

Turning Back the Clock: Ranibizumab Regression of DR— How Much, How Long, and How Durable?

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Purpose

- To evaluate the efficacy and durability of improvement in diabetic retinopathy (DR) severity with ranibizumab (RBZ) in the RIDE/RISE studies

Background and Methods

- DR is the leading cause of blindness in adults of working age in America¹
- As DR progresses, patients experience a number of serious complications, including vitreous hemorrhage, retinal ischemia, retinal neovascularization, and venous bleeding that can contribute to permanent vision loss^{1,2}
- The severity of DR is assessed using the Early Treatment Diabetic Retinopathy Study (ETDRS) DR severity scale (DRSS) (Figure 1)^{2,3}
- In RIDE/RISE, DR severity was measured using the ETDRS DRSS by masked evaluators at the University of Wisconsin Fundus Photograph Reading Center using color 7-field fundus photographs taken at baseline and throughout the study (Figure 1)^{4,5}
- Progression and improvement of DR severity were measured using step changes in ETDRS DRSS levels
- Per the ETDRS DRSS criteria, eyes that had received panretinal photocoagulation (PRP) could not receive a score better than 60⁵

Figure 1. The ETDRS Diabetic Retinopathy Severity Scale^{2,5}

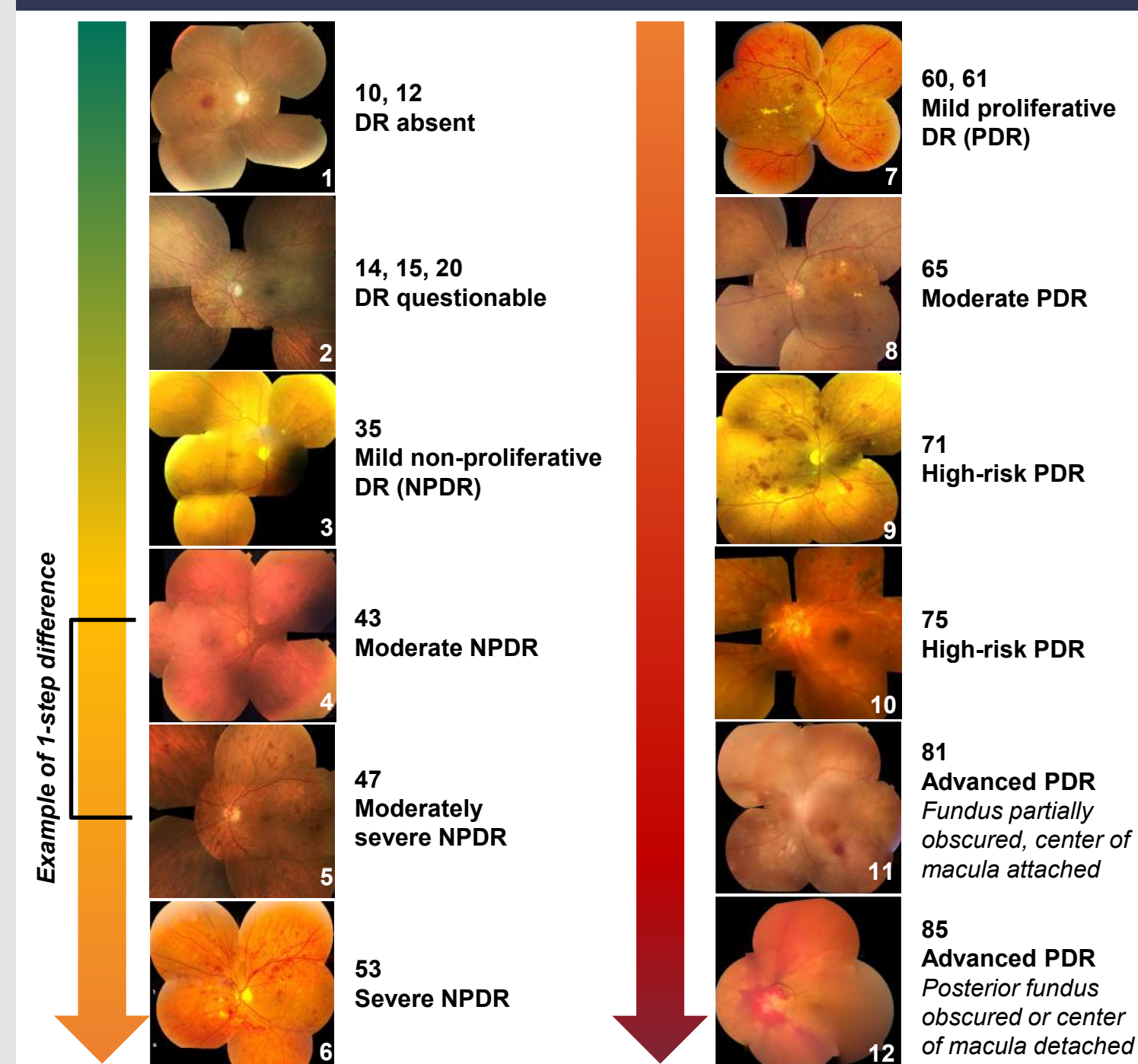
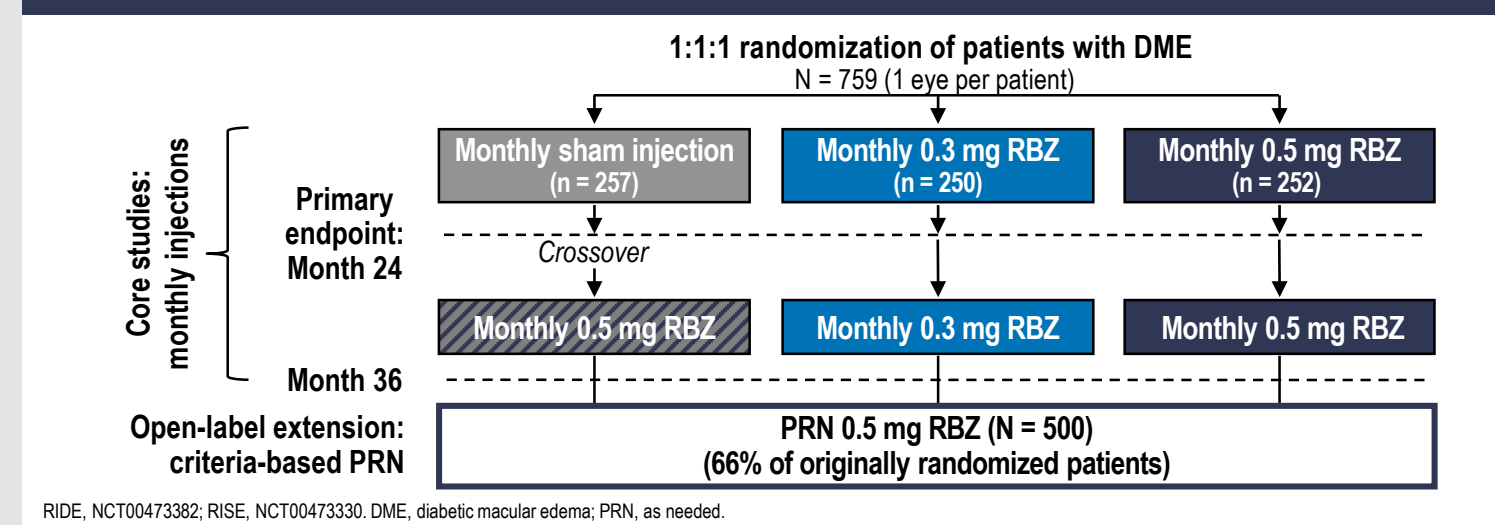


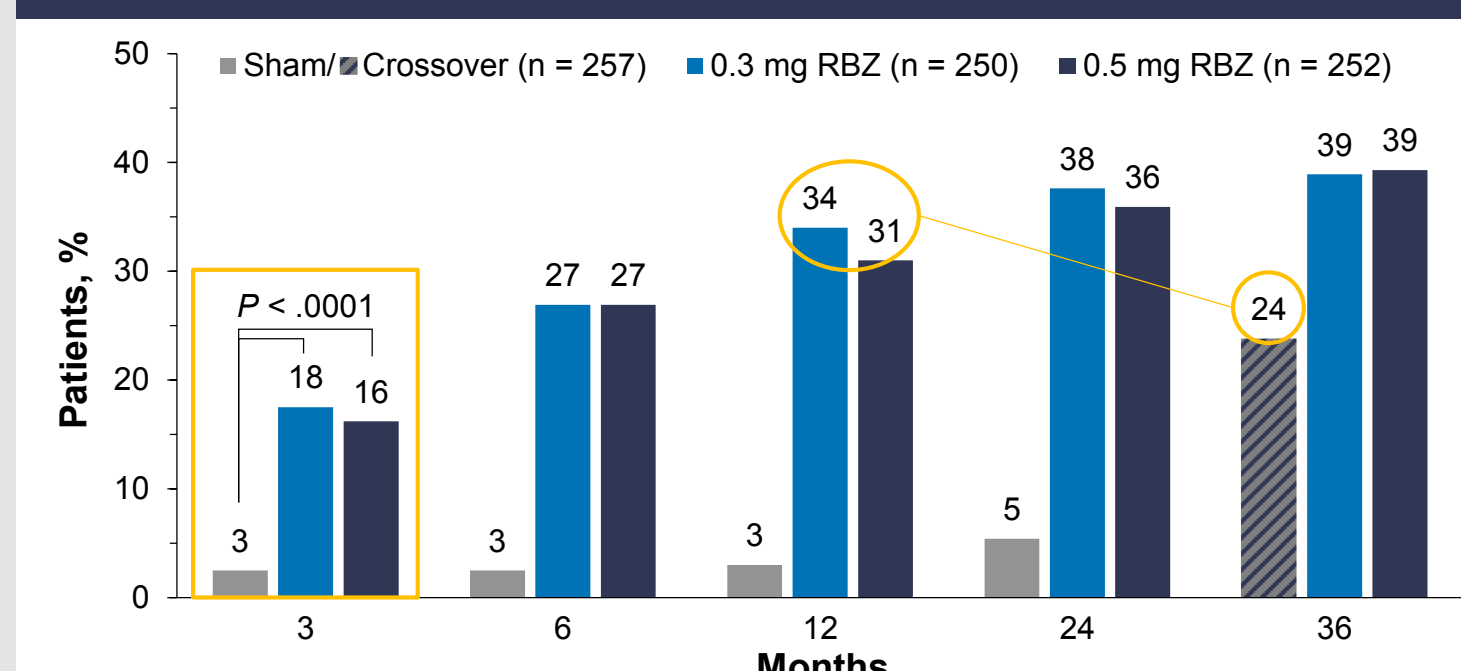
Figure 2. RIDE/RISE Study Design^{4,6}



Results

How Much?

Figure 3. Significant ≥ 2 -Step Improvements in DR Seen With Ranibizumab as Early as Month 3



After 12 months of 0.5 mg RBZ, sham/crossover patients experienced less DR improvement than patients who initially received 12 months of RBZ

Figure 4. Significant ≥ 3 -Step Improvements in DR Seen With Ranibizumab as Early as Month 12

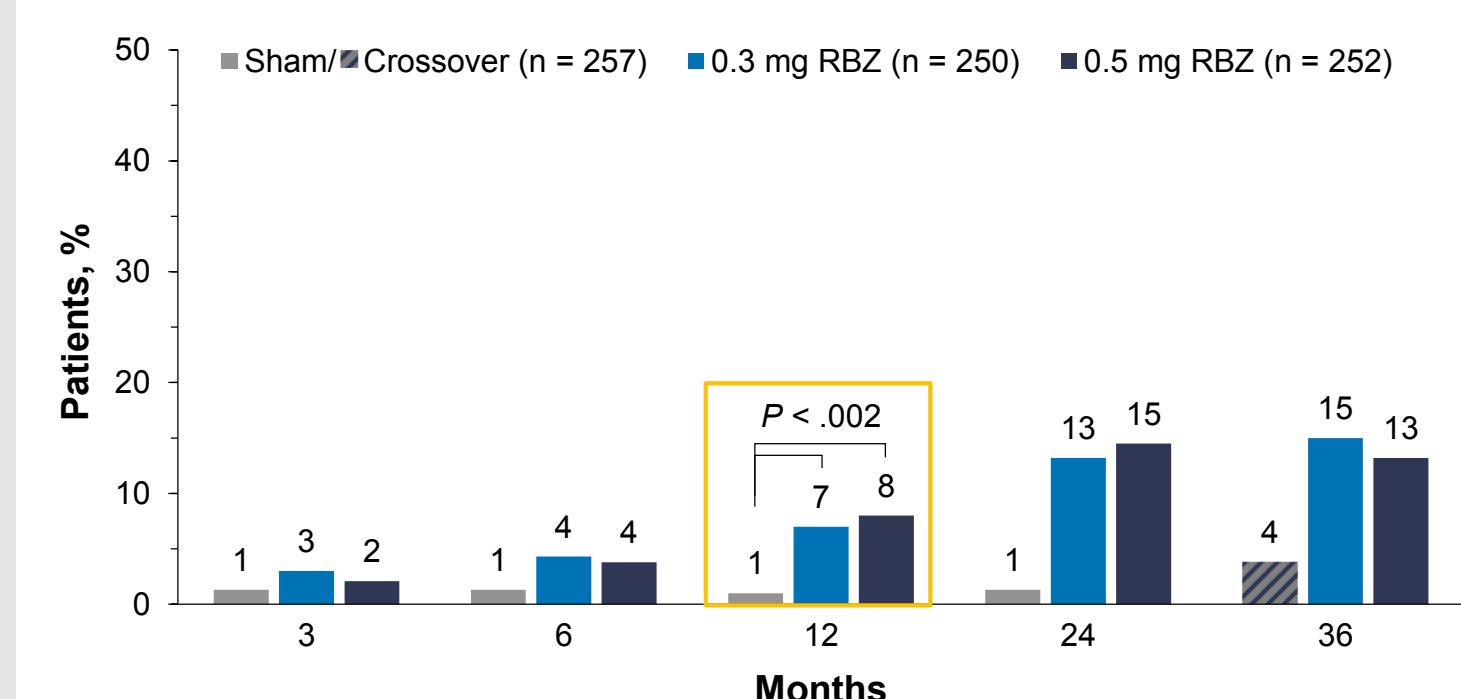
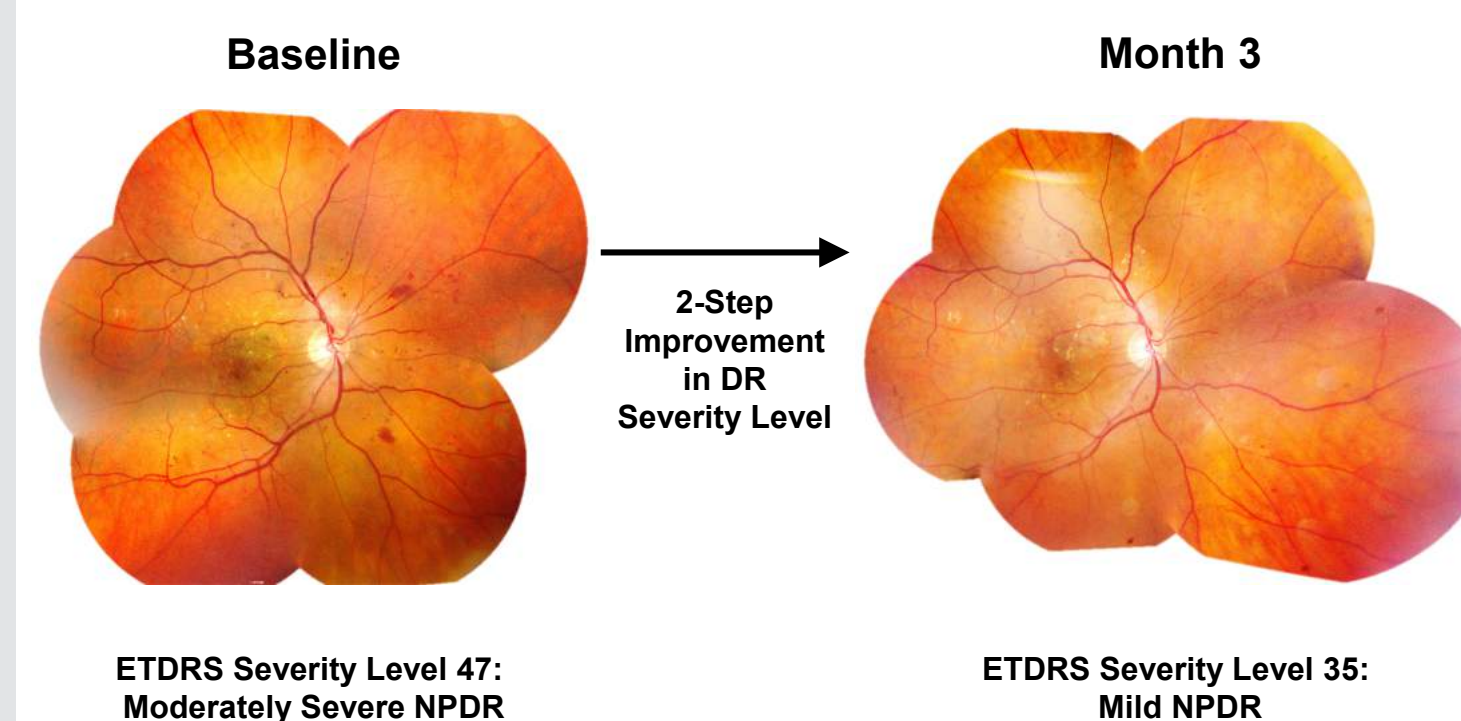


Figure 5. Case Example: Early 2-Step DR Severity Improvement With Ranibizumab



How Long?

Figure 6. Switch to PRN Ranibizumab Did Not Increase Rates of DR Worsening

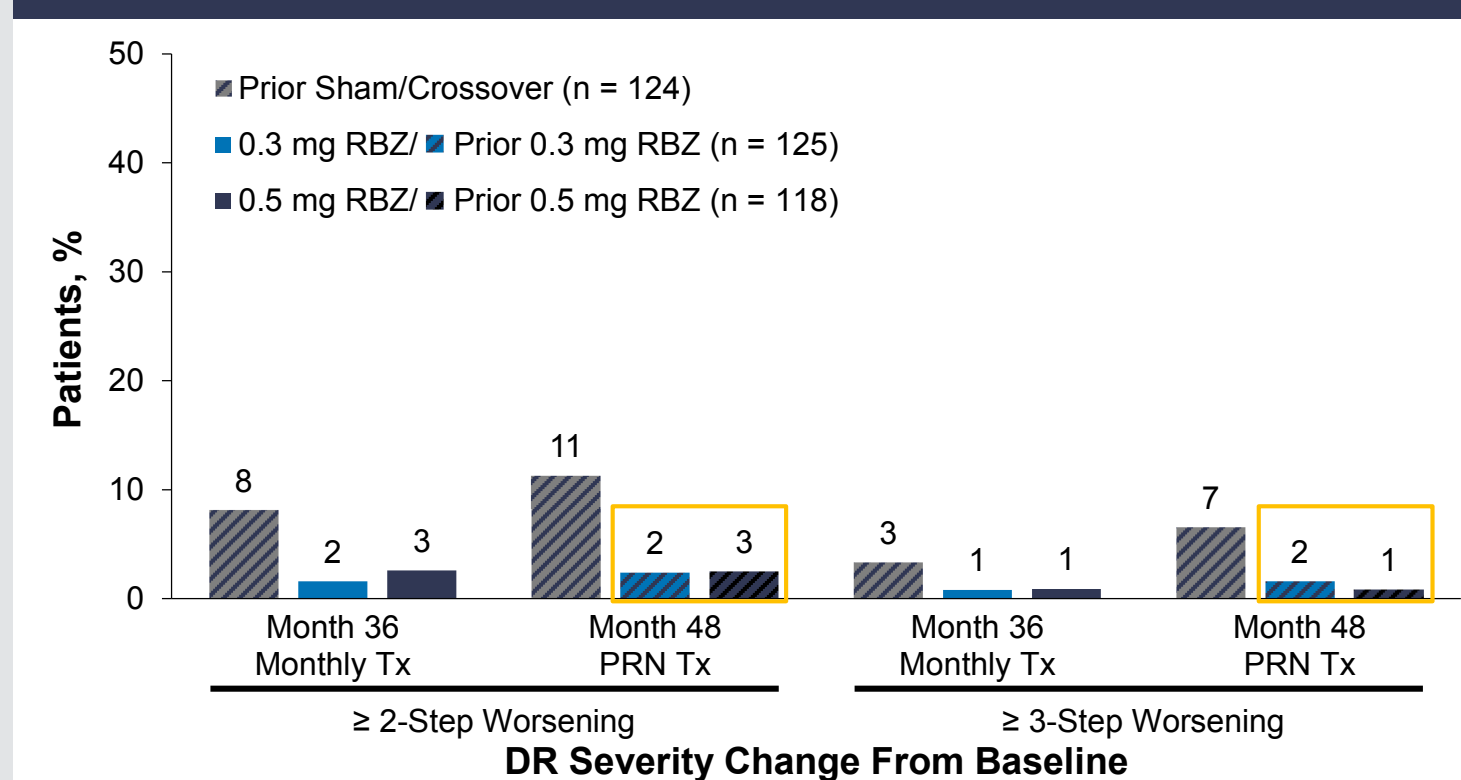


Figure 7. Patients Continued to Show Improvement in DR With PRN Ranibizumab Treatment

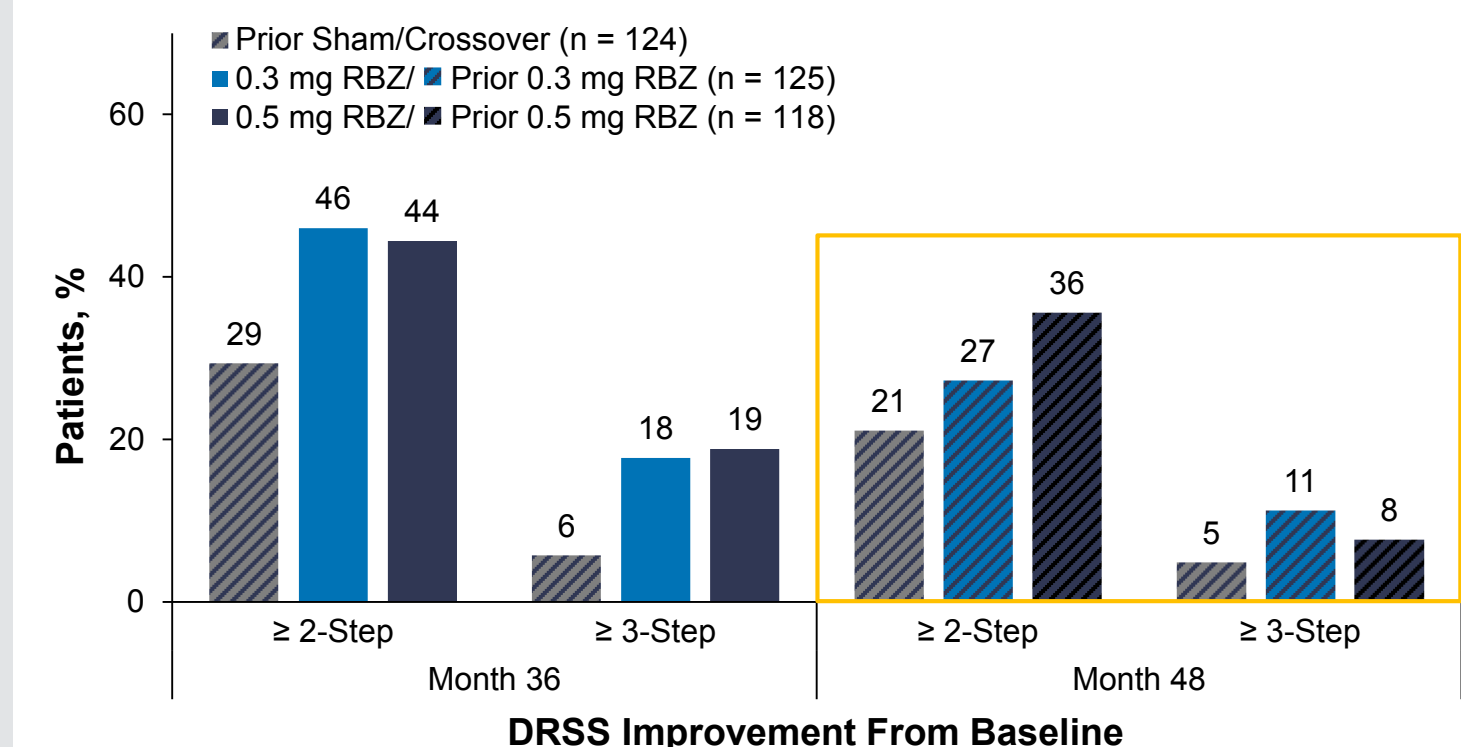
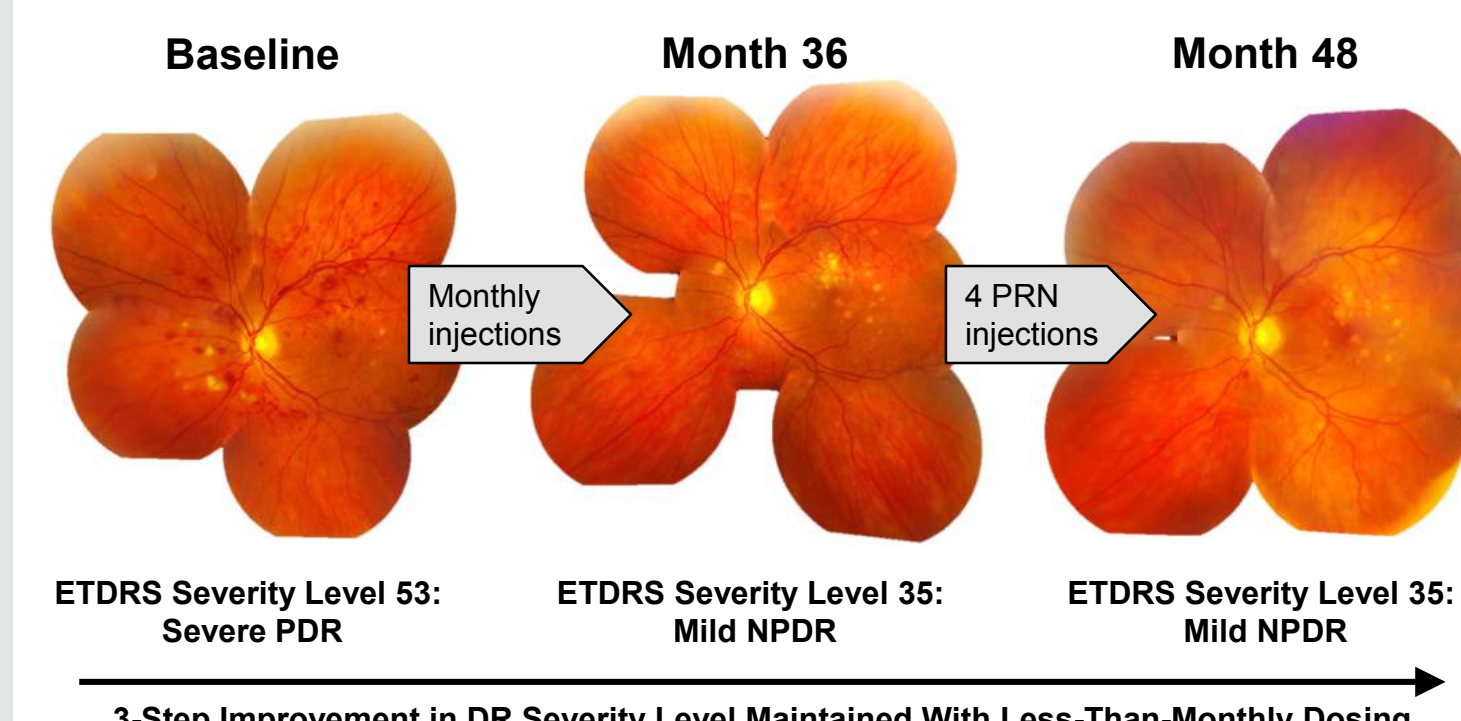
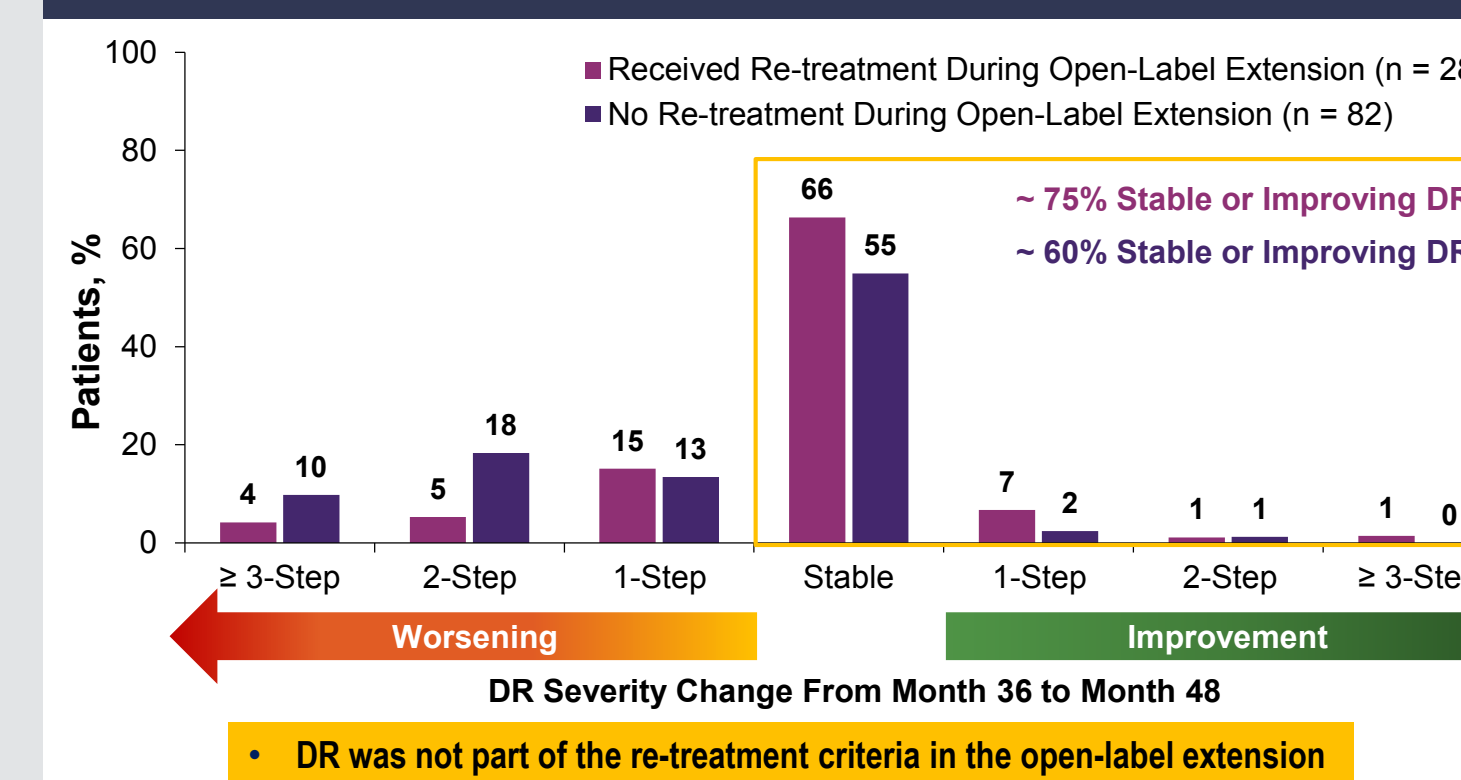


Figure 8. Case Example: Improvement in DR With Ranibizumab Maintained With PRN Dosing



How Durable?

Figure 9. Stability of DR From Month 36 to Month 48 With and Without PRN Ranibizumab



DR was not part of the re-treatment criteria in the open-label extension

Figure 10. Ranibizumab Treatment Delayed Time to New Proliferative Event

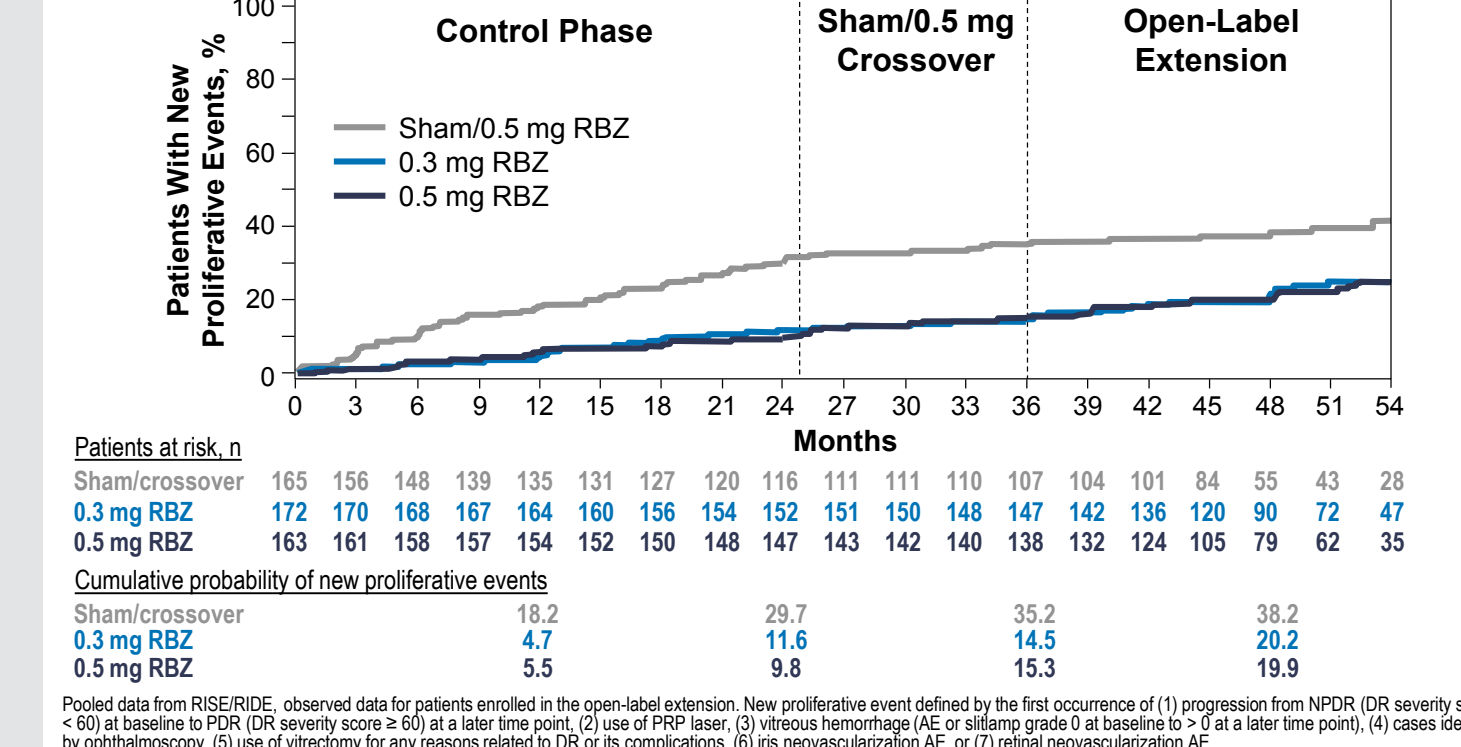
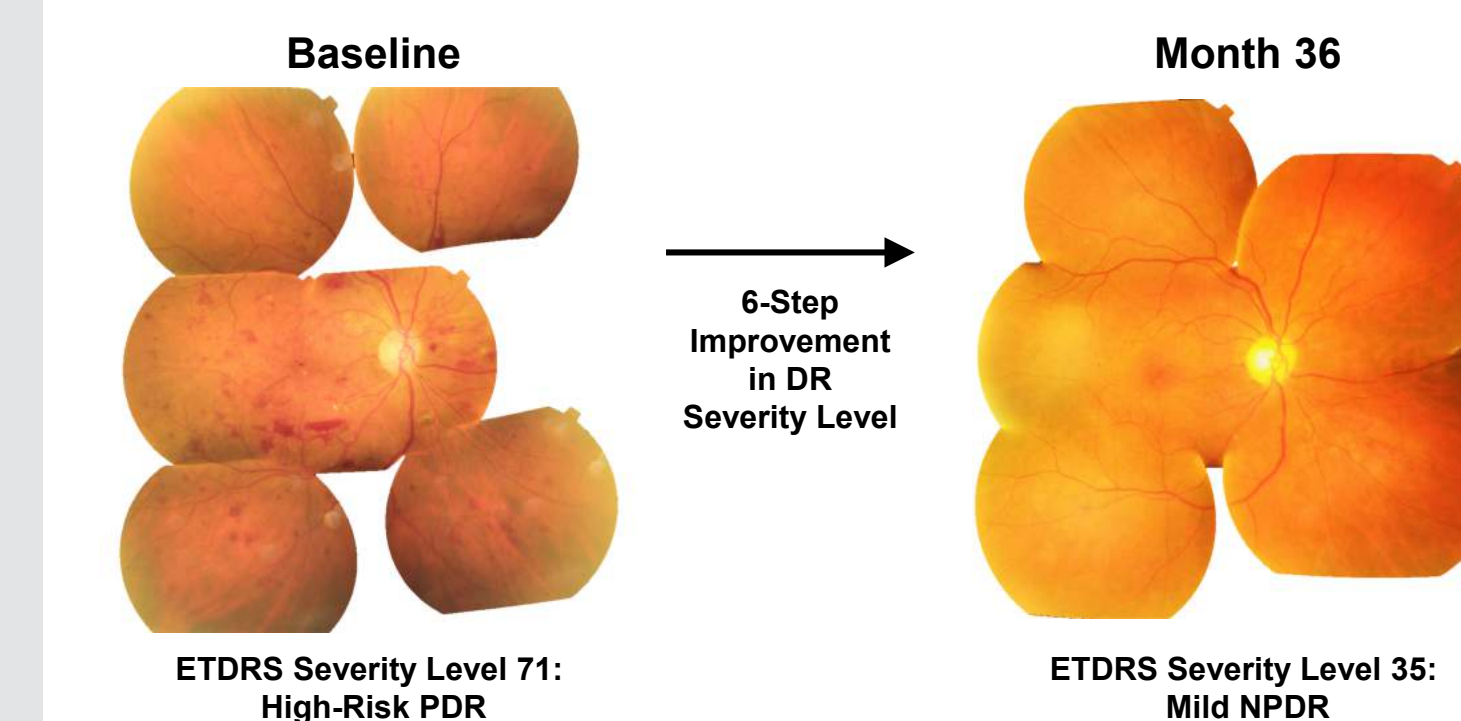


Figure 11. Case Example: Resolution of PDR With Ranibizumab Without PRP



Conclusions

- How much?**
 - Nearly 40% of ranibizumab-treated patients had ≥ 2 -step DR severity improvement
 - ~ 15% of patients had ≥ 3 -step improvement
- How long?**
 - Significant rates of DR improvement were seen as early as month 3 (≥ 2 -step) and month 12 (≥ 3 -step) and were sustained throughout the 3-year core study
- How durable?**
 - From month 36 to month 48, stable or improving DR was seen in
 - ~ 75% of patients receiving PRN ranibizumab
 - ~ 60% of patients receiving no ranibizumab after month 36
 - No increase in worsening of DR after switching to PRN
 - Monthly ranibizumab therapy led to meaningful improvements in DR severity that subsequently were maintained with a less-than-monthly PRN regimen

This is an interactive poster. Scan code at right using your smartphone or tablet to see a patient's response to ranibizumab over time, or visit <http://bit.ly/1P6rZtj>



References

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Disclosures

- ME: Genentech, Inc. (C, L, S), Merck (S), Notal (C, O, S), Novartis (S), Ohr Pharmaceutical, Inc. (C, O, S), PW, SG, AEF: Genentech, Inc. (E)
- This study includes research conducted on human subjects
- Institutional Review Board approval was obtained prior to study initiation
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