THE MOTHER OF INVENTION: MAKING CUSTOM EQUIPMENT IN SYRIA


Developing a custom-made needle for suprachoroidal steroid injections in Syria.

BY AMEEN MARASHI, MD; AND BENJAMIN J. THOMAS, MD

Two years ago, I spoke to a vitreoretinal surgeon from Aleppo, Syria, Ameen Marashi, MD, about the day-to-day realities of practicing in the midst of the Syrian crisis. It was a profile in bravery and an extreme example of how, as physicians, we must often go to significant lengths and employ significant creativity to keep our patients safe while effectively managing disease.

I wanted to check in with Dr. Marashi to see if he had any updates from his clinic and, sure enough, Dr. Marashi had another example of using an outside-the-box framework for addressing an issue in his clinic. He and I outline it here. At a time when we are all seeking to use our creativity and compassion to care for patients in very novel circumstances, we hope it serves as another small point of inspiration.

—Benjamin J. Thomas, MD

The growing global diabetic crisis is an impartial one—no corner of the world is spared. A massive increase in the prevalence of diabetes mellitus (DM) has been predicted,[1] and countries such as India are scrambling to prepare for the largest diabetic populations in history.[2] With these changes comes a concurrent increase in the prevalence of diabetic retinopathy (DR), and a sizeable portion of these patients will eventually lose vision because of diabetic macular edema (DME).

DME is a leading cause of vision loss in the working population,[3] a problem reported in multiple populations around the world.[4] Intravitreal VEGF-blocking agents have become the most common first-line treatment for DME management,[5] but the disease is often refractory to anti-VEGF monotherapy, as has been reported in a worrisome 40% of patients in some series.[6]

At the Marashi Eye Center in Aleppo, Syria, we (A.M.) seek to deliver excellent care to diabetic patients despite an ongoing crisis. In Aleppo, just as everywhere else, DR is a commonly encountered disease, constituting about 35% of our total ophthalmic practice; however, of these diabetic cases, refractory DME makes up about 20%, adding the difficulties of finding sustainable treatments for these patients to the baseline difficulties of follow-up and reimbursement.

Intraocular steroid therapies are helpful because they can address the complex inflammatory markers induced by DR.[7] This form of treatment also tends to be longer-acting, which is a distinct advantage in regions where frequent follow-up is limited by geographic distance or restricted resources. Unfortunately, steroid therapy carries the twin risks of cataract formation and IOP elevation.[8,9] Suprachoroidal injections offer a potential solution.

Injecting triamcinolone into the suprachoroidal space may reduce the risk of IOP spikes because drug delivery is directed to the choroid and the retina and is restricted from the trabecular meshwork, enhancing therapeutic efficacy in the target tissue and presenting less interference with the anterior chamber.[10]

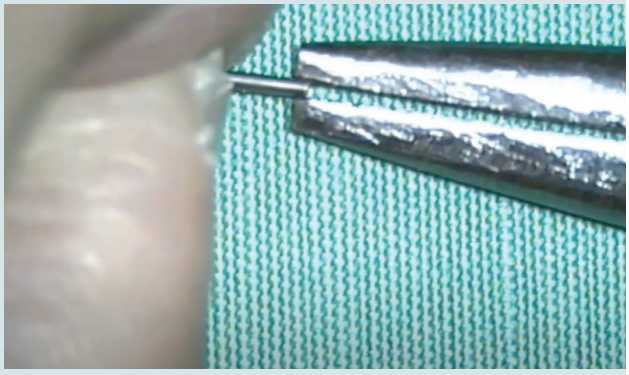
Recent studies have highlighted the safety and effectiveness of needle-based suprachoroidal drug delivery systems.[11] In this minimally invasive technique, a microneedle penetrates transconjuctivally to the appropriate depth during drug delivery. The problem for us was where to obtain the needles.

AT A GLANCE

- Diabetic macular edema (DME) is a leading cause of early-onset vision loss and blindness among working-age adults. The disease is commonly treated with steroids.
- Targeting the suprachoroidal space may represent a safe and effective option for steroid delivery in patients with DME.
- Without access to ready-made sources for appropriate needles, a vitreoretinal specialist in Syria developed his own to make intravitreal steroid injections available to his patients.

WATCH IT NOW

VIDEO 1: CREATING A NEEDLE FOR SUPRACHOROIDAL INJECTION



Ameen Marashi, MD, shows how to modify a 30-gauge needle so it can administer suprachoroidal injections.

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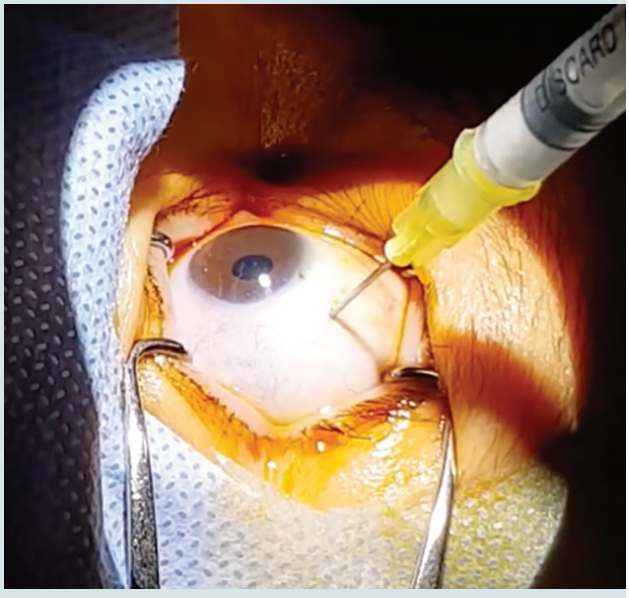
VIDEO 2: SUPRACHOROIDAL INJECTION TECHNIQUE



Ameen Marashi, MD, demonstrates his technique for suprachoroidal injection using a needle constructed in his clinic.

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NECESSITY, THE MOTHER OF INVENTION

Years of crisis and western embargo had presented extreme challenges to the practice of medicine. Because the required needle was unavailable in Syria, we set about the task of producing one (Figure 1). We identified a medical manufacturer and designed a needle to the following specifications:

The needle should be made from a 30-gauge needle with a 23-gauge sleeve stopper obtained from a 5-mL needle (Video 1). This would create a guarded sleeve over the 30-gauge needle and thus permit an injection depth of only 1,000 µm (including the shaft).

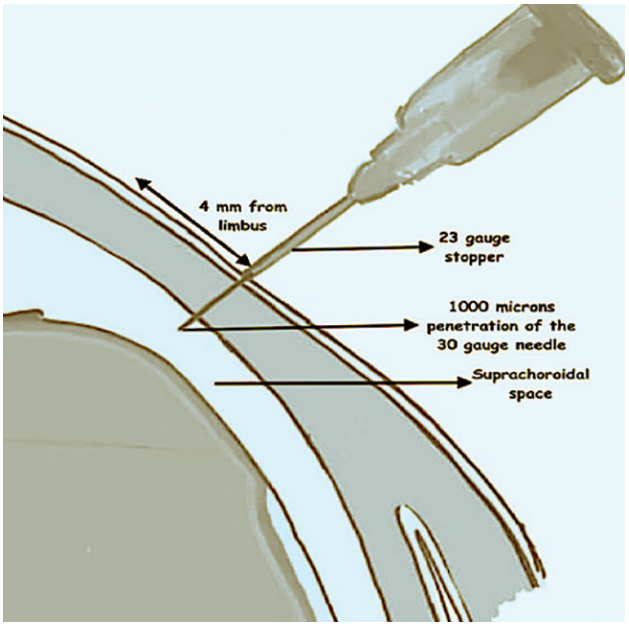

Figure 1. The position of the custom-made needle relative to the limbus, sclera, and suprachoroidal space.

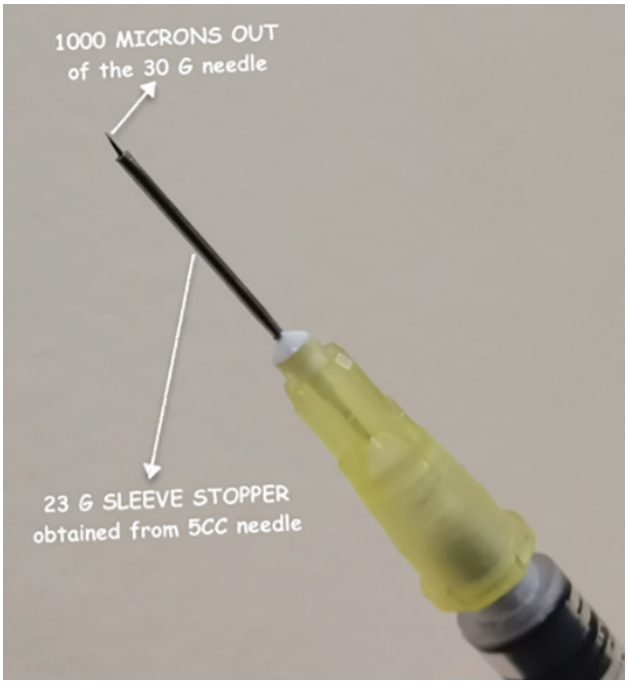

Figure 2. The design of the custom-made needle with a 23-gauge sleeve stopper that permits only 1,000 µm to exit the 30-gauge needle. Photo credit: Ameen Marashi, MD

The 23-gauge needle should be rasped to have smooth edges and to allow only 1,000 µm (± 200 µm) of the 30-gauge needle beyond the sleeve, as measured by Vernier calipers (Figure 2). The needle must be durable enough to undergo autoclaving. Once the needle had been created, I (A.M.) began administering suprachoroidal injections under sterile conditions after the skin and conjunctiva had

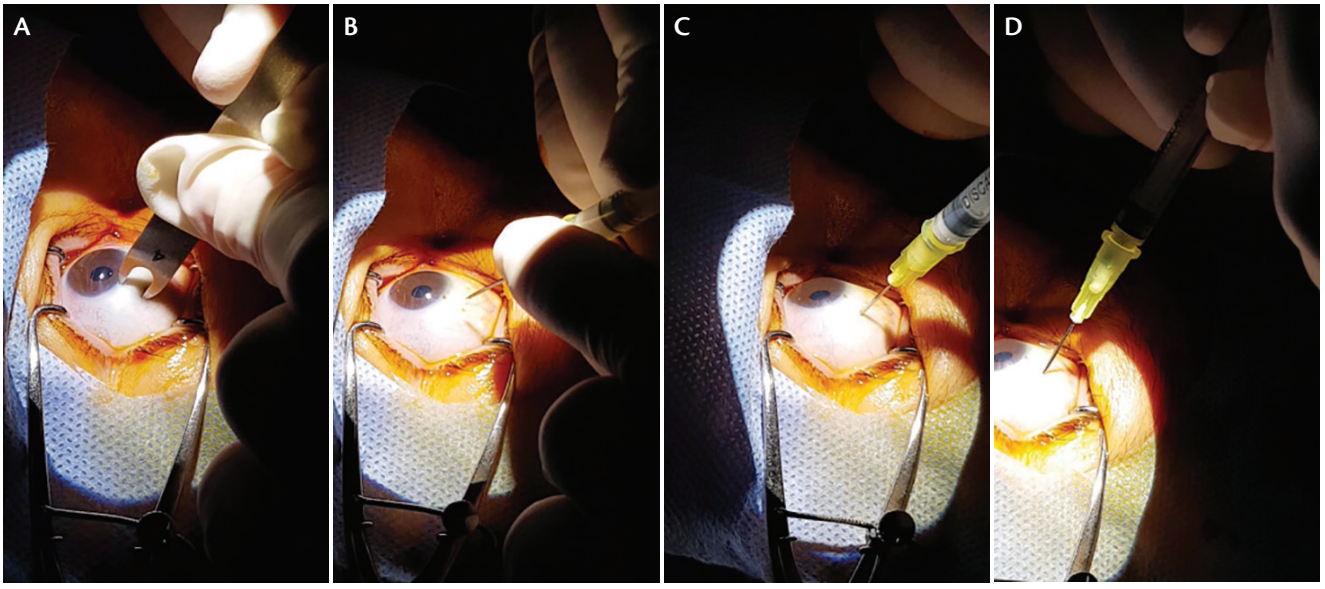

Figure 3. The injection site is located 4 mm from the limbus (A). The needle is positioned perpendicular to the sclera (B). Medication is injected with gentle pressure (C). The needle is withdrawn obliquely from the eye (D).

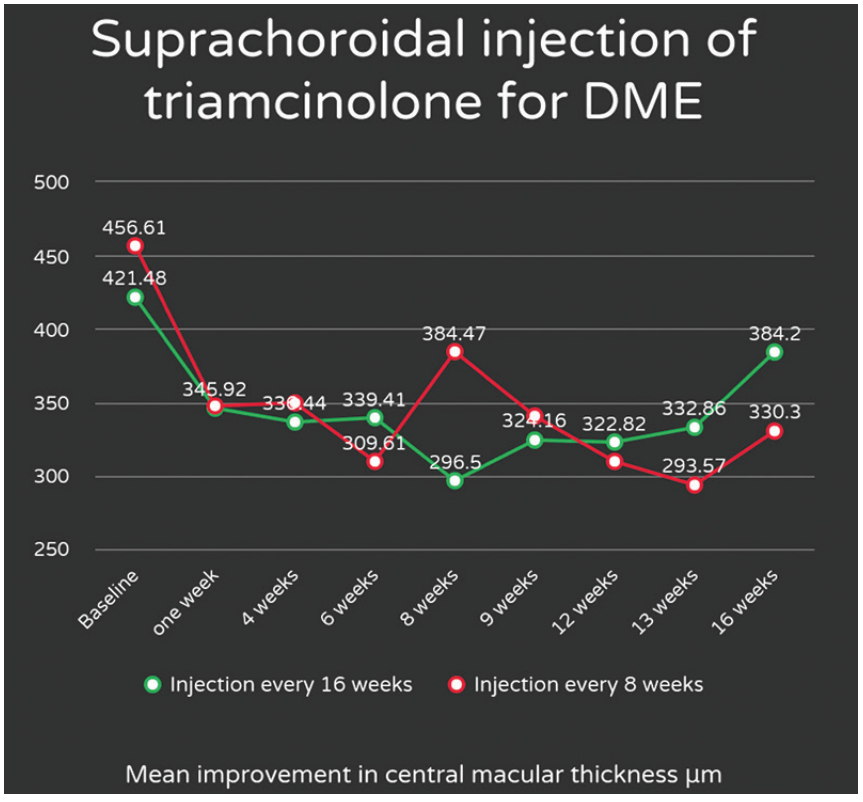

Figure 4. Mean improvement and changes in central macular thickness.

been disinfected using 10% and 4% povidone-iodine under topical anesthesia, respectively. Injections were performed after sterile draping and placement of a lid speculum to isolate the eyelashes.

Our technique is straightforward: In the superotemporal quadrant, the injection site is marked 4 mm from the corneal limbus (Video 2). Next, the needle is positioned with the bevel edge directed away from the limbus, and then the needle is inserted perpendicular to the sclera. Using gentle pressure, 0.1 mL of triamcinolone is slowly expressed into the suprachoroidal space (Figure 3). The needle is then withdrawn obliquely from the eye to prevent egress of the medication.

EFFICACY AND SAFETY

We assessed the safety and efficacy of our results in an interventional, single-center study of 50 eyes of 36 patients. Patients with DME received a suprachoroidal steroid injection using the custom-made needle every 8 or 16 weeks, based on the observed effect of treatment. We measured central macular thickness with spectral-domain OCT and evaluated BCVA, IOP, cataract progression, and treatment tolerability.

Approximately 42% of eyes required an injection within 8 weeks; the mean central macular thickness was 456 µm at baseline and decreased to 309 µm within 6 weeks, but the central macular thickness increased to 384 µm in 8 weeks and decreased again to 330 µm after the second injection (Figure 4). On average, BCVA improved from

20/125 to 20/45 at 16 weeks in these eyes. Approximately 58% of eyes required only one injection during 16 weeks; the mean central macular thickness was 421 µm at baseline and decreased to 339 µm within 6 weeks, but the central macular thickness increased to 384 µm at 16 weeks. On average, BCVA improved from 20/80 to 20/50 at 16 weeks in these eyes.

Suprachoroidal triamcinolone injections reduced central macular thickness by 147 µm on average by 8 weeks. In many of these patients, DME had previously been refractory to anti-VEGF monotherapy.

No patient experienced a suprachoroidal hemorrhage, choroidal or retinal detachment, or endophthalmitis.

More work is needed and more data must be collected, but we are pleased with the early efficacy and safety that we have observed in our first round of patients. More so, we are happy to see the treatment options in Syria expand through our efforts. The development of a custom needle available in Syria may offer an affordable, safe, and effective method to treat chronic DME in difficult settings. ■

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■ Financial disclosure: None

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■ Financial disclosure: Speakers fees, Research (Allergan, Regeneron)