Achieving Success with Presbyopic Correcting IOLs: Pre op Counseling, IOL Selection, and Treatment of Residual Refractive Error

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Achieving Success with Premium IOLs

Course Agenda

I. Introduction
II. Strategy/Philosophy for Correcting Presbyopia
III. Pre Op Consultation
IV. Evolution of Presbyopic IOLs
V. Multivariate Analysis of Overall Patient Satisfaction
VI. Alternatives for Correcting Residual Refractive Error
VII. Enhancing Cornea & Retina Function
VII. Questions & Answers

Presbyopic Correcting IOLs

1. TECNIS 3-piece
6. ReSTOR 3.0
2. TECNIS 1-piece
7. ReSTOR 4.0
3. ReZoom
8. TECNIS +4.00
4. Crystalens
9. TECNIS +3.25
5. Trulign
10. TECNIS +2.75

Disclosures

Abbott
Allergan
Bausch & Lomb
LENSAR
PRN

Glaukos
AqueSys
TearScience
Omeros
ALPHAEON

All consulting fees donated to
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Lima, Peru
Presbyopia Correcting IOLs

June April 2016

- ReSTOR 4.0 - 302
- ReSTOR 3.0 - 14
- Crystalens (5.0) - 95
- Crystalens HD -135
- Crystalens AO - 41

- ReZoom - 567
- TMF ~ 1992
- TMF +4.00
- TMF +3.25
- TMF +2.75

Introduction

"Freeing a cataract or a presbyopic lensectomy patient from their bifocals for the rest of their life is a very powerful event”

(for the patient and the surgeon)

Success with Premium IOLs

Editorial OSN August 2009

Richard L. Lindstrom, MD

Perspective

1. “Careful patient selection”
2. “Reducing patient expectations”
3. “Achieving the desired refractive outcome”

“My conclusion, after 25 years of studying the premium IOL field, is that the level of patient satisfaction is NOT dependent on careful patient selection.”

“I do NOT believe that patient satisfaction is really significantly influenced by extensive efforts to reduce patient expectations.”
“patient selection is LESS IMPORTANT THAN SURGEON PERFORMANCE if a reduction in spectacle independence is the desired outcome.”

“every refractive cataract surgeon must appreciate that it is the REFRACTIVE OUTCOME THEY GENERATE, NOT THE PATIENT or EVEN THE TECHNOLOGY they select, that is the primary determinant of patient satisfaction and word of mouth referrals.”

Success for the most part literally lies in the mind and hands of the surgeon

Is there any objective evidence that supports the message of Dr. Lindstrom’s editorial?
SURGIVISION / DATALINK

40,000 Premium Implants

60% - 24,000 eyes
with > 0.75D untreated residual K astigmatism

* Minimum goal < 0.50D

Success with Premium IOLs

The GOAL or END GAME
with Premium IOLs

Achieve

- patient satisfaction
- spectacle independence

Success with Premium IOLs

The GOAL or END GAME
with Premium IOLs

Achieve

- patient satisfaction
- spectacle independence

Success with Premium IOLs

Three Players in the Game

I. Patient

1. Visual needs
2. Exam findings
3. Personality
4. Expectations

II. Surgeon

1. Surgical skills
2. Experience
3. Personality
4. Perception

III. Premium IOLs

1. TECNIS Multifocal
2. ReZoom
3. Crystalens 5.0
4. Crystalens AO
5. ReSTOR 4.0
6. ReSTOR 3.0
7. Monofocal Asph.
8. Torics

Success with Premium IOLs

PATIENT

+ SURGEON

PREMIUM IOLs
(MANUFACTURERS)

ALL PLAYERS ARE IMPERFECT

ALL SEEKING A “PERFECT” RESULT
SUCCESS = Unite the Three Players to Achieve The Five Essential Visual Elements of Success

1. Relatively high quality distance acuity
2. Functional intermediate vision (seeing computer at arms length)
3. Functional near vision in bright light (comfortably reading the newspaper)
4. Functional near vision in moderate light (comfortably read menu in restaurant)
5. Experience acceptable light phenomenon while driving at night.

My approach is to aggressively attack the five visual elements of success (visual targets) with all the tools in the toolbox

- focus on how well you make them see
- not the technology you choose

"Patient Profile for Success"
The 10 “P”s of Correcting Presbyopia with IOLs

1. **Personality** - establish stronger relationship with pt. (perceive more as LASIK pt. not as typical cat. pt.)
2. **Patient selection** - critical
3. **Pre op counsel** - manage expectations
4. **Pre op exam** - assess visual potential esp. cornea & retina
5. **Presbyopic IOL selection** - target distance, inter., & near
6. **Prostaglandin inhibition** - use top. NSAIDs - pre & postop
7. **Phaco & IOL implant** - efficient & accurate
8. **Plano +/- target** - fix residual error (don’t give away distance)
9. **PCO** - treat early - pts. already lost contrast sensitivity
10. **Psychophysiology** - facilitate continued neuroadaptation (reinforce “work in progress”)

**Customized Preop Consultation**

**Three New Core Skills**

**Monofocal Surgeon** ——> **Premium IOL Surgeon**

1. **Communication** Skills
   - invest in a genuine doctor/patient relationship
   - determine visual needs and profile

2. **Skills for Selection of Premium IOLs**
   - know strengths & weaknesses of each IOL
   - apply information acquired from #1

3. **Skills for Correcting Residual Refractive Errors**
   - aggressively pursue refractive targets (intraop or postop)

**Introduction**

**Success with Premium IOLs**

- More complex than previously thought
- Presents new challenges to the average ophthalmologist
- Great upside potential with some reasonable paradigm shifts
Typical large volume cataract practice efficiently “moves information” about the surgical experience from the practice (doctor) to the patients.

- Brochures
- Technicians
- Videos
- Surgical counselor
  \[\text{↓} \quad \text{patient anxiety}\]
  \[\text{↓} \quad \text{doctor chair time}\]

Enter **Premium** IOLs

New **option** for cataract surgeons

Efficient High Quality Cat. Surgery

Efficient pt flow (clinic & ASC)

Excellent outcomes and high pt satisfaction

Economic Prosperity

Recent Survey

High Volume Cataract Surgeons reported

↑ Chair Time

Poor Conversion Rate
Response
Do more of what we do well!!
Drive new premium IOL information faster & harder from
practice → patient
“So the patient can decide”

Result
Frustration
• Continued poor conversion
• Excessive post op patient complaints

WHY?
The premium IOL component
Introduces the paradigm of
Elective Surgery

In the New Paradigm of Elective Surgery
“The quality of the preoperative decision making is directly related to, and dependent upon the amount of information moving NOT from the practice to the patient, but on the amount of valuable information moving from the patient to the doctor.”
**Educate Yourself**

to

“Who they really are”

“What they want to achieve”

↓

exam

↓

Make a **definite recommendation**

• select procedure

• select IOLs

---

**Who’s Coming for a Consult?**

**Key Characteristics of Potential Premium IOL Patients**

- Visual function and demands
- Personality (expectations, etc.)
- Economic status
- Refractive status: hyperopia, myopia, emmetropia
- Lens status: Cataract vs. Clear lens
  - Age / Culture
- Patient’s purpose for consultation

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**Potential PCI – Age & Culture**

**Cataract vs. Lensectomy**

- late 60’s, 70’s, 80’s
- “Brokaw cataract” WW II
- Accepting by culture
- Poor corrected pre op VA
- Reasonable expectations
- Pay less – expect less
- Less litigious
- Less computer

- 40’s, 50’s, early 60’s
- “Boomer cataract” & clear lens
- Demanding by culture
- Excellent corrected pre op VA
- High expectations
- Pay more – expect more
- More litigious
- More computer

---

* PCI – originally created for pre-cataract presbyopes - now 30 to 1 ratio cataract to lensectomy
“Three Core Questions”

1. Do you have any interest in achieving spectacle independence? Y/N

2. Would you be willing to tolerate some light phenomena while driving at night to achieve this freedom? Y/N

3. Would you be willing to pay something out of pocket to achieve this increased freedom from glasses? Y/N

Non-Emmetropic Presbyope

“1 Fundamental Question”
If we use Custom LASIK to give you excellent distance vision, and all you need is reading glasses after surgery – will that make you happy?

- Strong Yes – (briefly mention RL) – Do LASIK
- Strong No - (discuss RL in detail) – Likely do RL
- Weak Yes (discuss RL and LASIK in detail)
- Weak No Lead the discussion to the procedure you think will make the patient happy and let them choose

Emmetropic Presbyope

- Most challenging patients
- Strongly “counsel down” expectations
- Very respectful of surgery on a 20/20 eye
- Offer only non dominant eye
- Require an extended period of neuroadaptation in first eye before ever offering the 2nd eye
- Dangle the offer of surgery on one eye – then begin to take it away
  - Then observe their demand for spectacle indep.
  - They will give you the answer – if their demand was high, they will end up happy
**Educate Yourself**

“Who they really are”  
“What they want to achieve”  

↓  

exam  

*  

Make a definite recommendation  
• select procedure  
• select IOLs  

Now, “educate the patient” as you manage and massage their expectations appropriately.

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**Conclusions / Comments**

1. The new paradigm of elective surgery demands that you facilitate a genuine doctor/pt. relationship  

2. The “3 core questions”, “the opportunity” and “the 1 fundamental question” are only stimuli for presentation to the pt., so you can then observe and learn from the elicited response.

3. Do **NOT** manipulate a “yes” from the patient  
   • you will get burned  

4. Instead, **seek and perceive** the “truth” about the pt.  
   • the quality of your decision making will soar  

5. **Listen** to the pts.- they will give you the answers  

---

**Cohorts Studied Since 2005 (n = 1834)**

1. RS 4.0 / RS 4.0  
   n = 56  

2. RZ / RS 4.0  
   n = 129  

3. RZ / RZ  
   n = 100  

4. CR / CR  
   n = 47  

5. TMF / CR  
   n = 93  

6. TMF / RZ  
   n = 80  

7. TMF / RS 3.0  
   n = 12  

8. TMF / TMF +4.00  
   n = 400  

9. TMF / TMF +3.25  
   n = 47

---

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   n = 47
**TECNIS MF / ReZoom**

- Synergistic
  - ReZoom compliments TECNIS MF intermediate
  - TECNIS MF compliments ReZoom near
  - wider range at near
- Both IOLs target plano
  - not giving away distance
- TECNIS MF
  - pupillary independence covers for ReZoom w/small pupils

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   - n = 12
8. TMF / TMF
   - n = 400

**TECNIS MF / ReZoom**

Morbidity for this Combination

- halos & glare secondary RZ

**Clinical Reality**

- the morbidity from RZ’s halos with TMF/RZ exceeded the morbidity of less than ideal intermediate with TMF/TMF

**Introduction**

TECNIS Multifocal

+ Crystalens
Purpose • TECNIS Multifocal + Crystalens

To evaluate how well the combination of TECNIS Multifocal (TMF) & a Crystalens (CR) fulfills my “five visual elements of success”

Methods • TMF + Crystalens

- Retrospective analysis
- 80 patients (160 eyes)
- TMF non-dominant eye
- Crystalens HD (n=65)
- Crystalens 5.0 (n=15)

TECNIS MF/ Crystalens

Why mix Crystalens with a TMF?

- enhanced intermediate
- less halos for night driving with a CR
- wider range at near
- focal point of 45 cm complimenting the 33 cm focal point of the TMF

Methods • TMF + Crystalens

- Analysis of Visual Function
  - distance
  - intermediate
  - near
- Questionnaires
  - patient satisfaction
  - spectacle independence
Results • Distance Vision • TMF + CR

<table>
<thead>
<tr>
<th></th>
<th>Mean Vision</th>
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<tbody>
<tr>
<td>TMF</td>
<td>20/25.3</td>
<td></td>
</tr>
<tr>
<td>Crystalens</td>
<td>20/26.7</td>
<td></td>
</tr>
<tr>
<td>Bilateral (TMF + CR)</td>
<td>20/22.1</td>
<td></td>
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</tbody>
</table>

Bucci '16

Results • Near Vision • TMF + CR

<table>
<thead>
<tr>
<th></th>
<th>Vision Type</th>
<th>Mean</th>
<th>J1</th>
<th>J2</th>
</tr>
</thead>
<tbody>
<tr>
<td>TMF eyes</td>
<td>Near Vision</td>
<td>1.3</td>
<td>&gt; 85%</td>
<td>&gt; 95%</td>
</tr>
<tr>
<td>Crystalens eyes</td>
<td>Near Vision</td>
<td>3.5</td>
<td>&gt; 25%</td>
<td>&gt; 37%</td>
</tr>
<tr>
<td>Bilateral (TMF + CR)</td>
<td>Near Vision</td>
<td>1.15</td>
<td>&gt; 97.5%</td>
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</tbody>
</table>

Bucci '16

Results • Intermediate Vision • TMF + CR

<table>
<thead>
<tr>
<th></th>
<th>Vision Type</th>
<th>Mean</th>
<th>J1</th>
<th>J2</th>
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<tbody>
<tr>
<td>TMF</td>
<td>Intermediate</td>
<td>3.6</td>
<td>&gt; 61.3%</td>
<td></td>
</tr>
<tr>
<td>Crystalens</td>
<td>Intermediate</td>
<td>3.1</td>
<td>&gt; 25%</td>
<td></td>
</tr>
<tr>
<td>Bilateral (TMF + CR)</td>
<td>Intermediate</td>
<td>2.4</td>
<td>&gt; 97.5%</td>
<td></td>
</tr>
</tbody>
</table>

≥ J1 61.3%
≥ J2 71.3%

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Results • Simultaneous Vision • TMF + CR

<table>
<thead>
<tr>
<th></th>
<th>Distance</th>
<th>J1</th>
<th>J2</th>
</tr>
</thead>
<tbody>
<tr>
<td>20/20</td>
<td>70%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20/20</td>
<td>85%</td>
<td></td>
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</tbody>
</table>

• ideal outcomes

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Results • Patient Satisfaction • TMF + CR

Questionnaires

Functioning with no glasses: 93.8%
Pleased with their outcome and would have surgery again: 95.0%

TECNIS MF / Crystalens

Morbidity for this Combination

- unpredictable and inconsistent near and intermediate function in Crystalens eye
- frequent hyperopic shift with Crystalens post YAG (AAO, 2009)

Crystalens • Near Function

n = 216
(5.0 + HD)

Actual (-0.50)
Distance Corrected

\[ \geq J_1 \quad \frac{1}{4} \quad (24\%) \quad \frac{1}{7} \quad (14\%) \]
\[ \geq J_2 \quad \frac{1}{3} \quad (36\%) \quad \frac{1}{5} \quad (19\%) \]
\[ \geq J_3 \quad \frac{1}{2} \quad (53\%) \quad \frac{1}{3} \quad (36\%) \]

* Rule of thumb

Relatively Unhappy Patients

• poor intermediate & near in Crystalens eye combined with below average intermediate vision in their TMF eye
1. We observed a consistent performance in the TMF eyes with excellent vision at distance and near, but less than ideal intermediate vision can be present.

2. We observed a wide range of performance at near and intermediate in the CR eyes.

3. When the CR eyes perform at their best (J1 or J2) 1/3 of the time, this outcome in combination with a TMF essentially approaches or achieves the ideal.

4. However, when the CR eyes perform at their worst (J5 or J6) 1/3 of the time, this combination is frequently very vulnerable at intermediate.
Study Cohorts & Analyze Results

1. RS 4.0 / RS 4.0 (n = 56)
2. RZ / RS 4.0 (n = 129)
3. RZ / RZ (n = 100)
4. TMF / RZ (n = 80)
5. TMF / CR (n = 93)
6. TMF / RS 3.0 (n = 12)
7. TMF +4.00 / TMF +4.00 (n = 400)

TECNIS MF / ReSTOR 3.0

Objective

- ↓ intermediate morbidity
- best case scenario for RS 3.0
  - small mesopic pupil ≤ 3.5mm

Discussion

Retrospective Comparison of 8207 Eyes Implanted with Presbyopic IOLs

C. Buznego; W. B. Trattler; Elizabeth Davis, G. M. Kezirian

- Data Link Comparison
- Registry funded by Bausch & Lomb
- Administered by SurgiVision Consultants, Inc.

Morbidity for this Combination

- unfortunately best case scenario did not produce better intermediate
- gave away near (RS 3.0 vs. RS 4.0)
- confirmed with Elizabeth Davis study (ASCRS 2010, Boston)
2014 Clinical Observations

Reasonably high levels of patient satisfaction can be achieved with all of these combinations:

1. **TMF/TMF**
   - HD v. Tecnis
   - Either HD/Tecnis v. ReSTOR
   - p Not Significant
   - p < 0.05

2. **TMF/RZ**
   - ReZoom not functional with small pupils
   - Halos can still be an issue

3. **TMF/CR**
   - High variance in CR eyes – best outcomes or worst outcomes (feast or famine)

4. **TMF/RS 3.0**
   - ReSTOR not functional with large pupils
   - Did not see enhanced intermed. with RS 3.0 even in best case patients with small pupils
### Pearls & Suggestions

1. If you currently prefer **CR / CR**

2. And if you do **not** achieve a **J1** or **J2** near outcome in the first eye
   - > 64% of eyes failed to achieve **J1** or **J2** at near or intermediate

---

### RS 3.0 / RS 3.0 ➔ RS 3.0 / TMF

- **Highly consider** a TMF in at least **one eye**
  - will improve overall near performance
  - greatly improve **near function** in dim and **moderate** light (menu in restaurant)
  - allow visible blue light to enter eye/brain

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### Pearls & Suggestions

1. You will **need to pursue** monovision with myopia in the second eye (**giving away distance**)

2. Highly consider TMF in second eye vs. monovision with another CR
   - you will easily meet your **near visual targets**
   - **without giving away any distance** in either eye
Why TMF/TMF Combination of Choice?

Approaches ideal more consistently than any other combination

**TECNIS MF / TECNIS MF**

- Predictability makes pre op counseling for post op issues more straightforward, specific, and targeted:
  - halos: less than 3% clinically significant
  - sweet spot at near ~ 14”

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**Why TMF +4.00 / TMF +4.00 Combination of Choice 2009-2014**

1. Less halos (vs. TMF / RZ)
2. Very consistent outstanding near
3. Excellent distance (target plano)
4. No concern about pupil size
5. Never been easier to make patients happy
6. Bilateral intermediate competes favorably with other combinations
   - esp. after proper counseling
   - improves with time

**Current Status**

**TECNIS MF / TECNIS MF**

- > 2000 TMFs implanted
- least morbidity
- never been easier to make patients happy
- presbyopic IOLs
  - 22% (2008) → 36% (2013)
Multivariate Analysis of Overall Bilateral Satisfaction vs Preoperative and Outcome Data of Patients Receiving Diffractive Multifocal Implants

Frank A. Bucci, Jr., MD
Bucci Laser Vision Institute
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Cohorts Studied Since 2005 (n = 2034)

1. RS 4.0 / RS 4.0
   n = 56
2. RZ / RS 4.0
   n = 129
3. RZ / RZ
   n = 100
4. CR / CR
   n = 47
5. TMF / CR
   n = 93
6. TMF / RZ
   n = 80
7. TMF / RS 3.0
   n = 12
8. TMF / TMF
   n = 500

To report the preliminary results of a multivariate regression analysis trying to identify predictors of overall satisfaction of bilateral vision with diffractive multifocal IOLs.

Background

- Implanted > 3900 presbyopic correcting IOLs
- Studied numerous cohorts of mix & match and same IOL combos seeking highest levels of patient satisfaction

Purpose

TMF / TMF • Multivariate Regression

To report the preliminary results of a multivariate regression analysis trying to identify predictors of overall satisfaction of bilateral vision with diffractive multifocal IOLs.

Bucci '16
TMF/TMF • Multivariate Regression

Bias

This study is
NOT funded by industry

---

TMF/TMF • Multivariate Regression

Background

Age
- range 42 – 82 years
- mean = 65.4 years

Gender
- 28 female
- 27 male

Surgery
- 46 KPE
- 9 RL

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TMF/TMF • Multivariate Regression

Methods • Study Design

- 200 bilateral diffractive IOL (TMF/TMF)
- “Best Case” patients
  - at least 6 mon. neuroadaptation
  - aggressive correction of residual ref. error
  - all YAGs completed as necessary
  - aggressive mgt. of the ocular surface

---

TMF/TMF • Multivariate Regression

Study Design

- 41 variables
  - initial dependent variable
    - overall patient satisfaction
    - regress against other
    - 40 variables
• 9 variables derived from responses to pt. questionnaire

• 3 questions are related to frequency of glasses use:
  - distance
  - intermediate
  - near

• 4 others questions are related to performing activities without glasses:
  - reading small print
  - reading the newspaper
  - working on a computer
  - seeing at distance (TV & driving)

• patient prospectively randomized
  - eye dominance
  - first eye
  - 1-piece TMF vs 3-piece TMF
  - all patients have a 1-P & 3-P
    - unilateral preference study later
  - this study - all bilateral visual function

Numerous Post Op Clinical Metrics as Variables

UCVA
BCLV
Residual SE
Residual Astig.

SRI topography (dry eye)
IOL centration
Angle Kappa
Aspericity

Near – best focal
Inter. – best focal
Inter. – fixed focal

Sloan ETD
RS Trefoil

RMS
Coma

Reading speed
Reading accuracy

Sph. Aberration
First Challenge

- Detecting differences with regression is dependent on the variance in the data
  - Both dependent & independent variables

Patient Satisfaction by Questionnaire

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<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Very Satisfied</td>
<td>64%</td>
<td>35 / 55</td>
</tr>
<tr>
<td>Satisfied</td>
<td>35%</td>
<td>20 / 55</td>
</tr>
<tr>
<td>Neutral</td>
<td>0%</td>
<td>0 / 55</td>
</tr>
<tr>
<td>Dissatisfied</td>
<td>0%</td>
<td>0 / 55</td>
</tr>
<tr>
<td>Very Dissatisfied</td>
<td>0%</td>
<td>0 / 55</td>
</tr>
</tbody>
</table>

100% Very Satisfied or Satisfied

Angle Kappa

- Recommended no implantation > 0.4
- 51/55 (93%) < 0.42
- None greater than 0.55

Refractive

- I am very aggressive in treating residual refractive error
- Results in very low variance for residual astig. and sphere, and final uncorrected acuity
### Average Bilateral Post Op Astigmatism

<table>
<thead>
<tr>
<th>Mean Astigmatism</th>
<th>Percentage</th>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 0.75D</td>
<td>100%</td>
<td>55/55</td>
</tr>
<tr>
<td>≤ 0.63D</td>
<td>93%</td>
<td>51/55</td>
</tr>
<tr>
<td>≤ 0.50D</td>
<td>80%</td>
<td>44/55</td>
</tr>
<tr>
<td>≤ 0.38%</td>
<td>66%</td>
<td>36/55</td>
</tr>
</tbody>
</table>

\[ \text{mean} = 0.35 \pm 0.23 \text{D} \]

### Average Bilateral Post Op Sph. Equivalent

<table>
<thead>
<tr>
<th>Mean Sph. Equivalent</th>
<th>Percentage</th>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 0.50 D</td>
<td>95%</td>
<td>52 / 55</td>
</tr>
<tr>
<td>≤ 0.75 D</td>
<td>98%</td>
<td>54 / 55</td>
</tr>
</tbody>
</table>

\[ \text{mean} = 0.02 \pm 0.28 \text{D} \]

### Overall Patient Satisfaction

\[ \text{Overall Patient Satisfaction} = +2.37 \text{ (constant)} + .30 \text{ newspaper} \quad p < .005 \]
\[ + .18 \text{ computer} \quad p < .005 \]
\[ + .08 \text{ intermediate} \quad p = .05 \]

\( R^2 = .57 \)

- these kinds of visual results needed for high pt. satisfaction
- not talent but persistence (high rate of enhancements)
**Multivariate Regression Results**

- “newspaper” result not surprising
- other 2 variables related to **intermed. Va**
  - interesting
  - explainable
- questionnaire reveals **more variance** with intermediate variables

<table>
<thead>
<tr>
<th>Increasing Variance</th>
<th>Near (newspaper)</th>
<th>Inter. (computer)</th>
<th>Dist. (TV, driving)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 Excellent</td>
<td>31 / 55</td>
<td>21 / 55</td>
<td>31 / 55</td>
</tr>
<tr>
<td>3 Very good</td>
<td>18 / 55</td>
<td>17 / 55</td>
<td>18 / 55</td>
</tr>
<tr>
<td>2 Good</td>
<td>6 / 55</td>
<td>12 / 55</td>
<td>6 / 55</td>
</tr>
<tr>
<td>1 Fair</td>
<td>0 / 55</td>
<td>3 / 55</td>
<td>0 / 55</td>
</tr>
<tr>
<td>0 Poor</td>
<td>0 / 55</td>
<td>2 / 55</td>
<td>0 / 55</td>
</tr>
<tr>
<td><strong>mean</strong></td>
<td><strong>3.55</strong></td>
<td><strong>2.94</strong></td>
<td><strong>3.55</strong></td>
</tr>
</tbody>
</table>

**Multivariate & Bivariate Results**

- Bivariate analysis shows strong correlations
  - mesopic pupil & intermediate (fixed)
  - photopic pupil & intermediate (preferred)

smaller pupils associated with sign. better intermediate Va
  - data suggests influence **beyond pinhole effect**
  - does not occur with distance & near

- **Multivariate & Bivariate Results**
  - justify and support an analysis of intermediate vision as a dependent variable
  - yielded very interesting findings
Intermediate (fixed focal) = 
+ 112.87 (constant) 
- 2.89 mesopic pupil p < .005 
- 5.01 centration (IOL) p = .02

- as mesopic pupil decreases intermed. (fixed) Va increases
- as IOL centration increases fixed intermed. (fixed) Va increases

Optical scientists have suggested
• light passing through the zone (1.0 mm) inside the center most ring on the TMF optic enhances intermediate vision
• as the pupil diameter decreases the % of light passing through the central ring would increase

If the proprietary design of the center zone of TMF enhances intermediate vision beyond the pinhole effect

It makes intuitive sense that superior centration of this zone would be associated with a superior performance for intermediate vision

Pre op pupil size may be a meaningful predictor of post intermediate vision
TMF/TMF • Multivariate Regression

Discussion

Our regression results strongly suggests choosing “very satisfied” over “satisfied” is significantly influenced by intermediate vision &

Intermediate vision is significantly influenced by pupil size & IOL centration

TMF/TMF • Multivariate Regression

Conclusions

1. Patients with low residual refractive error and excellent uncorrected acuity have high patient satisfaction

2. Multivariate regression revealed that “overall patient satisfaction” is significantly influenced by the patients ability to “read the newspaper”, “work on the computer”, and their “intermediate visual function”

3. “Intermediate visual function” is significantly influenced by “pupil size” and “IOL centration”.

4. “Pupil size” may be a meaningful pre op predictor of post op intermediate vision when implanting the TMF
Alternatives for Correcting Residual Refractive Error Following Intraocular Lens Implantation

Correcting Residual Refractive Error

Goals

1. Astigmatism $\leq$ 0.50 D
2. +/- 0.25 D from spherical target

Current procedures most frequently used

1. LRI at the time of implantation
2. LASIK post op (months later)
3. PRK (surface ablation) post op

Alternative Procedure

Residual Refractive Errors

micro RK / AK

> 3 wks post op
Correcting Residual Refractive Error

Keratorefractive Options

- Laser
  - LASIK
  - Surface ablation (PRK)

- Incisional
  - LRI - intra op
  - micro RK / AK - post op

What is micro RK / AK?

Almost all cases need only one or two radial incisions

Refractive target with IOL selection
  - plano to slight myopia

Lindstrom 2 inc. nomogram – extremely accurate for low myopia (Bucci 20 yrs)

What is micro RK / AK?

1. Arcuate incisions in peripheral cornea as used in any other AK or LRI technique

2. Very small radial incisions to correct residual myopia

- OZ never smaller than 5.00 mm

Lindstrom 2 incision mini – RK Nomogram

Age > 45

OZ > 5.00

- No hyperopic shift
- No fluctuating vision
Correcting Residual Refractive Error

**LASIK** (possible PRK)

1. Higher myopia and/or higher astigmatism
2. Hyperopia with or without astigmatism

**micro RK/AK**

1. Low myopic astigmatism
2. History of severe dry eye, or dry eye after LASIK in opposite eye

---

**micro RK / AK vs. LASIK**

Advantages of micro RK / AK

1. Can perform sooner (patients demanding)
2. Central 5 mm of cornea untouched
3. No neurotrophic cornea (high risk pop.)
4. Enhance. does not further complicate dry eye
5. Introduces less new HOA (esp. compared to conv. LASIK – Custom usually not possible)

---

**micro RK / AK vs. LRI**

Advantages micro RK / AK

1. Know exact amount of cylinder
2. Know exact axis of cylinder
3. Know exact spherical error
4. Opportunity to correct sphere (micro RK)

---

**micro RK / AK vs. LASIK**

Advantages of micro RK / AK

6. No flap complications
7. No DLK
8. No central epith. defects
9. Large differences in cost
   - cost of laser
   - cost of "procedure card"
   - cost of facility
   - cost of enhancement
Advantages of micro RK / AK

1. Central 5 mm of cornea untouched
2. Quicker visual recovery (demanding pts.)
3. Bilateral possible (demanding pts.)
4. Less post op discomfort
5. No BCL required

Advantages of micro RK / AK vs. PRK

6. Less post op visits required
7. Much less costly
8. Enhancement less invasive – quicker recovery

Advantages of micro RK / AK vs. PRK

9. Less stress on patients with Ocular surface disorders
   - MGD
   - Aqueous dry eye
   - Allergies
   - CL intolerance
   - Delay epith. healing (i.e. diabetics)

10. Subtle sub epithelial haze undesirable in patients with already reduced contrast 2° multifocals (demanding patients)

Correcting Residual Refractive Error

LASIK
1. Higher myopia and/or higher astigmatism
2. Hyperopia with or without astigmatism

micro RK/AK
1. Low myopic astigmatism
2. History of severe dry eye or dry eye after LASIK in opposite eye
Correcting Residual Refractive Error

**LASIK**
1. Higher myopia and/or higher astigmatism
2. Hyperopia with or without astigmatism

**micro RK/AK**
1. Low myopic astigmatism
2. History of severe dry eye, or dry eye after LASIK in opposite eye

Conclusions:
1. Embrace the idea that correcting “residual” refractive errors is essential for achieving success with PC IOLs
2. Become comfortable and proficient with one or more techniques
   - avoid the “shortstop syndrome”

3. Aggressively pursue the goal of minimal residual refractive errors
   - resulting in high rates of:
     - spectacle independence
     - pt. Satisfaction
     - “word of mouth” referrals

**Conclusions • micro RK / AK**
- Excellent alternative for correcting residual refractive errors
  - Less costly
  - Less stress on ocular surface
  - Less invasive
Introduction • Omega-3 Fish Oils

Review something almost all of you already know

Discuss something that almost none of you know

Effect of Oral Re-esterified Omega-3 Supplementation on Dry Eye Disease: Double-masked Randomized, Multicenter, and Placebo-controlled Study

Frank A. Bucci, Jr, MD
Bucci Laser Vision Institute
Wilkes-Barre, PA.

- Dry eye
- ARMD
- Cardiovascular disease
- Arthritis
- Asthma
- Depression
- Kidney disease

That is what you probably already know
Introduction • Omega-3 Fish Oils

There are

Two distinctly different

Molecular forms

of concentrated fish oil supplements

used to deliver EPA & DHA

What is a Triglyceride?

glycerol backbone

ethanol backbone

1. Synthetic Ethyl Esters (EEs)

2. Natural Triglycerides (TGs)
Bioavailability / Absorption • TG vs. EE

J. Dyerberg “father of fish oil research”

- Best designed
- Best controlled
- Most noteworthy

Study comparing human TG vs. EE absorption

Re-esterified Omega-3s • Dry Eye

Purpose

Assess the effect of oral re-esterified omega-3s on classic outcomes of dry eye -- in a controlled manner !!
Re-esterified Omega-3s • Dry Eye

Methods
- Prospective
- Randomized
- Double-masked
- Placebo controlled
- Multicenter
- Interventional trial

Outcomes
- Tear osmolarity
- OSDI symptoms
- Tear film break–up time (TBUT)
- Omega-3 index score (RBC saturation)
- MMP-9 (inflammatory mediators in tears)

Re-esterified Omega-3s • Dry Eye

Methods
- 105 patients
  - 51 placebo group
  - 54 treatment group
  - mean age 56.8 yrs
  - gender 74.4% women

Outcomes
- 4 study visits per patient
  - screening
  - baseline
  - 6 week follow up
  - 12 week follow up
Re-esterified Omega-3s • Dry Eye

Starting at baseline visit each patient received:

Treatment group
- **4 Capsules** of PRN DEOB
  - 1680mg EPA & 560mg DHA (3:1 ratio)
  - Re-esterified triglycerides form

Placebo Group
- **4 Capsules** of safflower oil

**Results: Tear Osmolarity**

<table>
<thead>
<tr>
<th></th>
<th>Screening (Week -1)</th>
<th>Baseline (Week 0)</th>
<th>Week 6</th>
<th>Week 12</th>
<th>Change from Baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omega-3</td>
<td>326 (15)</td>
<td>326 (16)</td>
<td>309 (13)</td>
<td>307 (12)</td>
<td>-19</td>
</tr>
<tr>
<td>Placebo</td>
<td>326 (15)</td>
<td>326 (15)</td>
<td>317 (20)</td>
<td>318 (20)</td>
<td>-8</td>
</tr>
<tr>
<td>p-value*</td>
<td>0.042</td>
<td>0.004</td>
<td>0.004</td>
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</tr>
</tbody>
</table>

**Results: OSDI (symptoms)**

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Week 6</th>
<th>Week 12</th>
<th>Change from Baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omega-3</td>
<td>32 (19)</td>
<td>21 (14)</td>
<td>15 (11)</td>
<td>-17</td>
</tr>
<tr>
<td>Placebo</td>
<td>27 (23)</td>
<td>20 (17)</td>
<td>22 (19)</td>
<td>-5</td>
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<tr>
<td>p-value*</td>
<td>0.285</td>
<td>0.002</td>
<td>0.002</td>
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</table>
Re-esterified Omega-3s • Dry Eye

Tear Break Up Time (TBUT)

<table>
<thead>
<tr>
<th>TBUT (n=105)</th>
<th>Baseline</th>
<th>Week 6</th>
<th>Week 12</th>
<th>Change from Baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omega-3</td>
<td>4.78 (2.96)</td>
<td>6.64 (3.17)</td>
<td>8.25 (4.78)</td>
<td>3.47</td>
</tr>
<tr>
<td>Placebo</td>
<td>4.61 (2.04)</td>
<td>5.55 (2.43)</td>
<td>5.81 (3.13)</td>
<td>1.20</td>
</tr>
<tr>
<td>p-value*</td>
<td>0.126</td>
<td>0.002</td>
<td>0.002</td>
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</tbody>
</table>

MMP-9 positive subjects (%)

<table>
<thead>
<tr>
<th>MMP-9 biomarker (n=105)</th>
<th>Baseline</th>
<th>Week 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omega-3</td>
<td>43</td>
<td>20</td>
</tr>
<tr>
<td>Placebo</td>
<td>32</td>
<td>30</td>
</tr>
<tr>
<td>p-value*</td>
<td>0.095</td>
<td></td>
</tr>
</tbody>
</table>

Omega Index (%)

<table>
<thead>
<tr>
<th>Omega Index (n=105)</th>
<th>Baseline</th>
<th>Week 12</th>
<th>Change from Baseline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omega-3</td>
<td>4.19 (1.04)</td>
<td>7.19 (2.65)</td>
<td>3.00</td>
</tr>
<tr>
<td>Placebo</td>
<td>4.90 (1.36)</td>
<td>5.14 (1.74)</td>
<td>0.24</td>
</tr>
<tr>
<td>p-value*</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td></td>
</tr>
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</table>
Core Conclusion

Just over 2g (2240mg) of re-esterified oral omega-3s demonstrated statistically significant changes in 5 variables associated with dry eye in a well controlled prospective clinical trial.

Discussion

PRN Receives U.S. Patent for its Unique 3:1 Omega-3 Composition – 11/10/2015

Patent No. 9,115,078

“Compositions for Improving the Quality of the Meibum Composition of Inflamed or Dysfunctional Meibomian Glands.”

Take Home Message

Oral re-esterified omega-3s in the proper dose should be included in the primary treatment plan for dry eye, especially for dry eye with a MGD (evaporative dry eye) component.

Thank You!