Intraductal Meibomian Gland Probing for Meibomian Gland Dysfunction Using VAS Testing

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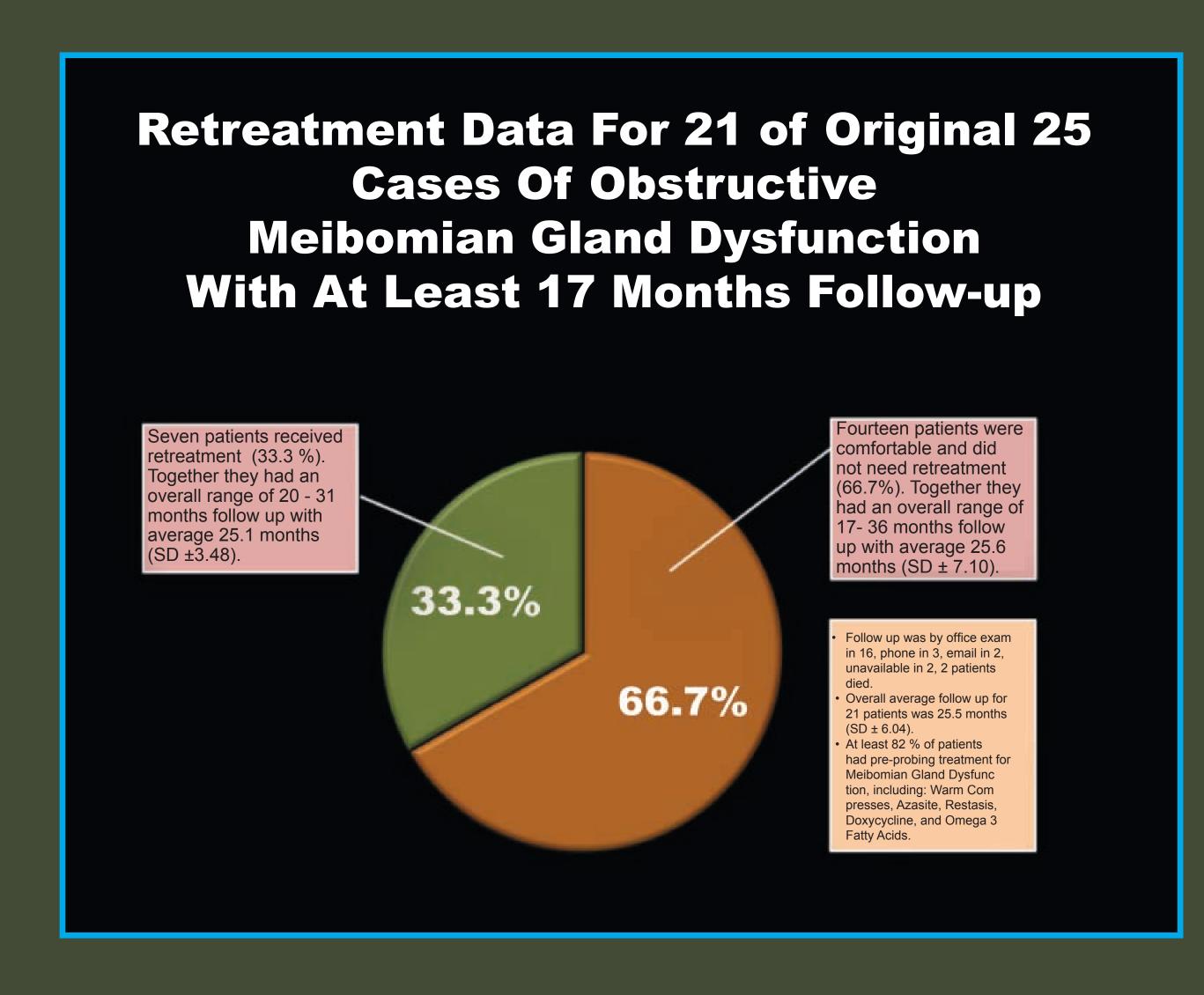
Disclosure: Patent Pending Commercial Relationship: Rhein Medical, Inc.

Background: Meibomian gland dysfunction (MGD) is arguably the most common cause of dry eye and has certainly been the most challenging to treat. Traditional therapies have failed to consistently provide effective results leading to ongoing suffering and frustration for patients and physicians alike.

PUTPOSE: To take a retrospective look at the longer term follow up of the initial 25 patients treated with intraductal meibomian gland probing (MGP) for obstructive MGD reported at ARVO 2009 and 2010 meetings.

Methods: Charts were reviewed looking at numbers of patients with follow up, length of follow up, status of symptoms at last follow up and number of patients needing retreatment.

Results: Twenty one (84%) of the initial group of twenty five patients had at least 17 months follow up with an average of 25.5 ± 6.04 months follow up. Follow up was by office exam in 16, by phone in 3, and email in 2 patients. Follow up was unavailable in 2 patients, and 2 patients had died. Fourteen pawith a male to female ratio of 5/9. The tients did not need retreatment (66.7% range of follow up for non retreated patients was 17 36 months with an average of 25.6 ± 7.10 months. These 14 patients had a total of 23 lids treated. For the seven patients needing retreatment (33.3° %) there was an overall range of 1 months follow up with average 25 1 ± 3.48 months with a male to female ratio of $\frac{2}{5}$. These seven patients had $\frac{14}{4}$ lids retreated out of $\frac{19}{5}$ lids overall treated with an average interval for first retreatment at 10 7 months. Seven of the fourteen retreated lids were retreated a second time. At the last follow up, all the t. No patient had worse symptoms and no adverse sequelae of probing were noted.



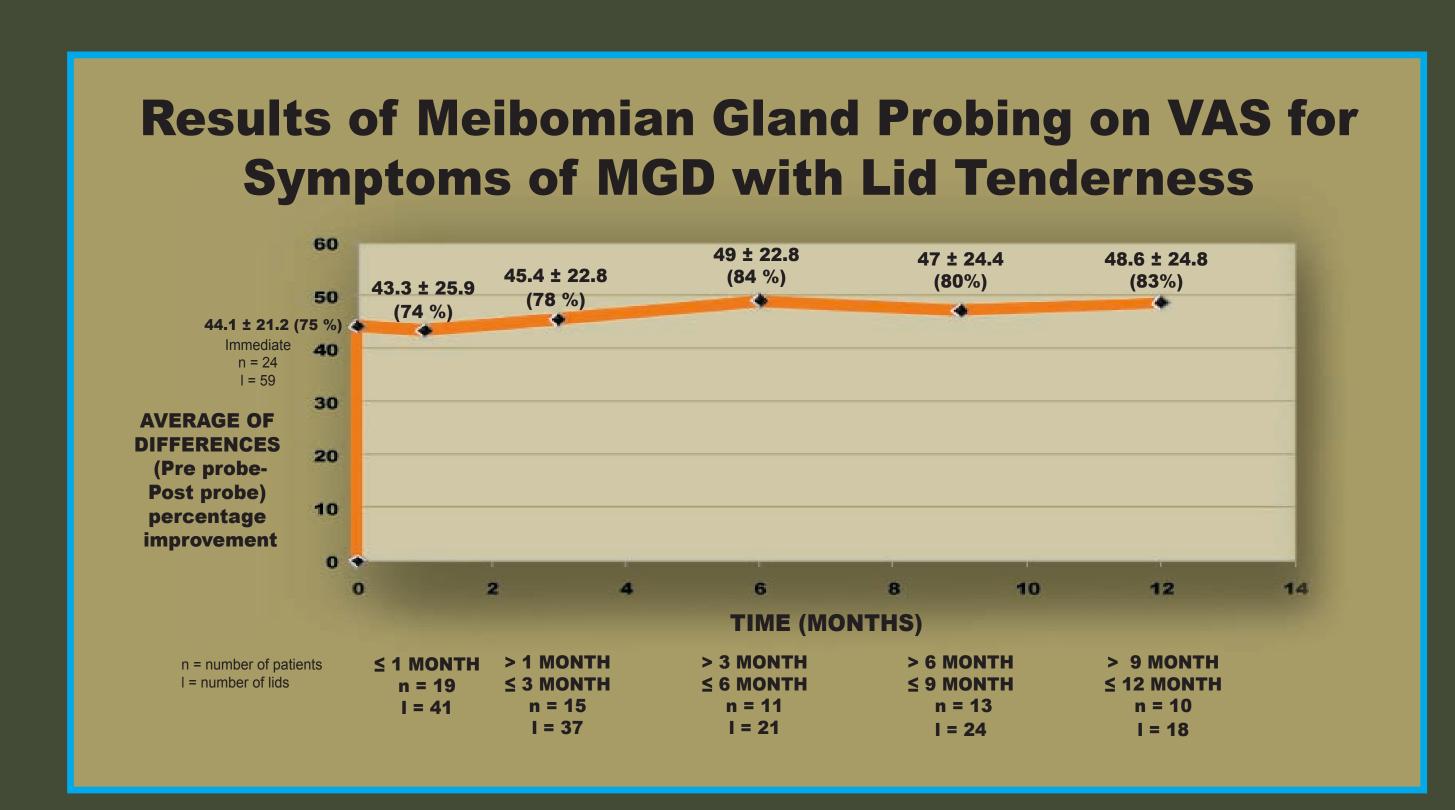
Follow Up Studies

Purpose: To evaluate results of intraductal meibomian gland probing for lid tenderness as well as for symptoms excluding lid tenderness using a standardized VAS test.

MCThous: Intraductal meibomian gland probing for MGD as previously described in ARVO abstract 2009 was performed on 24 patients with pre probing lid tenderness and 8 patients with symptoms excluding lid tenderness. Severity of pre probing lid tenderness and symptoms excluding lid tenderness was evaluated using a standardized VAS with post probing VAS responses at various post probing time points including immediately, weekly for the first month, then monthly. Inclusion criteria required pre probing VAS to be greater than 25mm.

Follow- Up Study # 1 Meibomian Gland Probing With Lid Tenderness

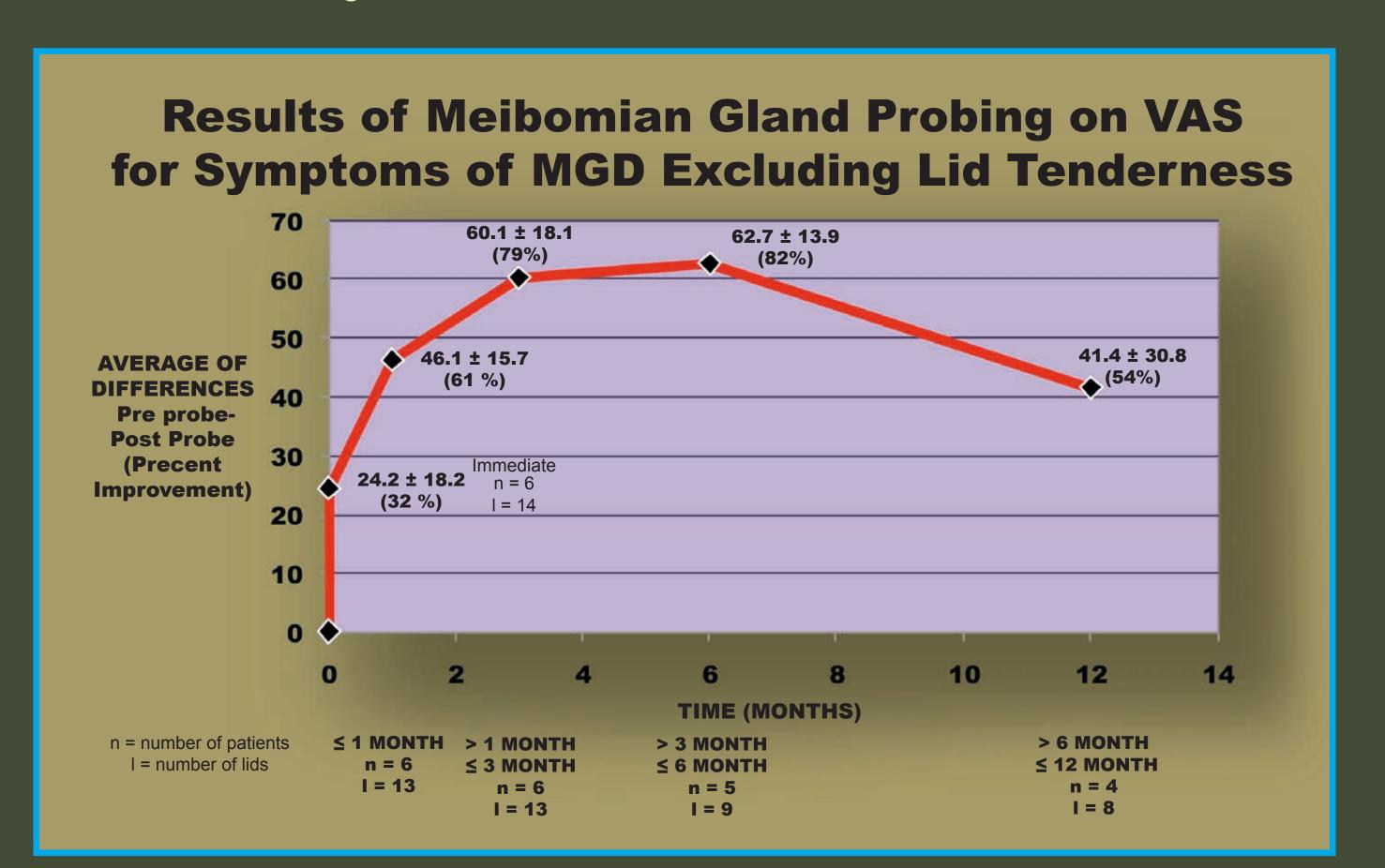
Results: Average patient age at probing was 64 ± 18.4 with a range from 17-85. Fifty nine (59) lids of 24 patients were probed with a pre probing VAS mean score of 58.5 ± 18.9 mm. There was an immediate reduction of mean VAS score of 44.1 ± 21.2 mm (75%) to 14.5 mm. Lid tenderness remained improved with a reduction of a mean score of 43.3 ± 25.9 mm (74%) at less than or equal to one month, 45.4 ± 22.8 mm (78%) at one to three months, and further improved to 49 ± 22.8 mm (84%) at three to six months, then 47 ± 24.4 (80%) at six to nine months, and at nine to twelve months to 48.6 ± 24.8 (83%). Eighteen lids of ten patients have reached the one year follow up visit. The average last VAS measurement was 14.3mm, an average reduction of 75.5% at an average follow up of 5.35 ± 4.86 months.



Follow- Up Study # 2 Meibomian Gland Probing Excluding Lid Tenderness

Results: Patients ages ranged from 17-85 at probing with average age of 56 ± 23.1 . In twenty one (21) lids of 8 patients, there was a mean pre prob-

.7 with an immediate post probing mean score of 52 6). Symptoms yielded a n and a reduction of 2 at less than or equal to one month, VAS reduction of 40 at one to three months, and 6 at three to six at six to twelve months. Eight lids of four months, and 4 patients made it to the six to twelve month follow up visit. The average last n, an average reduction 53% at an avmeasurement of all patients was 3 7 months. Lid symptoms which improved inerage last follow up of 5. cluded lid pressure, heaviness, puffiness, awareness, irritation, discomfort, sticky and gummy, itchy and scratchy under the lid, and sunburn under lid. Other symptoms that improved included: epiphora, ptosis, and photophobia. m, an average reduction of The average last VAS measurement was 28 % at an average follow up of \checkmark



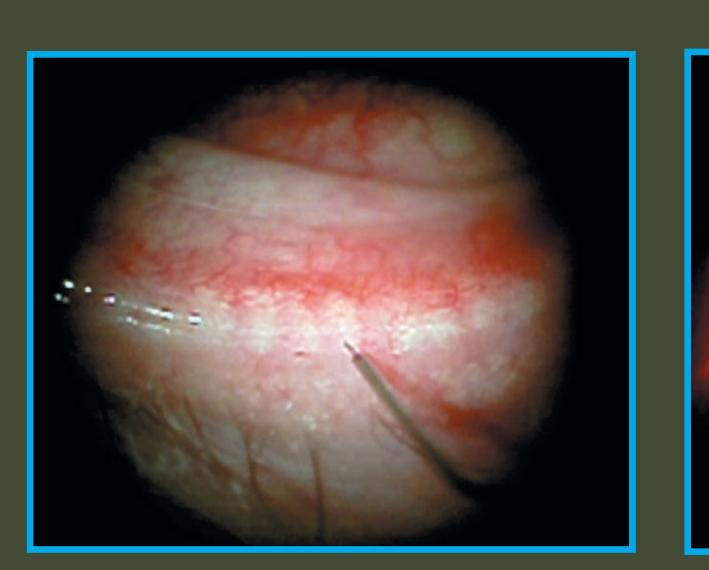
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Probing often identified four findings. Three of the four findings were of variable resistance which may be present in each gland. These included: (1) orifice resistance, (2) a mostly proximal gritty sensation like piercing through a "rice krispy", and (3) moderate resistance which released with a "pop" and was usually deeper in the duct and suggestive of fibrovascular tissue. (4) The fourth finding was frequent orifice hemorrhages which were self limited. There were no probe fractures in these studies. There were no adverse sequelae.

Technique

(1) The lid margin and glands were examined with and without trans-illumination to evaluate patency of orifice and status of the glands, specifically looking at gland proximal and distal atrophy, length of glands and signs of ductal dilation suggestive of proximal obstruction. Glands were palpated individually for gland tenderness seen with inflammation and obstruction, with presumed elevated intraductal pressure. (2) To anesthetize, first place a drop of proparacaine 0.5% or tetracaine 0.5% solution in the conjunctival sac. Then place a generous amount of jojoba ophthalmic anesthetic ointment on the

lower lid margin using a sterile cotton tipped applicator. Have the patient close their lids for 10-15 minutes. There will be some mild burning which gradually dissipates over 30 seconds. After 15 minutes, the patient opens eyes, and place another drop of the topical anesthetic solution into the conjunctival sac. Start with the shortest and stiffest probe, the 1 mm length probe. (3) After penetrating the orifice with the 1 or 2 mm, the 4 or 6 mm probe was then used depending on the length of the gland to achieve complete patency of the ductal highway. (4) At times resistance was encountered. Respecting the length of the gland prevented extending the probing too far. Therefore, if resistance was obtained, the probe was felt to be against a fibrotic band. After checking to ensure the probe was co-linear to the gland, additional mild force was used to pop through the intraductal fibrotic tissue.



A PLUG OF SEQUESTERED MEIBUM.

PENETRATION WITH A 2MM PROBE. NOTE HEMORRHAGE AT ORIFICE OF ADJACENT GLAND.

Clinical Photos





BEFORE INTRADUCTAL PROBING

TWO MONTHS POST PROBING.

Pre probing photo on left shows appearance of left upper lid with lid margin vascular engorgement and gland plugging. The photo on the right is two months after gland probing showing vessel regression with marked reduction in vascular caliber and gland plugging. There was an associated marked reduction in lid tenderness VAS from pre probing score of 45 out of 100 to his latest score of 0, 10 months post probing.

Conclusions

(1) With an average follow up of more than 25 months, there have been no long term adverse effects of Meibomian Gland Probing. (2) Intraductal Meibomian Gland probing appears highly effective in rapidly reducing standard-

ized VAS patient scores of a variety of symptoms associated with Meibomian Gland Dysfunction. (3) VAS scores remain markedly improved for at least 12 months. (4) At the 25 month follow up, 67 % of the patients had not required retreatment. (5) Three levels of probing resistance and orifice hemorrhage frequency may enable a grading scale of meibomian gland dysfunction for clinical use. (6) Jojoba wax ester anesthetic ointment containing lidocaine 8% plus jojoba 25% in petrolatum provided good topical anesthesia allowing for a well tolerated procedure.

Reference

Maskin, SL. Intraductal Meibomian Gland Probing Relieves Symptoms of Obstructive Meibomian Gland Dysfunction. *Cornea*. 2010; 29: 1145-1152.

Qualitative Evaluation of Anesthesia for **Meibomian Gland Probing TRANSDERMAL** Lidocaine 23 % (LC)* docaine 23 % Tetracaine 7 % (PB)* Lidocaine 23% Jojoba wax ester liquid 10 % (LC)* AktenTM Lidocaine Gel (3.5%) etraviscTM Tetracaine Gel (0.5%) idocaine 4 % (liquid) applied by technician with CTA) Jojoba wax ester liquid 25 % ung* docaine 6 % idocaine 2% with epi YES = Provided consistently good anesthetic block, enabling an overall well tolerated and comfortable probing procedure Provided inadequate anesthetic block, frequently requiring additional anesthetic consisting of Intermediate = provided borderline anesthetic block with variable comfort and tolerance, sometimes requiring additional Lipoderm transdermal cream applied to lid skin PB = Plasticized transdermal base ointment applied to lid skin CTA = cotton tip applicator Liquid reduced retention time on lid margin leading to inadequate anesthetic Infiltrative anesthetic sub-optimal due to use of needles, need for supplemental injection, risk of bruising and lid swelling *All compounded anesthetics provided by Leiter's Compounding Pharmacy, St Jose, California

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