Intraductal Meibomian Gland Probing to Restore Gland Functionality for Obstructive Meibomian Gland Dysfunction (MGD)

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DISCLOSURE: PATENT PENDING COMMERCIAL RELATIONSHIP: RHEIN MEDICAL, INC.

FOLLOW UP OF ORIGINAL MEIBOMIAN GLAND PROBING CASES (Cornea 29(10):1145-1152, October 2010)

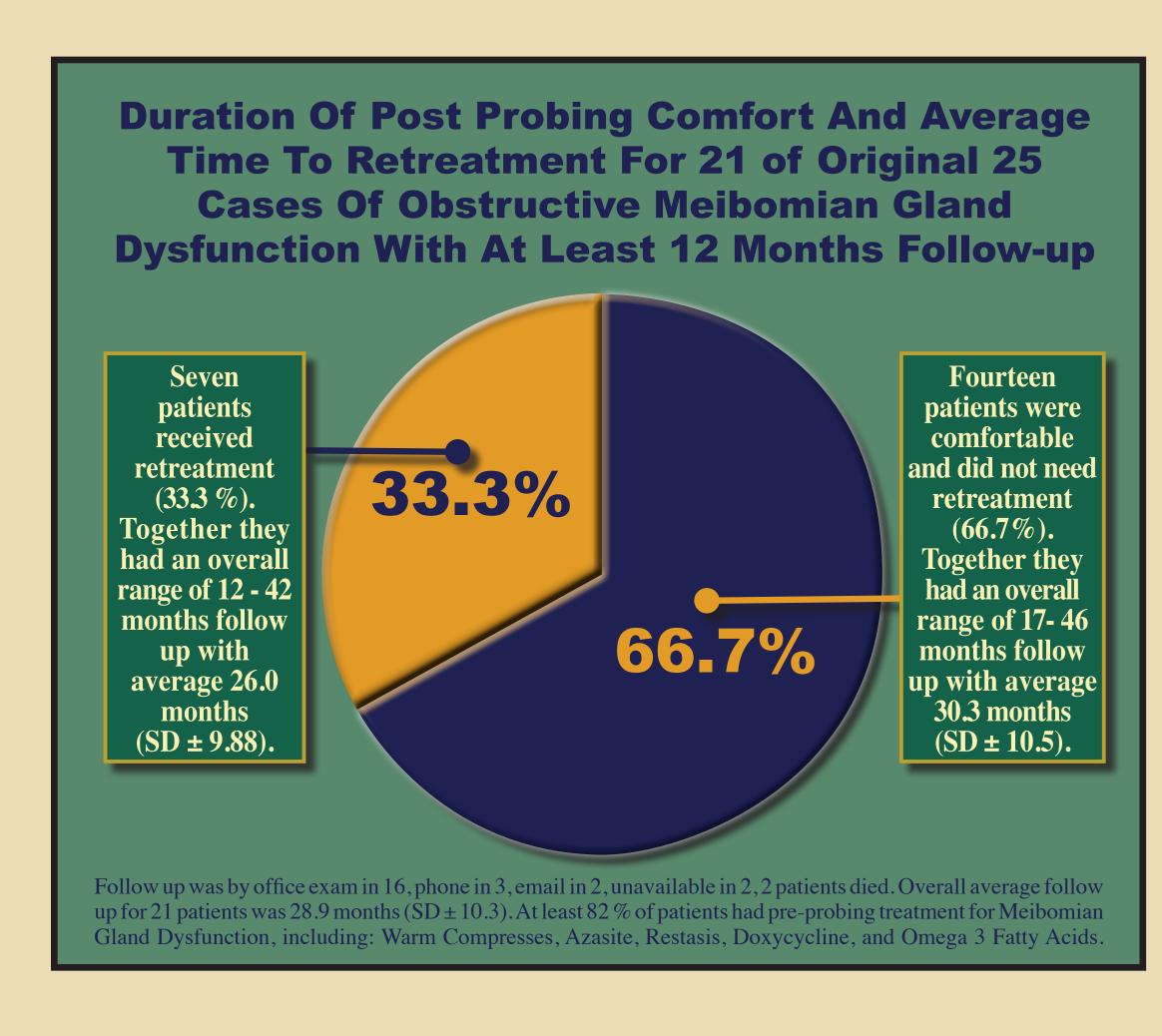
Background: Meibomian gland dysfunction (MGD) is arguably the most common cause of dry eye and has certainly been the most challenging to treat. Traditional therapies have failed to consistently provide effective results leading to ongoing suffering and frustration for patients and physicians alike.

Purpose: 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, 2010, and 2011 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 12 months follow up with an average of 28.9 ± 10.3 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 patients did not need retreatment (66.7%) with a male to female ratio of 5/9.

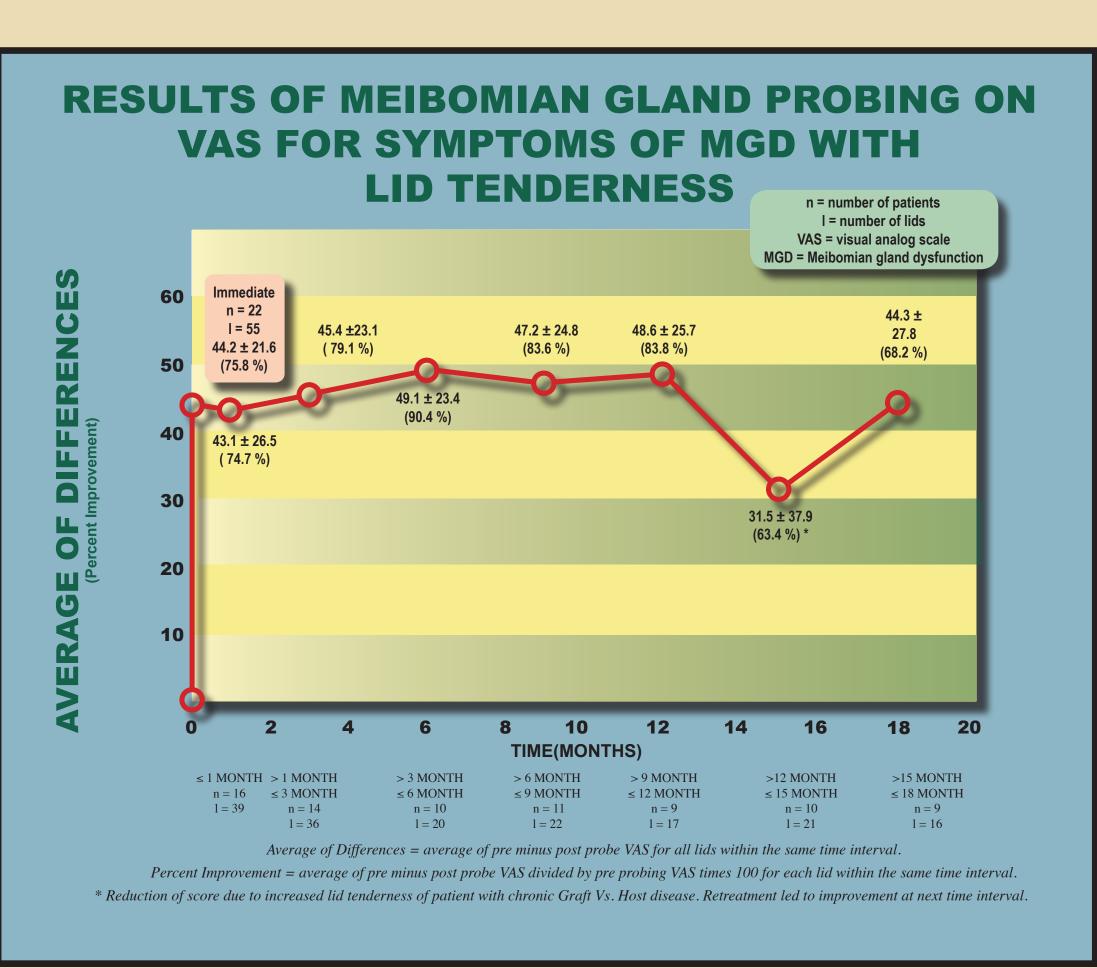
The range of follow up for non retreated patients was 17 to 46 months with an average of 30.3 ± 10.5 months. These 14 patients had a total of 23 lids treated. For the seven patients needing retreatment (33.3%) there was an overall range of 12 to 42 months follow up with average 26.0 ± 9.88 months with a male to female ratio of 2/5. These seven patients

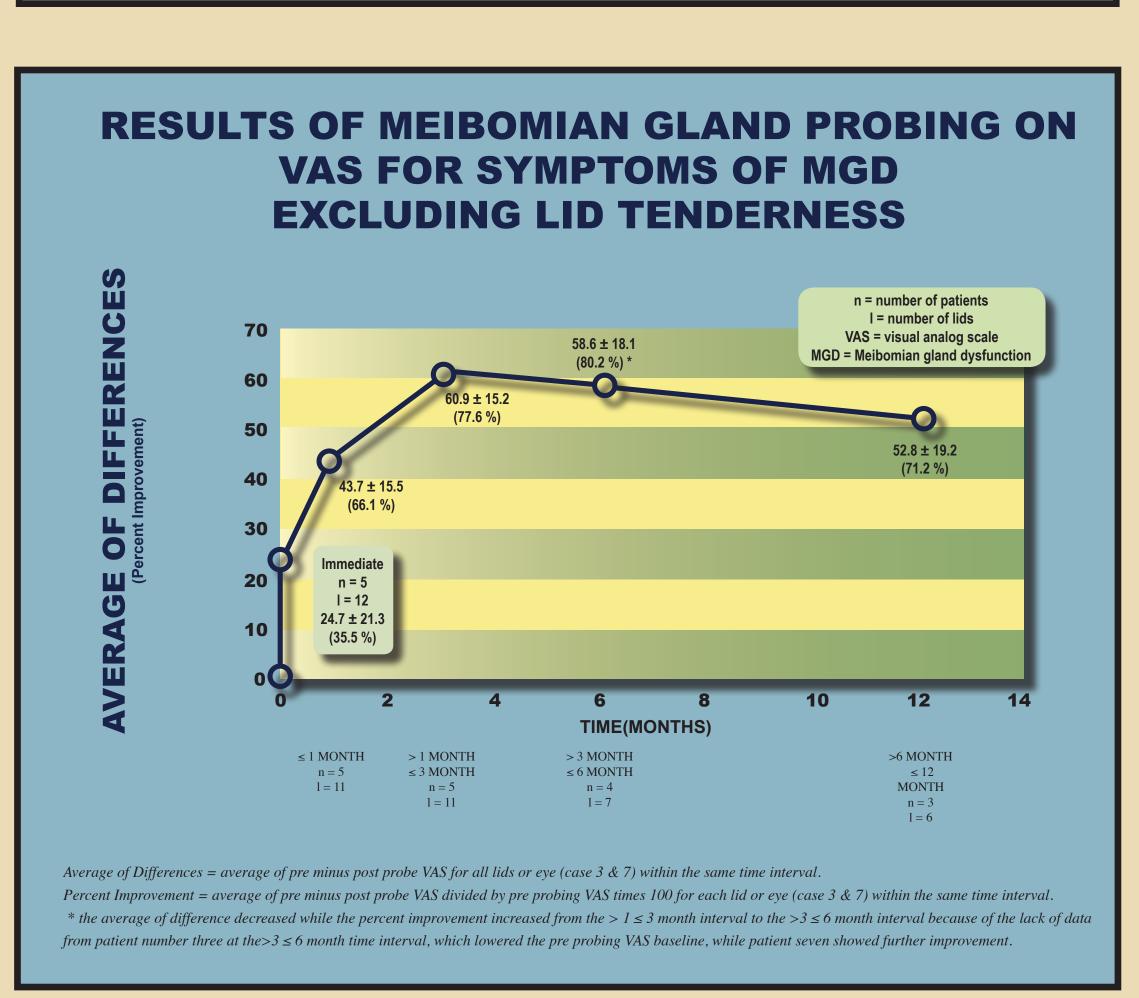


with an average interval for first retreatment at 10.3 ± 9.43 months with a range of 1 to 27 months. Seven of the fourteen retreated lids were retreated a second time. At the last follow up, all the patients reported ongoing improvement. No patient had worse symptoms and no adverse sequelae of probing

BACKGROUND STUDIES

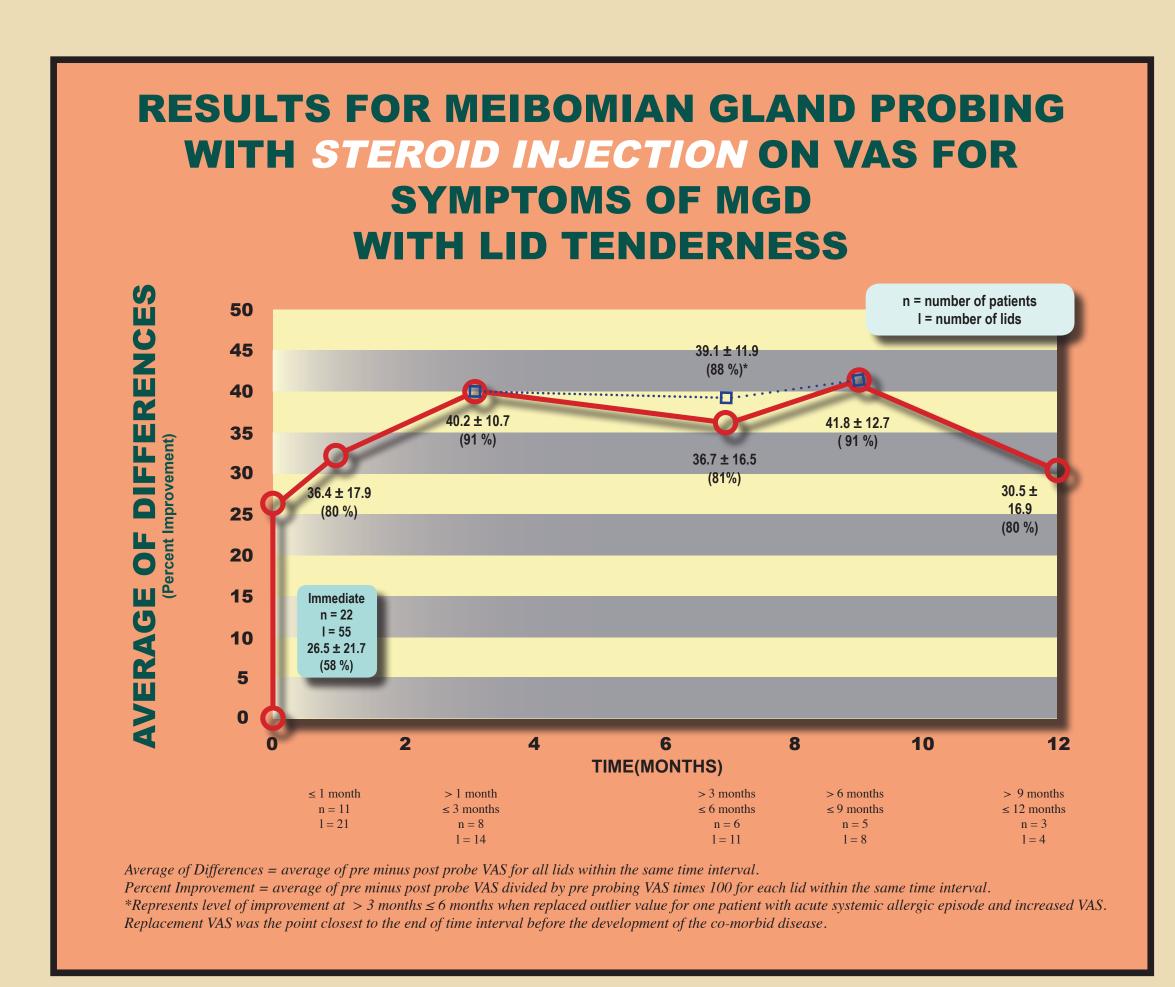
Background: Previous reviews looked at MGP for MGD symptoms of lid tenderness (LT) and except lid tenderness (XLT) without intraductal microtube steroid injection using Visual Analog Scale (VAS) to evaluate symptoms. The results showed two discrete types of VAS response profiles with LT responding immediately to 75% improvement maintaining between 74 and 90% through 9-12 months suggesting that equilibration of elevated intraductal pressure led to relief. For XLT, improvement was 35% immediately with gradual improvement to 80% by 3 to 6 months suggesting improvement through removal of stagnant intraductal contents and reduction of glandular

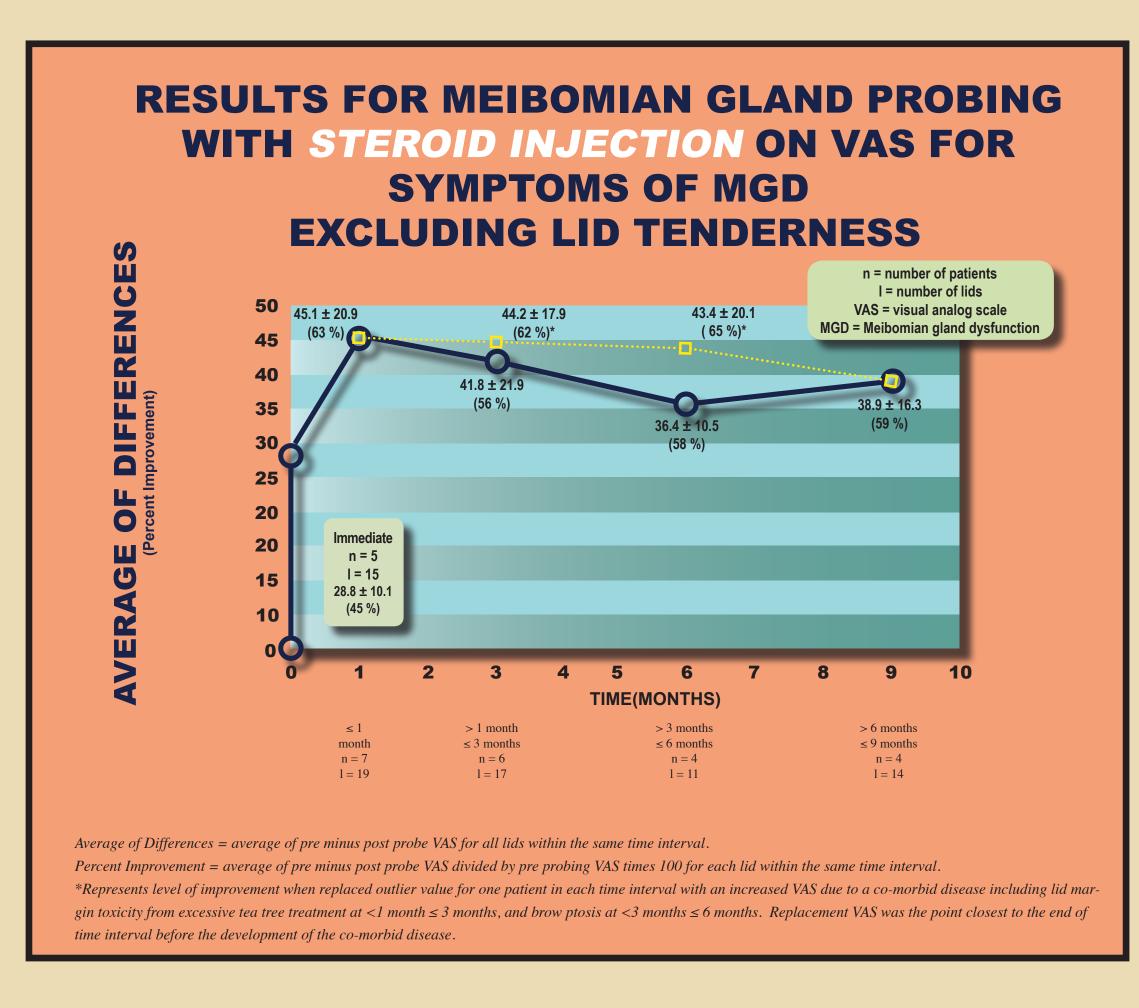




had 14 lids retreated out of 19 lids overall treated inflammation leading to improved gland function

We also looked at MGP with *adjunctive* intraductal microtube steroid injection in patients with MGD and more severe symptoms and/ or signs including lid tenderness (LT) and excluding lid tenderness (XLT). Visual Analog Scale (VAS) was used to evaluate symptoms. For LT, the results showed a gradual response from 58 % reduction in symptoms immediately to 91 % at >1 month \leq 3 months then maintained between 80 % and 91 % through 12 months follow up. For XLT, improvement was 45 % immediately with improvement to 63 % at 1 month and maintaining improvement in the 60 percentile until the latest follow up at > 6 months ≤ 9 months.

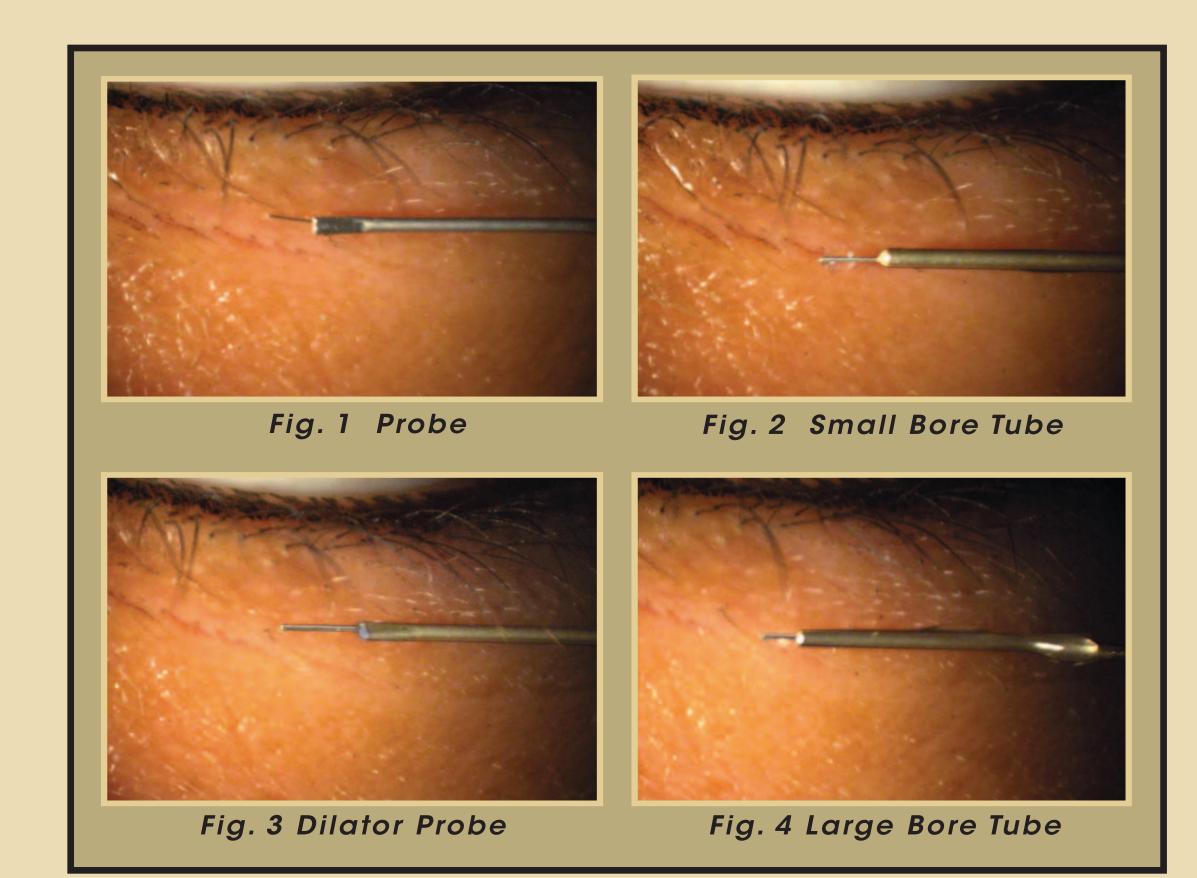


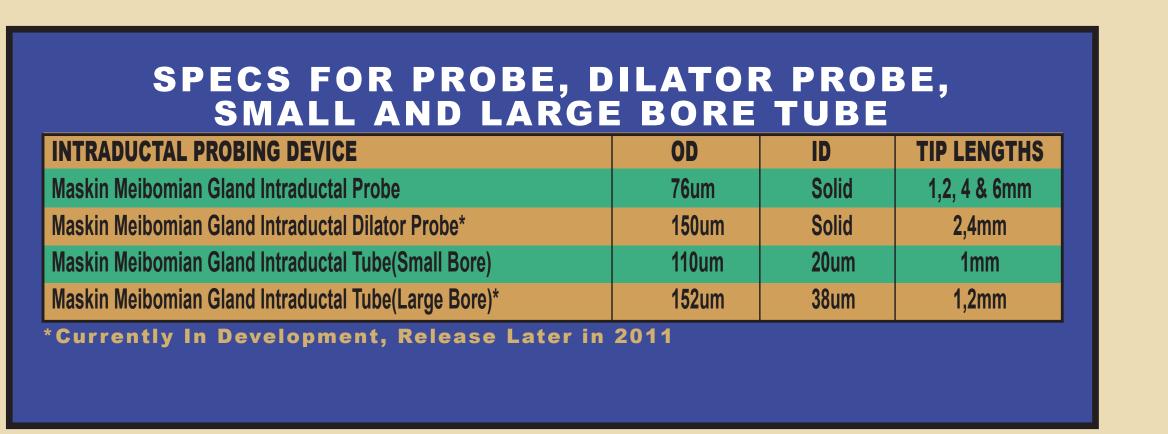


FOLLOW UP STUDIES

RESTORING FUNCTIONALITY AFTER MGP

Purpose: To retrospectively look at the restoration of meibum secreting lid functionality after probing. This was for all lids that had an initial diagnosis of non functional (NF) meibum secreting lids pre

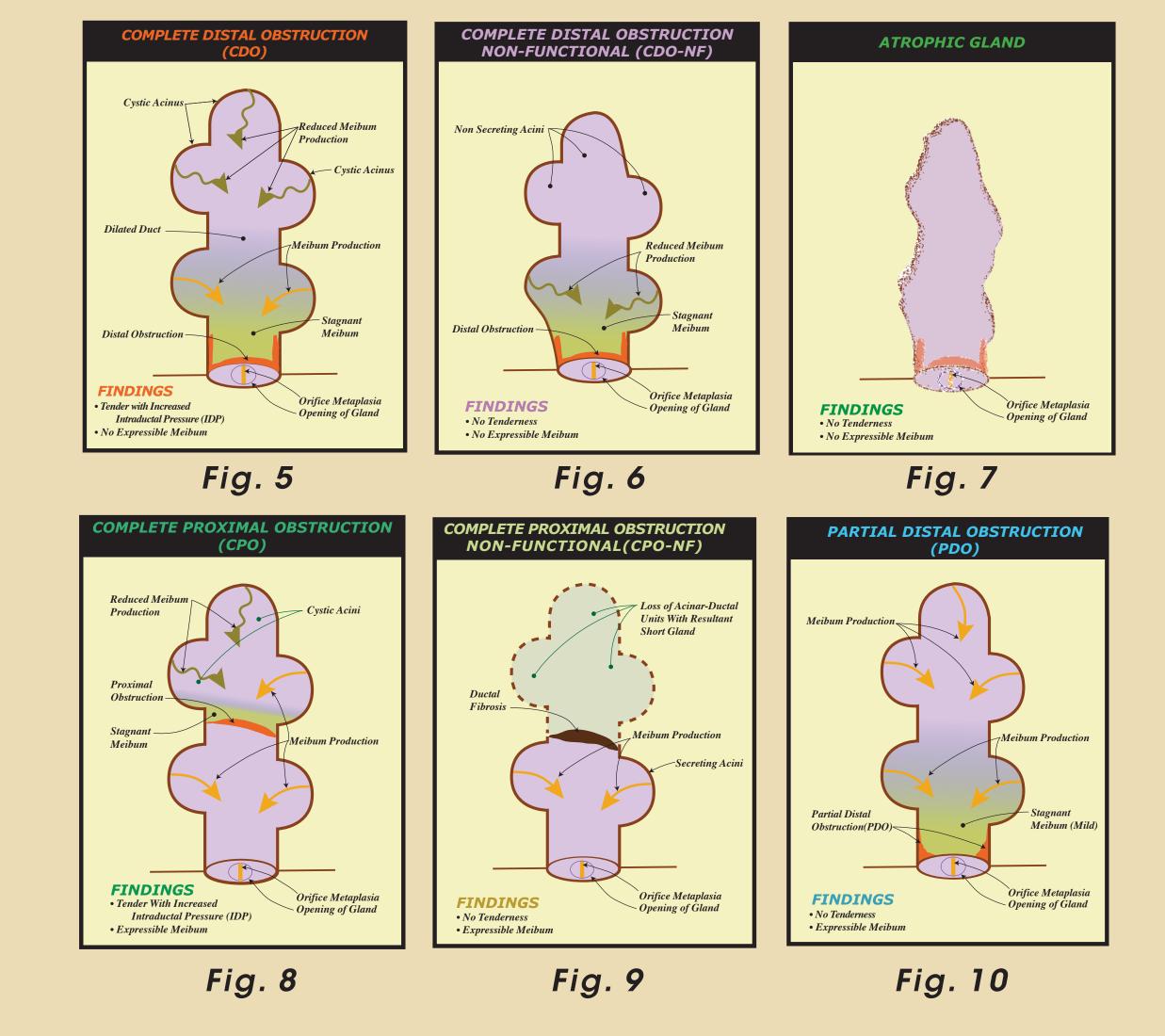




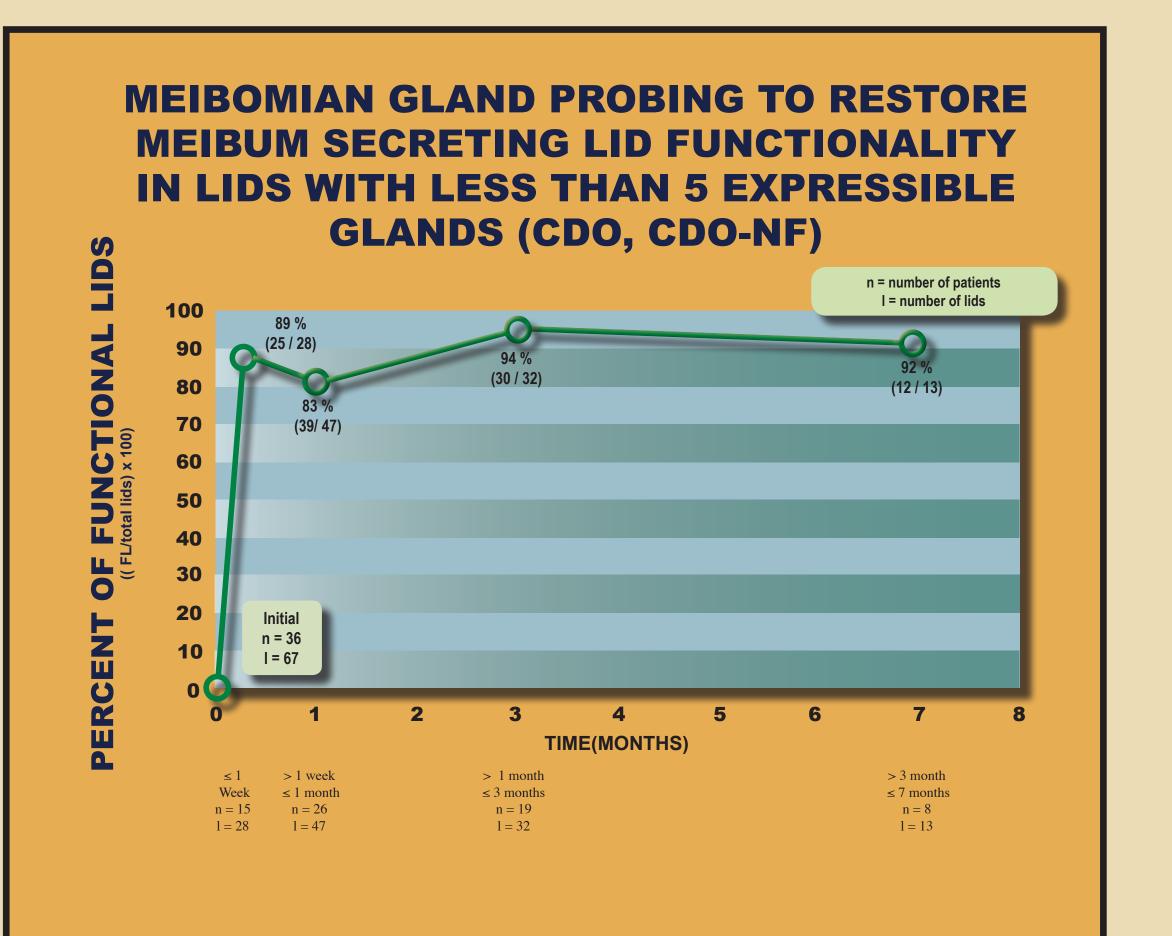
probing. Pre-probe diagnosis of NF lids could be categorized as complete distal obstruction (CDO) or complete distal obstruction non-functional (CDO NF). See nearby MGP classification diagram. Functionality means the patient must have at least 5 expressible glands in a lid with a maximum number of glands counted being 10 glands per lid.

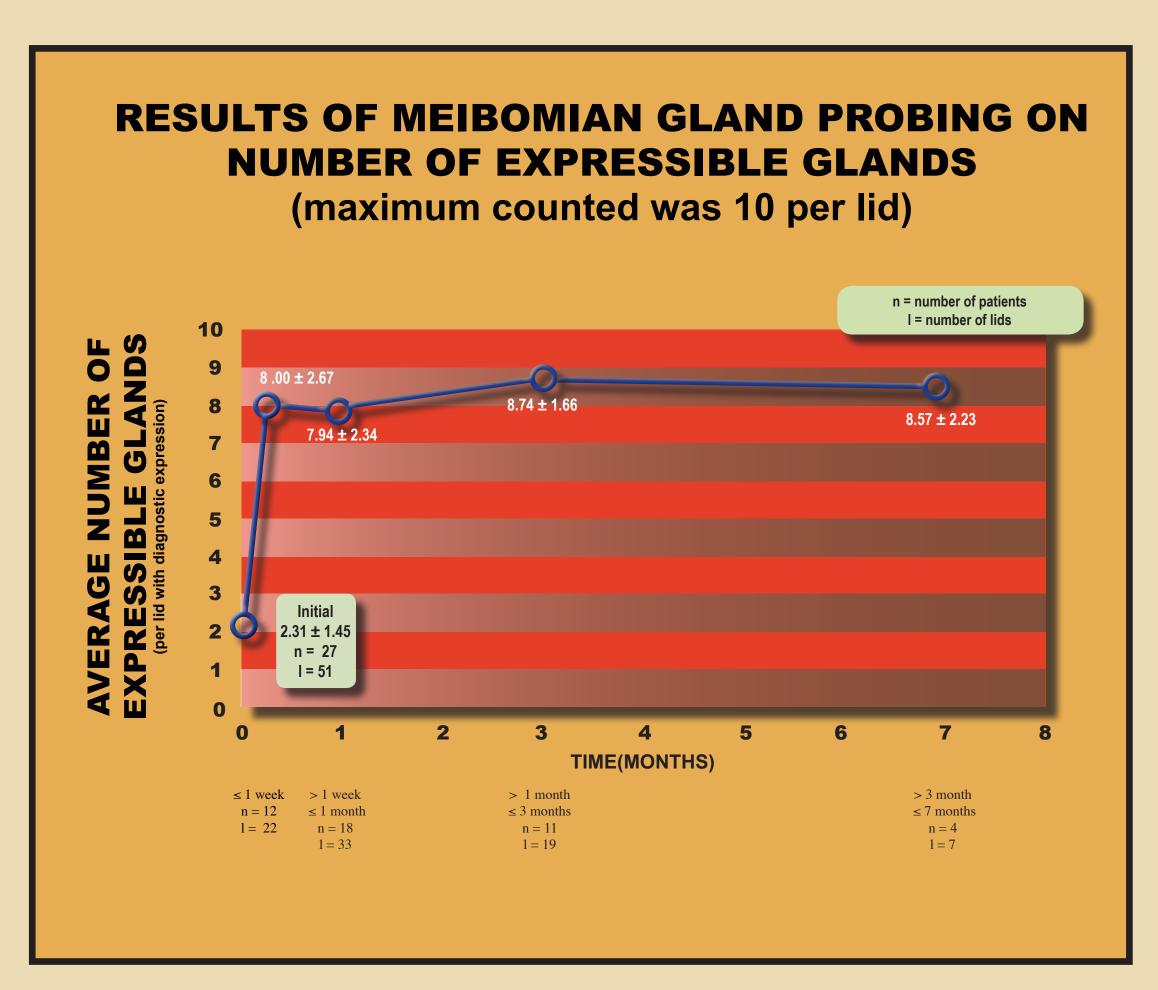
Methods: During examination, digital diagnostic expression was performed on each lid to see if there was a presence or absence of meibum secreted. A classification system was generated to explain the differences in functionality between NF meibum secreting lids and functional (F) meibum secreting

RESULTS: Post probing meibum secreting lid



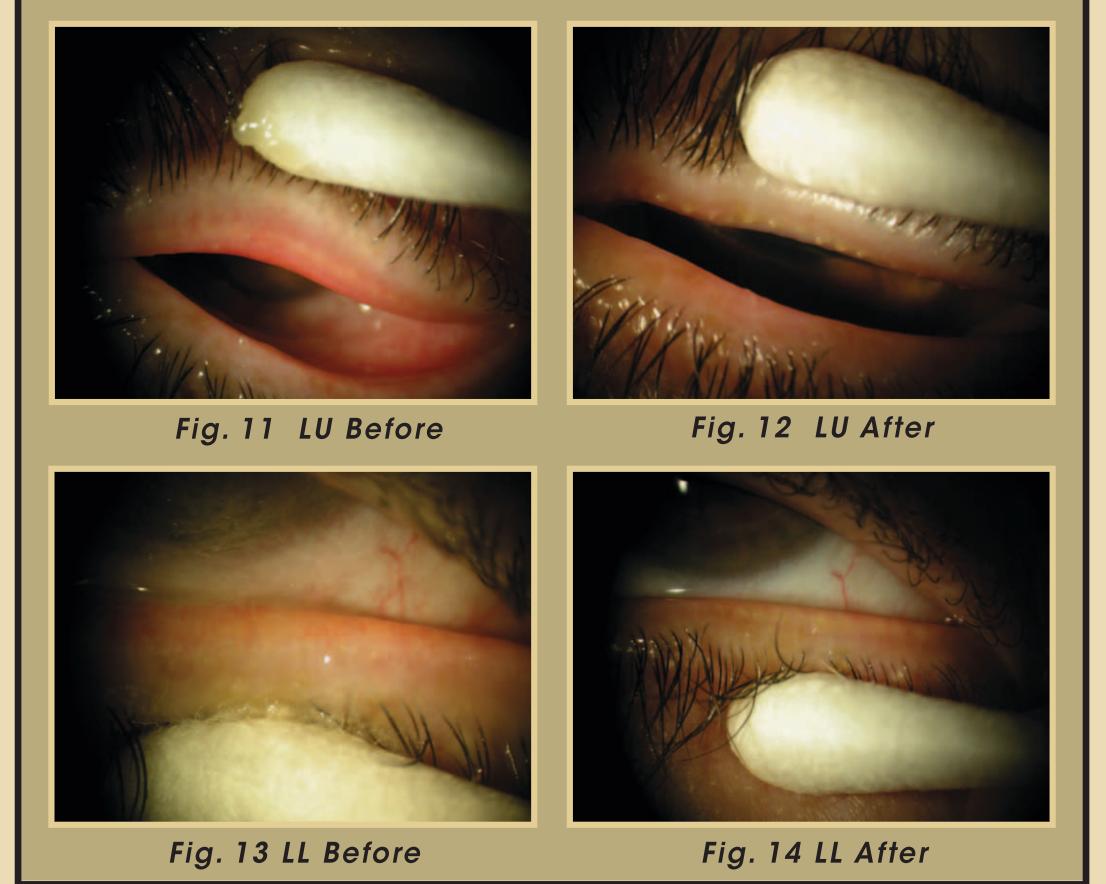
functionality was evaluated in 67 lids of 36 patients with initial NF lids. The average age was 64.5 ± 12.8 , with a M/F ratio of 5/31. Sixty two lids became functional and remained functional until their last follow up at average of 7.65 ± 6.82 weeks with a range of $\frac{1}{2}$ of a week to 7 months. Three initial NF lids have remained NF until their last follow up but all three lids, increased the number of glands expressible per lid.





Two lids started NF became functional but became NF again at their last follow up visit. At the initial pre-probe time, zero lids were functional with 2.31 ± 1.45 glands expressible per lid. When measuring functionality from any time less than or equal to one week after probing, 89 % (25/28) of the lids measured were functioning with 8.00 ± 2.67 glands expressible per lid. At greater than one week and less than or equal to one month post probing, 83 % (39/47) lids were functional with 7.94 ± 2.34 glands expressible per lid. At greater than one month and less than or equal to three months after probing, 94 % (30/32) lids were functioning with 8.74 ± 1.66 glands expressible per lid. At greater than three months and less than or equal to seven months

post probing, 92 % (12/13) lids were functioning with 8.57 ± 2.23 glands expressible per lid. The NF lids became functional at average 2.55 ± 2.13 weeks post probing and average last recorded expressible gland count was 8.10 ± 2.26 glands



(Fig. 11) Preprobing, the left upper lid had 0 expressible glands and VAS showed 44 of 100 tenderness for a diagnosis of Complete Distal Obstruction (CDO), while 1 week after probing (Fig. 12) the same lid had more than 10 expressible glands and VAS showed 7 of 100 in tenderness for a diagnosis of Partial Distal Obstruction (PDO).

(Fig. 13)Preprobing, the left lower lid had 0 expressible glands and VAS of 47 of 100 tenderness for diagnosis of CDO, while 1 week after probing (Fig. 14) the same lid had more than 10 expressible glands and VAS showed 0 of 100 tenderness for a diagnosis of PDO.

Patient	is 6	66 year	old w	oma	an
Probing 2/1/11	Which Lid	Number of Expressible Glands	VAS Tenderness (0-100)	Status of MG	Co-Morbid Disease
Day 1 (Pre probing)	Left Upper	0	44	CDO	
1 Week (Post probing)		>10	7	PDO	
1 Month		>10	32	СРО	Anterior Blepharitis
4 Months		10	38	СРО	GI Medicine- Stomach flu on Anticholinergic Meds
8 Months		>10	16	PDO	
Probing 2/1/11	Which Lid	Number of Expressible Glands	VAS Tenderness (0-100)	Status of MG	Co-Morbid Disease
Probing 2/1/11 Day 1 (Pre probing)		Expressible	Tenderness		Co-Morbid Disease
		Expressible Glands	Tenderness (0-100)	of MG	Co-Morbid Disease
Day 1 (Pre probing)		Expressible Glands 0	Tenderness (0-100)	of MG	Co-Morbid Disease Anterior Blepharitis
Day 1 (Pre probing) 1 Week (Post probing)	Lid	Expressible Glands 0 >10	Tenderness (0-100) 47 0	of MG CDO PDO	

FINDINGS:

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. (5) After completion of regular probing, seat dilator probe on orifice and advance into distal duct about 1mm. (6) With steroid in tuberculin syringe with attached microtube, advance plunger to eliminate air, then place through dilated orifice into distal duct and inject approximately 15ul into each gland. (7) Rinse eye copiously with saline to remove residual anesthetic and use cotton tipped applicator to remove anesthetic from lashes.

(8) Have patient use artificial tears every 30 to 60 minutes until bedtime.

CONCLUSIONS:

(1) MG Probing was highly successful in restoring meibum secreting lid functionality persisting up to at least 7 months. (2) MG Probing rapidly increased number of expressible glands per lid which was maintained up to at least 7 months post probing. (3) Improved meibum secreting lid functionality and number of expressible glands may explain the marked positive therapeutic effects of MG Probing previously reported. (4) A qualitative classification of MGD based on probing findings and slit lamp examination is proposed to help understand gland status. (5) MG Probing plus intraductal microtube steroid injection [MGP (s)] was successfully accomplished with presently available technology and was well tolerated by patients after topical anesthetic without adverse sequelae with longest follow up at 46 months. (6) Meibomian Gland intraductal microtubes are available in two different inner diameters to enable injection of aqueous solutions as well as small particle therapeutic suspensions. (7) MGP(s) may enable even greater symptom reduction than MGP alone in select cases of moderate to severe symptoms and/or signs, significant co-morbid disease, retreatment and possibly chalazion.

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