1

Financial Disclosures- Ibach

Disclosure Statement:

Alcon – consultant/speaker
Allergan – consultant
Bausch Health- consultant/speaker
C-Light Technologies - consultant
Dompe – consultant/speaker
Equinox/Balance Ophthalmics – consultant/shareholder
Glaukos - consultant/speaker
iCare -- consultant
NewWorld Medical – consultant
Sight Sciences – consultant/speaker
Tarsus pharmaceuticals -- consultant
Thea – consultant
Zeiss – consultant

VANCE THOMPSON VISION

All relevant relationships have been mitigated

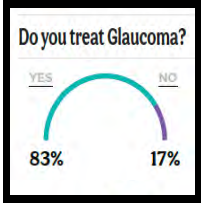
2

- Glaucoma is the second leading cause of blindness worldwide
- In the US, there are an estimated 4M cases of OAG, with a significant number of patients going blind every year[1]
- ~ 40,000 OD's in US, ~23,000 MD's = 60k ECP's
- Every ECP managed glaucoma - ~ 70 pts

1. 2017 Market Scope Glaucoma Report, data on file.

3

EOE's Glaucoma Survey



Geller, M., & Schweitzer, J. (2021). Eyes on Eyecare 2022 Glaucoma Report (2nded ed.). Eyes On Eyecare

4

Why MIGs?


Drops- SE's


Drops - convenience


Drops - compliance


Laser – duration


Drug delivery- single use


Tubes/Trabs – risks

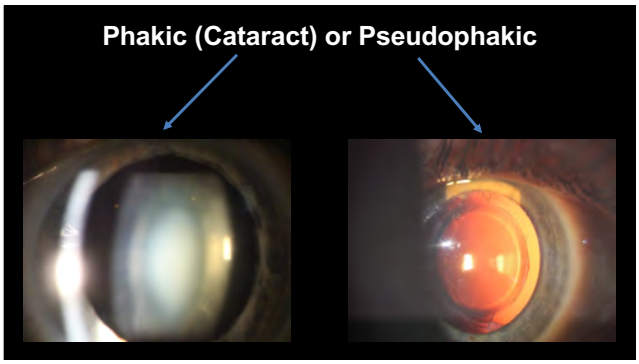
5

Minimally Invasive Glaucoma Surgery (MIGS)

Procedures that have an ab-interno approach, are minimally traumatic, with at least modest efficacy, extremely high safety and rapid recovery .

Saheb H, Ahmed, IIK. Micro-invasive glaucoma surgery: current perspectives and future directions. Curr Opin Ophthalmol. 2012;23(2): 96-104.

6



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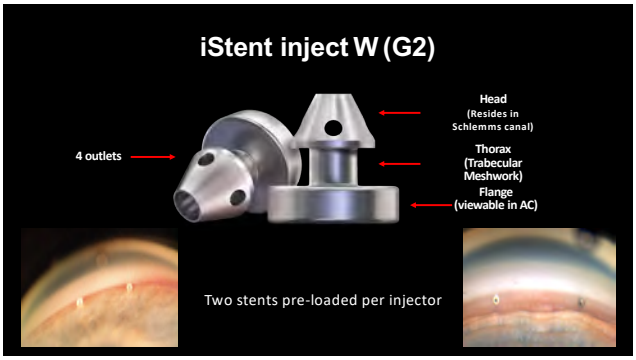
MIGs

Trabecular Meshwork / Schlemm's Canal				Suprachoroidal/ Supraciliary	Subconjunctival	Cyclophoto-coagulation
Stents	Ablation	Cutting	Dilation			Endoscopic Transcleral
iStent iStent Inject Hydrus iStent Infinite	Trabectome	Kahook Dual Blade iAccess GATT Sion	ABiC (Ab-interno Canaloplasty) iPrime Streamline OMNI (combo)	Cypass[xx] iStent-Supra*	Xen Microshunt*	ECP G6/MP3

http://glaucomanow.com/media/24823/glaucoma_issue_3_2016-web.pdf

9



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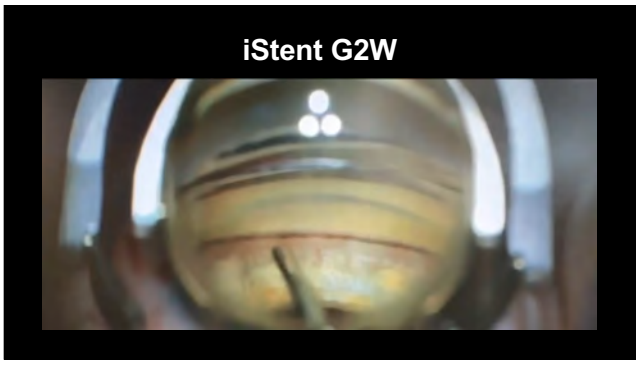

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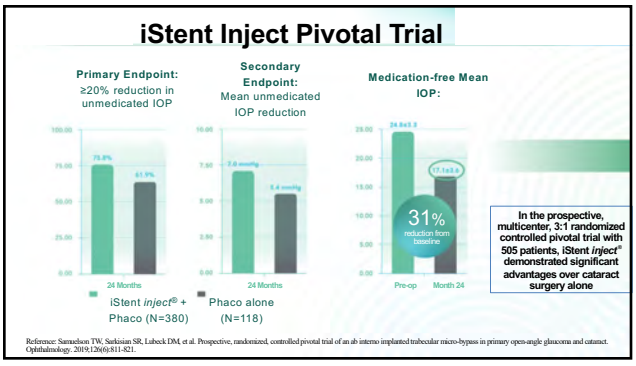

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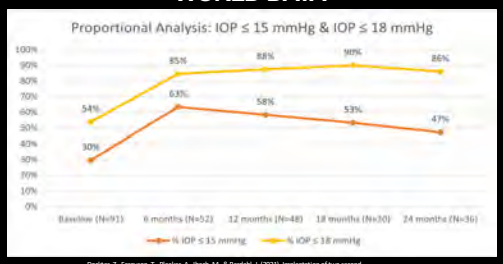
CATARACT SURGERY PLUS ISTENT INJECT: REAL WORLD DATA



Dockter, Z., Ferguson, T., Bleeker, A., Ibach, M., & Berdahl, J. (2021). Implantation of two second generation trabecular microbypass stents with cataract extraction in open-angle glaucoma: 2 year outcomes. *American Society of Cataract and Refraction Surgeons (ASCRS)*.

14

INCREASED AQUEOUS OUTFLOW

- In-vivo proof of increased outflow in glaucomatous eyes post-iStent *inject* implantation

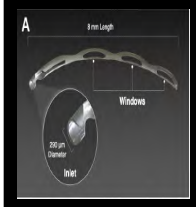
Aqueous Angiography
Before and After Stenting

Alex Huang, MD, PhD

Huang AS et al. Aqueous angiographic outflow improvement after trabecular microbypass in glaucoma patients. Ophthalmology Glaucoma. 2019

16

Hydrus MicroStent



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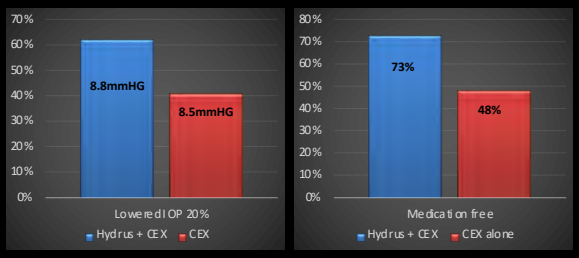
Hydrus – Horizon Trial 3 Year Data



Ahmed, I., Rhee, D., Jones, J., Singh, I., Radcliffe, N., Gazzard, G., ... Singh, K. (2020). Thre-Year Findings of the Horizon Trial. *Ophthalmology*.

18

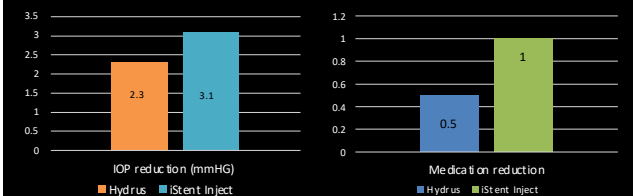
Horizon 4-Year Update

5-year HORIZON RCT: First MIGS device to demonstrated reduced VF progression

Montesano G, Ometto G, Ahmed IIK, et al. Five-year visual field outcomes of the HORIZON trial. Am J Ophthalmol. 2023;251:143-155.
Rhee, D. (2020, February 27). Four-year update of HORIZON. *American Glaucoma Society Meeting 2020*.

19

Comparative study of 2-year outcomes for Hydrus or iStent inject microinvasive glaucoma surgery implants with cataract surgery



Holmes, D., Clement, C., Nguyen, V., Healey, P., Lim, R., White, A., ... Lawlor, M. (2022). Comparative study of 2-year outcomes for Hydrus or iStent inject microinvasive glaucoma surgery implants with cataract surgery. *Clinical and Experimental Ophthalmology, 50*, 303-311.

20

iStent Infinite

- 12 month results of 72 pts treated with stand-alone iStent Infinite
- Baseline IOP 23 on 3.1 meds
- All patients on max meds or previous glaucoma surgery

76%

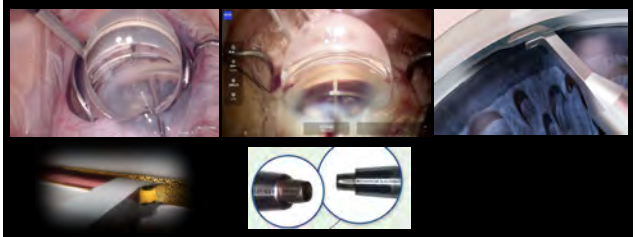
~6mmHG

Sarkisian, S., Grover, D., Gallardo, M., Brubaker, J., Giamporcaro, J., Hornbeak, D., ... Navratil, T. Effectiveness and Safety of iStent infinite Trabecular Micro-Bypass for Uncontrolled Glaucoma. *Journal of Glaucoma.*

21

TM removal procedures- Goniotomy

Excisional Goniotomy (Kahook Dual Blade) | Goniotomy (iAccess) | Goniotomy (SION)



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Combined Phaco+KDB Cohort

	Preoperative N=71	Day 1 (1-3 days) N=60	Week 1 (4-14 days) N=59	Month 1 (15-59 days) N=67	Month 3 (60-120 days) N=56	Month 6 (121-270 days) N=60	Month 12 (271-455 days) N=48
Mean IOP	17.4± 5.2	13.3± 3.9	13.4± 4.8	13.6± 3.4	12.6± 2.6	12.7± 2.3	12.4± 3.4
Mean Difference	Reference	-4.1*	-4.0*	-3.8*	-4.8*	-4.7*	-5.0*
IOP Percent Change	Reference	24%	23%	22%	28%	27%	29%
Mean Meds	1.6± 1.3	0.4± 0.9	0.7± 1.1	0.7± 0.9	0.9± 1.1	0.9± 1.1	0.6± 0.8
Mean Difference	Reference	-1.2*	-0.9*	-0.9*	-0.7*	-0.7*	-1.0*
Meds Percent Change	Reference	75%	56%	56%	44%	44%	63%

29% reduction in IOP at month 12 with baseline IOP below 18mmHg

Greenwood MD, Seibold LK, Radcliffe NM, Dorairaj SK, Aref AA, Jimenez Roman J, Lazcano-Gomez G, Darlington JK, Abdullah S, Jasek MC, Bahjiri KA, Berdahl JP, Goniotomy with a single-use blade:Short-term results. J Cataract Refract Surg 2017;43 1197-1201.

25

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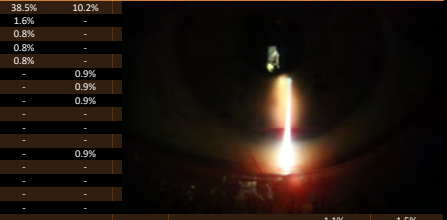
KDB Survey – AE

	Intraoperative N=122	Day 1 (1-3 days) N=108	Week 1 (4-14 days) N=104	Month 1 (15-59 days) N=116	Month 3 (60-120 days) N=91	Month 6 (121-270 days) N=92	Month 12 (271-455 days) N=68
Blood Reflux/Retained Heme	38.5%	10.2%					
Difficulty Removing TM	1.6%	-					
Cyclodialysis Cleft	0.8%	-					
Descemet Tear	0.8%	-					
Iridodialysis	0.8%	-					
Irritation	-	0.9%					
Hypotony	-	0.9%					
Corneal Edema	-	0.9%					
PAS	-	-					
Reoperation for high IOP	-	-					
IOP Spike	-	-					
Inflammation	-	0.9%					
Choroidal detachment	-	-					
Hazy vision	-	-					
Capsular opacification	-	-					
CME	-	-					
Pain	-	-	-	-	-	1.1%	1.5%
Floaters	-	-	-	-	2.2%	-	
Glare	-	-	-	-	1.1%	-	-



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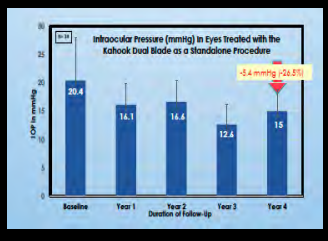
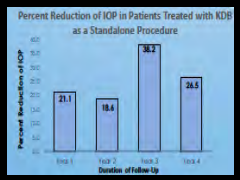
Stand-alone Goniotomy





Landry, T., ElMallah, M., Williamson, B., & Nelson, C. Long-Term Outcomes of Standalone Incisional Goniotomy Using the Kahook Dual Blade in Eyes with Glaucoma. *American Glaucoma Society Meeting 2022*

27

Canaloplasty- iPrime, ABiC, Streamline

Procedure Steps:

1. Piercing or opening up TM
2. Visco-dilation

TABLE 1. AB INTERNO CANALOPLASTY ALL EYES

Examination	n	Median IOP (mm Hg) ±SD	Median Medications (n) ±SD
Maximum recorded	106	21.0 ±5.4	2.0 ±1.0
Baseline	106	18.0 ±6.6	2.0 ±1.0
1 month	100	16.0 ±5.2	0.0 ±0.6
3 months	48	15.0 ±4.5	0.0 ±1.0
6 months	20	14.5 ±2.7	0.0 ±1.0

Abbreviation: SD, standard deviation.

Khaimi, M. (2015, November). Ab Interno Canaloplasty. *Glaucoma Today*, 13-15.

http://sightsciences.com/us/products/visco-360/
http://www.ellex.com/us/physicians/product-portfolio/canaloplasty/

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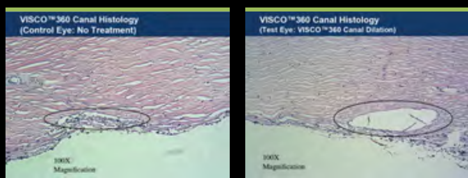
Canaloplasty

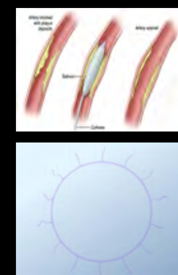
- Viscodilation of Schlemm's Canal 360
  - 2 x 180°



Courtesy of Sight Sciences

30

Omni (canaloplasty+trabeculotomy)



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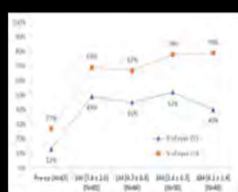
Canaloplasty+Trabeculotomy



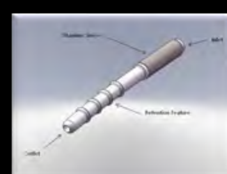
2.3 meds

1.6 meds

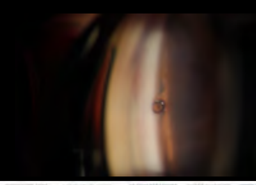
Bleeker, Adam. "Efficacy of Ab Interno Canaloplasty Followed by Trabeculotomy in Pseudophakic Eyes with Open-Angle Glaucoma." *American Society of Cataract and Refractive Surgeons, Paper session 2022.*

32

Suprachoroidal Space



iStent Supra
Currently finishing phase 3 FDA IDE clinical trial



Cypass- voluntarily recalled

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MIGS Considerations: Endothelial Cell Loss Rates

TABLE 1. COMPARISON OF ECL RATES ACROSS MIGS PROCEDURES

MIGS DEVICE	N	FOLLOW-UP TIME	MEAN % ECL	% WITH ECL >30%
Schlemm Canal				
iStent inject (Glaukos)	505	24 months	13.7% treatment 12.3% control	10.4% treatment 9.5% control
	20*	12 months	13.2%	
Hydrus Microstent (Ivantis)	556	24 months	14.0% treatment 10.0% control	13.6% treatment 7.2% control
		36 months	15.0% treatment 11.0% control	14.0% treatment 10.2% control
Trabectome (NeoMedix)	60*	12 months	No change	
Kahook Dual Blade (New World Medical)	Unknown			
Ab Interno Canaloplasty (Ellex)	Unknown			
Omni (Sight Sciences)	Unknown			
Supraciliary				
CyPass Micro-Stent (Alcon)	253	60 months	18.4% treatment 7.5% control	27.2% treatment 10.0% control
iStent Supra (Glaukos)	Unknown			
Subconjunctival				
Xen Gel Stent (Allergan)	11*	12 months	No change (+3.8%)	
InnFocus MicroShunt (Santen)	Unknown			

Key: N = number of patients, ECL = endothelial cell loss, MIGS = microinvasive glaucoma surgery

GM Durr, IK Ahmed.Glaucoma Today, September/October 2018: "Endothelial Cell Loss and MIGS: What We Know and Don't Know"
http://glaucomatoday.com/2018/10/endothelial-cell-loss-and-migs-what-we-know-and-dont-know/

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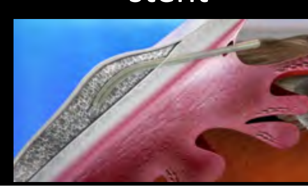
Xen- subconjunctival stent



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Xen 45 Gel Stent: US Pivotal Clinical Trial

Visits – IOP and Medications	Mean
Baseline	
Medicated IOP	25.1 (3.7)
Glaucoma Meds	3.5 (1.0)
12 Month	
IOP	15.9 (5.2)
Glaucoma Meds	1.7 (1.5)

76.3% of patients reported a mean diurnal IOP reduction of ≥ 20% from medicated baseline at 12 months

FDA approves Xen gel stent for glaucoma (2016, November 28). In *American Academy of Ophthalmology* .

36

Postoperative Adverse Events

Hypotony (IOP < 6 mmHg at any time)	16 (24.6%)
Anterior chamber shallow with peripheral irido-corneal touch	1 (1.5%)
Anterior chamber fill	1 (1.5%)
Bleb Needling	21 (32.3%)

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Endocyclophotocoagulation (ECP)

- TREATS **INFLOW**
- It uses a laser endoscope containing three fiber groupings:
  - a light source (**illuminate**)
  - an image guide (**visualize**)
  - diode laser (**treat**)
- Direct visualization
- Precise delivery to the ciliary processes
- **no damage to the underlying ciliary body and surrounding tissue**

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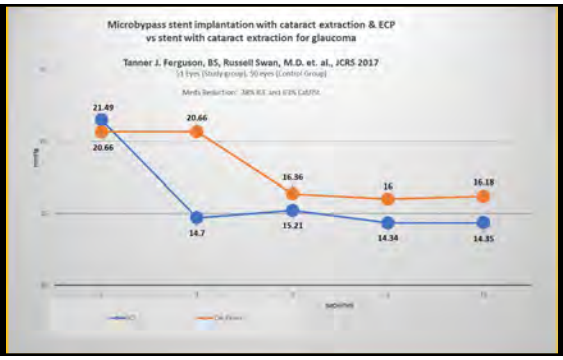

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Handing patients back- Collaborative Care

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Ever Changing World

Insurance changes/criteria

1. TM-bypass stents at time of phaco (G2W & Hydrus)
2. iStent Infinite label – max medical therapy/uncontrolled IOP or previous failed surgery.
3. Canaloplasty - difficult for coverage
4. Goniotomy- mild-moderate with max meds

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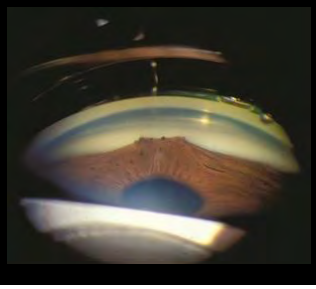
Minimally Invasive

Safety First

1. IOP Spikes
2. Microhyphema
3. Hypotony- Can it happen?
4. Endothelial Cell Loss
5. Peripheral Anterior Synechiae



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Following MIGS Further

- Continue monitoring
  - IOP
    - Immediate IOP spike, add med +/- burp para
    - Fluctuates early, +/- steroid effect
  - Slit lamp exam
    - Normal inflammation, hyphema?
  - Gonioscopy
    - 1 time in global period
  - OCT and HVF
    - 3-6 months post-operatively set new baselines.

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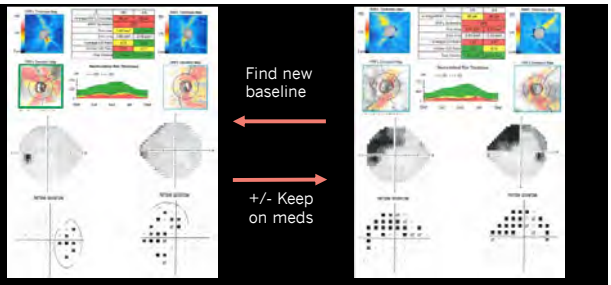

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How Do You Decide?

When we want to maximize safety –Canal

When we want to maximize quick visual recovery – Canal

When we need greater efficacy, and are willing to take a bit more risk, but still want greater safety than transcleral – iStent infinite or Xen

Quick progressing glaucoma and a need for low IOP – Transcleral, Trab, or Tube

Courtesy of Dr. Tom Samuelson

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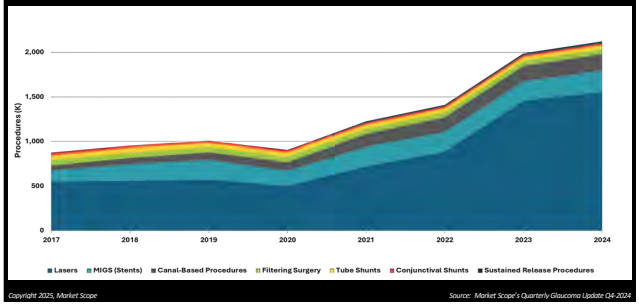
Historical US Glaucoma Procedures Mix



Source: Market Scope's Quarterly Glaucoma Update Q4-2024

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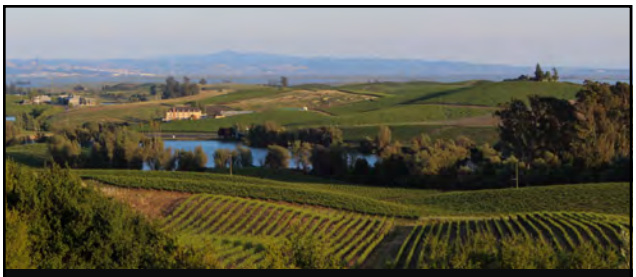

MIGS Landscape is a view worth watching

Thank You! Questions

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