

# Punctal Plugs Get Smart

**Space-age materials help to bring dry eye treatment into the 21st Century.**

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As Charles Darwin observed, nature favors adaptability. Now, thanks to the latest “smart” materials, “adaptable” is a description that can be applied to a punctal plug. The new SmartPlug from Medennium uses cutting-edge technology to eliminate many drawbacks associated with traditional plugs — while offering advantages that would make Darwin proud.

## **Shape-shifter**

A “smart” material is defined as one that alters its physical properties in response to an outside stimulus. This particular polymer — a thermosensitive, hydrophobic acrylic developed by scientists at Medennium — changes from a rigid solid to a soft, cohesive gel when its temperature changes from room temperature to body temperature.

Outside the punctum, at room temperature, the SmartPlug is a rigid rod about 0.4 mm in diameter and 9 mm long. Specially designed grooved forceps are used to insert two-thirds of the SmartPlug into the punctum, leaving one-third protruding. (Because the rod is thin and rigid, the punctum doesn’t need to be dilated.)

As the material inside the punctum rapidly warms, it shortens and expands in diameter, turning from a rigid rod into a gel-like plug, conforming to the size and shape of the punctum. (See illustrations, below, right.) Meanwhile, the shortening length draws the remainder of the rod down into the canal. When the transition is complete, the SmartPlug is totally contained

**As the SmartPlug is inserted into the punctum (see images A through D, right) the shift from room temperature to body temperature causes the material to change from a rigid, thin rod to a gel-like plug that conforms to the size and shape of the punctum.**



inside the lower vertical punctum.

Removal, if necessary, is accomplished with irrigation. A syringe of saline solution, introduced using a cannula, causes the plug to become slippery and pushes it out through the lacrimal system. Because the plug is tiny and has a gel-like consistency, it usually leaves the body unnoticed. (According to Medennium, thousands of patients around the world have used the SmartPlug, and no removal problems have been reported.)

## **SmartPlug vs. silicone**

The SmartPlug has numerous advantages over traditional silicone plugs:

- ▶ Because it adapts to the size of the individual punctum, you don’t have to measure the punctum before insertion.
- ▶ You don’t need to keep an inventory of multiple plug sizes in stock. One size fits all.
- ▶ You don’t need to dilate the punctum.
- ▶ Once inserted, the SmartPlug doesn’t protrude from the punctum to potentially irritate the patient’s cornea.
- ▶ Unlike silicone plugs, the SmartPlug has an extremely high retention rate, and is nearly impossible to rub out.
- ▶ The SmartPlug’s gel-like form (at body temperature) won’t distort the canaliculus or the osteum.

## **The SmartPlug in action**

Medennium conducted a clinical study of 120 dry eye patients to compare the effectiveness and ease of use of silicone

plugs and the SmartPlug. A conventional silicone plug was inserted in the lower punctum of one eye; a SmartPlug was inserted in the lower punctum of the other eye. All plugs were removed after 3 months.

Both plugs were effective at reducing itching, blurring, dryness and soreness. However:

- ▶ Eyes treated with SmartPlugs had less burning and stinging, foreign body sensation, tearing, discharge and photophobia symptoms.

- ▶ Eyes treated with the SmartPlug showed less superficial corneal erosion and fewer surface defects (as determined by fluorescein staining).

- ▶ Eyes treated with silicone plugs showed more devitalized tissue (as determined by Rose Bengal staining).

- ▶ Forty-two (35%) of the silicone plugs were extruded during the study; only a single SmartPlug was lost.

After removal of the SmartPlugs, all subjects were found to have a patent lacrimal system.

#### **Feedback from the field**

Dennis R. Conrad, M.D. FRCSC, who has performed cataract and refractive surgery for 17 years in Ottawa, Ontario, has used punctal occlusion for 6 years. He began using the SmartPlug at the beginning of 2002, and has inserted about 200 pairs. "The SmartPlug is a great innovation," he says. "It makes all the difference in the world.

"Silicone plugs irritated my patients' eyes. Sometimes I could actually see a mark on the eye where the plug was rubbing. With the SmartPlug, one size fits all, and when it's in position, nothing protrudes. Patients have no reaction; they don't feel the plug.

"Also, because of the irritation caused by silicone plugs, patients rubbed their eyes and often pushed the plug out. I used about 40% of my silicone plugs replacing others that popped out! Only one or two SmartPlugs have been rubbed out since

I began using them. Now I spend much less chair time fitting plugs, and I serve almost twice as many patients with the same number of plugs.

"I've been using the SmartPlug exclusively since the first month," he adds. "I sent back the other plugs."

Samuel Masket, M.D., who practices in Los Angeles, is an investigator in the U.S. clinical trials of the SmartPlug. "Unlike plugs with caps, patient acceptance is high," he says. "There's no learning curve; inserting the plug is a very simple process. And there are no reports of the SmartPlug causing any inflammation or occlusion of the canaliculus.

"The only drawback of the SmartPlug is that confirming the presence of the plug is difficult, and you can't absolutely confirm its removal. However, I haven't had any problems as a result of this."

Dr. Conrad says that, in his experience, the "invisibility" of the inserted plug isn't a significant problem. "Clinical signs, including the comfort of the patient, confirm that the plug is in place. The tear level across the eye and the look of the punctum under the microscope tell me when a SmartPlug is missing. And I've had no problems getting them out. Simply flush, and they're gone."

#### **The best is yet to come**

The SmartPlug has been available in Europe, Canada and Australia, and Medennium received FDA approval for sale in the United States in October. The price will be comparable to the price of other punctum plugs.

In the meantime, Medennium is hard at work on other applications for its smart materials. Jake Feldman, president and CEO of Medennium, reports that the company has developed a prototype of a "SmartLens" — a full-size accommodative IOL that fits through an incision about 2 mm wide. Like the SmartPlug, the SmartLens will come in the form of a solid rod; after entering the eye it will open up into a full-sized lens that fills the capsule.

For more information, contact Medennium at (949) 789-4907, e-mail [info@medennium.com](mailto:info@medennium.com), or visit [www.medennium.com](http://www.medennium.com) on the Web. **OM**

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