Outcomes of Intravitreal Anti-VEGF Therapy for Diabetic Macular Edema in Routine Clinical Practice

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Tuesday, July 24, 2018

Disclosures

- Regeneron - Investigator, consultant
- Genentech - investigator, speaker
- Allergan - consultant

Dosing Approaches in Clinical Trials are Varied

Quarterly	PRN[11,12]	Treat-and-Extend[11,12]	Monthly	Bimonthly
• PIER[8]	• HARBOR[3]	• LUCAS[17]	• ANCHOR[1]	• VIEW 1/2[6]
• SAILOR[9]	• CATT[4]	• TREX[18]	• MARINA[2]	• VISTA/VIVID[7]
• EXCITE[10]	• RESOLVE[13]		• HARBOR[3]	
	• RESTORE[14]		• CATT[4]	
	• Protocol I[15]		• RISE/RIDE[5]	
	• Protocol T[16]		• VIEW 1/2[6]	
			• VISTA/VIVID[7]	

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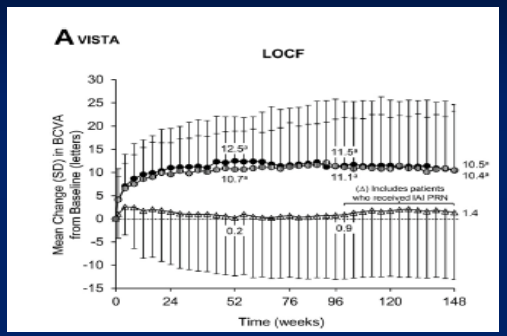
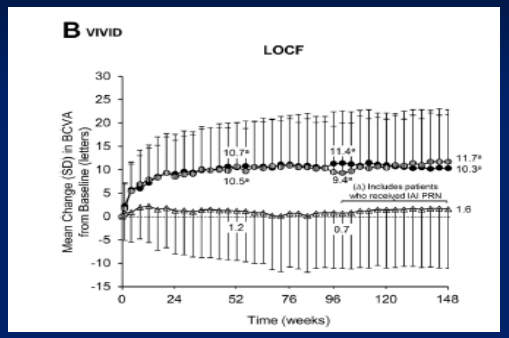
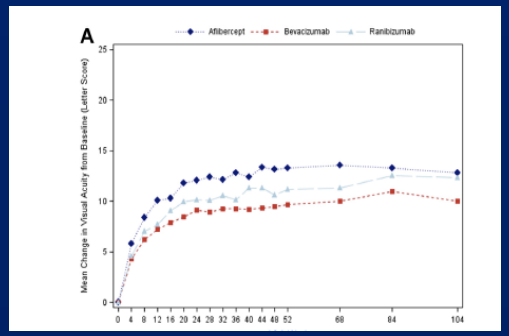
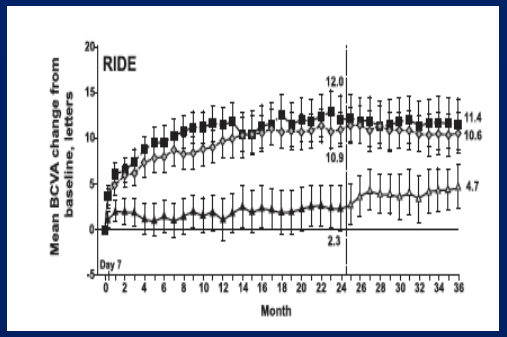
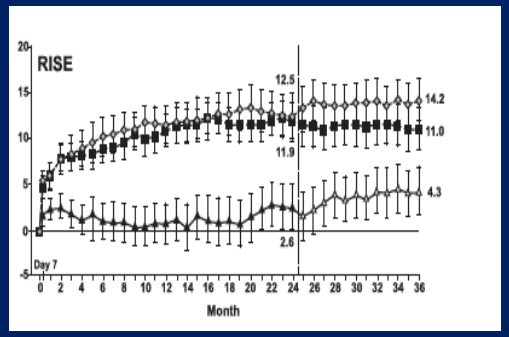
Frequent Monitoring and Consistent Treatment Resulted in Optimal Outcomes in Clinical Trials for DME





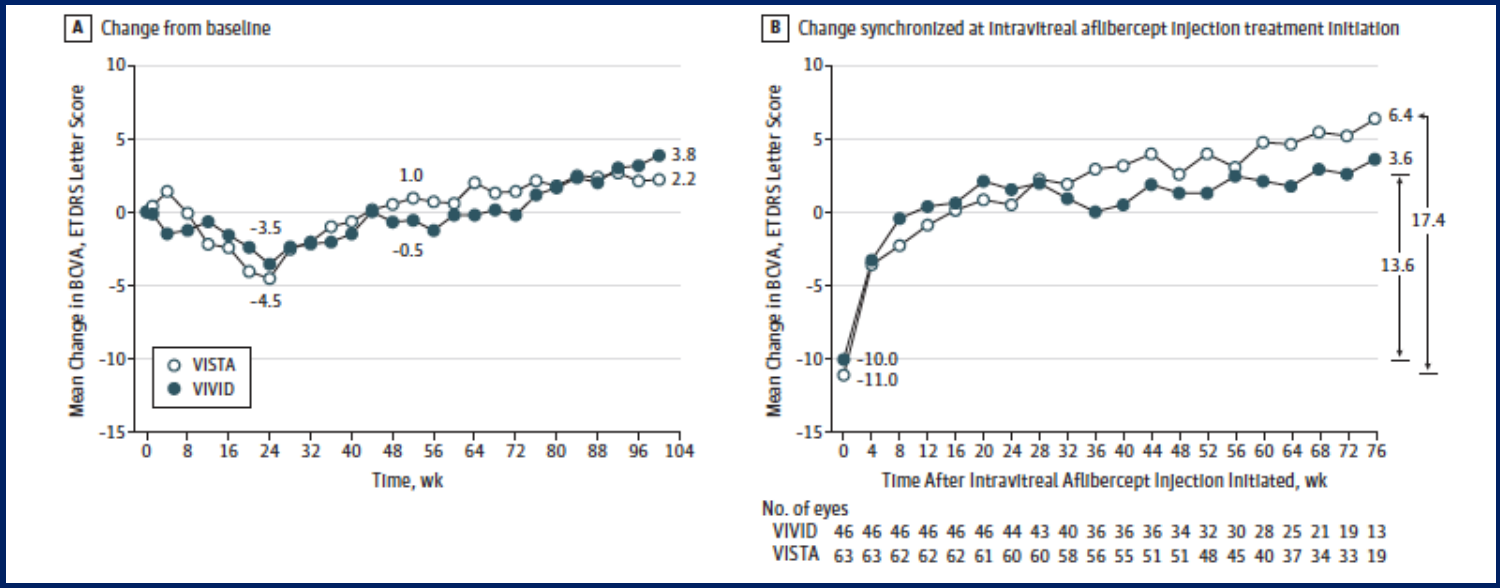






Limited Vision Improvement when Initial Treatment Approach was not Optimized in Patients with DME

- Final vision was limited in patients who were treated with intravitreal aflibercept following vision loss with initial laser treatment



Wykoff CC, Marcus DM, et al. Intravitreal Aflibercept Injection in Eyes With Substantial Vision Loss After Laser Photocoagulation for Diabetic Macular Edema Subanalysis of the VISTA and VIVID Randomized Clinical Trials. *JAMA Ophthalmol.* 2017;135(2):107–114.

Analysis of Outcomes in Routine Clinical Practice

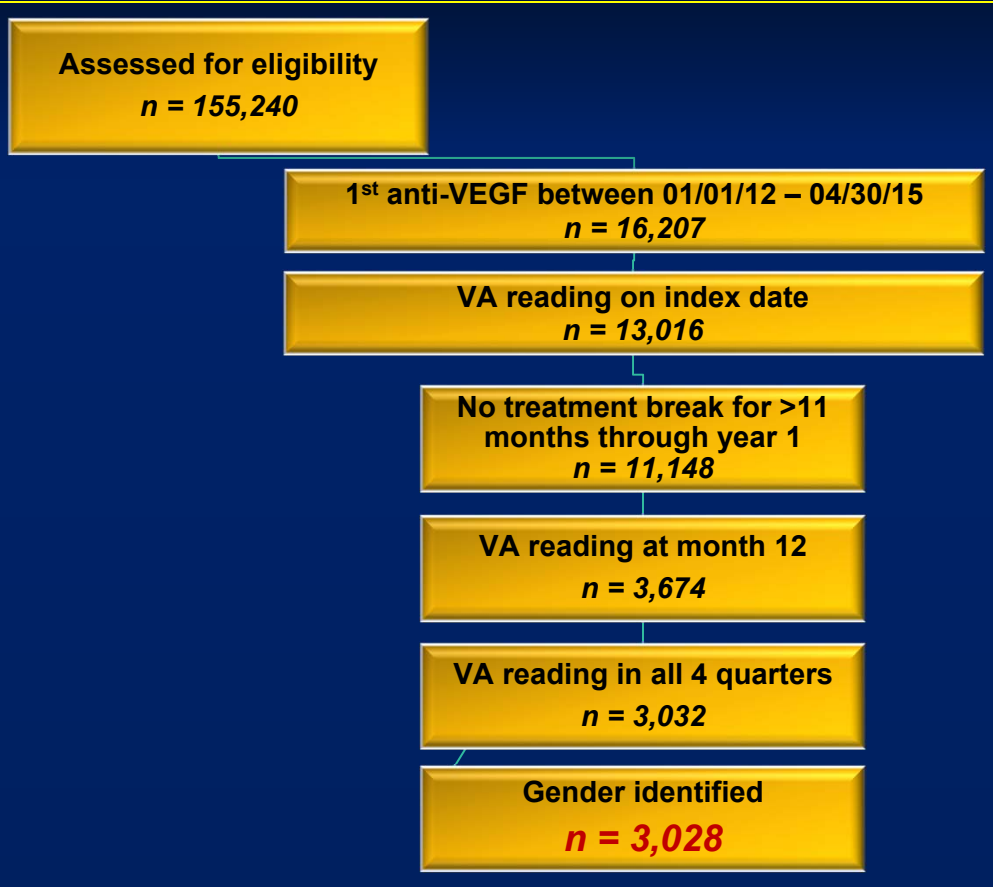
Study Design

- **Objective**
  - To evaluate visual acuity outcomes following treatment of DME with intravitreal anti-VEGF agents in routine clinical practice through 2 years

- **Methods**
  - Electronic medical record data* collected from 251 Retina Specialists for patients with –
    - *Diabetic macular edema*
  - Anti-VEGF treatment naïve eyes
    - 1st anti-VEGF injection between January 1st, 2012 and April 30th, 2015
  - Two subgroups evaluated –
    - *Group 1: ≤6 injections/year*
    - *Group 2: ≥7 injections/year*

*Source: Vestrum Database

Patient Selection
Year 1



Baseline Characteristics

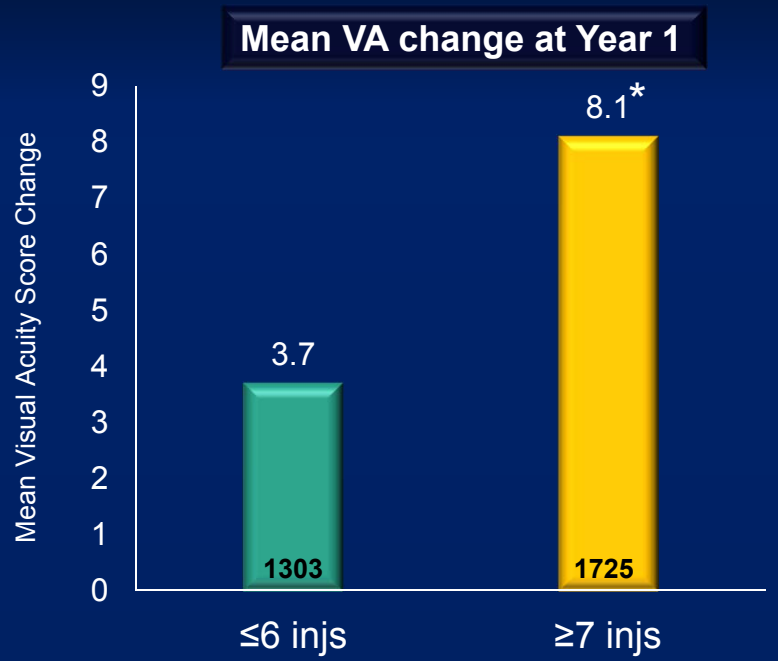
	Total *(n=3028)*	≤6 injections *(n=1303)*	≥7 injections *(n=1725)*
Mean age, years	62	61	63
Female, %	46%	47%	44%
Mean VA, letters	71	71	70
Median VA, letters	76	77	76
VA subgroups			
≥20/40	27%	29%	25%
<20/40 – 20/100	51%	50%	51%
<20/100 – 20/200	11%	11%	12%
<20/200	11%	10%	12%

Patients included in Year 1 analysis

Mean Visual Acuity Change By Injection Subgroups (*Year 1*)

Subgroup	Mean BSL VA
≤6 injs *(n=1303)*	71
≥7 injs *(n=1725)*	70

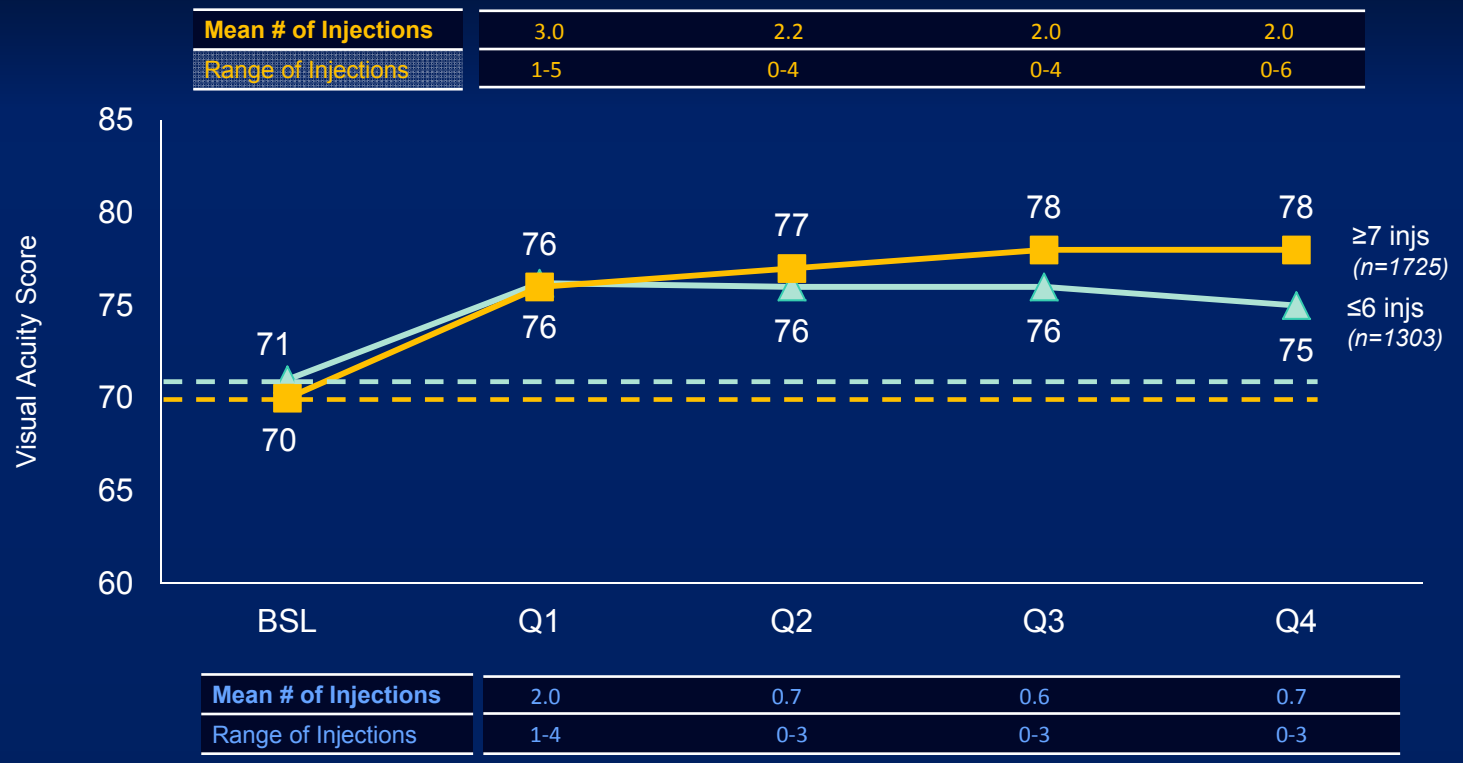
Subgroup	Mean Number of Injections
≤6 injs *(n=1303)*	4.0
≥7 injs *(n=1725)*	9.1



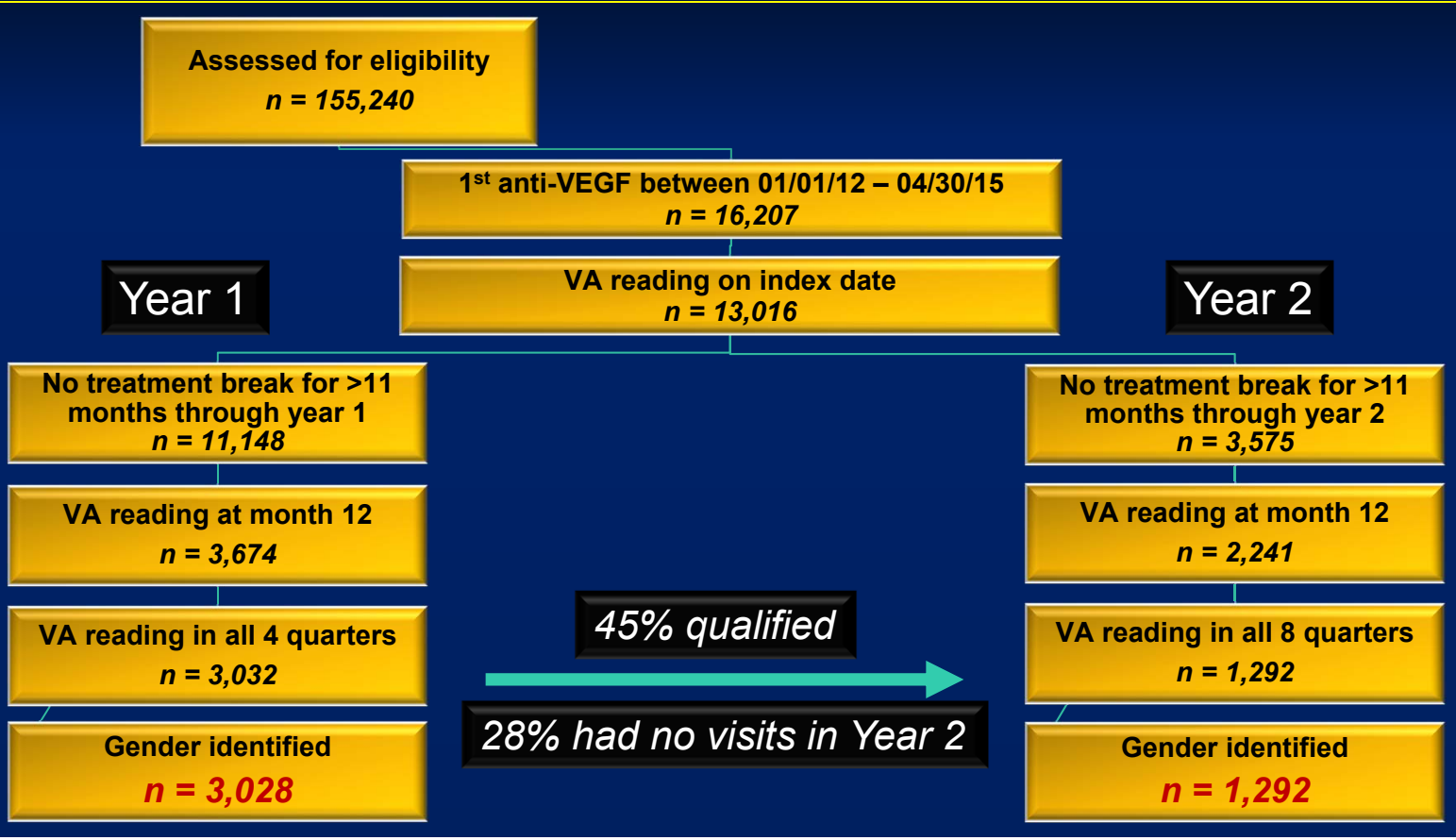
**P < 0.001 compared with ≤6 injs*

Visual acuity is reported in visual acuity score (VAS)

Mean Visual Acuity by Injection Subgroups (*Year 1)*

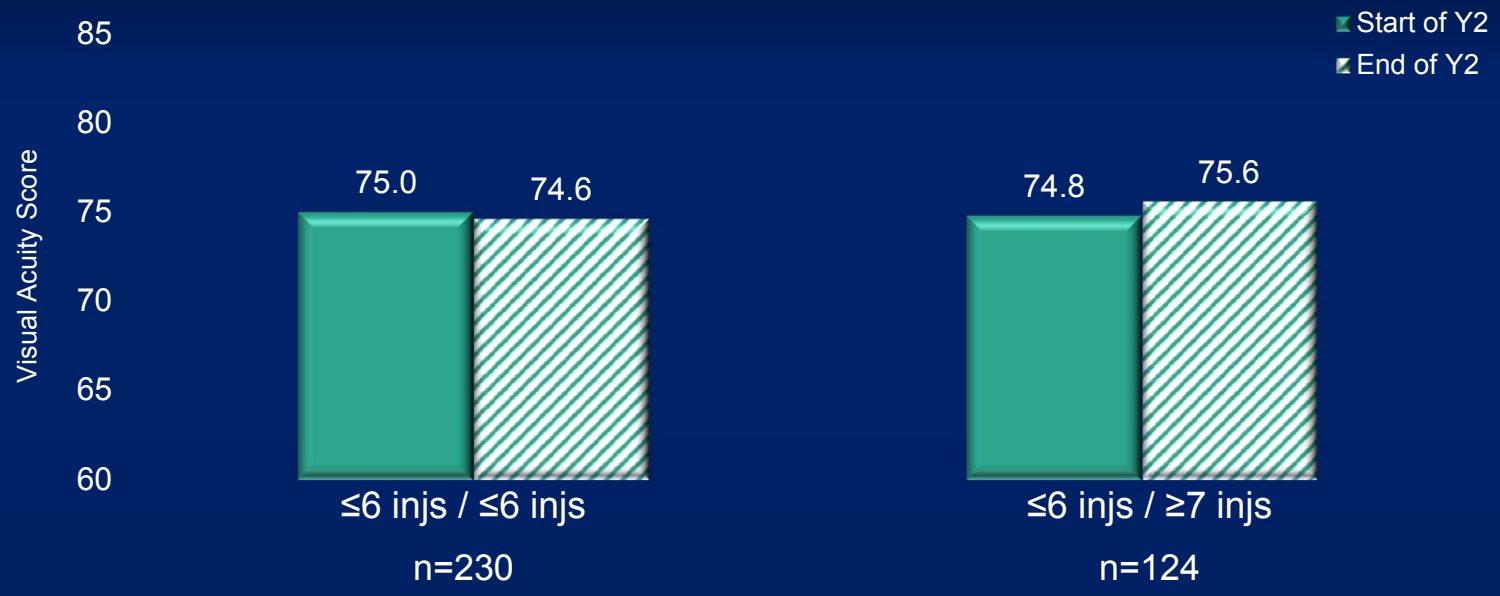


Patient Selection
Year 2



Mean Visual Acuity by Injection Subgroups *(Year 2)*

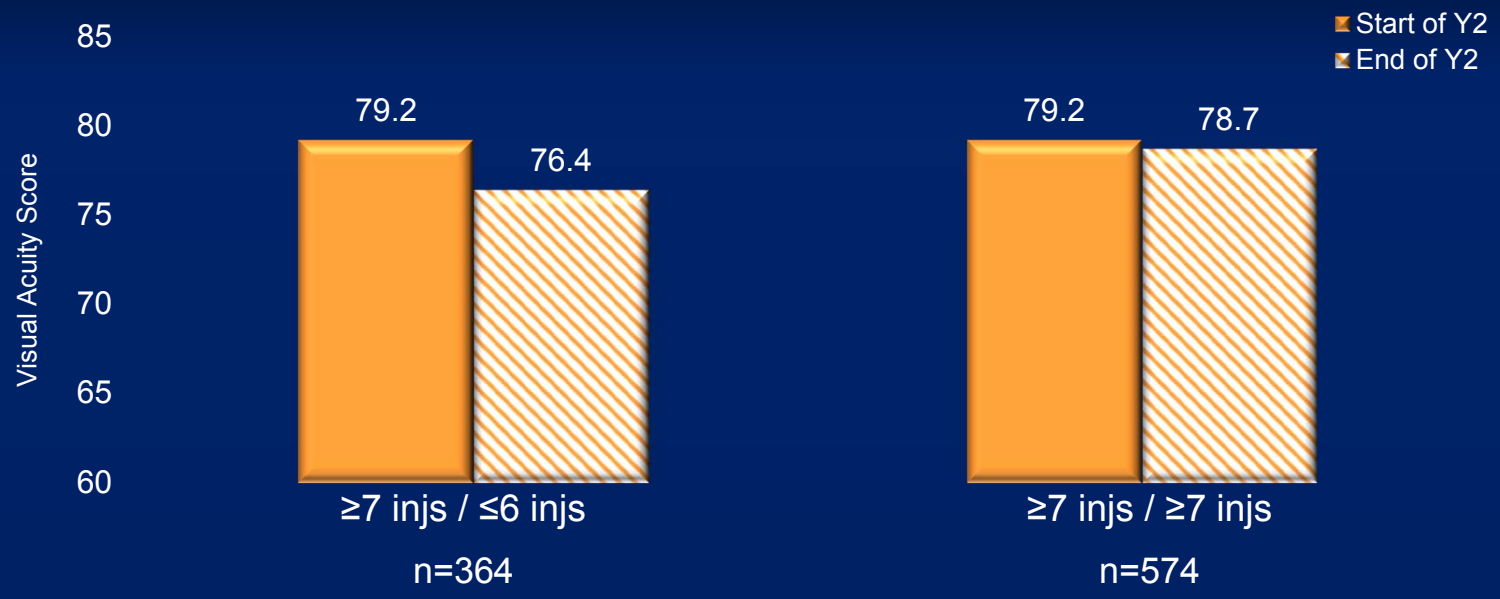
Patients Receiving ≤6 injections in Year 1



Mean number of injections		
Year 1	*4.6*	*4.9*
Year 2	*4.3*	*8.2*

Mean Visual Acuity by Injection Subgroups (Year 2)

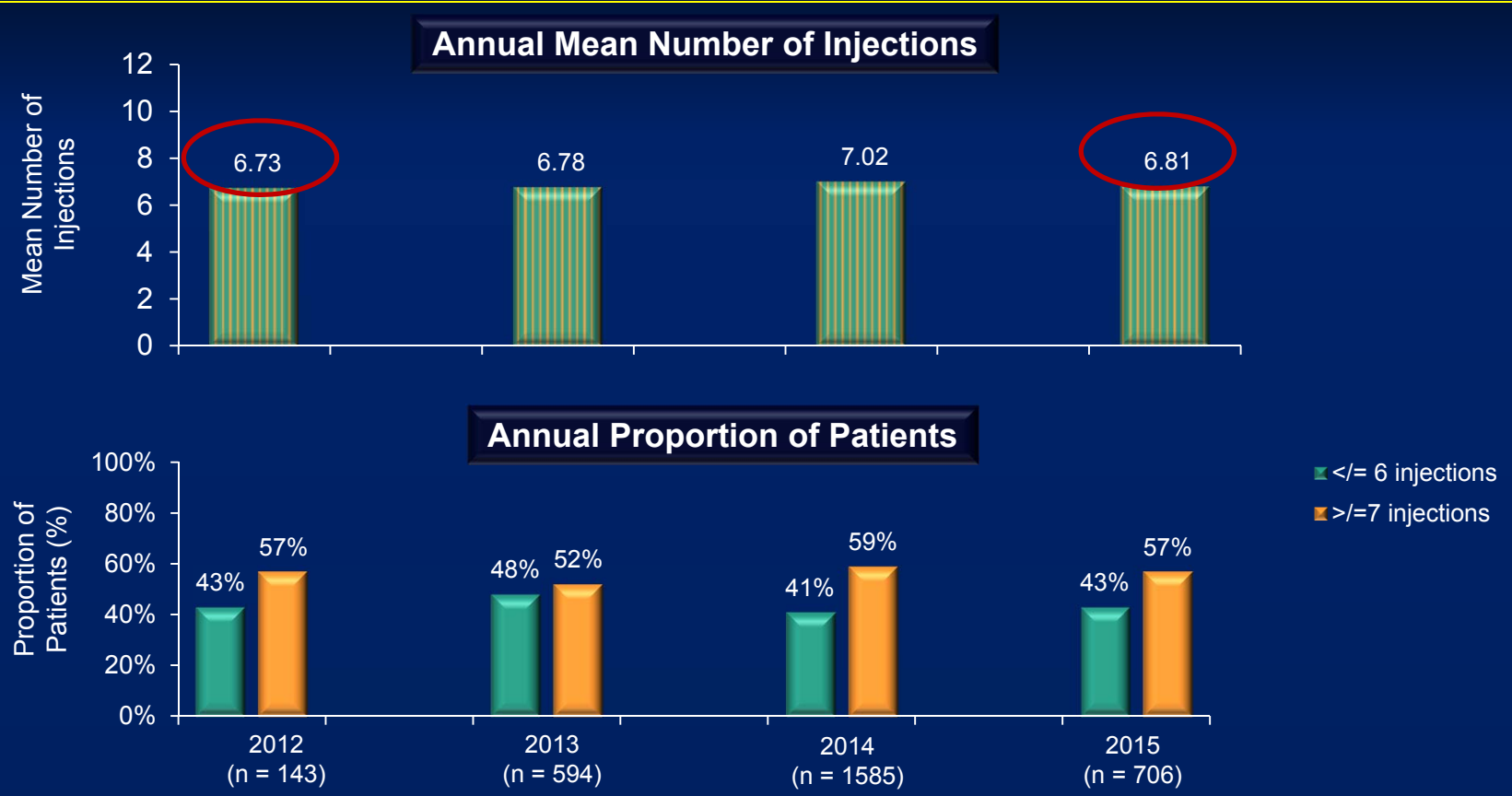
Patients Receiving ≥7 injections in Year 1



Mean number of injections

Year 1	*8.8*	*9.7*
Year 2	*4.7*	*9.0*

Change Over Time in Injection Frequency During Year 1 of Treatment



Summary

- Consistent with results of clinical trials, in routine clinical practice, maintenance of visual gains was associated with more frequent anti-VEGF injections in patients with DME
- Patients with DME were more likely to receive more frequent injections (≥7) rather than fewer injections (≤6) during the first year of treatment
  - A substantial proportion (43%) of DME patients received ≤6 injections during their first year of treatment

Thank You

Back-Up

Overview of Trials
Diabetic Macular Edema

Trial	Treatment Groups	Mean Change in BCVA at Year 2
RISE	RBZ 0.3mg monthly	+14.3
	sham	+5.1
RIDE	RBZ 0.3mg monthly	+13.1
	sham	+4.5
VISTA	IAI 2mg monthly	+12.5
	IAI 2mg bi-monthly*	+10.7
	laser	+0.2
VIVID	IAI 2mg monthly	+10.5
	IAI 2mg bi-monthly*	+10.7
	laser	+1.2
Protocol T	IAI 2mg PRN	+13
	RBZ 0.3mg PRN	+11
	BVZ 1.25mg PRN	+10

RBZ=ranibizumab, IAI=intravitreal aflibercept injection, BVZ=bevacizumab
**following 5 initial monthly doses*