

Custom Matching IOLs to Patient Needs: A Multicenter Study

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Approach to Patient

Presbyopic IOLs – Discuss with All Patients

- Does patient want reduced dependence on near spectacles after cataract surgery?
- Are they willing to tolerate some increase in glare or halos for that effect?
- Are they willing to bear extra cost?
- Are they accepting of issues with extra precision – LASIK or PRK after, still night or reading glasses?
- Pupil size
- Topography
- Distance, intermediate or near biased
- Both eyes same IOL vs. Mixing IOLs



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Custom Match Process

Experience Based – Custom Match Study in Progress

- Perform surgery on dominant eye or worst cataract first
- Aim for plano in dominant eye with ReZoom IOL first
- Assess at 1-2 weeks in between eyes
- Maximize speed of recovery (cool phaco, viscoelastic, posterior chamber phaco, NSAID, optimize ocular surface)
- Typically do ReZoom in second eye
- Typically aim for plano also
- If problems with near – ReZoom with -0.5 target or ReStor or Tecnis Multifocal IOL when available
- If halos significant concern – Crystalens or Aspheric Tecnis in second eye – plano
- Enhance with Laser vision correction or LRI if target not achieved



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Approach to Patient

Presbyopic IOLs

- Have a default position – what you do in most patients?
 - Something you are comfortable with
 - Staff used to the fact that you do it this way
 - Have reasons to vary from that position
- Assess status in between eyes to confirm original plan – or to change course slightly



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Postoperative Care

Presbyopic IOLs

- Very similar to cataract surgery
- We use Zymar, Pred Forte, Acular LS, artificial tears QID until they run out – typically 2 weeks for Antibiotic, 3-4 weeks for others
- Very commonly use Restasis and artificial tears a few weeks before and a few months after IOL surgery
- Follow-up 1 day, 1 week, 1 month
- Second eye typically at 1 to 4 weeks
- Satisfaction dramatically dependent on early recovery
 - Lubricate surface
 - Identify ocular surface disease preop
 - NSAID to prevent CME
 - Prevent PCO – may need earlier YAG to help function



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Post-Operative Management

Timing of Secondary Intervention

- Enhance large corrections earlier
- Small corrections – wait longer
- Typically wait 6 months to do laser vision correction
 - Capsule considerations
- Typically wait 1-2 months to do piggyback or IOL exchange for large corrections



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Custom Match Global Registry

Evaluate outcomes of patients undergoing MF IOL implantation

- Reflects typical patient selection & treatment
- Gain understanding of postoperative refractive management
- Registry data will assist surgeons in navigating the choices for MF IOL process & patient selection

Lens Indication

- Cataract extraction or RLE in adult patients
- Patient desires spectacle independence

Key Endpoints

- Patient satisfaction with their vision
- Rate of spectacle independence
- Secondary endpoints include uncorrected near, intermediate and distance VA and uncorrected and best corrected distance VA

Registry Follow-up Duration of SIX months after surgery



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Custom Match Global Registry

Tests approach of:

Patient Optimized Staged Implantation (POSI) of MF IOLs

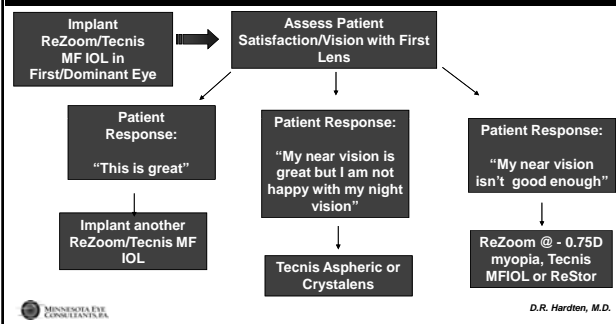
- Registry initiated in December 2007
- Expanded to 35 sites globally in 2008
- Regions represented in Registry

Canada
China
Europe
Middle East
India
Japan
South America
United States



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Staged Implantation: Flow Chart



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Study Results to Date

Study initiated December 2007

FIRST EYE: 20 subjects enrolled (Australia, France, Germany, US)

- 19 subjects received ReZoom first eye
- 1 subject received Tecnis Multifocal

SECOND EYE: 12 subjects enrolled

- 6 ReZoom, 3 ReStor, 3 Tecnis Multifocal

Early Visual Acuity Results – Postop 1 month first eye

- Distance BCVA 20/20
- Distance UCVA 20/22



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Other Studies:

Akaishi & Fabri

Measure	ReSTOR®/ReSTOR®	ReZoom™/ReZoom™	TECNIS® MF/ReZoom™	ReZoom™/ReSTOR®
Patients	100	100	45	88
Near	J 1.40	J 2.30	J 1.30	J 1.50
Intermediate	J 3.85	J 2.15	J 2.30	J 2.30
Distance	20/25	20/20	20/20	20/20
Reading Speed	165 wpm	125 wpm	180 wpm	155 wpm
Spectacle Indep.	89%	75%	100%	100%



Akaishi & Fabri (Brasil; ASCRS 2006)

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Other Studies:

Lopez-Castro

	Bilateral MIOLs	TECNIS®/ReZoom™ IOLs
Near Mesopic	J 4.1	J 2.4
Near Photopic	J 2.2	J 2.1
Intermediate Mesopic	J 5.3	J 4.2
Intermediate Photopic	J 5.6	J 3.7
Distance Mesopic	1.18	1.17
Distance Photopic	1.12	1.20



Lopez-Castro A (ESCRS 2006)

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Lopez-Castro

	Bilateral MIOLs	TECNIS®/ReZoom™ IOLs
Spectacle Independence	81.8%	84.6%
None or Moderate Difficulties in Night Vision	36%	100%
LASIK Touch Up Required	46%	33%

Lopez-Castro A (ESCRS 2006)



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Other Studies: Bucci

	Bilateral ReSTOR® IOLs n=55	ReZoom™/ReSTOR® IOLs n=110
Near Vision	J 1.00	J 1.00
Intermediate Vision	J 3.81	J 2.39

27% of bilateral ReSTOR® IOL patients spontaneously volunteered an intermediate complaint

Bucci F (RHEM 2007)



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Other Studies: Milne

	Bilateral ReSTOR® IOLs n=23	ReZoom™/ReSTOR® IOLs n=29
Patient satisfaction with Distance Vision	74% Satisfied 26% Dissatisfied	96% Satisfied 4% Dissatisfied
Patient satisfaction with Near Vision	83% Satisfied 17% Dissatisfied	96% Satisfied 4% Dissatisfied
Patient recommend procedure	64% Satisfied 18% Neutral 18% Dissatisfied	96% Satisfied 4% Dissatisfied
Spectacle independence	65%	94%

Milne R (RHEM 2007)



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Summary

Custom Match

- Have default plan
- Assess in between eyes
- Be prepared to use a different IOL in the opposite eye
- Choose motivated patients that are willing to go through extra work



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