TRANSACTIONS

AMERICAN ACADEMY
of
OPHTHALMOLOGY
and
OTOLARYNGOLOGY

SECTION ON OPHTHALMOLOGY

VOLUME 79
NUMBER 1
JANUARY - FEBRUARY
1975

PRINTED IN U.S.A.

TRANSACTIONS

American Academy of Ophthalmology and Otolaryngology

VOLUME 79 JANUARY - FEBRUARY 1975 NUMBER 1

Business and Editorial Offices
American Academy of Ophthalmology and Otolaryngology
15 Second St SW, Rochester, Minn 55901

Pre
FRANK V

Executive Secr
C. M

Second Vic
ALBERT D. RU

VOLUME 79
NOV-DEC 1975

THE PUNCTUM PLUG: EVALUATION OF A NEW TREATMENT FOR THE DRY EYE

JERRE MINOR FREEMAN, MD
MEMPHIS, TENNESSEE

KERATITIS sicca, or keratoconjunctivitis sicca, is a problem in almost every ophthalmologist's practice. Various types of topical drops and ointments have been and are being used with various rates of success. Occasionally, closure of the puncta and canaliculi by surgery or cauterization has been done with success in more extreme cases, such as Sjögren's syndrome.[1,2]

This paper describes a method of closing the punctum and canaliculus by a plug which can be removed if undesirable results occur. Jones et al[3] in 1972 devised a tapered polyethylene tube or cone to temporarily occlude either the upper or lower punctum and canaliculus, while they measured the relative speed of lacrimal excretion through the opposite canaliculus.

The anatomy involved is the slightly elevated punctum openings in both upper and lower lids about 6 mm from the medial canthus. These are round or slightly ovoid openings approximately 0.3 mm in size. This opening is surrounded by a fairly dense, relatively avascular connective ring of tissue about 1 mm in depth. This leads into the vertical portion of the canaliculus, which is about 2.5 to 3.5 mm in length, before turning horizontally for 8 mm to join the other canaliculus before entering the lacrimal sac. The canaliculi are about 0.5 mm in diameter, lined by stratified squamous epithelium surrounded by elastic tissue, allowing the canaliculi to be easily dilated to three times normal size.[4,5]

Although some authors[6,7] have suggested that the punctum has a sphincter ring of muscle, L. T. Jones, MD (personal communication, 1974), believes that practically speaking there is no muscle sphincter, but that the wall of the punctum is much like that of the canaliculi, consisting of a fibroelastic band of tissue. This band or ring of connective tissue is the structure that is dilated with great care and gentleness, as described later in this report.

METHODS AND MATERIALS

The punctum plug, or the device to close the punctum, is designed to completely close the punctum opening. It has a slightly larger portion projecting into the vertical portion of the canaliculus that prevents the plug from extruding or coming out, and a larger, smooth head at the opening that prevents the plug from passing down into the canaliculus. The head is approximately 1.5 to 2 mm in diameter and 0.7 mm high. Having the head smooth and dome-shaped allows it to rest in the lacrimal lake and against conjunctiva and cornea with little irritation. The neck or waist is approximately 0.7 mm in diameter and 1.5 mm in length. This connects to the larger tip, or barb, which is 1 mm long and 1.2 to 1.9 mm in diameter, coming to a flat point 0.5 mm across.

From the University of Tennessee Methodist Hospital, Memphis.

Presented at the Seventy-ninth Annual Meeting of the American Academy of Ophthalmology and Otolaryngology, Dallas, Oct 6-10, 1974.

Materials considered for this device were silicon, Teflon, methyl methacrylate, hydroxyethylmethacrylate (HEMA), and inert metals. Two materials were initially selected for their availability and proved high tissue tolerance: HEMA and Teflon.

HEMA showed excellent patient and tissue acceptance. In the dry state its firmness helped to ease the process of insertion, and it became almost immediately soft and flexible as tears or drops moistened it. Its approximate 28% swell rate when moistened undoubtedly helped close the punctum more effectively. The tensile strength of HEMA is a drawback, in that manipulation by a patient's finger can contribute to breakage.

Teflon also has excellent tissue tolerance, and it has had good patient acceptance after the design was perfected. The material strength is excellent. Both HEMA and Teflon are easily sterilized.

Technique of insertion is as follows. The eye is anesthetized with a topical anesthetic. A shortened cotton-tipped applicator is soaked in the same topical anesthetic and placed into the medial canthal area for five to ten minutes. Then a punctum dilator is carefully used to slowly dilate the punctum to about 1.2 mm without breaking the punctum connective tissue ring. Breaking this ring or splitting the punctum encourages a loose or sloppy fit and subsequent extrusion or loss of the plug.

Quickly after removing the dilator, the punctum plug, held in an inserter in the form of a rod, is placed into the punctum opening. The punctum plug tip is pointed to encourage some dilation and passage into the canaliculus. As soon as the head is seated at the punctum opening, a shearing or wobbling motion disengages the inserted punctum plug.

For removal, the head of the plug or the neck just under the head is grasped with forceps. If topical anesthetics do not relieve discomfort enough here, lidocaine hydrochloride or similar anesthetic can be injected directly into the medial lid area. This may be highly desirable, because the horizontal canalicular area can then be squeezed gently with smooth forceps, and with movement toward the plug, the punctum plug can literally be squeezed or expressed out.

The patients treated were usually suffering from symptomatic keratoconjunctivitis sicca, confirmed by positive rose bengal stain. The symptomatically drier eye was selected and a punctum plug was inserted into the lower punctum of that eye. There were two or three patients who had early extrusion before the design previously described was selected.

RESULTS

A group of seven patients had a HEMA punctum plug placed into one lower punctum. Although there was variation of expression of comfort, all patients accepted the plug and expressed that the involved eye became more comfortable than the fellow eye. Some patients could feel the plug at times, especially when the cornea was turned toward the punctum plug, but there was no discomfort. One plug had broken at approximately one week, and the rest of the plug was expressed from the canaliculus. Another plug, that apparently did not seat well from the beginning and projected from the punctum, showed some mild surrounding conjunctival injection, probably from excessive movement of the plug. This plug was removed at six weeks, although the patient had expressed no complaints. After removal, the patient stated her involved eye felt worse for about five days, but it symptomatically became sim-

ilar to her fellow dry eye, thus showing the reversible facet of this treatment both in the ability to remove the punctum plug if desired and in the treated eye showing comfort, then discomfort upon removal.

Four HEMA plugs came out inadvertently, probably during sleep. Two occurred at approximately six weeks, the other two at 13 and 16 weeks. All patients reported a return of their dry eye discomfort after loss of their plug. The one remaining patient is still tolerating the plug as of this date and continues to report improvement in symptoms.

A second group of 12 patients had insertion of a Teflon plug of similar design as the first HEMA plug. Unlike the HEMA plug, where there is almost 100% comfort, the initial Teflon plug was reported to be irritating by 25% of the patients in this group. Objectively, in two patients there was mild fluorescein staining on the cornea, where the cornea touched the plug head on rotating nasally. Without HEMA's flexibility, the same head design in the firmer Teflon was symptomatic to these patients. Of the 12 patients, three were removed within nine days and two were removed within nine weeks due to discomfort. One patient had the plug extrude or fall out. The remaining seven patients are doing well.

The third group of patients had a redesigned, smaller Teflon plug inserted. The main changes were a smaller (0.5 mm diameter) dome-shaped head and a smaller diameter (1.2 mm) barb. These plugs were initially better received, with comfort being acceptable by all patients and objectively there being no staining of the conjunctiva or cornea.

Of the 13 patients in group 3, four had had their plugs inadvertently wiped out or plugs fell out between one and three weeks. All four of these patients had had a larger Teflon or HEMA plug inserted previously, and possibly the punctum was still dilated from this, encouraging a looser fit and subsequent loss. The remaining nine patients reported increased or acceptable comfort of the dry eye and are doing well as of this date.

Of interest is that three patients were in all three groups. They then were able to compare a treated eye with a nontreated eye and to compare the comfort of the three different plugs. They reported increased comfort of the treated eye over that of the untreated eye. The HEMA plug and the smaller Teflon plug were reported as the more comfortable designs.

Four patients after having one punctum plug inserted with comfort, requested the insertion of a punctum plug in the fellow eye. One punctum plug was placed in one upper punctum, but came out overnight mainly due to a loose fit. All work in this report was done with the lower punctum. Thirty-two eyes were treated in this study. Twenty-six patients were female and six patients were male. Average age was 54 years.

Most of the work reported in this paper was carried out during the spring, summer, and fall in the mid-South area when heating was not necessary, allowing the sufferers of keratoconjunctivitis sicca to generally do their best. It is entirely possible that the lower humidity and dry heat experienced during the winter would have shown an even greater patient symptomatic difference between the treated eye and the nontreated eye.

CONCLUSIONS

In every case except where there was initial discomfort, the punctum plugs

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.