Further Discussion of Management of Complications after Insertion of the SmartPlug Punctal Plug

Dr. Joseph Mauriello and other members of SmartPlug Study Group recently published an article entitled Management of Complications after Insertion of the SmartPlug Punctal Plug, A Study of 28 Patients\textsuperscript{[1]}. Medennium would like to add some background information so that readers can put the complications associated with the SmartPlug and with silicone punctal plugs in a proper perspective. In addition, we want to share with readers that the original SmartPlug design has been improved for reducing complications.

Dr. Mauriello’s study is a compilation of case reports from 18 different oculoplastic and reconstructive surgeons with practices encompassing the US. The study included 28 patients with complications from the patient pool receiving the SmartPlug from January 2004 to October 2005. To put the study in perspective, more than 215,000 SmartPlugs were distributed during the specified time period. If we compare the complication cases (28 patients with 13 bilateral complications, giving us 41 complications) to the total number of SmartPlug units distributed, the incidence of problems would be 0.019%. Even if we were off by a factor of 100, the incidence of all complications would be 1.9%, lower than the 4.2% granuloma formation rate in the headed silicone punctal plug study recently reported by Kim\textsuperscript{[2]} et. al after 903 headed silicone punctal plugs were used between 2000 and 2004.

Complications with punctal occlusion have been well known, whether the plug being silicone canalicular plugs\textsuperscript{[3]} or headed punctal plugs\textsuperscript{[4-9]} or SmartPlug\textsuperscript{[1,10]}. Mauriello’s\textsuperscript{[1]} study mainly focuses on canaliculitis, dacryocystitis, and nasolacrimal duct obstruction (NLDO). Among 28 patients, 9 of them were successfully treated without surgery. 17 of them had surgical treatment and 2 refused further treatment. In comparison, Dr. Chou\textsuperscript{[10]} reported complications from a large ophthalmic group which has used at least 1000 SmartPlugs during 2003 to 2005. He found 10 cases of complications with 7 of them characterized as canaliculitis, a complication rate of 0.7%. Eight of the ten complications were resolved with antibiotics and office irrigation while the last two required DCR. On the other hand, it has been widely reported that silicone headed punctal plugs have migrated proximally into the lacrimal drainage system causing canaliculitis or dacryocystitis: Rumelt\textsuperscript{[4]} reported two cases of silicone punctal plug spontaneous migration into the canaliculus or lacrimal sac with canaliculitis and dacryocystitis respectively. In a separate report, Soparkar\textsuperscript{[5]} reported that 14 silicone headed punctal plugs migrated distally within the lacrimal drainage system in 12 patients.

Nasolacrimal duct obstruction and canalicular blockage are rare complications associated with punctal occlusion. They may be resolved by surgical intervention, such as DCR, though more conservative management is recommended for initial treatment. Treatment should start with topical and/or oral antibiotics, followed by high-pressure irrigation\textsuperscript{[13,14]}. Mauriello\textsuperscript{[1]} and Chou\textsuperscript{[10]} respectively reported 4 and 2 cases of complications which were resolved by DCR. As indicated above, silicone headed punctal plugs have been reported to spontaneously migrate into the lacrimal drainage system,
causing NLDO. Soparkar and Rumel reported on 16 cases requiring surgical intervention. Numerous other reports of silicone punctal plugs migrating into the canaliculus causing complications which required surgical removal can be found in the literature. Although the complication rate for such a migration is not known, it is more likely that complications caused by this kind of migration will demand a surgical removal of the silicone plugs since the silicone punctal plugs were not designed for positioning in canaliculi or for ease of removal. They are designed to embed themselves in tissue.

Another complication briefly mentioned in Mauriello’s study is pyogenic granuloma. A recent paper by Kim et al concluded that “pyogenic granuloma-related spontaneous plug extrusion may be more common than previously thought and can present with a range of clinical findings” for the silicone punctal plugs. Kim reported that pyogenic granuloma development led to extrusion of 4.2% of all 903 silicone punctal plugs in 404 subjects between 2000 and 2004 in a median time period of 141 days. They found that the larger plug size is associated with a greater risk of pyogenic granuloma formation for the silicone punctal plugs. Another study of pyogenic granuloma in silicone external plugs by Dr. Will et al at New York Eye and Ear looked at a series of 194 eyes and found 10 cases (5.2%) of pyogenic response to the plugs. In comparison, Dr. Chou et al at Ophthalmic Consultants of Long Island, New York reported three cases of pyogenic granuloma formation after at least one thousand SmartPlugs were inserted between 2003 and 2005. This granuloma occurrence rate of about 0.3% for SmartPlug is much lower than the 4.2 and 5.2 % rates cited for the silicone external punctal plugs. We believe this low granuloma formation rate is a direct result of the gel-like soft material used for making SmartPlug, its shape adaptive property causing minimum irritation or trauma to the surrounding tissue, and the relatively mild insertion procedure. Two of these papers, references [2] and [10], are the most recent comprehensive studies which can be found in the English language literature. Both studies involved a large number of plugs (in the neighborhood of 1,000 plugs) with 3-4 years of follow-up time at the same study site. Medennium was not aware of these two studies until their results were published.

Since Dr. Chou’s study theorizes that a probable cause of canaliculitis is stagnant fluid above the plug, Medennium has improved its original SmartPlug design with the purpose of reducing its potential complications. This second generation design is a rod with the same diameter of 0.4 mm but with a length reduced from 9 mm to 6 mm. After insertion, the improved plug will have a length of about 1.2 mm. Reducing the plug length and following the recommended implantation procedure of leaving about 2 mm outside the punctum will position the plug in the vertical punctum just below the surface, reducing the possibility of stagnant fluid and, hence, canaliculitis. The shorter length may also reduce granuloma formation because of both reduction in inflammation/infection and an easier, less traumatic insertion. The improved SmartPlug has been used for over 1 year with a positive response from physicians using the product. Product reports of breakage during insertion have been drastically reduced, indicating less trauma for the patient.
We applaud the recommended sequence of treatment by the Mauriello and the SmartPlug Study Group and would like to add the following pearls provided by other physicians for avoiding unnecessary surgical procedures. This advice has worked well in resolving cases where surgical procedures had been scheduled.

1. Our clinical experience and the Medennium clinical study of 120 patients submitted to the FDA has shown that irrigation is a safe and effective removal method that does not result in permanent occlusion of the lacrimal drainage system\textsuperscript{[11]}. As recommended by the SmartPlug Study Group, one should avoid irrigation in the presence of inflammation and/or infection. The inflammation/infection should be treated with antibiotics and/or anti-inflammatorives per the normal procedures. Only proceed with irrigation after the inflammation is resolved. Swollen canalicul tissue can only make irrigation more difficult.

2. We discourage probing – the hydraulic action of irrigation is much more effective. Probing can imbed the SmartPlug into the tissue or it can deform the plug, allowing fluid to go past it and rendering irrigation useless. Probing may also lead to inflammation and scarring.

3. Medennium is now including a shoulder cannula in the Starter Pack designed to seal the punctum during irrigation and to prevent fluid backflow. Irrigation with warm BSS will keep the SmartPlug malleable for easier removal. In cases where irrigation is more difficult, backflow may be observed from the opposite punctum. A silicone punctual plug can be temporarily used to seal the opposite punctum and irrigation should be attempted again. Temporary sealing of the opposite punctum will make the irrigation more effective. Occasionally, irrigation will need to be repeated to remove the SmartPlug, as reported by Dr. Chou\textsuperscript{[10]}.

4. Massaging the plug out can be performed in cases of granuloma formation. Massaging may become a more common removal method with the second generation plug, even for resolving epiphora, as it is positioned close to the surface.

5. Finally, SmartPlug is contraindicated for patients with prior history of nasolacrimal duct obstruction. Patency testing (irrigation) used as part of the diagnostic visit is an important tool in screening your patients for possible lacrimal obstructions.

We would like to thank Dr. Chou, Dr. Mauriello and the entire SmartPlug Study Group once again for their valuable studies and contribution to making our existing product safer. Studies like this are very important for product evolution. We also would like to encourage product users to visit the FDA web site where these complications are reported and discussed at length and also to report complications to the manufacturer so that they can be posted in the Medwatch program. For those who may be interested in learning more, please access the link:

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUST/search.cfm

and then type SmartPlug.

Sincerely,

Medennium, Inc.
References:


[11] SmartPlug® Directions for Use, Medennium part no. 100347-001 Revision D

