross head displacement and load generated. The compressive strength of these devices was determined at 75% deformation. Resilience in this test was assessed as a percentage of the height recovered after the off-loading cycle.

As shown in Figure 2, NASASTENT nasal dressing exhibited greater compressive strength throughout the compression cycle as compared to Nasopore Firm. The maximum load generated in the compression test was 25.22 +/- 1.48 N and 97.15 +/- 8.92 N for Nasopore Firm and NASASTENT nasal dressing, respectively.

Both the devices exhibited resilient dimensional recovery and returned to nearly 100 percent of their initial height after the compressive load was removed (Table 1). NASASTENT nasal dressing, however, had 6 times more compressive strength when compared to Nasopore Firm.

![Figure 2: Representative load - Displacement profile of NASASTENT nasal dressing and Nasopore Firm during axial compression](image)

<table>
<thead>
<tr>
<th>Device</th>
<th>Dimensional Recovery (%)</th>
<th>Compressive Strength (kPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NASASTENT</td>
<td>98 +/- 2 %</td>
<td>114.28 +/- 10.50</td>
</tr>
<tr>
<td>Nasopore Firm</td>
<td>100 +/- 1%</td>
<td>17.20 ± 1.70</td>
</tr>
</tbody>
</table>

Table 1: Resilience of intranasal splints – Dimensional recovery and compressive strength after a compressive loading/off-loading cycle

These values confirm that NASASTENT nasal dressing can support up to 6 times the load per unit area of Nasopore Firm.
Tissue separation force

Another important function of intranasal splints is to prevent adhesions by keeping mucosal tissues separated after trauma or surgery. To determine the ability of the NASASTENT™ nasal dressing and Nasopore Firm to keep tissues separated after placement, they were inserted into a simulated nasal cavity and the separation force exerted by the devices on their surroundings was recorded over time. The simulated nasal cavity gap ranged from 7 to 10mm, which encompasses the nasal cavity spaces for most adults. The test setup is shown in Figure 3 below.

NASASTENT nasal dressing exhibited 2 to 3 times more tissue separation force compared to Nasopore Firm over the gap distances tested, (Figure 3). To simulate the common practice of packing Nasopore Firm upon itself in order to provide sufficient bulking, a second series of tests was conducted wherein the Nasopore Firm was folded in half (double thickness) and placed in the gap. In this “double fold” test, however, no increase in the tissue separation load value was observed. The separation force of Nasopore Firm for the 10 to 7mm simulated nasal cavity gaps ranged from 1.19 to 5.83 N for single fold and 2.04 to 8.25 N for double fold samples. NASASTENT nasal dressing, by contrast, exhibited separation force values ranging from 3.92 to 17.15 N over the same simulated nasal cavity gap range (Figure 4).

Figure 3: Tissue separation force test setup – intranasal splint placed between two parallel plates while recording the load generated by the device over time

Figure 4: Tissue Separation Force of NASASTENT nasal dressing and Nasopore Firm after being placed in simulated nasal cavity gaps ranging from 7 to 10mm. NASASTENT nasal dressing provides significantly higher separation forces compared to Nasopore Firm over all nasal cavity gap sizes tested, even when Nasopore Firm nasal dressing had been double-folded before insertion.
Modulation of the tissue separation force

In certain clinical situations it may be desired to tailor the tissue separation force to a particular level for the application at hand. Since NASASTENT™ nasal dressing is trimmable, its separation force can be modified by cutting the product to a desired size. Additionally, this separation force can be reduced by injecting the NASASTENT nasal dressing with physiological fluids after placement. To examine this phenomenon, both devices were injected with 4cc saline solution after being placed in the simulated nasal cavity and the separation force was observed over time (Figure 5). The separation force of NASASTENT nasal dressing was reduced by about a factor two when the device was injected with saline for simulated nasal cavity gaps of 7 to 10mm. For example, at the simulated nasal cavity of 8mm, the NASASTENT nasal dressing support load was reduced from 13.60 +/- 1.27 N to 7.48 +/- 1.71 N. However, the separation force generated by Nasopore Firm, as a single or double-fold, is minimal and the introduction of saline did not change this value. This data shows that NASASTENT nasal dressing is capable of providing significant tissue separation force without the need for folding or packing of the device upon itself and this separation force can be modulated by either trimming to a desired size or exposure to physiological solutions via injection.

Fluid uptake

Nasal splints have fluid absorption characteristics that help in controlling minimal bleeding following surgery or nasal trauma. The fluid uptake property of NASASTENT nasal dressing and Nasopore Firm was measured by immersing the devices in Lactated Ringer’s solution and incubating at room temperature overnight to allow for hydration. The water-uptake was calculated as the ratio between the hydrated and dry weights of the devices.

NASASTENT nasal dressing and Nasopore Firm exhibited high fluid uptake characteristics with an ability to absorb fluids to more than 15 times their original weight.

NASASTENT nasal dressing can absorb more than 16 times its dry weight. Our study showed that the Nasopore Firm absorption ratio under these test conditions is 18.49 +/- 0.72.

<table>
<thead>
<tr>
<th>Device</th>
<th>NASASTENT</th>
<th>Nasopore Firm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dry Weight (Wd)</td>
<td>0.902 ± 0.01</td>
<td>0.93 ± 0.01</td>
</tr>
<tr>
<td>Final Weight (Wf)</td>
<td>14.67 ± 0.79</td>
<td>17.21 ± 0.71</td>
</tr>
<tr>
<td>Fluid Uptake Ratio (Wf/Wd)</td>
<td>16.04 ± 0.31</td>
<td>18.49 ± 0.72</td>
</tr>
</tbody>
</table>

Table 2: Fluid absorption characteristics

![Figure 5](image-url): Representative response of NASASTENT nasal dressing and Nasopore Firm after saline injection. NASASTENT nasal dressing tissue separation force can be modulated with exposure to saline. Data shown for 8mm simulated nasal cavity.
Form retention

An essential function of intranasal splints is to provide a physical barrier between mucosal tissues over the initial healing time of two to three days to prevent adhesions between nasal tissues. Since these devices are water degradable, the worst case scenario to prove their ability to provide this physical barrier is to directly immerse them in an aqueous solution and observe their behavior over three days of incubation time. Presence of the splint after the incubation time was determined by visual inspection.

The devices were placed directly in Lactated Ringer’s solution and their ability to retain their form over three days at 32 to 34ºC was visually evaluated. Since these nasal splints degrade by either dissolving (NASASTENT™ nasal dressing) or fragmenting (Nasopore Firm) when exposed to aqueous solutions, this direct submersion into the physiological solution was considered a challenge condition to assess the form retention performance requirement of these devices. The abilities of the nasal splints to retain physical form after three days of direct exposure to physiological solution is shown in Figures 6. The NASASTENT nasal dressing and Nasopore Firm are able to take up the solution and retain their physical form over the three days.

Conclusions

NASASTENT nasal dressing is a dissolvable nasal dressing made from plant-derived CarboxyMethyl Cellulose (CMC), a material that is ‘generally regarded as safe’ (GRAS) by FDA. NASASTENT nasal dressing is a robustly resilient and highly hydroscopic device with an ability to absorb more than 16 times its dry weight of aqueous media. During placement into a nasal cavity, NASASTENT nasal dressing quickly springs-back to recover its form and has a compressive strength six times higher than Nasopore Firm. Also, NASASTENT nasal dressing provides significantly higher Tissue Separation Force than Nasopore Firm and the this separation force can be modulated by exposure to physiological solutions via injection. Although fully dissolvable, NASASTENT nasal dressing maintains its form over the important three day initial healing post-op period typical in nasal procedures while in direct contact with physiological fluids. This affords NASASTENT nasal dressing the ability to prevent tissue adhesions (synechiae) after surgery and/or trauma. In total, this study demonstrates that NASASTENT nasal dressing is a highly absorbent and resilient intranasal splint that can conform to nasal cavity geometries, possesses sufficient strength to help control bleeding via tamponade effect, and can exert sufficient tissue separation force on nasal structures such as the middle turbinate to keep them in a desired location in order to prevent adhesion formation.

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Figure 6: Form retention of NASASTENT dissolvable nasal dressing (left) and Nasopore Firm 8cm (right) following three days direct exposure/immersion to aqueous solution.
References


2. Cowin A, McIntosh D, Wormald P. Healing of wounds created in the nasal mucosa following endoscopic sinus surgery can be affected by different nasal packing materials. 2002 August; 10(3):114-117


