

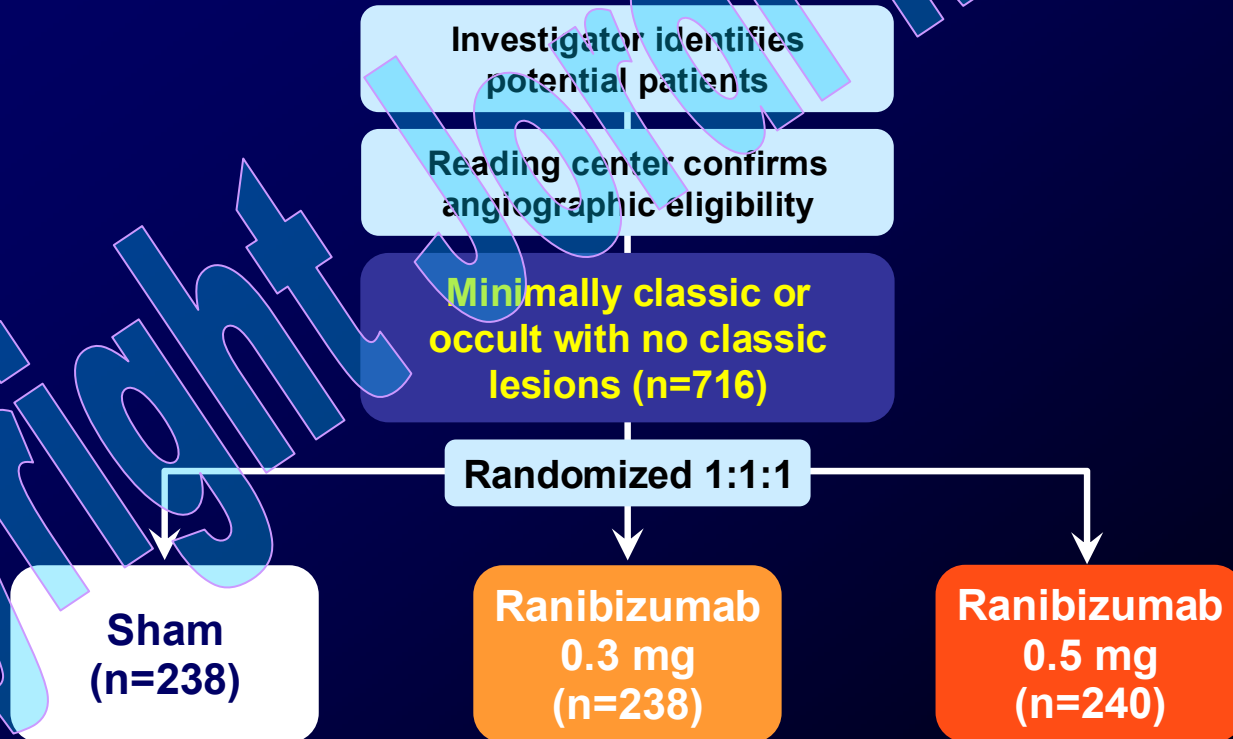
## Update in RANIBIZUMAB

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Institut de la Màcula i de la Retina

CM Teknon, Barcelona

## MARINA trial design



Rosenfeld et al, N Engl J Med 2006; 355(14): 1419

MARINA and ANCHOR

Rationale for less dosing

Pier Study

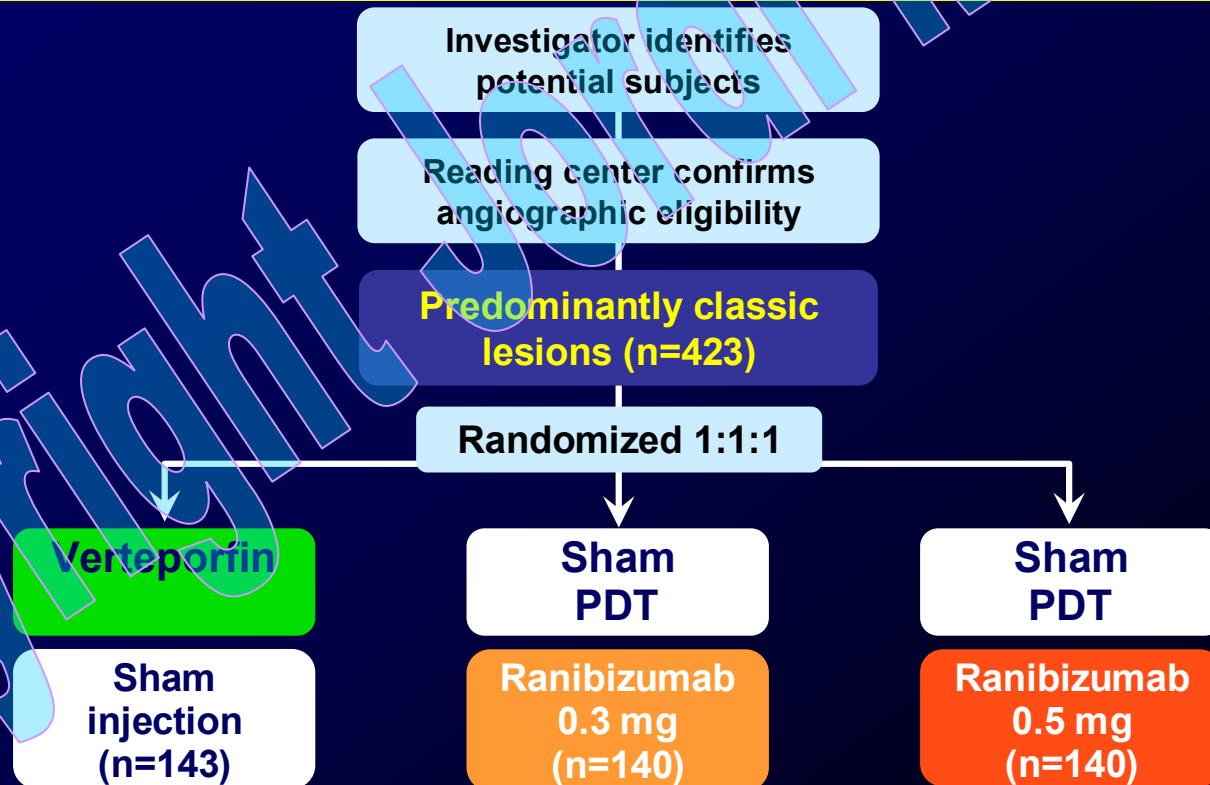
Pronto Study

Combined therapies

summary

# Update in Ranibizumab

## ANCHOR trial design



*Brown et al, N Engl J Med 2006; 355(14): 1432*

# Update in Ranibizumab

MARINA and ANCHOR

Rationale for less dosing

Pier Study

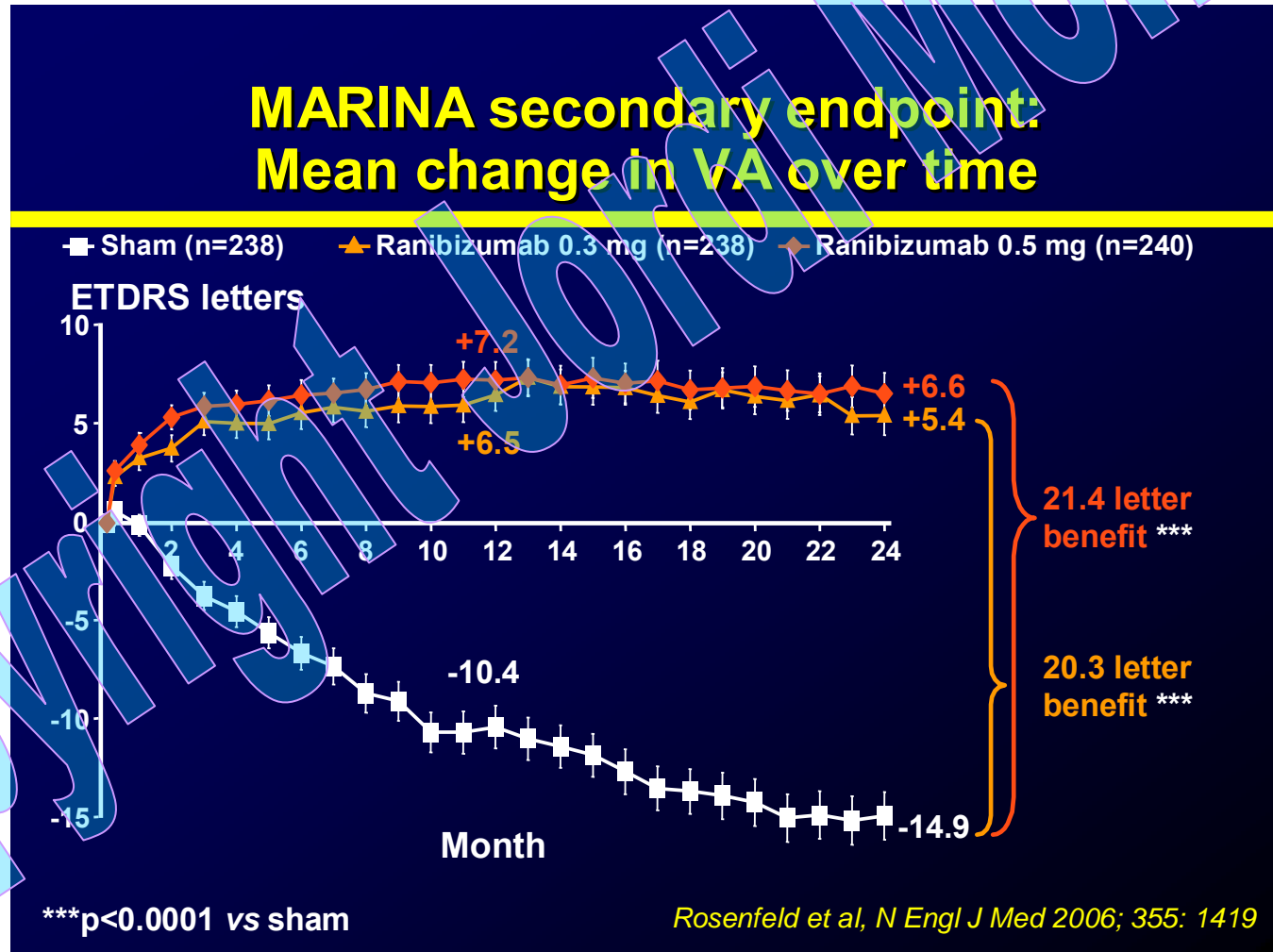
Pronto Study

Combined therapies

summary

## Marina: Mean VA GAIN >1 line

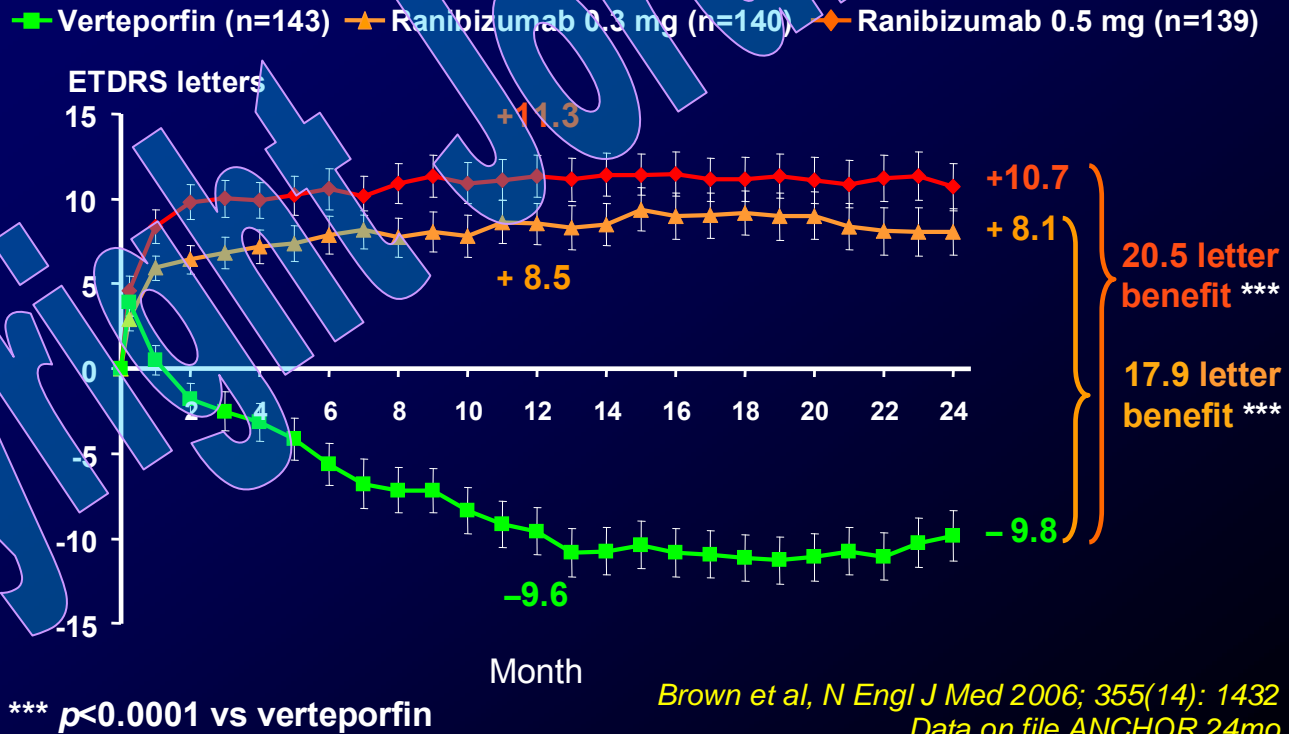
### MARINA secondary endpoint: Mean change in VA over time



# Update in Ranibizumab

## ANCHOR: Mean VA GAIN: 2 lines

### ANCHOR secondary endpoint: Mean change in VA over time



# Update in Ranibizumab

## MARINA & ANCHOR: 90% at 2y lost less than 3 lines

MARINA and ANCHOR

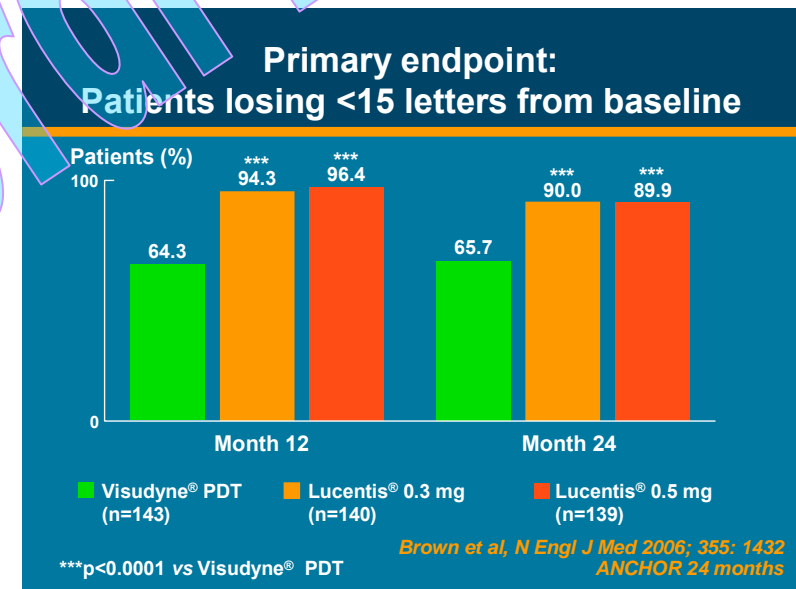
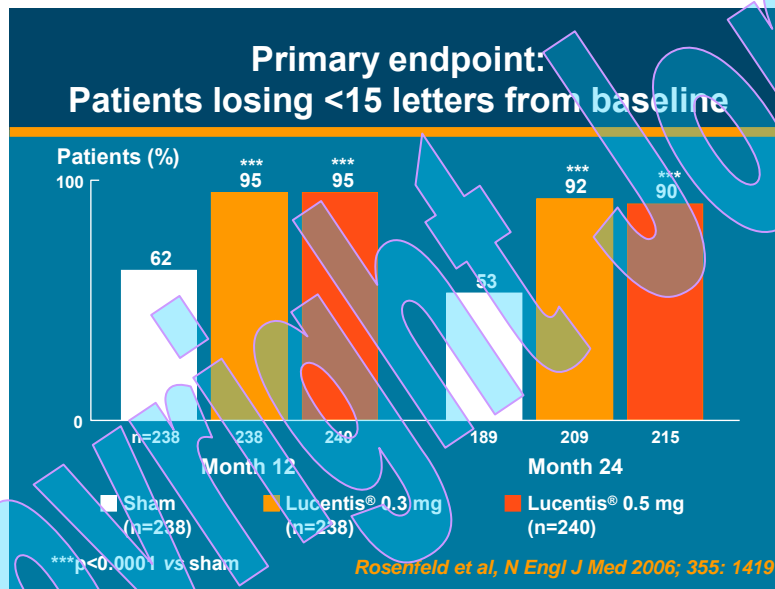
Rationale for less dosing

Pier Study

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Combined therapies

summary



# Update in Ranibizumab

**MARINA & ANCHOR:**  
**70 -78% no letter loss at all or gain**  
**33-41% 3 lines gain**

MARINA and ANCHOR

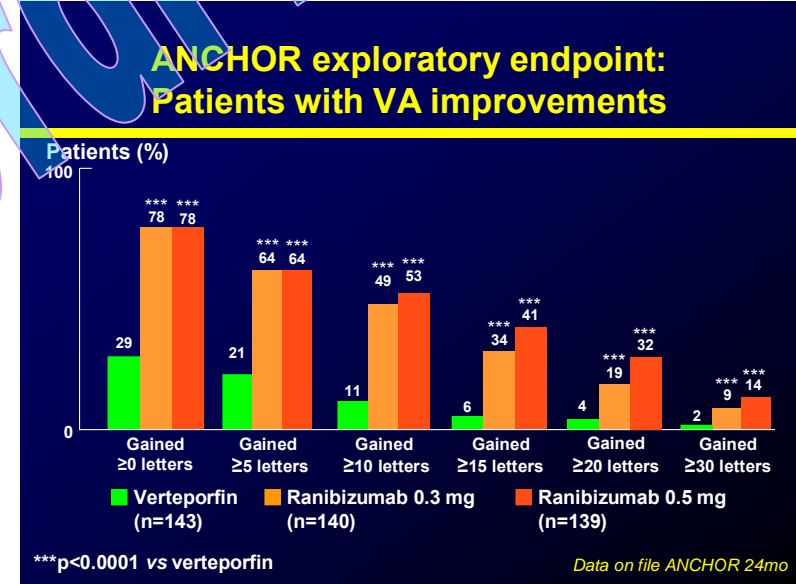
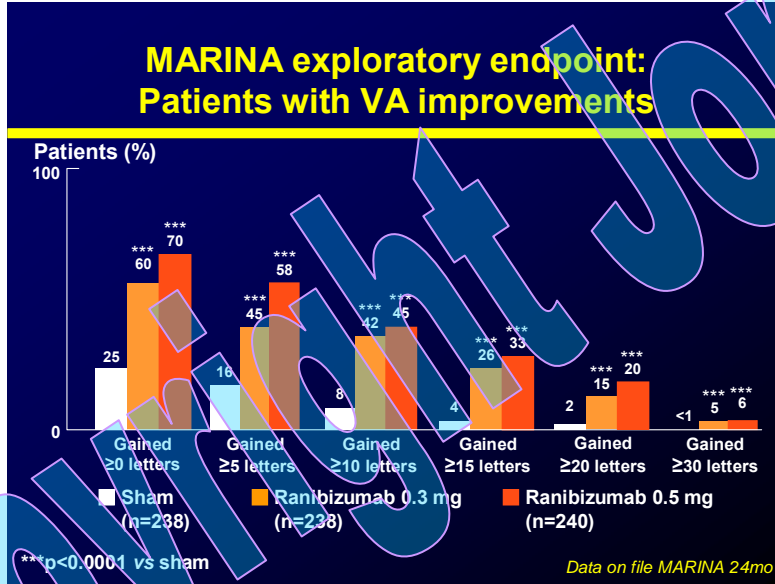
Rationale for less dosing

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summary



# Update in Ranibizumab

## MARINA & ANCHOR: 40% of 20/40 or better at 2 years

MARINA and ANCHOR

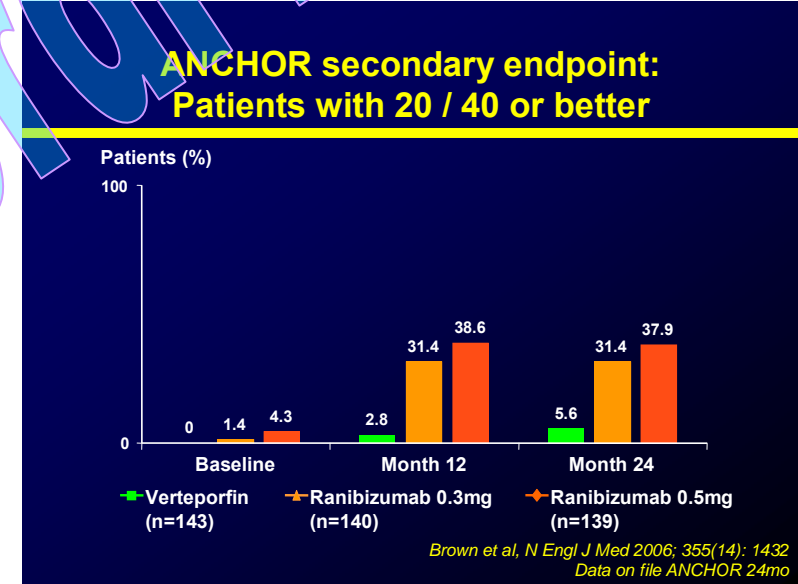
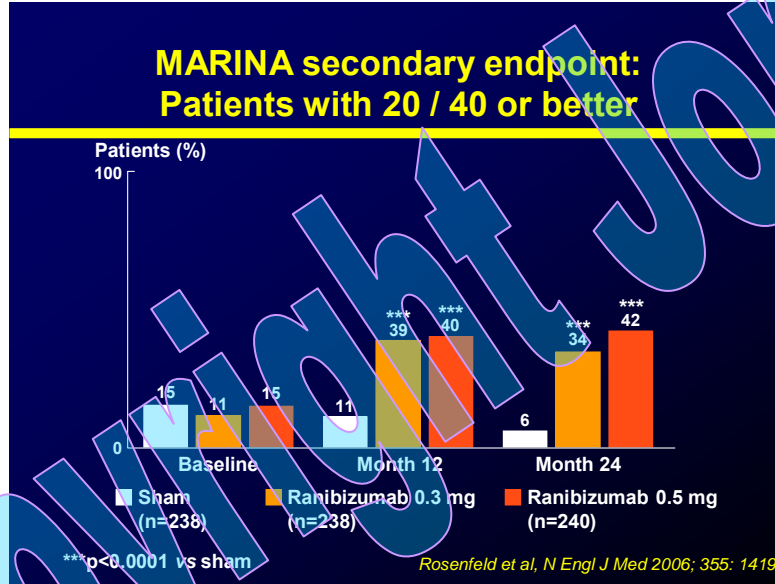
Rationale for less dosing

Pier Study

Pronto Study

Combined therapies

summary



## ANCHOR & MARINA: No increase in % of patients with 20/200 or worse

MARINA and ANCHOR

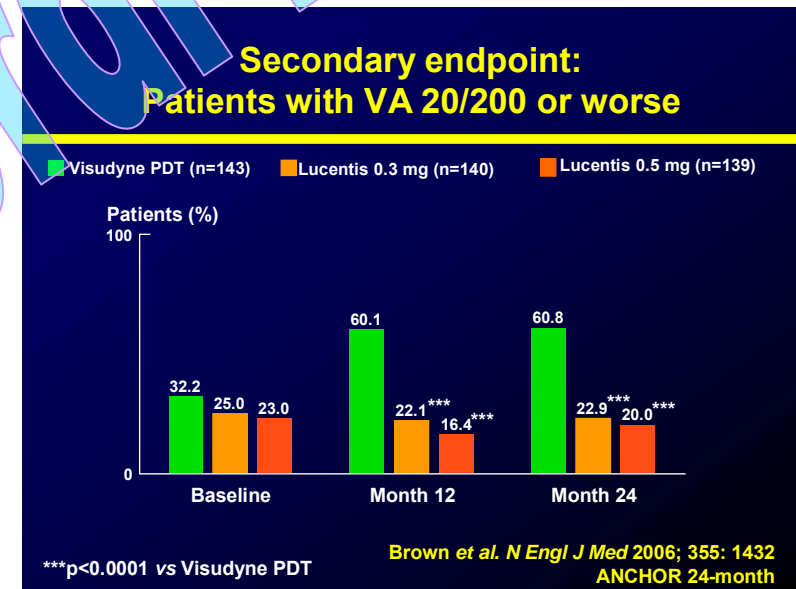
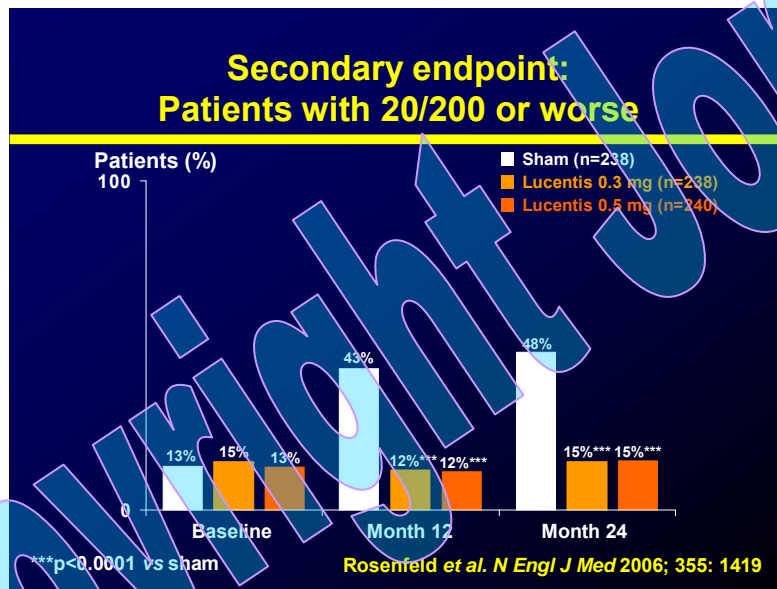
Rationale for less dosing

Pier Study

Pronto Study

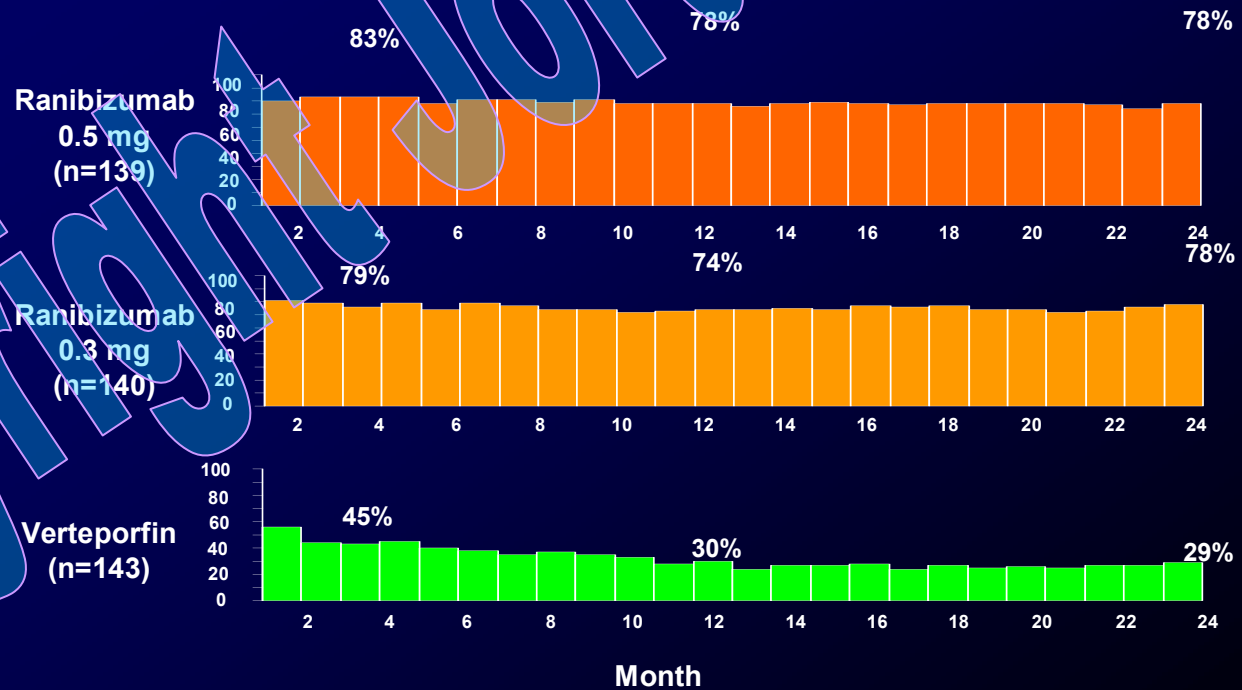
Combined therapies

summary



## MARINA & ANCHOR: Early GAIN and sustained

### ANCHOR: Gain $\geq 0$ Letters over time



Data on file ANCHOR 24mo

MARINA and ANCHOR

Rationale for less dosing

Pier Study

Pronto Study

Combined therapies

summary

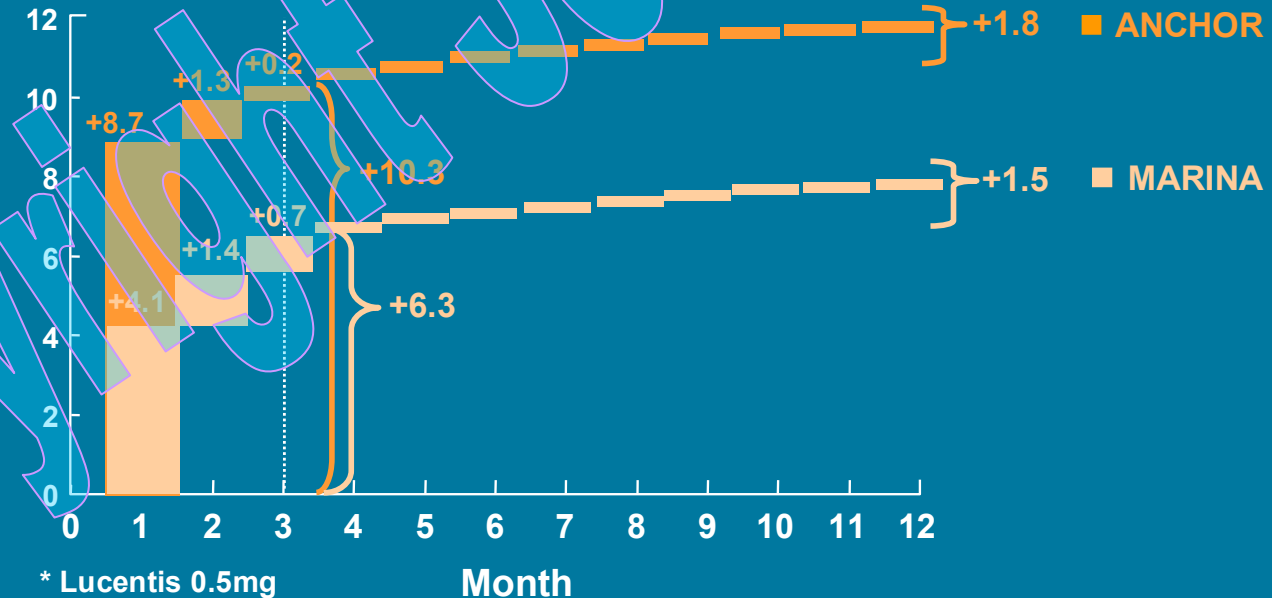
# Update in Ranibizumab

## Most of the gain within 1st 3 months

### Observation from phase III trials: A biphasic treatment effect

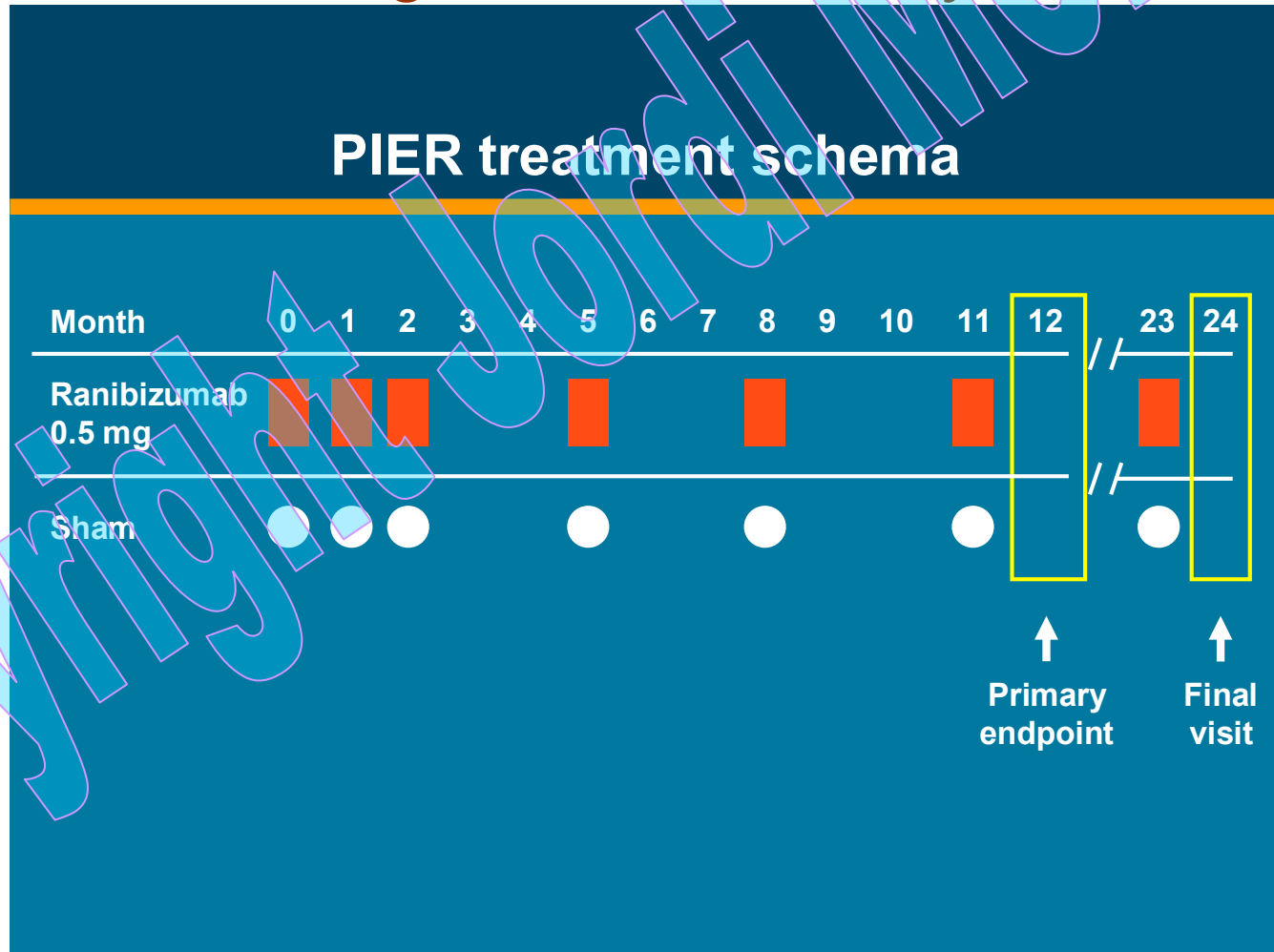
Duration of loading phase of 3 months:  
justified by mean change of VA between visits

VA gain\* (letters)



# Update in Ranibizumab

PIER: Fixed Regimen:  
3 loading dose, then every 3m



# Update in Ranibizumab

MARINA and ANCHOR

Rationale for less dosing

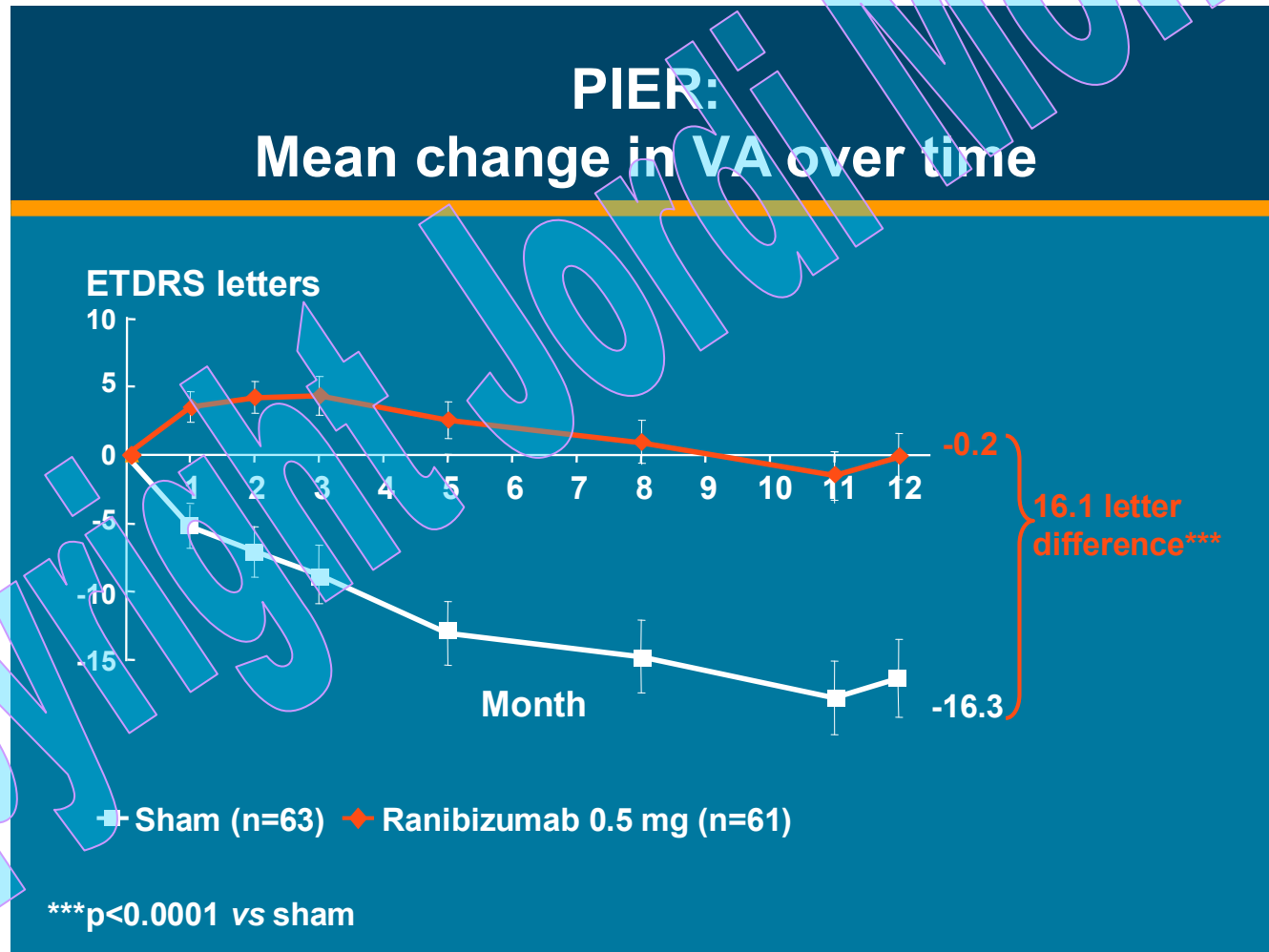
Pier Study

Pronto Study

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summary

## PIER: Avoids visual loss but LESS gain

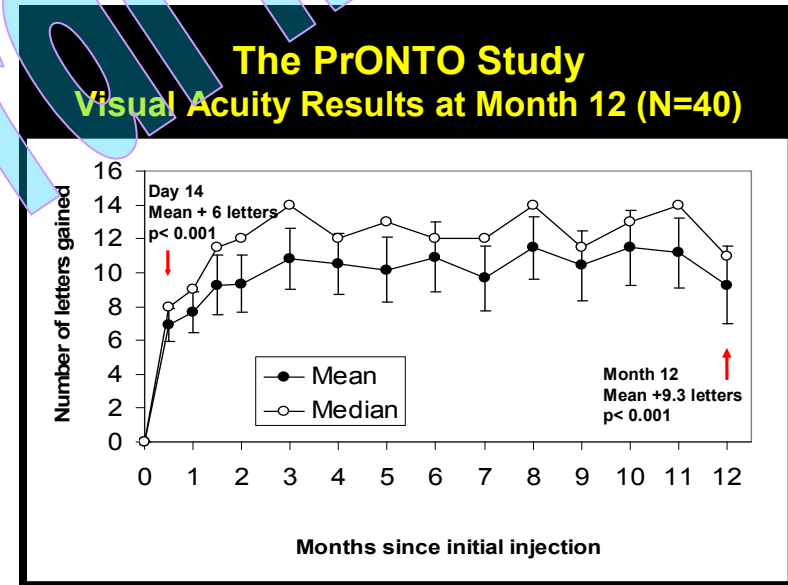
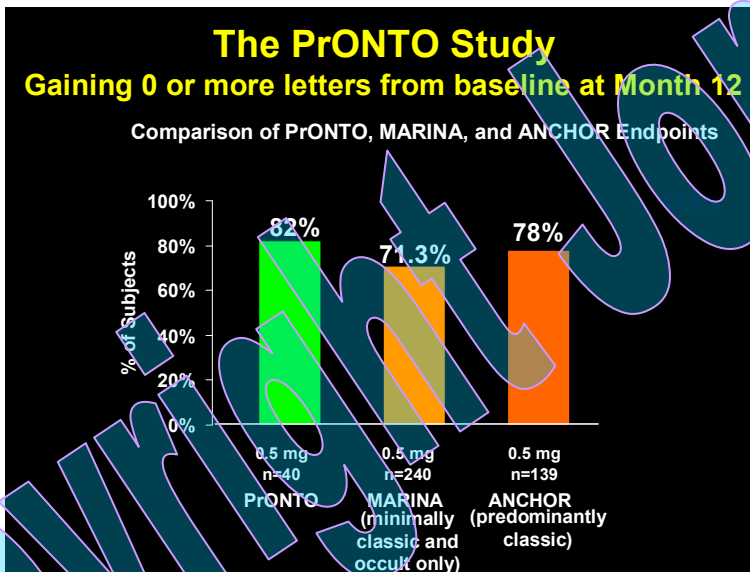


## PRONTO Study Variable Regimen loading doses then PRN

- -criteria for reinjection after 3 months
  - Increase in central retinal thickness  $\geq 100 \mu\text{m}^*$
  - Loss of  $\geq 5$  letters with any fluid by OCT\*
  - New hemorrhage\*
  - New classic CNV\*
  - Persistent fluid detected by OCT 1 month after an injection

# Update in Ranibizumab

PRN dosing may be similar than monthly tx  
82% lost less than 3 lines  
Mean VA GAIN of 9 letters 1 y



## Combined therapy a proven concept

MARINA and ANCHOR

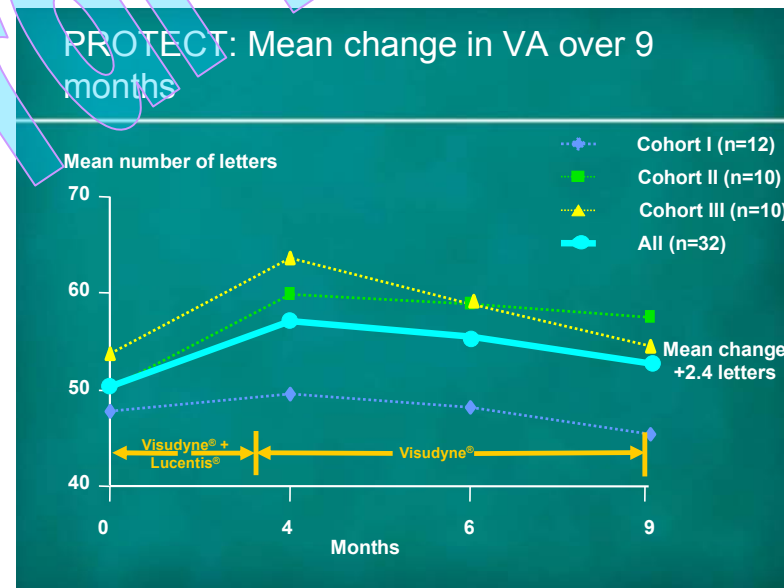
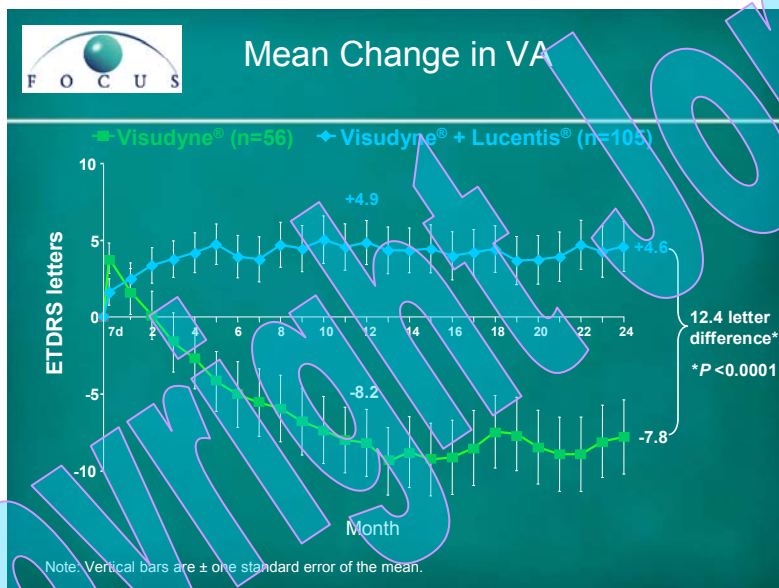
Rationale for less dosing

Pier Study

Pronto Study

Combined therapies

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## Summary

- Ranibizumab 0.5mg is proven to help patients gain and sustain vision up to 24 months in MARINA and ANCHOR
  - Mean gain over baseline: 6.6 and 10.7 letters
  - Remain 20/40 or better VA: 42% and 38 %
  - Gain  $\geq 0$  letters: 70% and 78%
  - Gain  $\geq 15$  letters: 33% and 41%
- Less dosing regimens are possible
  - 3 loading doses and every 3 months as in PIER less efficacy
  - 3 loading doses and then PRN as in PRONTO same efficacy