

Bevacizumab and Ranibizumab in  
the treatment of diabetic macular  
oedema: Can results from clinical  
trials be reproduced in the National  
Health Service?

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# Introduction

- Royal College Ophthalmologist guidance 2005

“Diabetic retinopathy remains the major sight threatening eye disease in the working age population in the developed world and is increasing as a cause of blindness in other parts of the world”

“Photocoagulation therapy **remains the mainstay of therapy** for sight-threatening diabetic macular oedema”

Based on ETDRS – **Laser can stabilize vision rarely improving vision**

# Current Research

- Systematic review of RCT for Anti-VEGF in DMO – published in *BJO Jan 2012*
  - Identified 6 worthy RCT
  - 5/6: only 6 months follow up
  - Avastin or lucentis vs laser/triamcinolone/ sham injection
  - Results Steroid and Anti-VegF can improve vision but **long term benefits unclear**

# Objective

- Retrospective study assessing visual outcomes in patients receiving Avastin or Lucentis for DMO with a 12 month follow up

# Outcome Measures

- **Primary outcome:**
  - Difference in ETDRS best-corrected visual acuity (BCVA) at Baseline and 12 months.
- **Secondary outcomes:**
  - Mean change in BCVA
  - Proportion gaining at least 15 and at least 10 ETDRS letters
  - Change in central macular thickness

# Study Design

- Electronic & case note review
- 5 year (2007 - 2012) data Avastin
- 1 year Lucentis
- 12 month Follow up
- Treatment regime: if meeting inclusion criteria
  - Loading dose of 3 injections
  - Initially monthly review, if reoccurrence:
    - Avastin: retreat with another x3 injections (Majority)
    - Lucentis: x1 injection and review

# Study Design

- Inclusion Criteria
  - BCVA Snellen 6/9 – 6/95 (logMar 0.2- 1.2)
  - Centre involving DMO confirmed on optical coherence tomography (OCT) > 350µm (note: To be published NICE guidelines for lucentis in DMO recommend >400µm)
  - Untreated or refractory DMO
  - Follow up 12 months
- Exclusion Criteria
  - Macular oedema not secondary to diabetes

# **RESULTS FOR AVASTIN IN DMO**

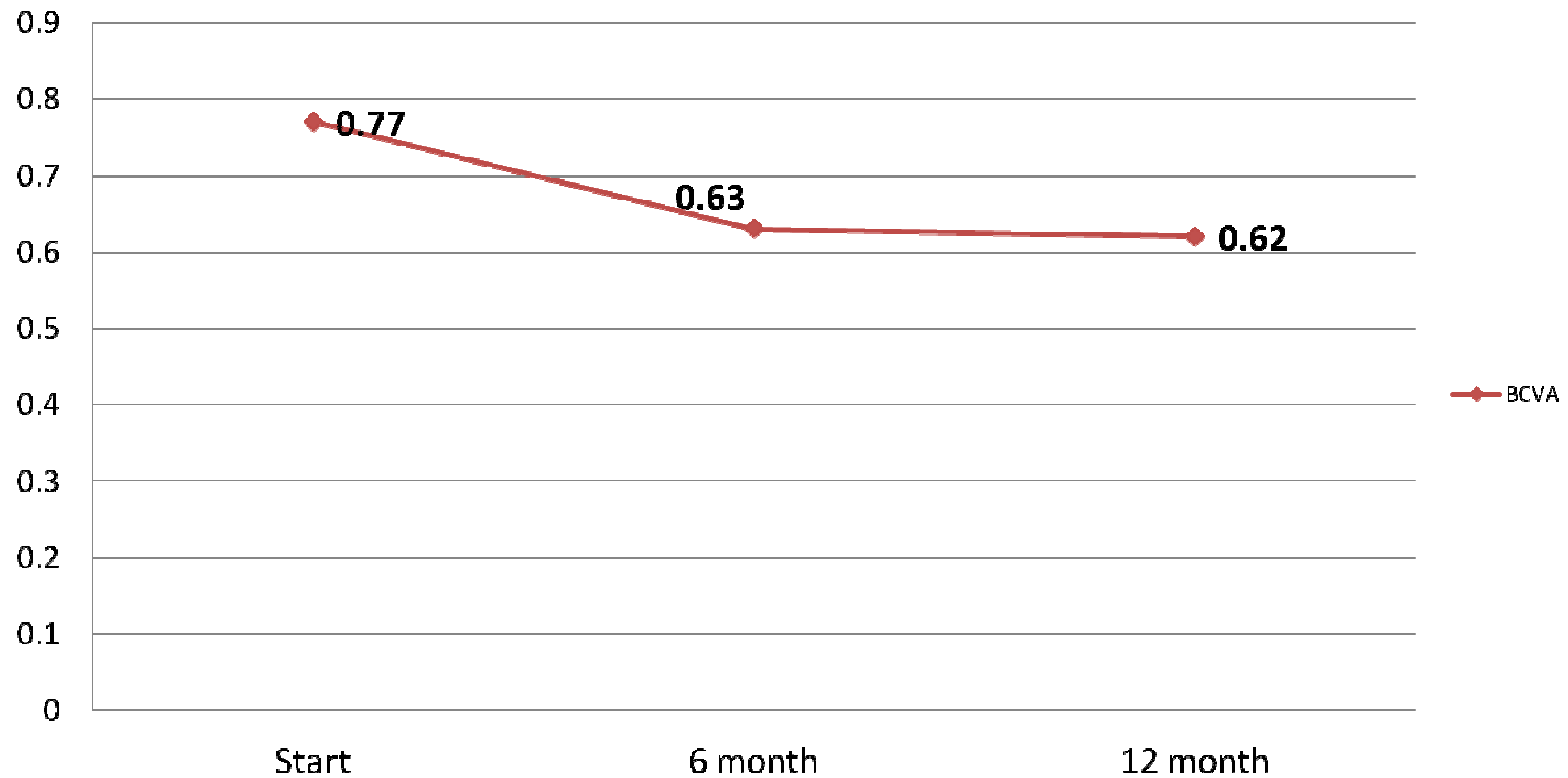


# Results - AVASTIN

Study	Eyes receiving AVASTIN alone
Western Eye	91
Paccola (2008)	14
Ahmadieh (2008)	41
Soheilian (2009)	50
Lam (2009)	52
Solaiman (2010)	19
Michaelides (2010)	37

# Primary Outcome - Mean Change in BCVA

Mean change in BCVA 0.14 logMar = Mean gain of 7 EDTR letters



# Primary Outcome - Visual acuity outcome Comparison **AVASTIN**

Study	Mean Change	$\geq 15$ letter gain	0-15 letter gain
Western Eye Hosp	+ 7 letters	7 (22%)	15 (48.4%)
Ahmadieh (2008	+10 letters		
Soheilian (2009)	+9 letters		
Lam (2009)	+6.5 letters		
Michaelides (2012)	+11.3 letters		168 (49%)

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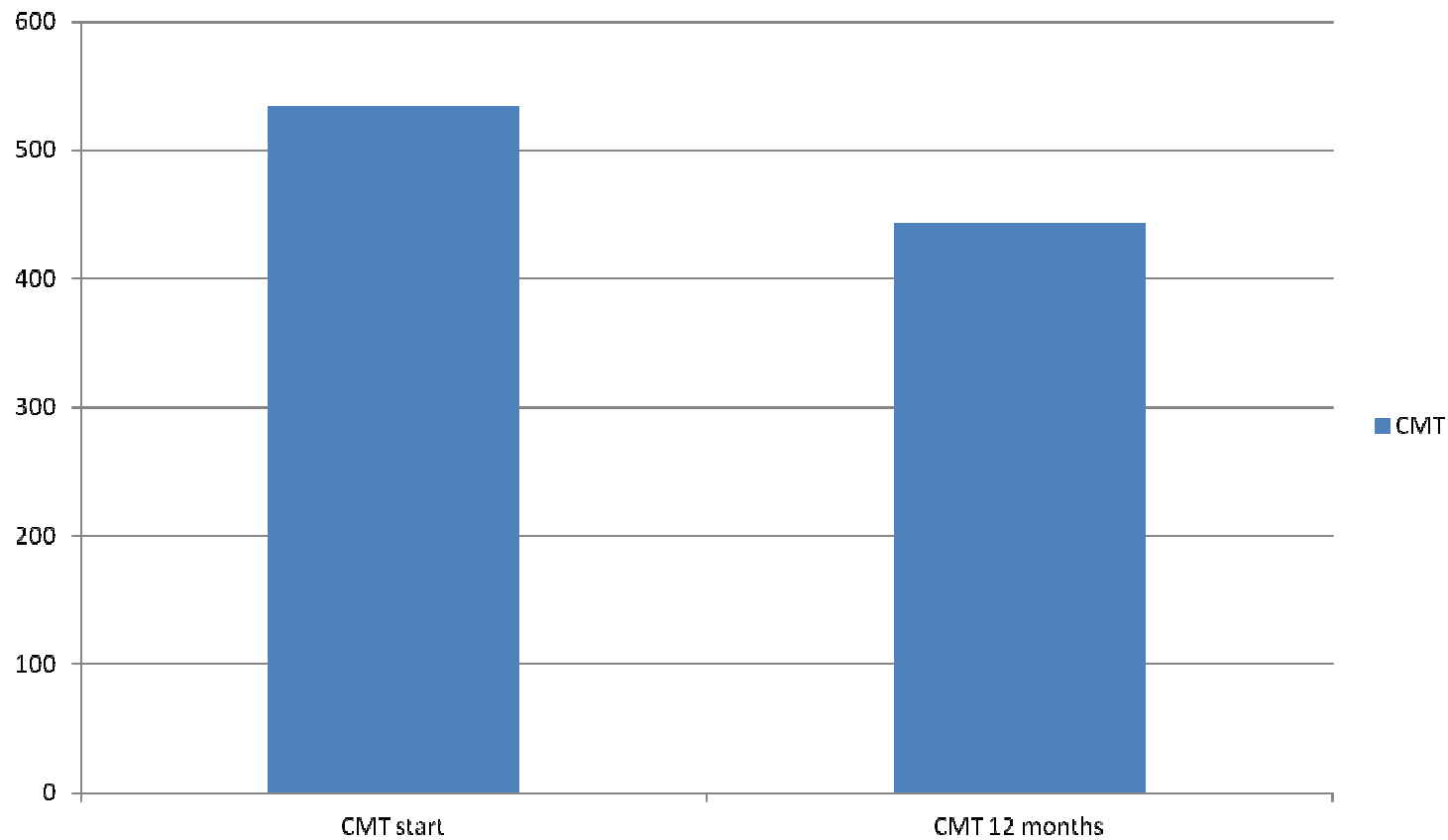
# Mean Change in Central Macular thickness

**AVASTIN**

**Start CMT: 533.5  $\mu\text{m}$**

**12 Month CMT: 443.5  $\mu\text{m}$**

**Mean Change CMT = 90 $\mu\text{m}$**



# **RESULTS FOR LUCENTIS IN DMO**

# Results - LUCENTIS

Study	Eyes receiving LUCENTIS alone
Western Eye	15
READ-2 (2010)	33
RESOLVE (2010)	51
RESTORE (2011)	116
RISE (2012)	250
RIDE (2012)	252

# Primary Outcome - Visual acuity outcome Comparison - LUCENTIS

Study	Mean Change	≥ 15 letter gain	0-15 letter gain
Western Eye Hosp	+ 4 letters	2 (13%)	4 (27%)
Resolve 2010	+ 10.3 letters	12 (32%)	60.8%
Restore 2011	+6.1 letters	22.6%	
Rise - phase III	N/A	39%	
Ride – Phase III	N/A	45%	



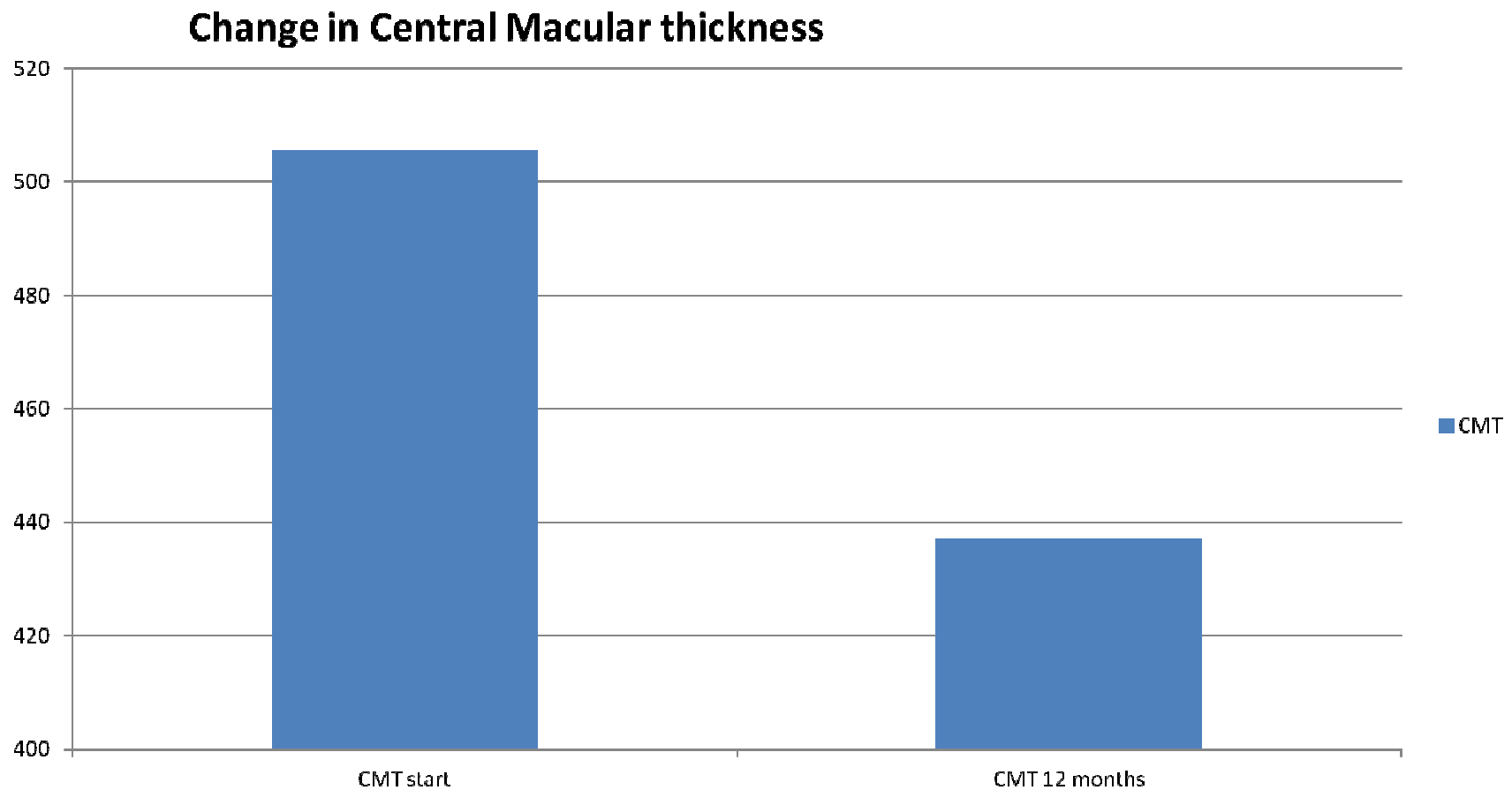
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Ride – Phase III	N/A	45%	

# Mean Change in Central Macular thickness - LUCENTIS

Start CMT: 505.5  $\mu\text{m}$   
12 Month CMT: 437.5  $\mu\text{m}$

Mean Change CMT = 68 $\mu\text{m}$



# Comparison of mean change in CMT

Study	Mean Change in CMT ( $\mu\text{m}$ ) AVASTIN	Mean Change in CMT ( $\mu\text{m}$ ) LUCENTIS
Western Eye Hospital	90	64
Michaelides	146	
Solaiman	142	
Restore		118.7
Resolve		194.2

# Sub Group Analysis

Group	≥15 letters	≥10 letters	Loss of 0-15 letters
<b>No Previous laser Tx</b> (5 patients)	60%	40%	0%
<b>Ischaemia on FFA</b> (9 patients)	0%	44%	56%

# Conclusion

- Using Avastin and lucentis in the treatment of DMO at the WEH and HH is a **useful treatment as 70% and 40% of patients responded respectively**
- Previously untreated and non-ischaemic patients responded best
- **Better than Laser alone but not as successful as clinical trials**
- Future work will attempt to identify factors in the non-responding patients