

Meibomian Gland Probing Findings Suggest Fibrotic Obstruction Is A Major Cause of Obstructive Meibomian Gland Dysfunction (O-MGD)

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

FOLLOW UP OF ORIGINAL MEIBOMIAN GLAND PROBING CASES

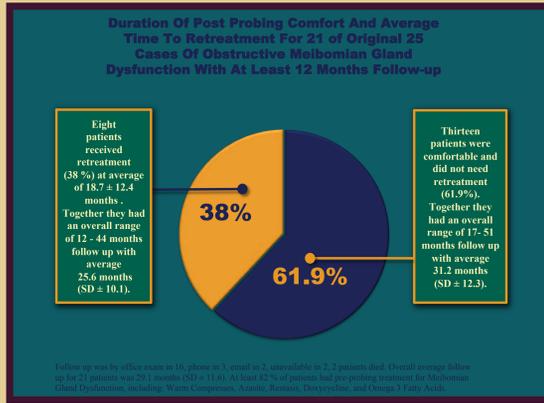
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Background: Meibomian gland dysfunction (MGD) is arguably the most common cause of dry eye and has certainly been the most challenging to treat. Traditional therapies have failed to consistently provide effective results leading to ongoing suffering 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 29.1 ± 11.6 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. Thirteen patients did not need retreatment (61.9%) with a male to female ratio of 4/9. The range of follow up for non retreated patients was 17 to 51 months with an average of 31.2 ± 12.3 months. These 13 patients had a total of 21 lids treated. For the eight patients needing retreatment (38%) there was an overall range of 12 to 44 months follow up with average 25.6 ± 10.1 months with a male to female ratio of 3/5. These eight patients had 15 lids retreated out of 18 lids overall treated with an average interval for first retreatment at 18.7 ± 12.4 months with a range of 1 to 44 months. Seven of the fifteen 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 were noted.

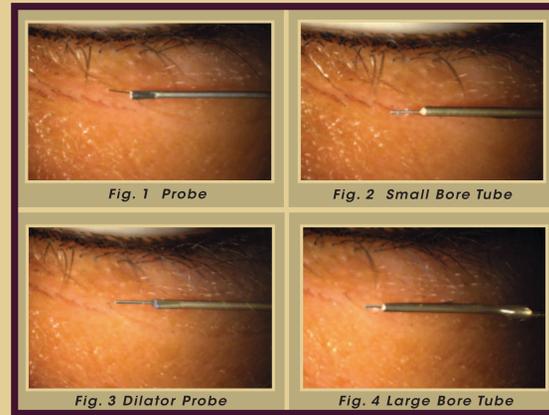
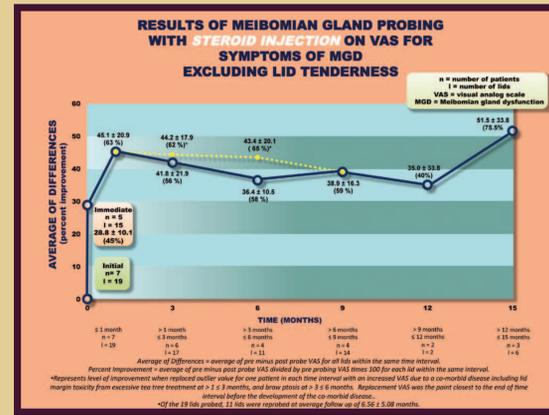
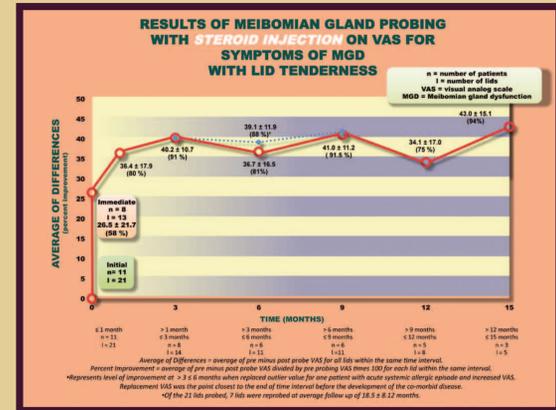
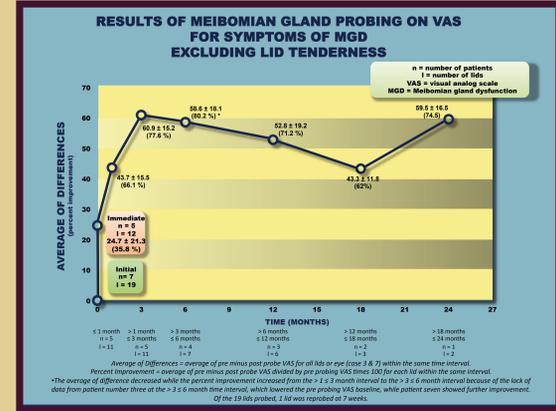
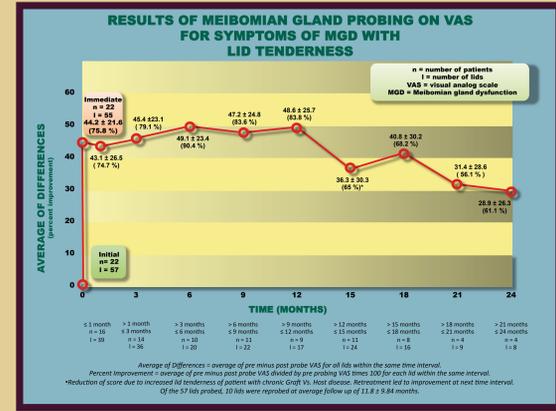


BACKGROUND STUDIES: SUBJECTIVE RESPONSE STUDIES USING VISUAL ANALOG SCALE

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 56 and 90.4% through 21-24 months suggesting that equilibration of elevated intraductal pressure led to relief. For XLT, improvement was 35% immediately with gradual improvement to 74.5% by 18 to 24 months suggesting improvement through removal of stagnant intraductal contents and reduction of glandular inflammation leading to improved gland function.

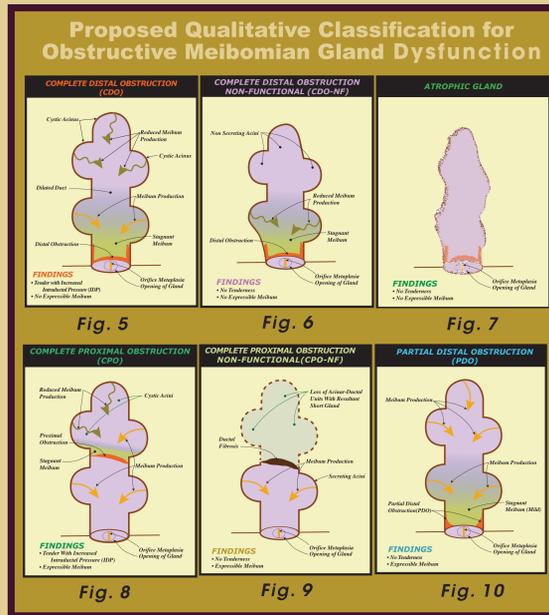
We also looked at MGP with **adjunctive intraductal microtube steroid injection** in patients with MGD and more severe symptoms and/or signs including lid tenderness (LT) and excluding lid tenderness (XLT). Visual Analog Scale (VAS) was used to evaluate symptoms. For LT, the results showed a gradual response from 58 % reduction in symptoms immediately to 91 % at > 1 month ≤ 3 months then maintained between 75 % and 94 % through 15 months follow up. For XLT, improvement was 45 % immediately with improvement to 63 % at 1 month and maintaining improvement between 40% and 75% until the latest follow up at > 12 months ≤ 15 months.



SPECS FOR PROBE, DILATOR PROBE, SMALL AND LARGE BORE TUBE

INTRADUCTAL PROBING DEVICE	OD	ID	TIP LENGTHS
Maskin Meibomian Gland Intraductal Probe	76um	Solid	1,2, 4 & 6mm
Maskin Meibomian Gland Intraductal Dilator Probe*	150um	Solid	2,4mm
Maskin Meibomian Gland Intraductal Tube(Small Bore)	110um	20um	1mm
Maskin Meibomian Gland Intraductal Tube(Large Bore)*	152um	38um	1,2mm

*Currently in Development, Release Later in 2012

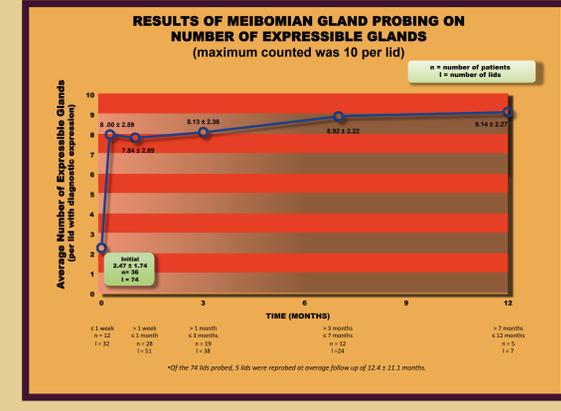
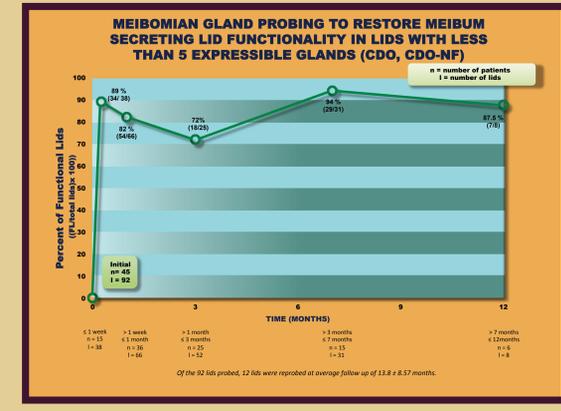


BACKGROUND STUDIES: RESTORING FUNCTIONALITY AFTER MGP

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 obstructive MGD classification diagram in previous column. 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 lids.

Results: Post probing meibum secreting lid functionality was evaluated in 92 lids of 45 patients with initial NF lids. The average age was 64.4 ± 12.9, with a M/F ratio of 6/39. Eighty one (88%) lids became functional and remained functional until their last follow up at average of 12.4 ± 11.0 weeks with a range of 1/2 of a week to 10 months. Six initial NF lids have remained NF until their last follow up but 5 of the 6 lids increased the number of glands expressible per lid. Five 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 2.47 ± 1.74 glands expressible per lid. When measuring functionality from any time less than or equal to one week after probing, 89 % (34/38) of the lids measured were functioning with 8.00 ± 2.59 glands expressible per lid. At greater than one week and less than or equal to one month post probing, 82 % (54/66) lids were functional with 7.84 ± 2.89 glands expressible per lid. At greater than one month and less than or equal to three months after probing, 72 % (18/25) lids were functioning with 8.13 ± 2.36 glands expressible per lid. At greater than three months and less than or equal to seven months post probing, 94 % (29/31) lids were functioning with 8.92 ± 2.22 glands expressible per lid. At greater than seven months and less than or equal to 12 months post probing, 87.5% (7/8) lids were functioning with 9.14 ± 2.27 glands expressible per lid. The NF lids became functional at average 3.13 ± 3.47 weeks post probing and average last recorded expressible gland count was 8.31 ± 2.63 glands.



FOLLOW UP STUDY: FINDINGS FROM MEIBOMIAN GLAND PROBING

Purpose: To review characteristics of intraductal meibomian gland probing (MGP) findings to evaluate frequency of an audible "pop" and

tactile relief (pops) of intraductal resistance suggestive of fibrotic obstruction as well as gritty sensations (grits) suggestive of keratinized cell debris as factors of O-MGD.

Methods: Intraductal meibomian gland probing data were reviewed retrospectively of patients status post MGP for O-MGD as previously described in Cornea 2010;29:1145-1152. There were 216 patients and 756 lids probed. Average age was 62.12 ± 16.03 with a range of 17-95. Male: female ratio was 66/150 or 0.4/1.

Results: Of a total of 18,459 glands probed, 7595 or 41% had pops with a range of 0-100%, 4657 or 25% had grits with a range of 0-91% and 6155 or 33% had neither. Looking at upper vs lower lids, there were 11476 total upper glands and 6983 lower lid glands probed. The upper lid glands had 4956 or 44% pops, 3501 or 31%grits and 3007 or 26% neither while the lower lid glands had 2639 or 38% pops, 1156 or 17% grits and 3148 or 45% with neither. Of all the glands probed, only 20 (.10%) had both pop and gritty. There was a total of up to 75% of upper glands and 55% of lower glands showing some detectable intraductal resistance.

	Total Glands	Pop	% Pop	Gritty	% Gritty	Pop + Gritty	% P + G	None	% None	Heme	% Heme
Upper	11476	4956	43.19%	3501	30.51%	8457	73.69%	3007	26.20%	2125	18.52%
Lower	6983	2639	37.79%	1156	16.55%	3795	54.35%	3148	45.08%	837	11.98%
Total	18459	7595	41.15%	4657	25.23%	12252	66.37%	6155	33.34%	2962	16.05%

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 transillumination 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. (3) Place bandage contact lens. (4) 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. (5) 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. (6) 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 fibrotic tissue. (7) After completion of regular probing, if indicated, seat dilator probe on orifice and advance into distal duct about 1mm. (8) With steroid in tuberculin syringe with attached microtube, advance plunger to eliminate air, then place through dilated orifice into distal duct and inject approximately 10ul into each gland. (9) Rinse eye copiously with saline to remove residual anesthetic and use cotton tipped applicator to remove anesthetic from lashes. (10) Remove bandage contact lens. (11) Have patient use artificial tears every 30 to 60 minutes until bedtime.

CONCLUSION

(1) Orifice penetration and intraductal meibomian gland probing has uncovered characteristics consistent with mechanical resistance to meibum flow. (2) Mechanical resistance to meibum flow occurred in majority of glands (66% of all glands). (3) The most frequent component of resistance appeared to be from "pops" which was suggestive of fibrotic obstruction and occurred in 41% of all glands probed. Lacking histopathologic evidence of intraductal fibroses suggested the location of fibrotic obstruction is periglandular (Hamrah). (4) The "pops" then represent release of this fibrotic "collar". (5) Release of fibrotic collar caused reduced intraductal pressure, enhanced meibum flow and reduced symptoms of O-MGD.

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