Giuliano de Oliveira Freitas

COMPARAÇÃO ENTRE O USO DE INCISÕES RELAXANTES LIMBARES E LENTES INTRAOCULARES TÓRICAS NO TRATAMENTO DO ASTIGMATISMO CORNEANO PRÉ-EXISTENTE NA FACOEMULSIFICAÇÃO

Orientador: Prof. Doutor Joel Edmur Boteon

Faculdade de Medicina
Universidade Federal de Minas Gerais
Belo Horizonte – MG
2013

Giuliano de Oliveira Freitas

COMPARAÇÃO ENTRE O USO DE INCISÕES RELAXANTES LIMBARES E LENTES INTRAOCULARES TÓRICAS NO TRATAMENTO DO ASTIGMATISMO CORNEANO PRÉ-EXISTENTE NA FACOEMULSIFICAÇÃO

Tese apresentada ao Programa de Pós-Graduação em Ciências Aplicadas à Cirurgia e à Oftalmologia da Faculdade de Medicina da Universidade Federal de Minas Gerais como requisito parcial para obtenção de título de Doutor em Medicina.

Orientador: Prof. Doutor Joel Edmur Boteon

Área de concentração: Oftalmologia.

Linha de pesquisa: Resposta morfofuncional dos tecidos oculares a agentes químicos, físicos e biológicos.

Faculdade de Medicina
Universidade Federal de Minas Gerais
Belo Horizonte – MG
2013

Freitas, Giuliano de Oliveira.
F866c Comparação entre o uso de incisões relaxantes limbares e lentes intraoculares tóricas no tratamento do astigmatismo corneano pré-existente na facoemulsificação [manuscrito]. / Giuliano de Oliveira Freitas. - - Belo Horizonte: 2013.
143f.: il.
Orientador: Joel Edmur Boteon.
Área de concentração: Oftalmologia.
Tese (doutorado): Universidade Federal de Minas Gerais, Faculdade de Medicina.

1. Facoemulsificação. 2. Astigmatismo. 3. Lentes Intraoculares. 4. Modelos Lineares. 5. Dissertações Acadêmicas. I. Boteon, Joel Edmur. II. Universidade Federal de Minas Gerais, Faculdade de Medicina. III. Título

NLM: WW 310

Ficha catalográfica elaborada pela Biblioteca J. Baeta Vianna – Campus Saúde UFMG

UNIVERSIDADE FEDERAL DE MINAS GERAIS

MAGNÍFICO REITOR
Prof. Clélio Campolina Diniz

VICE-REITORA
Profa. Rocksane de Carvalho Norton

PRÓ-REITOR DE PÓS-GRADUÇÃO
Prof. Ricardo Santiago Gomez

PRÓ-REITOR DE PESQUISA
Prof. Renato de Lima dos Santos

DIRETOR DA FACULDADE DE MEDICINA
Prof. Francisco José Penna

VICE-DIRETOR DA FACULDADE DE MEDICINA
Prof. Tarcizo Afonso Nunes

DIRETOR GERAL DO HOSPITAL DAS CLÍNICAS
Prof. Antônio Luiz Pinho Ribeiro

COORDENADOR DO CENTRO DE PÓS-GRADUAÇÃO DA FACULDADE DE MEDICINA
Prof. Manoel Otávio da Costa Rocha

SUBCOORDENADORA DO CENTRO DE PÓS-GRADUAÇÃO
Profa. Teresa Cristina de Abreu Ferrari

COORDENADOR DO PROGRAMA DE PÓS-GRADUAÇÃO EM CIÊNCIAS APLICADAS À CIRURGIA E À OFTALMOLOGIA
Prof. Marcelo Dias Sanches

Subcoordenadora do Programa de Pós-Graduação em Ciências Aplicadas à Cirurgia e à Oftalmologia
Profa. Ivana Duval de Araújo

Chefe do Departamento de Oftalmologia e Otorrinolaringologia
Profa. Ana Rosa Pimentel de Figueiredo

Chefe do Departamento de Cirurgia
Prof. Marcelo Eller Miranda

Membros do Colegiado do Programa de Pós-Graduação em Ciências Aplicadas à Cirurgia e à Oftalmologia
Prof. Alcino Lázaro da Silva
Profa. Ivana Duval de Araújo
Prof. Marcelo Dias Sanches
Prof. Márcio Bittar Nehemy
Prof. Renato Santiago Gomes
Prof. Tarcizo Afonso Nunes
Representante Discente Titular: Sumara Marques Barral
Representante Discente Suplente: Hévila Tamar Rolim Lima

Aos meus pais, Ademir e Antônia, exemplos de amor e dedicação incondicionais.

Aos meus queridos avós Antônio e Ana, tia Ana Rosa e jovem prima Ana Júlia pelo carinho incomparável que nos une.

A minha amada esposa Luciana, que completa sentido de minha vida, por ser minha companheira de todos os momentos.

AGRADECIMENTOS

A Deus, causa primeira de todas as coisas.

Ao Prof. Doutor Joel Edmur Boteon, pelos ensinamentos, empenho e apoio durante a elaboração do trabalho, bem como, pelo exemplo de postura pessoal e profissional.

Ao Prof. Doutor Rogério de Melo Costa Pinto, da Universidade Federal de Uberlândia (UFU), Uberlândia-MG, que prestou enorme contribuição ao supervisionar a análise estatística de nosso trabalho.

Aos professores da Disciplina de Medicina Preventiva e Comunitária da UFU, em especial, à Profa. Doutora Rosuita Fratari Bonito, amiga e grande incentivadora desta empreitada e ao Prof. Doutor Carlos Henrique Alves de Rezende, entusiasta do método científico, por ter fomentado o interesse pela pesquisa acadêmica.

Aos Oftalmologistas de Goiânia-GO: Dr. Wagner José Xavier Vieira e Dr. Francisco Wellington Rodrigues, bem como aos Prof. Doutores José Beniz Neto e Rodrigo Salustiano Corrêa, que pelo exemplo profissional, serviram-me de modelo a ser seguido.

À Alcon™ do Brasil, por fornecer gratuitamente as lentes intraoculares utilizadas no estudo. Em especial, ao Oftalmologista encarregado pelo departamento de desenvolvimento tecnológico da companhia, Dr. Claudio Spera, pelo total apoio prestado ao nosso projeto, apoio este, sem o qual, nosso projeto não seria viável.

Ao Oftalmologista Dr. Mário José Carvalho e equipe pela realização das cirurgias nas quais o estudo foi embasado.

Aos funcionários do Departamento de Oftalmologia e Otorrinolaringologia da Faculdade de Medicina da Universidade Federal de Minas Gerais (UFMG), representados pela Srta. Rosemary Rodrigues Silva, sempre gentil e atenta a minhas frequentes solicitações.

Aos funcionários do Centro de Pós-Graduação da Faculdade de Medicina da UFMG, representados pela Srta. Mari Rocha.

A todos aqueles que, embora não mencionados aqui, contribuíram de alguma maneira para concretização desta tese.

"O aprender é a única coisa da qual a mente nunca se cansa, não tem receio, nem se arrepende..."

LEONARDO DA VINCI

RESUMO

TÍTULO: Comparação entre o uso de incisões relaxantes limbares e lentes intraoculares tóricas no tratamento do astigmatismo corneano pré-existente na facoemulsificação.

OBJETIVO: Comparar o uso de incisões relaxantes limbares (IRL) e lentes intraoculares (LIO) tóricas, tanto em termos não-vetoriais quanto vetoriais, pelos métodos de Alpins e Thibos, no tratamento do astigmatismo corneano pré-existente por ocasião da facoemulsificação.

MÉTODO: Estudo longitudinal, prospectivo e randomizado sessenta e dois olhos de trinta e um pacientes consecutivos de catarata, com astigmatismo corneano entre 0,75 e 2,50 dioptrias (D) em ambos os olhos, foram aleatoriamente distribuídos em dois grupos: Grupo LIO tórica, os pacientes submetidos a implantes de LIO tórica (modelo AcrySof Toric^{TM}, Alcon^{TM}, Inc.) em ambos os olhos; nos do Grupo IRL foram implantadas LIO esférica (modelo AcrySof Natural^{TM}, Alcon^{TM}, Inc.), sendo confeccionadas IRL também em ambos os olhos. Todos os pacientes foram reavaliados com 1, 3 e 6 meses de pós-operatório, sendo feitas as análises não-vetorial e vetorial do astigmatismo refracional. Variações de resultados entre os grupos e internamente a eles foram estudadas. A razão entre os vetores astigmáticos pós- e pré-operatório de Thibos ($VA_{pós/pré}$), bem como, as regressões lineares dos mesmos com os índices de Alpins também foram avaliadas.

RESULTADOS: Não houve diferença estatística, considerando-se o índice de segurança, entre os grupos IRL e LIO tórica. Os índices de efetividade e eficácia mostraram-se discretamente favoráveis ora a um grupo, ora ao outro. Dentro de um mesmo grupo, houve menor variação de resultados para o grupo LIO tórica. As médias

das magnitudes dos vetores astigmatismo-alvo foram semelhantes entre os grupos, mas as médias das magnitudes dos vetores astigmatismo cirurgicamente induzido mostraram-se vantajosas no grupo LIO tórica. Maior número de olhos alcançou a correção pretendida no grupo LIO tórica, no entanto, casos de hipercorreção também foram mais numerosos nesse grupo. Correlação negativa significativa entre $VA_{pós/pré}$ e o percentual de sucesso ($\%_{Sucesso}$) de Alpins foi demonstrado (ρ=-0,93), sendo a equação de regressão linear dada por: $\%_{Sucesso}$=(-$VA_{pós/pré}$+1.00)x100.

CONCLUSÕES: Nossos dados sugerem que tanto o uso de IRL, quanto o de LIO tórica podem ser consideradas opções efetivas, seguras e eficientes no tratamento do astigmatismo corneano pré-existente. Entretanto, o grupo LIO tórica exibiu estabilidade de resultados ligeiramente maior ao longo do tempo. Análises vetoriais do astigmatismo também são sugestivas de menores diferenças entre a redução planejada e efetivamente obtida favoravelmente ao grupo LIO tórica. A equação de regressão linear entre $VA_{pós/pré}$ e $\%_{Sucesso}$ constitui-se em instrumento matemático validado para avaliação do sucesso da cirurgia do astigmatismo em termos gerais.

DESCRITORES

Facoemulsificação. Astigmatismo. Tratamento. Lente intraocular. Modelo linear.

ABSTRACT

TITLE: Comparison between the usage of limbal relaxing incisions and toric intraocular lenses in the treatment of preexisting corneal astigmatism during phacoemulsification.

OBJECTIVE: To compare limbal relaxing incisions (LRI) and toric intraocular lenses (IOL) in terms of non-vectorial methods and both Alpins and Thibos vectorial analises in the treatment of preexisting corneal astigmatism during phacoemulsification.

METHODS: This longitudinal, randomized, prospective study assessed 62 eyes of 31 consecutive cataract patients with preoperative corneal astigmatism between 0.75 and 2.50 diopters in both eyes. Patients were randomly assorted among two phacoemulsification groups: one assigned to receive AcrySof Toric^{TM} IOL in both eyes and another assigned to have AcrySof Natural^{TM} IOL associated with LRI, also in both eyes. All patients were evaluated postoperatively at 1, 3 and 6 months, when refractive astigmatism analysis was performed using non-vectorial and vectorial methods. Outcomes variability within each group and between groups was assessed. The ratio between Thibos post- and preoperative astigmatic power vectors (APV_{ratio}) and its linear regression to Alpins indices were also assessed.

RESULTS: There was no statistical difference in safety index between LRI and toric IOL groups. Predictability and efficacy index seldom exhibited differences, favorable to one or another group. Within each group, toric IOL group showed slightly greater outcomes stability. Mean magnitudes of target induced astigmatism vectors were similiar between groups, but mean magnitudes of surgically induced astigmatism, difference vectors and indices derived from such vectors were advantageous in the

toric IOL group. A greater number of eyes achieved the intended correction in the toric IOL group. Overcorrection cases occured more often in the toric IOL group. Significant negative correlation between the ratio of post- and preoperative Thibos APV_{ratio} and Alpins percentage of success ($\%_{Success}$) was found (Spearman's ρ=-0.93); linear regression we found is given by the following equation: $\%_{Success}=(-APV_{ratio}+1.00)x100$.

CONCLUSIONS: Our data suggest that both LRI and toric IOL are predictable, safe and efficient options in the treatment of preexisting astigmatism. However, toric IOLs exhibited a slightly greater stability in outcomes over time. Vectorial analisys also suggests lesser differences between planned and achieved reductions were observed more often in toric IOL group. Linear regression we found between APV_{ratio} and $\%_{Success}$ permits a validated mathematical inference concerning the overall success of astigmatic surgery.

KEYWORDS

Phacoemulsification. Astigmatism. Treatment. Intraocular lens. Linear model.

LISTA DE ABREVIATURAS

ABO	Arquivos Brasileiros de Oftalmologia
APV	*Thibos Astigmatic Power Vectors*
APV_{ratio}	*Ratio between Thibos post- and preoperative astigmatic power vectors*
AVCC	Acuidade visual com correção
AVSC	Acuidade visual sem correção
CI	*Correction Index*
D	*Diopter (*ou *Diopters)* / Dioptria (ou dioptrias)
DCVA	*Distance Corrected Visual Acuity*
DV	*Difference Vector*
EI	*Efficacy Index*
F	*Females* / Feminino
FI	*Flattening Index*
G.F.	Giuliano de Oliveira Freitas
Inc.	*Incorporated*
IOL	*Intraocular lens (*ou *Intraocular Lenses)*
IoS	*Index of Success*
IRL	Incisão Relaxante Limbar (ou Incisões Relaxantes Limbares)
J_0	*Thibos J_0-coordinate at astigmatic plane*
J_{45}	*Thibos J_{45}-coordinate at astigmatic plane*
LIO	Lente Intraocular (ou Lentes Intraoculares)
LRI	*Limbal Relaxing Incision (*ou *Limbal Relaxing Incisions)*
logMAR	Logarítmo de resolução angular mínima
M	*Males* / Masculino
M	*Spherical power in Thibos coordinate*
M.C. **ou** MJC	Mário José Carvalho
ME	*Magnitude of Error*
mm	*Milimeters* / Milímetros

n	*Number*
Preop.	*Preoperative period*
R^2	*Pearson's linear correlation coefficient* / Coeficiente de correlação linear de Pearson
RBO	Revista Brasileira de Oftalmologia
SD	*Standard Deviation*
SDCVA	*Spectacle Distance Corrected Visual Acuity*
SE	*Spherical Equivalent*
SI	*Safety Index*
SIA	*Surgically Induced Astigmatism*
SPSS	*Statistical Package for the Social Sciences*
T3	*AcrySof Toric™ T3 IOL* / LIO AcrySof Toric™ T3
T4	*AcrySof Toric™ T4 IOL* / LIO AcrySof Toric™ T4
T5	*AcrySof Toric™ T5 IOL* / LIO AcrySof Toric™ T5
TCLE	Termo de Consentimento Livre e Esclarecido
TIA	*Target Induced Astigmatism*
UDVA	*Uncorrected Distance Visual Acuity*
UFMG	Universidade Federal de Minas Gerais
$VA_{pós/pré}$	Razão entre os vetores astigmáticos pós- e pré-operatório de Thibos
y	*Years*
6 m **ou** 6-m PO	*6-month postoperative period*
α	*Thibos meridian of maximum positive power or anlge of astigmatic prescription*
ΔSE_1	*1-month postoperative spherical equivalent minus preoperative target spherical equivalent*
ΔSE_3	*3-month postoperative spherical equivalent minus preoperative target spherical equivalent*
ΔSE_6	*6-month postoperative spherical equivalent minus preoperative target spherical equivalent*
µm	*Micrometers* / Micrômetros
#	*Número ordinal*

^{TM}	*Trade Mark* / Símbolo indicativo de nome comercial
ρ	*Spearman's linear correlation coefficient* / Coeficiente de correlação linear de Spearman
^{o}	*Degree (*ou *degrees) /* Grau (ou graus)
$\%_{Success}$	*Alpins percentage of success*
$\%_{Sucesso}$	Percentual de sucesso de Alpins

LISTA DE TABELAS

PRIMEIRO TRABALHO

TRATAMENTO DO ASTIGMATISMO POR OCASIÃO DA FACOEMULSIFICAÇÃO: REVISÃO E EMBASAMENTO DAS ESTRATÉGIAS CIRÚRGICAS ATUAIS

NÃO SÃO APRESENTADAS TABELAS NESTE TRABALHO

SEGUNDO TRABALHO

TRATAMENTO DO ASTIGMATISMO DURANTE A FACOEMULSIFICAÇÃO

TERCEIRO TRABALHO

COMPARAÇÃO DE RESULTADOS CLÍNICOS ENTRE INCISÕES RELAXANTES LIMBARES E LENTES INTRAOCULARES TÓRICAS EM OLHOS COM CÓRNEAS ASTIGMÁTICAS

QUARTO TRABALHO

ANÁLISES VETORIAIS DE ALPINS E THIBOS PARA O ASTIGMATISMO – PROPOSTA DE MODELO DE REGRESSÃO LINEAR ENTRE ESTES MÉTODOS

LISTA DE FIGURAS

PRIMEIRO TRABALHO

TRATAMENTO DO ASTIGMATISMO POR OCASIÃO DA FACOEMULSIFICAÇÃO: REVISÃO E EMBASAMENTO DAS ESTRATÉGIAS CIRÚRGICAS ATUAIS

SEGUNDO TRABALHO

TRATAMENTO DO ASTIGMATISMO DURANTE A FACOEMULSIFICAÇÃO

TERCEIRO TRABALHO

COMPARAÇÃO DE RESULTADOS CLÍNICOS ENTRE INCISÕES RELAXANTES LIMBARES E LENTES INTRAOCULARES TÓRICAS EM OLHOS COM CÓRNEAS ASTIGMÁTICAS

QUARTO TRABALHO

ANÁLISES VETORIAIS DE ALPINS E THIBOS PARA O ASTIGMATISMO – PROPOSTA DE MODELO DE REGRESSÃO LINEAR ENTRE ESTES MÉTODOS

SUMÁRIO

1 INTRODUÇÃO

O astigmatismo é um erro refracional que acarreta prejuízos à visão, podendo acometer a população geral, em especial na faixa de idade para a qual a catarata assume relevância. Ao menos, 15 a 20% dos pacientes com catarata têm 1,50 dioptrias (D), ou mais, de astigmatismo corneano. Com o aumento das expectativas por bons resultados refracionais, por parte dos pacientes, a tendência atual é de não somente remover a catarata, mas também, de eliminar o problema do astigmatismo pré-existente, por ocasião da facoemulsificação. Por isso, a facoemulsificação vem sendo considerada como procedimento verdadeiramente refrativo. (1)

Um modo de abordar o astigmatismo, simultaneamente à cirurgia da catarata, consiste no tratamento do cilindro corneano pré-existente por meio da confecção de incisões relaxantes limbares (IRL). (2, 3) No entanto, é possível que fatores biomecânicos da córnea comprometam, ao menos parcialmente, os resultados refracionais a longo prazo. (4)

O implante de lente intraocular (LIO) tórica constitui-se em alternativa às IRL para a correção do astigmatismo corneano pré-existente em pacientes candidatos à facoemulsificação. Diversos estudos têm analisado os resultados da implantação de diferentes modelos de LIO tóricas, mostrando bons resultados na correção do astigmatismo. Rotação indesejada da LIO tórica, após a implantação, tem sido o principal problema associado a esta estratégia. Estima-se que, para cada grau de rotação da LIO tórica, haja perda de cerca de 3,3% da correção cilíndrica pretendida. (5)

Considerando-se vantagens e limitações inerentes a cada técnica, afirmar que uma opção é inequivocamente superior à outra, para a correção do astigmatismo corneano pré-existente durante a facoemulsificação, permanece controverso. (6)

2 OBJETIVOS

Comparar o emprego de IRL e LIO tórica no tratamento do astigmatismo corneano pré-existente por ocasião da facoemulsificação, não-vetorialmente em termos de efetividade, segurança e eficácia, bem como, vetorialmente, tanto pelos métodos de Alpins quanto de Thibos, buscando correlacionar ambos os métodos de análise vetorial.

3 REVISÃO DA LITERATURA

Apresentada sob a forma de artigo de revisão, aceito para publicação, em inglês, pela Revista Brasileira de Oftalmologia (RBO), como pode ser visto na seção: "**PRIMEIRO TRABALHO -** TRATAMENTO DO ASTIGMATISMO POR OCASIÃO DA FACOEMULSIFICAÇÃO: REVISÃO E EMBASAMENTO DAS ESTRATÉGIAS CIRÚRGICAS ATUAIS" a partir da página 36.

4 MÉTODO

4.1 DESENHO DO ESTUDO

Estudo longitudinal, prospectivo e randomizado, no qual 31 pacientes consecutivos de catarata, com astigmatismo corneano entre 0,75 e 2,50 D em ambos os olhos (totalizando 62 olhos), foram aleatoriamente distribuídos em dois grupos: Grupo LIO tórica, com pacientes a serem submetidos a implantes de LIO tóricas (modelo AcrySof Toric^{TM}, Alcon^{TM}, Inc.) em ambos os olhos e Grupo IRL, no qual foram confeccionadas IRL e implantadas LIO esféricas em ambos os olhos (modelo AcrySof Natural^{TM}, Alcon^{TM}, Inc.). Idealmente, o número teórico de olhos estudados, ao se considerar o nível de sensibilidade e especificidade de 80% e intervalo de confiança de 95% (7), bem como a prevalência de cerca de 28% da faixa de astigmatismo estudada (8), deveria ser de 318 olhos (159 pacientes). Tal número, no entanto, inviabilizaria a realização do estudo no prazo compatível com a conclusão da pós-graduação. Estudos semelhantes ao nosso, publicados em periódicos de alto impacto, contam com amostras menores ou semelhantes à nossa (1, 3, 5, 6). Todos os pacientes assinaram um termo de consentimento livre e esclarecido (TCLE), após serem informados não só sobre a natureza do estudo, mas também das complicações potenciais do mesmo, de acordo com as recomendações da Declaração de Helsinki, mediante aprovação prévia pelo Comitê de Ética em Pesquisa da UFMG. As cirurgias foram realizadas entre maio de 2010 e junho de 2012 no ISO Olhos, Instituto de Saúde Ocular em Uberlândia-MG.

4.2 CRITÉRIOS DE INCLUSÃO

Idade acima de 40 anos, ocorrência de catarata clinicamente significativa (melhor acuidade visual corrigida pior que LogMAR

0,3), astigmatismo corneano regular pré-existente entre 0,75 e 2,50 D, midríase farmacológica de, ao menos, 6,0 milímetros (mm), em ambos os olhos, para permitir visualização intraoperatória adequada das marcações indicativas do eixo na LIO tórica.

4.3 Critérios de exclusão

Cirurgia ocular prévia, pterígio, qualquer condição ocular que pudesse cursar com baixa de acuidade visual no pós-operatório (leucoma, uveíte, glaucoma avançado, neurite óptica, maculopatia clinicamente significativa ou retinopatia), anormalidades zonulares ou pupilares e qualquer astigmatismo corneano irregular.

4.4 Avaliação pré-operatória

Cada paciente foi submetido a avaliação oftálmica que incluiu a aferição da melhor acuidade visual corrigida, refratometria dinâmica, biomicrosopia à lâmpada de fenda, tonometria de aplanação e fundoscopia sob midríase farmacológica. Bem como topografia corneana (Orbscan™ II, Bausch&Lomb™, Inc.) e biometria ultrassônica de imersão (OcuScan™, Alcon™, Inc.).

4.5 Planejamento cirúrgico

Empregou-se a fórmula biométrica Hoffer Q em olhos com comprimento axial menor que 22 mm e a fórmula SRK/T em todos os demais casos.

A seleção do grupo ao qual cada paciente pertenceria deu-se por meio de sorteio conduzido por examinador (*G.F.*), que não o cirurgião, pelo emprego da função "***ƒ*=RANDBETWEEN(1;2)**" do Microsoft Excel™, sendo 1 = grupo LIO tórica e 2 = grupo IRL.

A seleção do poder cilíndrico, bem como o posicionamento da LIO tórica foram determinados pelo *software online* do fabricante (www.acrysoftoriccalculator.com). A extensão e localização das IRL também foram determinadas via *software online* (www.lricalculator.com), conforme o nomograma de Donnenfeld.

Tanto para o Grupo LIO tórica, quanto para o Grupo IRL, além dos dados biométricos, ceratométricos e localização temporal da incisão principal, também o astigmatismo cirurgicamente induzido por ela (padronizado em -0,50 D) foram levados em consideração no planejamento cirúrgico. A refratometria desejada para o pós-operatório foi a mais próxima possível da emetropia, ou seja, ametropia esférica nula (plano), associada ao menor cilindro residual possível. (9, 10)

4.6 Técnica cirúrgica

Todas as cirurgias foram realizadas pelo mesmo cirurgião (*M.C.*), sob sedação leve e anestesia tópica. Imediatamente antes da cirurgia, uma caneta hidrográfica estéril foi usada com a finalidade de marcar o limbo corneano nas posições de zero e 180^{o} com o paciente à lâmpada de fenda, para diminuir os efeitos da oculotorsão.

Em ambos os grupos, empregou-se incisão principal temporal, limbar e monoplanar com 2,75 mm de largura. Para o Grupo LIO tórica, a LIO foi alinhada com o eixo planejado. No Grupo IRL, as incisões foram confeccionadas no limbo, empregando-se bisturi específico de diamante, ajustado para 600 micrômetros (µm) de profundidade.

4.7 Acompanhamento pós-operatório

Todos os pacientes foram reavaliados aos um, três e seis meses de pós-operatório, por outro examinador, que não o

cirurgião (*G.F.*). Nova refratometria dinâmica (ametropias esférica e cilínrica, a partir das quais, calculou-se o equivalente esférico), acuidade visual sem correção para longe (AVSC) e melhor acuidade visual corrigida, ao refrator, para longe (AVCC) foram aferidas. Efetividade, expressa pelo percentual de olhos entre ±1,00 D ou entre ±0,50 D do equivalente esférico pretendido; índice de segurança, determinado pela razão entre AVCC pós-operatória e a AVCC pré-operatória e, ainda, o índice de eficácia, calculado pela razão entre AVSC pós-operatória e a AVCC pré-operatória. (11) Os cálculos dos parâmetros de Alpins (12) e dos vetores de Thibos (13, 14), para o astigmatismo refracional, foram feitos, para cada reavaliação, empregando-se planilhas do Microsoft Excel™ (versão 12.2.7, Microsoft para MacIntosh™). Testes do normalidade de Shapiro-Wilk foram realizados por meio do *software* IBM™ SPSS™ (versão 20.0.0 para Microsoft Windows™). Valores de $p \leq 0,05$ foram considerados estatisticamente significativos. (15) Coeficientes de correlação linear (R^2) de Pearson's ou (ρ) de Spearman, para regressões paramétricas e não-paramétricas respectivamente, foram usadas conforme o caso. (16) *Bootstrapping* (com intervalo de confiança de 95%) foi empregado a cada regressão. (17) O teste de Wilcoxon foi utilizado para análises estatísticas não-paramétricas entre diferenças dentro de um mesmo grupo ao longo de período estudado. O teste U de Mann-Whitney foi empregado na determinação de diferenças entre os grupos LIO tórica e IRL a cada reavaliação. (3)

5 RESULTADOS, DISCUSSÃO E CONCLUSÕES

Apresentação e análise, em profundidade, dos resultados, bem como, as conclusões advindas dessas análises são expostas ao longo de três trabalhos originais aceitos para publicação, apresentados na seção "**ARTIGOS ORIGINAIS**", do segundo ao quarto trabalho, a partir da página 57.

REFERÊNCIAS

1. Alió JL, Agdeppa MCC, Pongo VC, Kady BE. Microincision cataract surgery with toric intraocular lens implantation for correcting moderate and high astigmatism: Pilot study. J Cataract Refract Surg. 2010;36:44-52.

2. Muftuoglu O, Dao L, Cavanagh HD, McCulley JP, Bowman RW. Limbal relaxing incisions at the time of apodized diffractive multifocal intraocular lens implantation to reduce astigmatism with or without subsequent laser in situ keratomileusis. J Cataract Refract Surg. 2010;36:456-64.

3. Carvalho MJ, Higashitani-Suzuki S, Lemes-Freitas L. Limbal relaxing incisions to correct corneal astigmatism during phacoemulsification. J Refract Surg. 2007;23:499-504.

4. Kamiya K, Shimizu K, Ohmoto F, Amano R. Evaluation of corneal biomechanical parameters after simultaneous phacoemulsification with intraocular lens implantation and limbal relaxing incisions. J Cataract Refract Surg. 2011;37:265-70.

5. Mendicute J, Irigoyen C, Aramberri J, Ondarra A, Montés-Micó R. Foldable toric intraocular lens for astigmatism correction in cataract patients. J Cataract Refract Surg. 2008;34:601-7.

6. Mingo-Botín D, Muñoz-Negrete F, Kim HRW, Morcillo-Laiz R, Rebolleda G, Oblanca N. Comparison of toric intraocular lenses and peripheral corneal relaxing incisions to treat astigmatism during cataract surgery. J Cataract Refract Surg. 2010;36:1700-8.

7. Bochmann F, Johnson Z, Azuara-Blanco A. Sample size in studies on diagnostic accuracy in ophthalmology: a literature survey. Br J Ophthalmol 2007;91:898–900.

8. Ferrer-Blasco T, Montés-Micó R, Peixoto-de-Matos SC, González-Méijome JM, Cerviño A. Prevalence of corneal astigmatism before cataract surgery. J Cataract Refract Surg. 2009;35:70-5.

9. Behndig A, Montan P, Stenevi U, Kugelberg M, Zetterström C, Lundström M. Aiming for emmetropia after cataract surgery: Swedish National Cataract Register Study. J Cataract Refract Surg. 2012;38:1181-6.

10. Goggin M, Moore S, Esterman A. Outcome of Toric Intraocular Lens Implantation After Adjusting for Anterior Chamber Depth and Intraocular Lens Sphere Equivalent Power Effects. Arch Ophthalmol. 2011;129(8):998-1003.

11. Ferrer-Blasco T, García-Lázaro S, Albarrán-Diego C, Belda-Salmerón L, Montés-Micó R. Refractive lens exchange with a multifocal diffractive aspheric intraocular lens. Arq Bras Oftalmol. 2012;75:192-6.

12. Alpins N. A new method of analyzing vectors for changes in astigmatism. J Cataract Refract Surg. 1993;19:524-33.

13. Thibos LN, Wheeler W. Power vectors: an application of Fourier analysis to the description and statistical analysis of refractive error. Optom Vis Scie. 1997;74:367-75.

14. Thibos LN, Horner D. Power vector analysis of the optical outcome of refractive surgery. J Cataract Refract Surg. 2001;27:80-5.

15. Razali NM, Wah Y. Power comparisons of Shapiro-Wilk, Kolmogorov-Smirnov, Lilliefors and Anderson-Darling tests. Journal of Statistical Modeling and Analytics. 2011;2(1):21-33.

16. Shi R, Conrad S. Correlation and regression analysis. Annals of Allergy, Asthma & Immunology. 2009;103(4):S35-S42.

17. Carpenter J, Bithell J. Bootstrap confidence intervals: When, which, what? A practical guide for medical staticians. Stat Med. 2000;19:1141-64.

PRIMEIRO TRABALHO

Status: Artigo de revisão aceito pela RBO em 11/04/2013.

Astigmatism treatment by the time of phacoemulsification: a review of current surgical strategies and their rationale

Tratamento do astigmatismo por ocasião da facoemulsificação: revisão e embasamento das estratégias cirúrgicas atuais

Giuliano de O. Freitas, M.D., Research Fellow at the Federal University of Minas Gerais, Belo Horizonte-MG, Staff of Cataract Surgery Department at ISO Olhos – Instituto de Saúde Ocular, Uberlândia-MG, Brazil.

Joel E. Boteon, Ph.D., M.D., Ophthalmology Professor at the Federal University of Minas Gerais, Belo Horizonte-MG, Brazil.

Mario J. Carvalho, M.D., Head of Cataract Surgery Department at ISO-Olhos – ISO Olhos – Instituto de Saúde Ocular, Uberlândndia-MG, Brazil.

Rogerio M.C. Pinto, D.A., Biostatistics Professor at the Federal University of Uberlândia, Uberlândia-MG, Brazil.

Financial Disclosure: No author has a financial or proprietary interest in any material or method mentioned.

Corresponding author: Giuliano de O. Freitas

Address: ISO Olhos, R. Eduardo Marquez 50

Martins, Uberlândia-MG/Brazil, ZIP Code 38.400-442

Phone: +55 (34) 3230-5050

Fax: + 55 (34) 3230-5055

E-mail: gofreitas@ufmg.br

Abstract

Preexisting corneal astigmatism, present at the time of cataract surgery, is reviewed in detail throughout this article on its most important aspects such as occurrence rates, clinical relevance and current treatment options. Special emphasis is given to the latter aspect. Each method's rationale, advantage and limitation is highlightened. Comparisons between treatment options, whenever possible, are also provided.

Key-words

Astigmatism; cataract; phacoemulsification; opposed clear corneal incisions; limbal relaxing incisions; toric intraocular lenses.

Resumo

O astigmatismo corneano pré-existente, por ocasião da cirurgia de catarata, é detalhadamente revisado neste artigo sob aspectos como: ocorrência, relevância clínica e opções de tratamento atualmente disponíveis. Ênfase é dada a este último critério. O embasamento téorico de cada método, bem como vantagens e imitações foram destacados. Comparações ente as opções terapêuticas, sempre que possível, são oferecidas.

Descritores

Astigmatismo; catarata; facoemulsificação; incisões *clear cornea* opostas; incisões relaxantes limbares; lentes intraoculares tóricas.

Introduction

Cataract surgery has evolved over the past few years with new surgical techniques, devices and improvements in the design of intraocular lenses, shifting from traditional spheric-monofocal lenses to aspheric, toric, pseudoaccomodative, accomodative or a combination of these features. (1, 2) It is, currently, among the most performed planned surgical procedures worldwide, positively impacting over patients' quality of life. (3, 4)

Astigmatism is a visually disabling refractive error affecting the general population, specially those with cataracts. (5) With increased patients' expectations, the trend is not only to remove the cataract, but also to address the problem of preexisting astigmatism at the time of phacoemulsification. In addition to being a therapeutic procedure, cataract surgery is currently considered as a surgical approach for refractive errors. (5) The amount of techniques available to correct astigmatism during phacoemulsification suggests that the issue of astigmatism treatment by the time of phacoemulsification is currently under debate. (6)

Methods of Literature Search

PubMed and SciELO were searched on February 22nd 2013 using search words *astigmatism* and *phacoemulsification*. Retrieved references with no abstracts were not considered. This initial search retrieved 896 abstracts in English, Portuguese or Spanish, published from 1993 to 2013. Fifty-eight relevant references, concerning pre-existing corneal astigmatism or surgically induced astigmatism, were, thus, obtained and reviewed in detail.

Results

Definition of Astigmatism

In an optimal stigmatic (point-like) optical system, a point in the object space is focused as a point image. The shape of the blurred image, for out-of-focus point objects, is always a circle.

An astigmatic optical system is nonpoint-like. In a regular astigmatic optical system an object point is focused as two mutually perpendicular line segments delimiting an intermediate interval, termed Sturm's conoid. No point focus is formed, but the blurred image attains different shapes and directions in Sturm's interval. The focal lines define the orthogonal principal meridians of the conoid. Differential magnification in the principal meridians means that the focal line segments have different lengths. Irregular astigmatism is the non-stigmatic and non-regular astigmatic part of the refractive spectrum. In wave-front analysis, stigmatic and regular astigmatic powers – correctable by spherocylinders - are termed lower-order aberrations. Irregular astigmatic elements are called higher-order aberrations. (7)

Prevalence of Astigmatism

A significant number of patients having cataract surgery have a degree of preexisting corneal astigmatism. (8-11) Estimates of the incidence of significant, naturally occurring astigmatism vary widely from 7.5% to 75%. (11-13) In a study comprising 4540 eyes (in 2415 patients), 13.2% of eyes did not present corneal astigmatism, 64.6% had corneal astigmatism between 0.25 and 1.25 D, and 22.2% had

astigmatism of 1.50 D or higher, as can be seen from figure 1. (9)

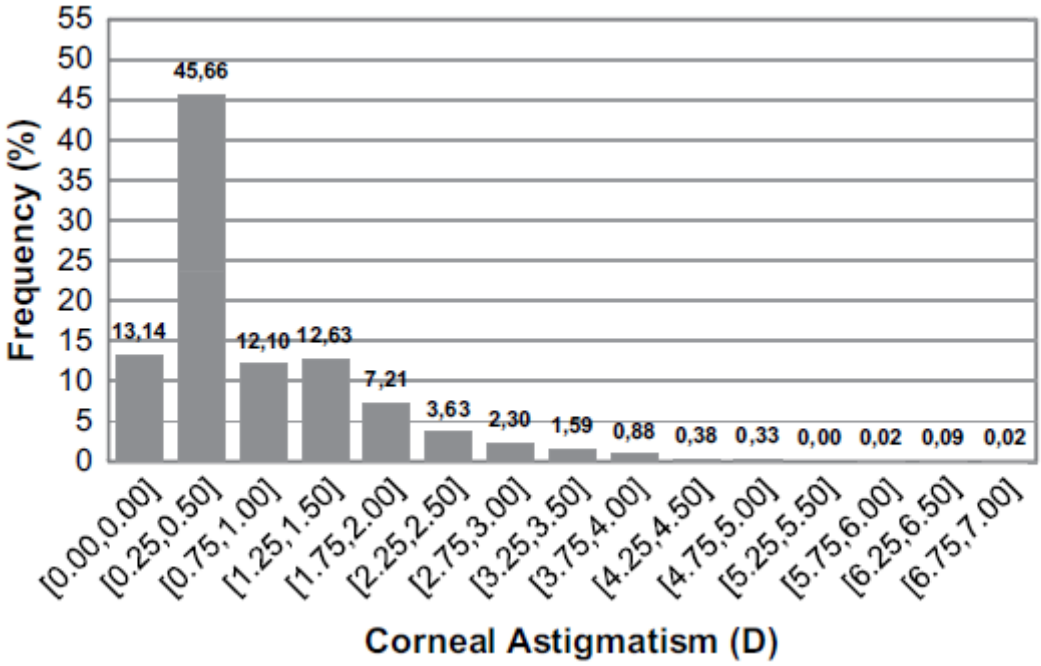


Figure 1. Histogram of the corneal astigmatism distribution in the entire sample (4540 eyes). (9)

Classification of Corneal Astigmatism Magnitudes

Corneal astigmatism power may be considered as mild up to 1.00 D. Moderate, for magnitudes between 1.0 D and 2.00 D, or highly astigmatic if equals to, or greater than the upper limit of 2.00 D. (14)

Astigmatism Analysis

Meaningful analysis of astigmatic data is essential to understanding the results of refractive and cataract surgical procedures. Certain elements of astigmatic analysis are simple and straightforward, but other aspects can be extraordinarily complex. Several investigators have developed

elaborate methods of further describing and characterizing astigmatic change. Such methods may exhibit marked differences among each other: (15)

Alpins and coworkers (16-19) use vector analysis to generate various indices to more fully describe astigmatic outcomes. Many of these indices, such as difference vector, index of success and coefficient of adjustment, provide remarkably useful and intuitive means of understanding the effects of the surgery.

Thibos and coworkers (20, 21) take another approach to analyzing astigmatic data. This method separates refractive data into 3 power vectors: spherical equivalent and 2 Jackson crossed cylinders separated by 45 degrees. With these, they can demonstrate analysis of the data with useful graphic depictions. Thibos also calculates the blur strength, which is another index that can be used to characterize the effect on vision of the spherical and astigmatic components of the residual refractive errors.

Naeser and Hjortdal use polar analysis, as an alternative to vectorial analisys, in which they characterize any astigmatic value by 2 polar values that are separated by 45 degrees. In a subsequent work, Naeser and Hjortdal extended their methodology to trivariate analysis, which provides a 3-dimensional depiction that displays both polar values and the spherical equivalent. (15)

Optical and Physiological Effects of Ocular Astigmatism

Optical effects of ocular astigmatism are blur and distortion. (7) Astigmatism of as little as 0.75 D may leave a patient symptomatic (12, 13) Blur is the lack of point focus and altered shape of the retinal image caused by the astigmatism. Distortion is the altered shape of objects caused

by unequal magnification of the retinal image in the various meridians. (7)

Treatment options

Perhaps the most challenging aspect of astigmatism surgery involves the determination of the quantity and exact location of the cylinder that is to be corrected. (12, 22, 23), Unfortunately, preoperative measurements (keratometry, refraction, and corneal topography) do not always correlate. Lenticular astigmatism may account for some of this disparity, particularly in cases where there is a wide variance between refraction and corneal measurements; however, some discrepancies are likely caused by the inherent shortcomings of traditional measurements of astigmatism. Standard keratometry, for example, measures only two points in each meridian at a single optical zone of approximately 3 mm. Corneal topography can be very helpful when refraction and keratometry do not agree, and it is increasingly becoming the overall guiding measurement on which the surgical plans are based. (12)

Posterior corneal astigmatism contribution to total corneal astigmatism is gaining interest, in recent years, due to increasing number of cases of unintended astigmatism under- or overcorrections. (24, 25)

a) Incisional approach

Incisional surgery creates gaping of the wound, addition of tissue in the incision, and elongation of the radius of curvature with subsequent flattening of the central cornea along the surgical meridian. Surgically induced astigmatism following tangential and arcuate incisions is characterized by coupling, by which an astigmatic change in one meridian is

followed by a similar change in the orthogonal meridian with no net change in spherical equivalent refraction. Tight sutures will flatten the tissue around the incision with an initial steepening of the central cornea. Sutures have no long-time effect on astigmatism and an initial with-the-rule astigmatism is followed by against-the-rule decay after superior sutured cataract incisions. Surgically induced astigmatism after incisional surgery is predominantly influenced by wound length and placement, while patient age, preoperative astigmatism, and intraocular pressure play minor roles. Ablational laser surgery does not generate a coupling effect, and the spherical effect of ablation for astigmatism must be taken into account. (7)

A viable and relatively simple way to decrease astigmatism is to manipulate the cataract incision to impact favorably pre-existing astigmatism. This may be accomplished by first centering the incision on the steep corneal meridian (hence to be termed “on axis” technique) and then by varying its size and design, to affect a desired amount of wound flattening, and hence a decrease in cylinder. Such an approach, however, presents logistical challenges including movement around the surgical table, often producing awkward hand positions. (12, 26-28)

Opposite clear corneal incisions may also be used to address pre-existing astigmatism. (12, 29) In this technique, a second opposite penetrating clear corneal incision is placed over the steep meridian 180 degrees away from the main incision. This approach is technically simple and requires no additional instrumentation; however, a second substantial penetrating incision is now present, possibly increasing the risk of wound leak or even infection. In addition, single-plane beveled incisions are known to be less effective, for a given arc length, at flattening the cornea as compared with traditional perpendicular relaxing incisions. (12)

For the reasons mentioned above, both on axis and opposite clear corneal incisions techniques have largely been supplanted by the use of a consistent and astigmatically neutral phacoincision, typically placed temporally, for stability, and then adding supplemental limbal relaxing incisions (LRI). (12, 30) Such an approach have become the most popular way to manage astigmatism at the time of cataract surgery. (12, 31-39) The use of LRI offer several advantages over astigmatic incisions placed within the cornea, at smaller optical zones, including less chance of causing a shift in the resultant cylinder axis and a lesser tendency to cause irregular corneal flattening with irregular astigmatism. Technically, LRI are easier to perform and more forgiving than shorter and more central corneal astigmatic incisions. (12, 31) Another important advantage gained by moving out to the limbus involves the coupling ratio, which describes the amount of flattening that occurs in the incised meridian relative to the amount of steepening that results 90 degrees away; paired LRIs (when kept at or under 90 degrees of arc length) exhibit a very consistent 1:1 ratio, and elicit no change in spherical equivalent refraction, obviating the need to make any change in implant power. Admittedly, these more peripheral incisions are less powerful, but are still capable of correcting up to 3.50 D of astigmatism in the cataract-aged population. One must keep in mind that the goal is to reduce the patient's cylinder, without overcorrecting or shifting the resultant axis. Their stability may well be caused by the proximity of well-vascularized limbal tissue. Nonetheless, as with any surgical technique, potential complications exist, the most likely to be encountered is the placement of incisions on the wrong axis. When this occurs, it typically takes the form of a 90-degree error with positioning on the opposite, flat meridian. This results in an increase and likely doubling of the patient's preexisting cylinder. (12)

b) Non-incisional approach

A recent advance in cataract surgery was the introduction of toric intraocular lenses (IOL) for the correction of preexisting corneal astigmatism. (40-46) The use of toric IOL have been reported to be an effective method of reducing postoperative refractive astigmatism and spectacle dependence following cataract surgery. (47) Rotational stability of toric IOL is an issue of major concern, once proper alignment is critical for compensating corneal cylinder, resulting in good uncorrected vision. Each degree of rotation causes an average loss of cylinder power of approximately 3%; thus, when an IOL rotates 30 degrees there is no astigmatic correction, although there is a change of axis. (44, 48-55). Articles comparing the use of toric IOL to other astigmatism reducing techniques, such as opposed clear corneal incisions (56) or LRI (57), are still scanty in number on literature. Slightly advantageous outcomes, favoring toric IOL have been reported (56, 57), but debate on which technique unequivocally offers better results is just at the beginning. Toric IOL may also be employed in conjunction to such techniques aiming further refractive improvements. (38)

Correction of unintentional residual ametropia may be achieved by excimer laser enhancement procedures. Such an approach exploits the advanced technology and exquisite accuracy of the excimer lasers. (12, 58) Phacoemulsification wound healing, along with a stable refractive error, must be confirmed prior to enhancement procedures. Custom wavefront-guided ablations are particularly well suited in the scenario of a pseudophakic eye, because the dynamic lens component no longer exists. For a few cataract surgeons, excimer laser enhancements have become part of the routine preoperative discussion with patients. (12)

Conclusions

Due to the prevalence of preexisting corneal astigmatism among cataract patients and its effects on final visual acuity, it is demanding for the cataract surgeon to address astigmatism, by the time of phacoemulsifcation, effectively as possible. Although several astigmatism reducing techniques exist, LRI and toric IOL are the most often used methods. Both strategies show limitations, advantages and drawbacks inherent to their use. The present review is part of an on going Doctorate Thesis designed to further compare these two methods.

References

1. Hida WT, Motta AFP, Kara-Junior N, Alves E, Tadeu M, Cordeiro LN, Nakano CT. Comparison between OPD-Scan results and visual outcomes of monofocal and multifocal intraocular lenses. Arq Bras Oftalmol. 2009;72(4):526-32.

2. Kara-Jose Junior N, Santhiago MR. Lentes asféricas: avaliação da indicação clínica e das opções de lentes. Rev Bras Oftalmol. 2009;68(3):175-9.

3. Kara-Jose Junior N, Santhiago MR, Parede TRR, Espindola RF, Mazurek MGG, Germano R, Kara-Jose N. Influência da correção cirúrgica da catarata na percepção laborativa. Arq Bras Oftalmol. 2010;73(6):491-3.

4. Gothwal VK, Wright TA, Lamoureux EL, Pesudovs K. Measuring outcomes of cataract surgery using the Visual Function Index-14. Cataract Refract Surg. 2010;36:1181-8.

5. Alió JL, Agdeppa M, Pongo VC, Kady BE. Microincision cataract surgery with toric intraocular lens implantation for correcting moderate and high astigmatism: Pilot study. J Cataract Refract Surg. 2010;36:44-52.

6. Carvalho MJ. Correção do astigmatismo corneano com incisão relaxante limbar na cirurgia de catarata. Tese (Doutorado) – Universidade Federal de São Paulo – Escola Paulista de Medicina – São Paulo 2003. 2003:1-21.

7. Naeser K. Assessment and statistics of surgically induced astigmatism. Acta Ophthalmol Scand. 2008(Thesis):5-28.

8. Bauer NJC, de Vries N, Webers CAB, F Hendrikse, Nuijts RMMA. Astigmatism management in cataract surgery with the AcrySof toric intraocular lens. J Cataract Refract Surg. 2008;34:1483-8.

9. Ferrer-Blasco T, Montés-Micó R, Peixoto-de-Matos SC, González-Méijome JM, Cerviño A. Prevalence of corneal

astigmatism before cataract surgery. J Cataract Refract Surg. 2009;35:70-5.

10. Guan Z, Yuan F, Yuan YZ, Niu WR. Analysis of corneal astigmatism in cataract surgery candidates at a teaching hospital in Shanghai, China. J Cataract Refract Surg. 2012;38:1970-7.

11. Kohnen T. Astigmatism measurements for cataract and refractive surgery. J Cataract Refract Surg. 2012;38:2065.

12. Nichamin LD. Astigmatism control. Ophthalmol Clin N Am. 2006;19:485-93.

13. Wolffsohn JS, Bhogal G, Shah S. Effect of uncorrected astigmatism on vision. J Cataract Refract Surg. 2011;37:454-60.

14. Höfling-Lima AL, Freitas D, Moeller CTA, Martins EN. Manual de Condutas em Oftalmologia. UNIFESP - Instituto da Visão. 2008 (Atheneu):724-5.

15. Koch DD, Kohnen T, Obstbaum SA, Rosen ES. How should we analyze astigmatic data? J Cataract Refract Surg. 1998;24:285-7.

16. Alpins N. A new method of analyzing vectors for changes in astigmatism. J Cataract Refract Surg. 1993;19:524-33.

17. Alpins N. New method of targeting vectors to treat astigmatism. J Cataract Refract Surg. 1997;23:65-75.

18. Alpins N. Astigmatism analysis by the Alpins method. J Cataract Refract Surg. 2001;27:31-49.

19. Alpins N, Goggin M. Practical Astigmatism Analysis for Refractive Outcomes in Cataract and Refractive Surgery. Surv Ophthalmol. 2004;49:109-22.

20. Thibos LN, Wheeler W. Power vectors: an application of Fourier analysis to the description and statistical analysis of refractive error. Optom Vis Scie. 1997;74:367-75.

21. Thibos LN, Horner D. Power vector analysis of the optical outcome of refractive surgery. J Cataract Refract Surg. 2001;27:80-5.

22. Kobashi H, Kamiya K, Igarashi A, Ishi R, Sato N, Wang G, Shimizu K. Comparison of corneal power, corneal astigmatism, and axis location in normal eyes obtained from an autokeratometer and a corneal topographer. J Cataract Refract Surg. 2012;38:648-54.

23. Norrby S, Hirnschall N, Nishi Y, Findl O. Fluctuations in corneal curvature limit predictability of intraocular lens power calculations. J Cataract Refract Surg. 2013;39:174-9.

24. Koch DD, Ali S, Weikert MP, Shirayama M, Jenkins R, Wang L. Contribution of posterior corneal astigmatism to total corneal astigmatism. J Cataract Refract Surg. 2012;38:2080-7.

25. Ho JD, Liou S, Tsai RJF, Tsai CY. Effects of Aging on Anterior and Posterior Corneal Astigmatism. Cornea. 2010(29):632-7.

26. Amesbury EC, Miller K. Correction of astigmatism at the time of cataract surgery. Curr Opin Ophthalmol. 2009;20:19-24.

27. Lombardo A, Linstrom R. Arcuate and Transverse Incisions for Managing Astigmatism. In: A Complete Surgical Guide for Correcting Astigmatism. 2003;Thorofare, NJ. Slack Inc:87-96.

28. Borasio E, Mehta J, Maurino V. Surgically induced astigmatism after phacoemulsification in eyes with mild to moderate corneal astigmatism: Temporal versus on-axis clear corneal incisions. J Cataract Refract Surg. 2006;32:565-72.

29. Qammar A, Mullaney P. Paired opposite clear corneal incisions to correct preexisting astigmatism in cataract patients. J Cataract Refract Surg. 2005;31:1167-70.

30. Hida WT, Motta AFP, Inomata DL, Jales MQM, Facio-Jr AC, Kara-Junior N, Nakano CT. Incisões relaxantes limbares ou incisões no meridiano mais curvo associadas a facoemulsificação com implante de lente intra-ocular

multifocal: relato de três casos. Arq Bras Oftalmol. 2008;71(2):273-7.

31. Carvalho MJ, Higashitani-Suzuki S, Lemes-Freitas L. Limbal relaxing incisions to correct corneal astigmatism during phacoemulsification. J Refract Surg. 2007;23:499-504.

32. Arraes JC, Cunha F, Arraes TA, Cavalcanti R, Ventura M. Limbal relaxing incisions during cataract surgery: one-year follow-up. Arq Bras Oftalmol. 2006;69(3):361-4.

33. Coloma-Gonzáles I, Gonzáles-Herrera M, Megual-Verdú E, Hueso-Abancens JR. Limbal Relaxing Incisions and Cataract Surgery: Our Experience. Arch Soc Esp Oftalmol. 2007;82:551-554.

34. Gills JP, Wallace R, Miller K, Fine HI, Friedlander M, McFarland M, Zhang X, Granet NS. Reducing Pre-Existing Astigmatism with Limbal Relaxing Incisions. In: A Complete Surgical Guide for Correcting Astigmatism. 2003;Thorofare, NJ. Slack Inc:99-119.

35. Cristóbal JA, del Buey M, Ascaso FJ, Lanchares E, Calvo B, Doblare M. Effect of Limbal Relaxing Incisions During Phacoemulsification Surgery Based on Nomogram Review and Numerical Simulation. Cornea. 2009;28:1042 - 9.

36. Ganekal S, Dorairaj S, Jhanji V. Limbal relaxing incisions during phacoemulsification: 6-month results. J Cataract Refract Surg. 2011(37):2081-2.

37. Kamiya K, Shimizu K, Ohmoto F, Amano R. Evaluation of corneal biomechanical parameters after simultaneous phacoemulsification with intraocular lens implantation and limbal relaxing incisions. J Cataract Refract Surg. 2011;37:265-70.

38. Ouchi M, Kinoshita S. AcrySof IQ Toric IOL Implantation Combined With Limbal Relaxing Incision During Cataract Surgery for Eyes With Astigmatism > 2.50 D. J Refract Surg. 2011;29(9):643-7.

39. Muftuoglu O, Dao L, Cavanagh HD, McCulley JP, Bowman RW. Limbal relaxing incisions at the time of apodized diffractive multifocal intraocular lens implantation to reduce astigmatism with or without subsequent laser in situ keratomileusis. J Cataract Refract Surg. 2010;36:456-64.
40. Carey PJ, Leccisotti A, McGilligan VE, Goodall A, Moore CBT. Assessment of toric intraocular lens alignment by a refractive power/corneal analyzer system and slitlamp observation. J Cataract Refract Surg. 2010(36):222-9.
41. Gills JP, Cherchio M. Using the Toric Intraocular Lens in a Complete Astigmatism Management Program. Thorofare, NJ Slack Inc. 2003;A Complete Surgical Guide for Correcting Astigmatism.:157-67.
42. Horn JD. Status of toric intraocular lenses. Curr Opin Ophthalmol. 2007(18):58-61.
43. Ruíz-Mesa R, Carrasco-Sanches D, Díaz-Álvarez SB, Ruíz-Mateos MA, Ferrer-Blasco T, Montés-Micó R. Refractive Lens Exchange with Foldable Toric Intraocular Lens. Am J Ophthalmol. 2009;147:990-6.
44. Freitas GO, Carvalho MJ, Boteon JE. Refractive lens exchange using SN60T5 AcrySof Toric intraocular lens in stage 2 keratoconus. Rev Bras Oftalmol. 2011;70(5):296-9.
45. Hill W. Expected effects of surgically induced astigmatism on AcrySof Toric intraocular lens results. J Cataract Refract Surg. 2008(34):364-7.
46. Ahmed IIK, Rocha G, Slomovic AR, Climenhaga H, Gohill J, Greagore A, Ma J. Visual function and patient experience after bilateral implantation of toric intraocular lenses. J Cataract Refract Surg. 2010;36:609-16.
47. Statham M, Apel A, Stephensen D. Comparison of the AcrySof SA60 spherical intraocular lens and the AcrySof Toric SN60T3 intraocular lens outcomes in patients with low amounts of corneal astigmatism. Clin Exper Ophthalmology. 2009;37:775-9.

48. Koshy JJ, Nishi Y, Hirnschall N, Crnej A, Gangwani V, Maurino V, Findl O. Rotational stability of a single-piece toric acrylic intraocular lens. J Cataract Refract Surg. 2010;36:1665-70.

49. Sha GD, Praveen M, Vasavada AR, Vasavada VA, Rampal G, Shastry LR. Rotational stability of a toric intraocular lens: Influence of axial length and alignment in the capsular bag. J Cataract Refract Surg. 2012;38:54-9.

50. Buckhurst PH, W Wolffsohn J, Naroo SA, Davies LN. Rotational and centration stability of an aspheric intraocular lens with a simulated toric design. J Cataract Refract Surg. 2010;36:1523-8.

51. Entabi M, H Harman F, Lee N, Bloom PA. Injectable 1-piece hydrophilic acrylic toric intraocular lens for cataract surgery: Efficacy and stability. J Cataract Refract Surg. 2011;37:235-40.

52. Cervantes-Coste G, Garcia-Ramirez L, Mendoza-Schuster E, Velasco-Barona C. High-cylinder Acrylic Toric Intraocular Lenses: A Case Series of Eyes With Cataracts and Large Amounts of Corneal Astigmatism. J Refract Surg. 2012;28(4):302-4.

53. Ernest P, Potvin R. Effects of preoperative corneal astigmatism orientation on results with a low-cylinder-power toric intraocular lens. J Cataract Refract Surg. 2011;37:727-32.

54. Wolffsohn JS, B Buckhurst P. Objective analysis of toric intraocular lenses rotation and centration. J Cataract Refract Surg. 2010;36:778-82.

55. Biancardi AL, Walsh A, Barreto RPP, Crema AS. Correção do astigmatismo irregular com lente intraocular tórica em um paciente com catarata e degeneração marginal pelúcida: relato de caso. Rev Bras Oftalmol. 2012;71(6):400-2.

56. Mendicute J, Irigoyen C, Ruíz M, Illarramendi I, Ferrer-Blasco T, Montés-Micó R. Toric intraocular lens versus opposite clear corneal incisions to correct astigmatism in eyes having cataract surgery. J Cataract Refract Surg. 2009;35:451-8.

57. Mingo-Botín D, Muñoz-Negrete F, Kim HRW, Morcillo-Laiz R, Rebolleda G, Oblanca N. Comparison of toric intraocular lenses and peripheral corneal relaxing incisions to treat astigmatism during cataract surgery. J Cataract Refract Surg. 2010;36:1700-8.

58. Vianna LMM, Nascimento HM, Campos M. Retratamento de LASIK com fotoablação personalizada versus fotoablação convencional utilizando o LADAR–Alcon. Rev Bras Oftalmol. 2011;70(3):162-7.

TRABALHOS ORIGINAIS

Os manuscritos, do segundo ao quarto trabalho, trazem contribuições originais da Tese. Esse manuscritos foram enviados para apreciação pelos periódicos, originalmente em inglês, com o resumos em português.

A cada um dos manuscritos, foi indicado o periódico a que foi enviado, bem como, colocado o *status* por ocasião da impressão desta tese: se em avaliação, em revisão ou aceito para publicação.

A formatação quanto às seções, ou padronização de figuras e tabelas, obedeceu às normas dos referidos periódicos. Apenas o modelo das fontes e o espaçamento entre elas, bem como, entre as linhas, foi ajustado, para que não houvesse discrepâncias à leitura da Tese.

SEGUNDO TRABALHO

Status: Manuscrito aceito pelos Arquivos Brasileiros de Oftalmologia (ABO) em 10/07/2013.

TREATMENT OF ASTIGMATISM DURING PHACOEMULSIFICATION

TRATAMENTO DO ASTIGMATISMO DURANTE A FACOEMULSIFICAÇÃO

Giuliano O. Freitas, M.D., Research Fellow at the Federal University of Minas Gerais, Belo Horizonte-MG, Staff of Cataract Surgery Department at ISO Olhos – Instituto de Saúde Ocular, Uberlândia-MG, Brazil.

Joel E. Boteon, Ph.D., M.D., Ophthalmology Professor at the Federal University of Minas Gerais, Belo Horizonte-MG, Brazil.

Mario J. Carvalho, M.D., Head of Cataract Surgery Department at ISO Olhos – ISO Olhos – Instituto de Saúde Ocular, Uberlândia-MG, Brazil.

Rogerio M.C. Pinto, D.A., Biostatistics Professor at the Federal University of Uberlândia, Uberlândia-MG, Brazil.

Financial Contributors

- Private: Alcon Labs. Brazil (São Paulo-SP) provided all intraocular lenses, at no cost, for scientific purposes.

- Public: Municipal Health Authority of Uberlândia-MG funded surgical procedures as regular governmental assistance policy.

Financial Disclosure: No author has a financial or proprietary interest in any material or method mentioned.

Corresponding author: Giuliano O. Freitas

Address: ISO Olhos, R. Eduardo Marquez 50, Martins

Uberlândia-MG/Brazil, ZIP Code 38.400-442

Phone: +55 (34) 3230-5050

Fax: + 55 (34) 3230-5055

E-mail: gofreitas@ufmg.br

Abstract

Objective: To compare limbal relaxing incisions (LRI) and toric intraocular lenses (IOL) in terms of non-vectorial (predictability, safety and efficacy) and vectorial analyses in the treatment of astigmatism during phacoemulsification.

Methods: This longitudinal observational case series assessed 62 eyes of 31 consecutive cataract patients with preoperative corneal astigmatism between 0.75 and 2.50 diopters (D) in both eyes. Patients were randomly assorted in two groups: “1” assigned to receive AcrySof Toric^{TM} IOL in both eyes; and “2” to have AcrySof Natural^{TM} IOL associated with LRI, also in both eyes. All patients were evaluated postoperatively at 1, 3 and 6 months, when refractive astigmatism analysis was performed using both non-vectorial and Alpins vectorial methods. Outcomes within each group and between groups were assessed.

Results: The percentage of eyes within ±0.50 D of the intended correction in the LRI group, at 3rd and 6th postoperative months, was 75% and 71.88%, respectively, compared to 40% and 66.67% for the toric IOL group. In the remaining period, percentages were favorable to the toric IOL group. Safety index showed no difference at any period studied. Efficacy index was statistically higher for toric IOL group in 1-month and 3-month postoperatively (0.43 and 0.44), compared to LRI group (0.31 and 0.36). At the 6th month, the percentage of eyes, in the LRI group, was: 53.13% were under-corrected, 43.74% reached the intended correction and 3.13% were over-corrected; in the toric IOL group, 16.76% were under-corrected, 76.67% reached the intended

correction and 6.67% were over-corrected. The percentages of success of astigmatic surgery, astigmatism reduction at the intended axis and astigmatism corrected are shown respectively, in the LRI group: 43%, 62% and 64%; and in the toric IOL group, they were: 57%, 81% and 94%.

Conclusions: Our results suggest the use of toric IOL to be advantageous over LRI in the treatment of astigmatism during phacoemulsification. Although such advantages seem subtle from non-vectorial analysis, they are highlighted by the vectorial approach.

KEYWORDS

Phacoemulsification, astigmatism, predictability, safety, efficacy.

RESUMO

Objetivo: Comparar incisões relaxantes limbares (IRL) e lentes intraoculares (LIO) tóricas tanto em termos não-vetoriais (efetividade, segurança e eficácia), quanto vetoriais no tratamento do astigmatismo por ocasião da facoemulsificação.

Método: Estudo observacional longitudinal (série de casos) no qual foram avaliados 62 olhos de 31 pacientes consecutivos de catarata com astigmatismo corneano pré-operatório entre 0,75 e 2,50 dioptrias (D) para ambos os olhos. Os pacientes foram aleatoriamente distribuídos entre 2 grupos: "1" submetido a implante de LIO AcrySof Toric™ em ambos os olhos e "2" com implante bilateral da LIO AcrySof Natural™ complementada por IRL. Todos os pacientes foram reavaliados com 1, 3 e 6 meses de pós-operatório, sendo feitas análises do astigmatismo refracional por métodos não-vetoriais, como pela análise vetorial de Alpins, interessando os resultados dentro de cada grupo e entre os grupos.

Resultados: O percentual de olhos entre ±0,50 D da correção pretendida no grupo IRL foi de 75 e 71,88%, respectivamente, em comparação aos 40 e 66,67% do grupo LIO tórica aos 3 e 6 meses de pós-operatório. Nos outros períodos avaliados, os percentuais foram favoráveis ao grupo LIO tórica. O índice de segurança não demonstrou diferença em nenhum dos períodos. O índice de eficácia foi estatisticamente maior para o grupo LIO tórica com 1 e 3 meses de pós-operatório (0,43 e 0,44), em comparação ao grupo IRL (0,31 e 0,36). Aos 6 meses, o percentual de olhos, para o grupo IRL, foi: hipocorreção em 53,13%; 43,74% alcançaram a correção

pretendida e 3,13% ficaram hipercorrigidos; no grupo LIO tórica, a hipocorreção ocorreu em 16,76%; 76,67% alcançaram a correção pretendida e 6,67% ficaram hipercorrigidos. Os percentuais de sucesso da cirurgia astigmática, da redução do astigmatismo no eixo pretendido e do astigmatismo corrigido foram, respectivamente, para o grupo IRL: 43%, 62% e 64%; para o grupo LIO tórica: 57%, 81% e 94%.

Conclusões: Nossos resultados sugerem que o uso de LIO tóricas é vantajoso ao de IRL no tratamento do astigmatismo por ocasião da facoemulsificação. Apesar de que tais vantagens mostraram-se sutis na análise não-vetorial, elas foram consistentes na perspectiva vetorial.

DESCRITORES

Facoemulsificação, astigmatismo, efetividade, segurança, eficácia.

INTRODUCTION

Astigmatism is a visually disabling refractive error. At least 15% to 20% of cataract patients have 1.50 diopters (D), or more, of corneal astigmatism. (1)

One way to correct astigmatism simultaneously to cataract surgery is to perform limbal relaxing incisions (LRI). (2, 3) It is possible, however, that late corneal biomechanics, may play an unfavorable role in refractive outcomes over time. (4) Toric intraocular lens (IOL) implantation is another valuable option for astigmatism correction in cataract patients. Undesired rotation of the toric IOL is the main problem associated with this modality. Approximately 1 degree of off-axis rotation results in a loss of up to 3.3% of the expected cylinder correction. (5)

Vectors are mathematical expressions that combine values for magnitude and direction. Astigmatism, with cylinder power and axis (refractive) or magnitude and meridian (corneal), fits such a description. (6, 7) The Alpins method is a vectorial analysis that allows determination of the effectiveness of a specific astigmatic treatment. Such method has been used by several authors to analyze the astigmatic changes induced by different surgical approaches, such as excimer laser refractive surgery, LRI (3, 8-11) and toric IOL implantation. (1, 12, 13)

In light of the advantages and limitations of each approach, to ascertain which option is superior, LRI or toric IOL, remains controversial. (14) This study compared such techniques both on non-vectorial (predictability, safety and efficacy indices) (15) and vectorial basis in the treatment of preoperative astigmatism during cataract surgery.

PATIENTS AND METHODS

This longitudinal observational case series assessed 31 consecutive cataract patients with preoperative corneal astigmatism between 0.75 D and 2.50 D in both eyes. Patients were randomly assorted, employing Microsoft Excel™ "***ƒ*=RANDBETWEEN(1;2)**" function, in two phacoemulsification groups: "1" for toric IOL group, assigned to receive toric IOL in both eyes (model AcrySof Toric™, Alcon™, Inc.), and "2" for LRI group, assigned to have spherical IOL (AcrySof Natural™, Alcon™, Inc.) associated with LRI, also in both eyes. All patients provided a written informed consent, after they had received an explanation about the nature of the study and its potential complications, in accordance with the tenets of the Declaration of Helsinki. All surgeries were performed, between May 2010 and June 2012.

Inclusion criteria were age older than 40 years; visually significant cataract, defined as spectacle distance corrected visual acuity (SDCVA) worse than Snellen 20/40 (LogMAR scale of 0.3); regular corneal astigmatism ranging from 0.75 D to 2.50 D and pharmacologic mydriasis of, at least, 6.0 mm (measured at slit lamp) to allow proper intraoperative visualization of axis marks on the surface of toric IOL.

The following were exclusion criteria: previous surgery in the eye under study; pterygium; ocular disease that would lead to poor postoperative corrected visual acuity (corneal scarring, uveitis, advanced glaucoma, neuro-ophthalmic disease, significant macular disease or other retinopathy); zonule or pupil abnormalities.

Preoperatively, every patient had a complete ophthalmic evaluation by an examiner other than the surgeon (*G.F.*), including manifest refraction and spectacle distance corrected visual acuity, slit lamp examination, applanation tonometry, and fundoscopy under pharmacological mydriasis, in addition to corneal topography (OrbscanII™, Bausch&Lomb™, Inc.) and ultrasound immersion biometry (OcuScan™, Alcon™, Inc.). Hoffer Q formula was used in eyes with an axial length shorter than 22 mm, and SRK/T formula was used for all other cases.

Toric IOL cylinder power and axis placement were determined using the IOL manufacturer's online calculator (www.acrysoftoriccalculator.com). Size and location of LRI were also determined via online open source application (www.lricalculator.com), according to Donnenfeld's nomogram. For both Toric IOL and LRI groups, data such as biometry, keratometry, main incision location, and surgeon's default surgically induced astigmatism (set at -0.50 D) were entered into the calculators, aiming postoperative zero sphere and the smallest residual cylinder possible. (16, 17)

The same surgeon (*M.C.*) performed all surgeries under mild sedation and topical anesthesia. Just before surgery, a sterile ink pen was used to make two marks on the corneal limbus at the 0-degree and 180-degree positions with the patient sitting upright at the slit lamp to avoid ocular torsion. In both groups, phacoemulsification, followed by IOL implantation, was performed through a 2.75 mm single-plane temporal incision at corneal limbus, a Mendez ring was used to mark the steepest meridian. In the toric IOL group, the IOL was rotated to align with the intended axis. For LRI group patients, LRI were created inside the limbus using a calibrated diamond knife with the blade depth set at 600 µm.

All patients were evaluated at 1, 3 and 6 months postoperatively (*G.F.*).

Postoperative manifest refraction, uncorrected distance visual acuity (UDVA) and SDCVA were obtained. Spherical equivalent refraction (SE), predictability, safety and efficacy indices, were then calculated. Predictability, expressed as the percentage of eyes within ±1.00 D of the intended SE or, alternatively, as the percentage of eyes within an even more strict limit of ±0.50 D of the intended SE. The intended SE, on its turn, was calculated from the difference of postoperative SE and target SE. The target SE was defined as a half of the goal residual cylinder. Safety index (SI) was calculated from the ratio between postoperative SDCVA and preoperative SDCVA. Efficacy index (EI) was calculated from the ratio between postoperative UDVA and preoperative SDCVA.

Alpins vectorial method of astigmatism analysis is based on three elementary vectors: target induced astigmatism (TIA), surgically induced astigmatism (SIA) and difference vector (DV). In an ideal scenario, TIA equals SIA and DV is null. Several relations between such vectors, as magnitude of error (ME=SIA-TIA), index of success (IoS=DV/TIA), correction index (CI=SIA/TIA), among others, if analyzed together, are capable of fully describe surgical astigmatic change. (6) Calculations of Alpins vectorial parameters for refractive astigmatism were performed using Microsoft™ Excel™ for MacIntosh™ spreadsheets (version 12.2.7, Microsoft™ Corp.).

Shapiro-Wilk normality tests of data set were performed using IBM™ SPSS™ for Microsoft™ Windows™ software (version 20.0.0). A *P* value of 0.05 or less was considered statistically significant. (18) Pearson's (R^2) was used, as necessary. (19) Bootstrapping (95% confidence interval) was performed in such cases. (20) Wilcoxon test was used to analyze statistical non-parametric differences within the same

group throughout the follow up period and Mann-Whitney U test was used to determine differences between toric IOL and LRI groups at each evaluation. (3)

RESULTS

The study enrolled 62 eyes of 31 consecutive eligible patients. Patient demographics and preoperative data are presented in Table 1.

Table 1. Patient demographics and preoperative data.

	Group		
	LRI	Toric IOL	*P* value*
Patients (n)	16	15	-
Eyes (n)	32	30	-
Sex (F/M)	8/8	11/4	-
Age (y)			
Range	51 to 84	52 to 80	-
Mean ± SD	71.75 ± 8.87	65.67 ± 6.28	.01
Topographic astigmatism (D)			
Range	0.75 to 2.40	0.80 to 2.50	-
Mean ± SD	1.32 ± 0.47	1.41 ± 0.54	.60
Steepest topographic 180º- semimeridian angle (n)			
0 to 30º or 151º to 180º	18	5	-
61º to 120º	8	24	-
31º to 60º or 121º to 150º	6	1	-
Axial length (mm)			
Range	21.40 to 24.33	21.75 to 25.93	-
Mean ± SD	23.05 ± 0.63	23.33 ± 0.92	.25
Biometric formulae (n)			
SRK/T	30	28	-
Hoffer Q	2	2	-
Spherical IOL power (D)			
Range	18.50 to 27.00	13.50 to 24.50	-
Mean ± SD	21.50 ± 1.87	21.38 ± 2.58	.61
Toric IOL model (n)			
T3	-	14	-
T4	-	7	-
T5	-	9	-

F = females; D = diopters; IOL = intraocular lens; M = males; LRI = limbal relaxing incisions; mm = milimeters; n = number; SD = standard deviation; T3 = AcrySof Toric™ T3 IOL; T4 = AcrySof Toric™ T4 IOL; T5 = AcrySof Toric™ T5 IOL; y = years; (*) Mann-Whitney U test.

The mean age found in LRI group was 71.75 years, statistically higher than 65.67 years from toric IOL group. Accordingly, the number of with the rule astigmatism was three times as lower in the LRI group (8 eyes), than in the toric IOL group (24 eyes).

All surgeries were uneventful. None of the eyes required a second intervention. No potentially sight-threatening complications, such as persistent corneal edema, pupillary block, retinal detachment or endophthalmitis, were observed.

All patients have accomplished the follow up period of 6 months.

Table 2 shows the preoperative intended astigmatic correction, based on topographic astigmatism, and 1-month, 3-month and 6-month postoperative achieved astigmatic corrections, based on manifest refractive astigmatism for each follow up period, for both groups.

Table 2. Preoperative intended astigmatism, 1-month, 3-month and 6-month postoperatively achieved astigmatism.

	Group		
Cylinder diopters	LRI	Toric IOL	*P* value*
Preoperative intended astigmatism			
Range	-2.40 to -0.75	-2.50 to -0.80	-
Mean ± SD	-1.32 ± 0.47	-1.41 ± 0.54	.60
1-month postoperative achieved astigmatism			
Range	-1.25 to 0.00	-1.00 to 0.00	-
Mean ± SD	-0.66 ± 0.30	-0.58 ± 0.24	.25
P value†	.00	.00	-
3-month postoperative achieved astigmatism			
Range	-1.00 to 0.00	-1.00 to -0.25	-
Mean ± SD	-0.70 ± 0.21	-0.63 ± 0.20	.17
P value††	.00	.00	-
6-month postoperative achieved astigmatism			
Range	-1.25 to -0.25	-1.00 to -0.25	-
Mean ± SD	-0.74 ± 0.26	-0.62 ± 0.17	.06
P value†††	.00	.00	-

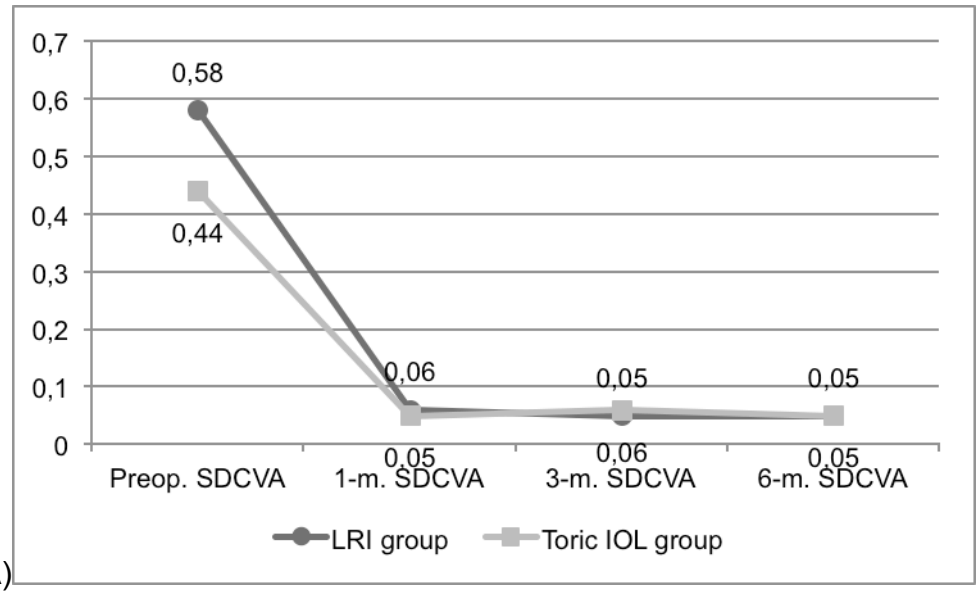
IOL = intraocular lens; LRI = limbal relaxing incisions; SD = standard deviation; (*) Mann-Whitney U test; (†,††,†††) Wilcoxon test – preoperative intended astigmatism x 1-month, 3-month and 6-month achieved astigmatism, respectively.

There was no statistical difference in preoperative intended astigmatic correction between groups: -1.32 D in the LRI group and -1.41 D in the toric IOL group. The manifest refractive astigmatism at 6 months postoperatively was -0.74 D for LRI group and -0.62 D for toric IOL group, those means where close to statistical significance (*P* value =0.06).

At 6-month postoperatively, manifest refraction, as SE (means ± standard deviation), was -0.20±0.42 in the LRI group and -0.21±0.49 in the toric IOL group, showing no statistical difference (*P* value = 0.84).

Figure 1A compares mean preoperative, 1-month, 3-month and 6-month postoperative SDCVA between LRI and toric IOL groups. Figure 1B compares mean 1-month, 3-month and 6-month postoperative UCVA between LRI and toric IOL groups.

A)



B)

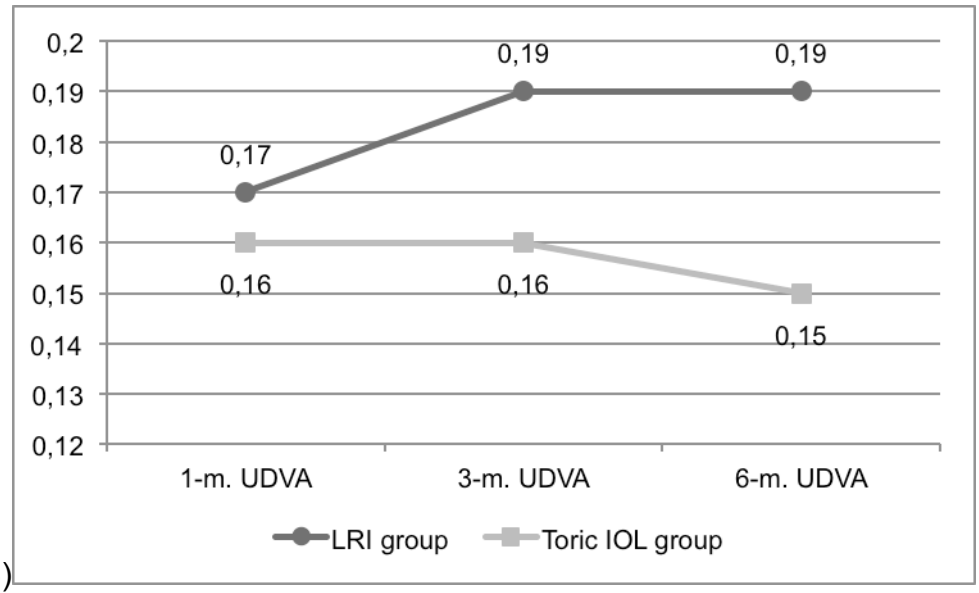


Figure 1. A) Preoperative, 1-m., 3-m. and 6-m. postoperative mean SDCVA (logMAR scale). B) One-month, 3-m. and 6-m. postoperative mean UDVA (logMAR scale). (IOL = intraocular lens; LRI = limbal relaxing incisions; m. = *n*-month postoperative; Preop. = preoperative period; SDCVA = spectacle distance corrected visual acuity; UDVA = uncorrected distance visual acuity).

Preoperative mean SDCVA was statistically lower in the toric IOL group when compared to the mean of LRI group (Mann-Whitney U test, *P* value = 0.01). There was no significant difference for the remaining periods, between groups, in terms of mean SDCVA (Mann-Whitney U test, *P* value > 0.05). Within a single group, postoperative SDCVA were statistically lower then preoperative corrected acuity, remaining stable thereafter (Wilcoxon test – *P* value = 0.00).

Mean postoperative UDVA was statistically similar between groups throughout the follow up period (Mann-Whitney U test, *P* values > 0.05).

There was no significant difference for the remaining periods between groups. Within a single group, postoperative visual acuities were statistically lower then preoperative corrected acuity, remaining stable thereafter.

Table 3 shows postoperative 1-month, 3-month and 6-month percentage of eyes within ±1.00 D and within ±0.50 D of the intended spherical equivalent refraction of both groups.

Table 3. One-month, 3-month and 6-month postoperative refractive predictability.

	Group		
	LRI	Toric IOL	*P* value*
	Fraction ; (%)	Fraction ; (%)	
1-month postoperative			.05
ΔSE_1 ± 1.00 D	27/32 ; (84.38)	28/30 ; (93.33)	-
ΔSE_1 ± 0.50 D	17/32 ; (53.13)	18/30 ; (60.00)	-
3-month postoperative			.09
ΔSE_3 ± 1.00 D	30/32 ; (93.75)	24/30 ; (80.00)	-
ΔSE_3 ± 0.50 D	24/32 ; (75.00)	12/30 ; (40.00)	-
P value†	.10	.00	
6-month postoperative			.77
ΔSE_6 ± 1.00 D	31/32 ; (96.88)	30/30 ; (100)	-
ΔSE_6 ± 0.50 D	23/32 ; (71.88)	18/30 ; (66.67)	-
P value††	.02	.71	

D = diopters; IOL = intraocular lens; LRI = limbal relaxing incisions; SD = standard deviation; ΔSE_1 = 1-month postoperative spherical equivalent minus preoperative target spherical equivalent; ΔSE_3 = 3-month postoperative target spherical equivalent minus preoperative target spherical equivalent; ΔSE_6 = 6-month postoperative target spherical equivalent minus preoperative target spherical equivalent; (*) Mann-Whitney U test of ΔSE means between groups for 1, 3 or 6 months postoperatively; (†) Wilcoxon test – 1-month postoperative ΔSE_1 x 3-month postoperative ΔSE_3; (††) Wilcoxon test – 1-month postoperative ΔSE_1 x 6-month postoperative ΔSE_6

The percentage of eyes within ±0.50 D was greater for the LRI group in the 3-month and 6-month postoperatively: 75% and 71.88%, respectively, compared to 40% and 66.67% found in the toric IOL group in the same periods. In the remaining periods, percentages were favorable to the toric IOL group.

Table 4 shows 1-month, 3-month and 6-month postoperative safety and efficacy indices of both groups.

Table 4. One-month, 3-month and 6-month postoperative safety and efficacy indices.

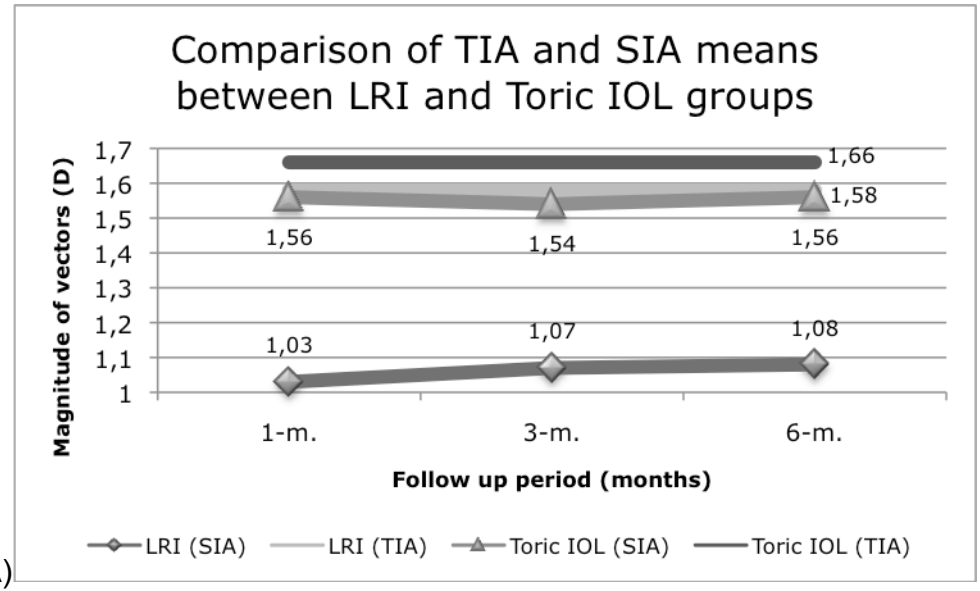
	Group		
	LRI	Toric IOL	*P* value*
1-month postoperative SI			
Range	0.00 to 0.60	0.00 to 0.60	-
Mean ± SD	0.11 ± 0.14	0.13 ± 0.20	.94
3-month postoperative SI			
Range	0.00 to 0.33	0.00 to 0.60	-
Mean ± SD	0.10 ± 0.13	0.18 ± 0.21	.27
P value†	.92	.13	-
6-month postoperative SI			
Range	0.00 to 0.38	0.00 to 0.60	-
Mean ± SD	0.09 ± 0.12	0.12 ± 0.18	.81
P value††	.66	.68	-
1-month postoperative EI			
Range	0.00 to 1.00	0.00 to 1.00	-
Mean ± SD	0.31 ± 0.18	0.43 ± 0.23	.01
3-month postoperative EI			
Range	0.17 to 1.00	0.00 to 1.00	-
Mean ± SD	0.36 ± 0.18	0.44 ± 0.25	.04
P value‡	.04	.32	-
6-month postoperative EI			
Range	0.17 to 1.00	0.00 to 1.00	-
Mean ± SD	0.37 ± 0.19	0.42 ± 0.27	.23
P value‡ ‡	.03	.72	-

EI = efficacy index; LRI = limbal relaxing incisions; SD = standard deviation; SI = safety index; (*) Mann-Whitney U test; (†) Wilcoxon test – 1-month SI x 3-month postoperative SI; (††) Wilcoxon test – 1-month SI x 6-month postoperative SI; (‡) Wilcoxon test – 1-month EI x 3-month postoperative EI; (‡ ‡) Wilcoxon test – 1-month EI x 6-month postoperative EI.

SI showed no difference at any period studied between groups. EI was statistically higher for toric IOL group in 1-month and 3-month postoperatively (0.43 and 0.44, respectively), compared to LRI group (0.31 and 0.36, respectively).

Figure 2A compares mean TIA to postoperative 1-month, 3-month and 6-month mean SIA between LRI and toric IOL groups.

A)



B)

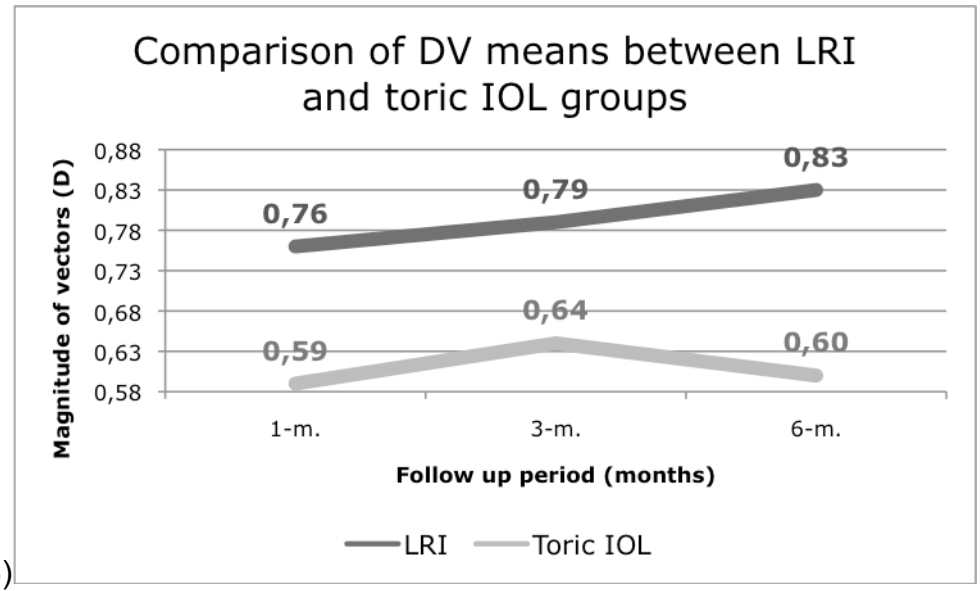
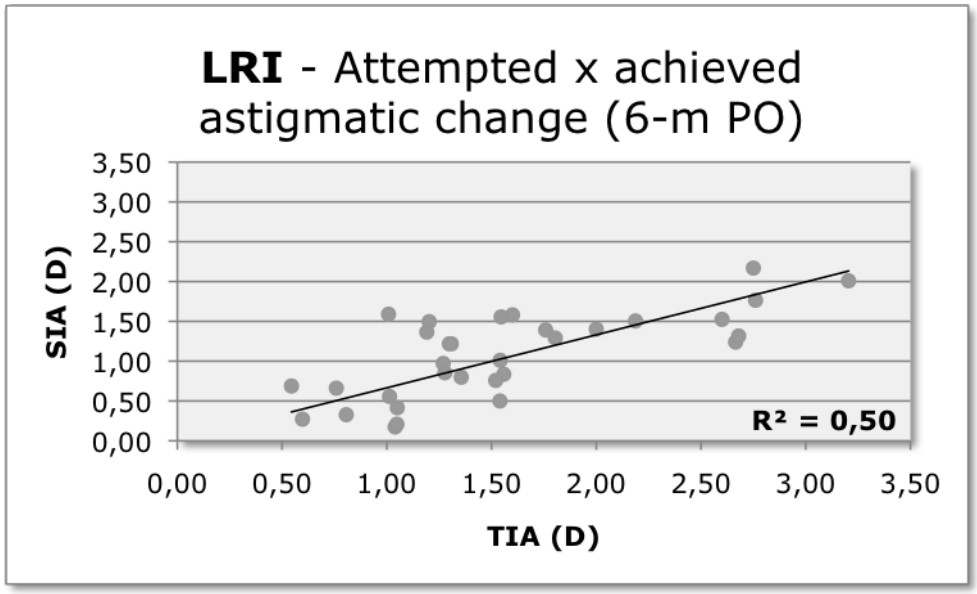


Figure 2. A) Comparison of TIA and SIA means, over time, between LRI and toric IOL groups and within each group. B) Comparison of DV means, over time, between LRI and toric IOL groups. (DV = difference vector; IOL intraocular lens; LRI = limbal relaxing incisions; SIA = surgically induced astigmatism vector; TIA = target induced astigmatism vector; m. = *n*-month postoperative).

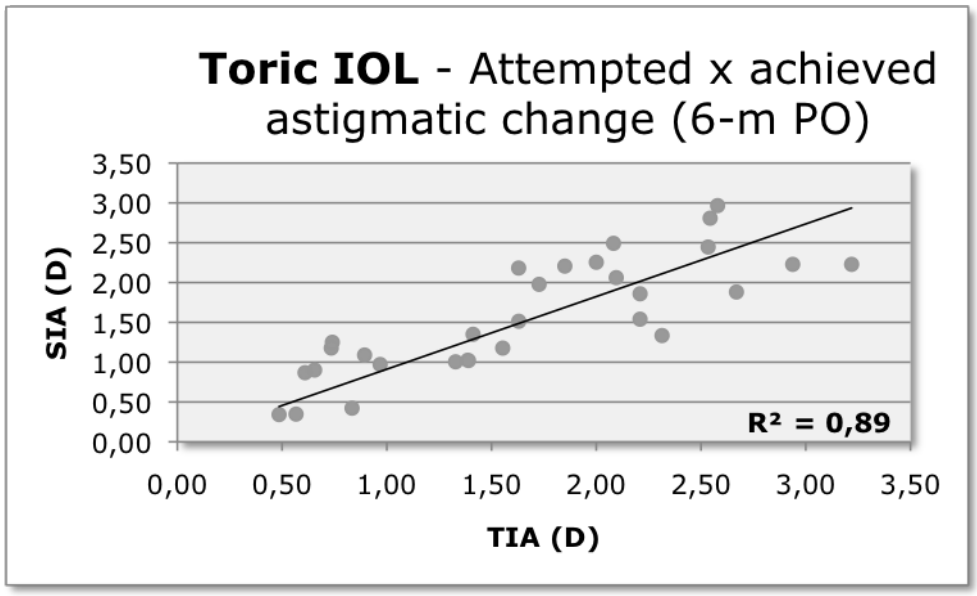
Between groups, there were no statistical differences in TIA means (Mann-Whitney U test – *P* value > 0.05). For LRI

group, SIA means were significantly lower than means found in the toric IOL group (Mann-Whitney U test – *P* value < 0.05). Within each group there were no differences in SIA means throughout follow up, however (Wilcoxon test *P* value > 0.05). In the LRI group, SIA means were significantly lower than TIA mean (Wilcoxon test *P* value < 0.05). There were no statistically significant differences, in terms of means, between TIA and SIA, in the toric IOL group (Wilcoxon test *P* value > 0.05). Figure 2B compares postoperative 1-month, 3-month and 6-month mean DV between LRI and toric IOL groups. Between groups, DV means were statistically higher for LRI group than those found in the toric IOL group throughout all follow up period (Mann-Whitney U test – *P* value < 0.05). There were no statistical differences within the same group over time (Wilcoxon test *P* value > 0.05).

Figure 3 compares attempted versus achieved astigmatism 6-month postoperatively in the LRI and toric IOL groups.



A)



B)

Figure 3. Scatterplots of attempted astigmatic correction and achieved astigmatic change at 6 months postoperatively: A) LRI group; B) Toric IOL group (D = diopters; LRI = limbal relaxing incisions; SIA = surgically induced astigmatism; R^2 = Pearson's coefficient of determination; TIA = target induced astigmatism; 6-m PO = 6-month postoperative period).

Pearson's (R^2) coefficient of determination for each group is also shown: 0.50 and 0.89 for LRI and toric IOL groups, respectively.

Figure 4 shows the percentage distribution of astigmatic correction, based on ME, at 6 months postoperatively for both groups.

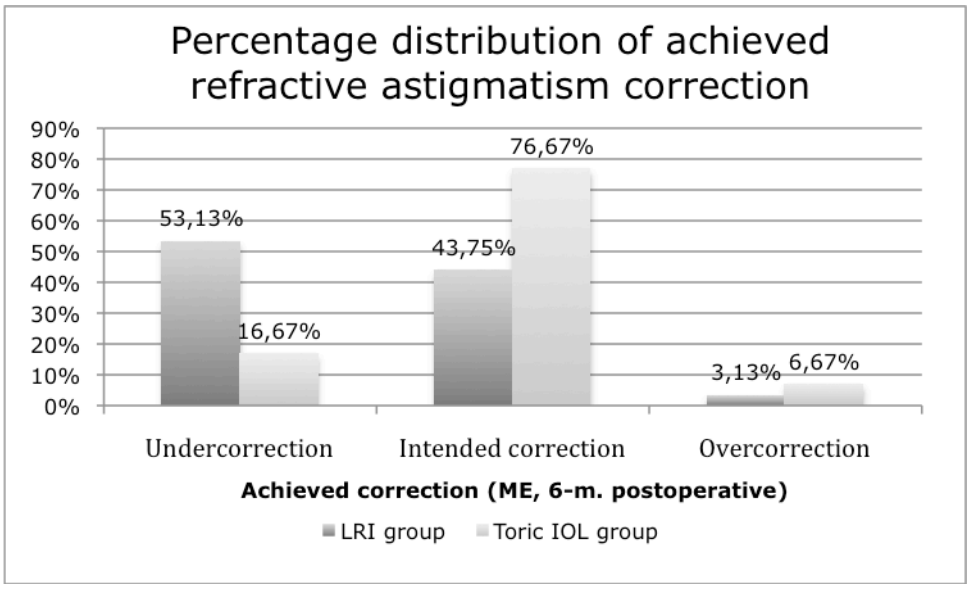
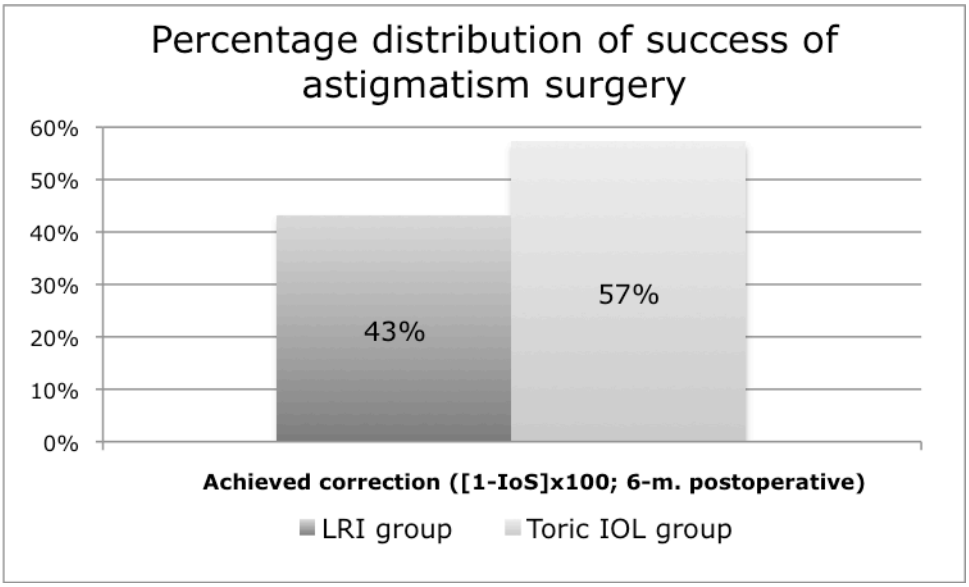


Figure 4. Histogram of percentage distribution of achieved astigmatic correction at 6 months postoperatively (IOL = intraocular lens; ME = magnitude of error; LRI = limbal relaxing incisions; 6-m. = 6-month postoperative period).

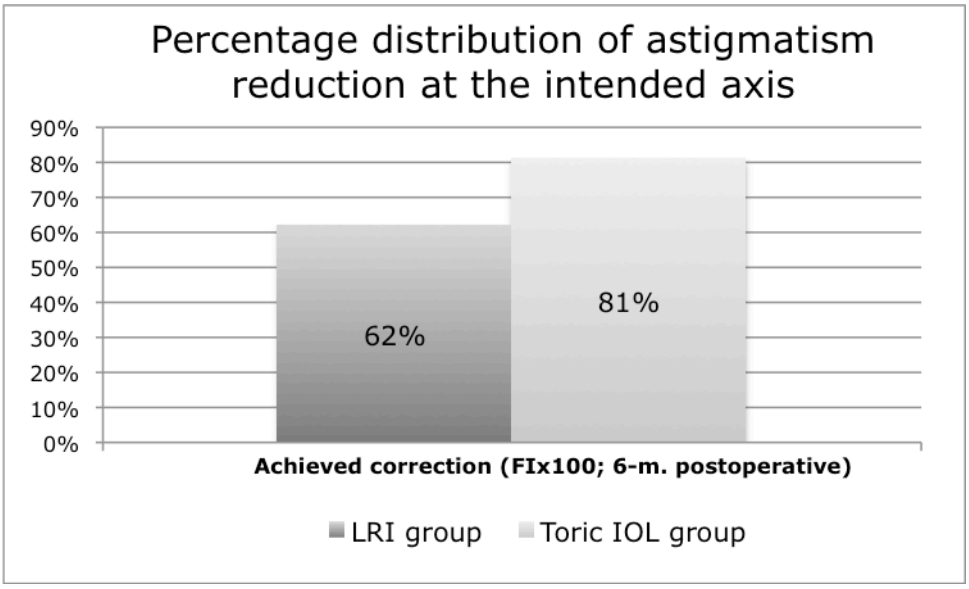
In the LRI group, under-correction was found in 53.13% of eyes, 43.74% of eyes reached the intended correction and 3.13% of eyes were over-corrected. In the toric IOL group, on its turn, under-correction was found in 16.76% of eyes, 76.67% of eyes reached the intended correction and 6.67% of eyes were over-corrected.

Figure 5 shows the percentage distribution success of astigmatic surgery, astigmatism reduction at the intended axis and percentage of astigmatism corrected at 6 months postoperatively in both groups.

A)



B)



C)

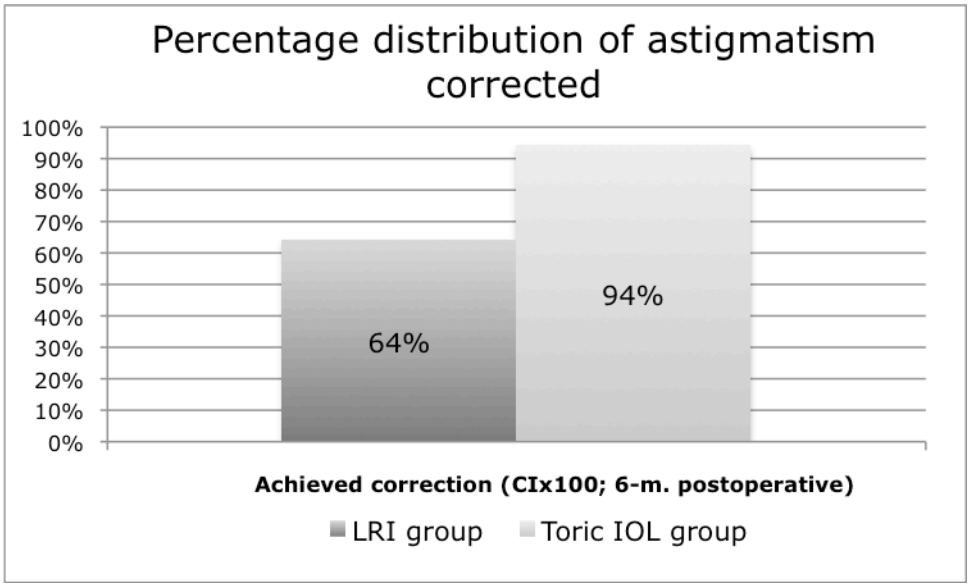


Figure 5. Histograms of percentage distribution at 6 months postoperatively: A)

Success of astigmatism surgery at 6 months postoperatively; B) Achieved astigmatic correction at the intended axis; C) Percentage of astigmatism corrected (CI x 100 = percentage of astigmatism corrected FI x 100 = astigmatism reduction at the intended axis; IOL = intraocular lens; LRI = limbal relaxing incisions; 6-m. = 6-month postoperative period; Mann-Whitney U test ≤ 0.01 for all cases).

In the LRI group, such percentage distributions were, respectively: 43%, 62% and 64%. In the toric IOL group, they were: 57%, 81% and 94%.

DISCUSSION

In our study, both LRI and toric IOL groups presented similar preoperative characteristics for most aspects of interest, as shown in Table 1, in accordance with the randomization design. However one difference was remarkable: in the toric IOL group, the mean age of patients was statistically lower, if compared to mean age found in the LRI group. It is known that both oblique and against the rule astigmatisms increase, in percentage of cases, as age increases. (21) Both of these forms of corneal astigmatism seem to respond somewhat poorly to LRI. (10, 22) So, it might be expected that overall capacity of LRI to treat preexisting corneal astigmatism may have been underestimated, and overall outcomes could possibly be different, if there were no such discrepancies, in mean age, between groups.

Postoperative manifest cylinder refraction at 6 months (as means ± standard deviation), of -0.74 D ± 0.26 D in LRI group and of -0.62 D ± 0.17 D in toric IOL group, are in accordance with current literature: -0.71 D ± 0.42 D (13), -0.94 D ± 0.40 D (23) and exhibited similar behaviors: consistently lower than intended astigmatism, within each group, and comparable outcomes between groups, as seen in Table 2. One consideration must be taken here, however: differences between groups were close to the cutoff value at 6-month reevaluation. Postoperative spherical equivalents of both groups, throughout follow up period, exhibited consistent homogeneity between them.

Visual acuity means, in LogMAR scale, are shown for both groups in Figure 1. Figure 1A shows pre- and postoperative SDCVA. Figure 1B shows postoperative UDVA

(preoperative UDVA was not an object of interest in our study). Preoperative SCDVA was a little better in the toric IOL group. There was no statistically significant difference, in the remaining periods, between groups.

Predictability means are shown in Table 3. Predictability oscillated widely throughout follow up period within groups and, also, between groups. We hypothesize that such variation arises from the subjective nature of manifest refraction. The means of ΔSE were statistically different from one another only at 1-month postoperative (better in the toric IOL group). In both groups, a considerable number of eyes achieved refraction within 1.00 D (nearly 97% in LRI group and 100% in toric IOL group), or within 0.50 D of the goal refraction (nearly 72% in LRI group and 67% in toric IOL group), in accordance to current literature that is roughly up to 90% within 1.00 D of the goal refraction. (24)

SI means, shown in Table 4, remained stable throughout the follow up period and had no major difference between groups for any follow up period. EI means, also shown in Table 4, depicts that in LRI group, means increased over time (statistically significant). In the toric IOL group, EI remained stable throughout follow up period. EI exhibited lower values in the 1- and 3-month postoperative periods, although such difference was no longer important by the 6-month postoperative. We believe that such EI behavior in the LRI group may be related to cicatricial demands associated to this technique (4), once the cicatricial process of incisions reached completion, outcomes in the LRI and in the toric IOL groups became comparable.

Several studies have shown that both LRI and toric IOL implantation provide good safety, predictability, and efficacy outcomes, associated with postoperative improvements in

visual acuity. (3, 22, 25-36) Such studies, however, dealt with LRI or toric IOL implantation against controls. A straightforward comparison between LRI and toric IOL in terms of predictability, safety and efficacy is one of the original contributions of our study.

We believe that predictability, safety and efficacy should be interpreted in a complementary fashion to one another, rather than as discrete parameters. Our results suggest that both LRI and toric IOL implantation may be considered predictable, safe and efficient treatment options. Statistically significant differences, whenever present, are subtle, although they should be taken into account for surgical planning. A slightly greater stability in outcomes, over time, was found in toric IOL group. That seems to constitute an advantage of toric IOL over LRI in the treatment of astigmatism.

Figure 2A provides information concerning TIA and SIA behaviors, over time, within each group and between groups: TIA means may be considered statistically similar between groups (Mann-Whitney U test *P* value = 0.62), SIA means, however, are statistically lower in the LRI group (Mann-Whitney U test *P* value ≤ 0.01). Also, SIA means are significantly lower than TIA means in the LRI group (Wilcoxon test *P* value = 0.00), in accordance with current literature, that states LRI most often under-corrects astigmatism (2, 3, 10). In both LRI and toric IOL groups, there were no significant differences in SIA means throughout follow up period (Wilcoxon test *P* value ≥ 0.25). The behavior of DV means between groups, and within each group, over time is presented in figure 2B. In LRI group, DV means were always higher than their counterparts in the toric IOL groups (Mann-Whitney U test *P* value ≤ 0.03), such differences were

significant. Within each group, variations over time were statistically insignificant (Wilcoxon test *P* value ≥ 0.17). Consequently, toric IOL group outcomes exhibited greater similarity to surgical planning: SIA means closer to TIA means and lesser DV mean values.

Scatterplots of attempted (TIA) versus achieved (SIA) astigmatic changes are shown in LRI group (figure 3A) and in toric IOL group (figure 3B). Within each group, a trendline correlating TIA and SIA has been drawn. Points distributed along the trendline indicate eyes that achieved the desired correction (TIA = SIA). Eyes that were under-corrected (TIA > SIA) or, alternatively, over-corrected (TIA < SIA) are represented by points under and above the trendline, respectively. (12) The strength of such correlations has been assessed by Pearson's R^2 coefficient of determination, in order to determine which group astigmatism correction has been more accurate. (19) The toric IOL group coefficient of determination (R^2=0.89) was greater than the one found for the LRI group (R^2=0.50).

Alternatively, the assessment of eyes that achieved the intended astigmatic correction, as well as the ones that were under or over-corrected, can be done by the analysis of a parameter termed ME. Percentage distribution of eyes that achieved intended correction and those under and over-corrected based on ME, for both groups, is shown in figure 4. Nearly 77% of eyes achieved intended correction in the toric IOL group, compared to 44% in the LRI group. Under-correction was found in 17% of eyes in the toric IOL group and 53% in the LRI group. Over-correction took place in about 7% of eyes in the toric IOL group and 3% in the LRI group. In our study, the greater number of cases of against the rule and oblique astigmatisms found in the LRI group may have

induced some bias to our analysis, due to the fact that such categories of astigmatism are somewhat less responsive to LRI. (2, 3, 10) The percentage of eyes that achieved intended correction in toric IOL group is remarkable, if compared to those of LRI group. Although over-correction cases occurred in both groups, over-corrected eyes were more often found in the toric IOL group.

Figure 5 depicts three indices that, if examined together, enable complete assessment of any astigmatic change: success of astigmatic surgery, calculated from index of success (Figure 5A), indicating a relative measure of success; flattening index (FI – Figure 5B) related to the proportion of SIA at the TIA axis, suggestive of treatment effectiveness; and correction index (CI – Figure 5C), the overall astigmatism correction achieved by SIA, pointing out treatment efficacy. (7) Regarding such indices, the toric IOL group outcomes were advantageous, if compared to the ones of LRI group: 57% against 43% for success of astigmatic surgery; 81% against 62% for FI and 94% against 64% for CI.

In conclusion, from both non-vectorial and vectorial standpoints, our results suggest the use of toric IOL to be advantageous over LRI in the treatment of astigmatism during phacoemulsification. Although such advantages seem often subtle in non-vectorial analysis, their importance is highlighted by vectorial approach. The main limitation of our study is the considerable proportion of against the rule and oblique astigmatisms found in LRI group, what introduced some bias of uncertain extent to our analyses.

REFERENCES

1. Alió JL, Agdeppa MCC, Pongo VC, Kady BE. Microincision cataract surgery with toric intraocular lens implantation for correcting moderate and high astigmatism: Pilot study. J Cataract Refract Surg. 2010;36:44-52.
2. Muftuoglu O, Dao L, Cavanagh HD, McCulley JP, Bowman RW. Limbal relaxing incisions at the time of apodized diffractive multifocal intraocular lens implantation to reduce astigmatism with or without subsequent laser in situ keratomileusis. J Cataract Refract Surg. 2010;36:456-64.
3. Carvalho MJ, Higashitani-Suzuki S, Lemes-Freitas L. Limbal relaxing incisions to correct corneal astigmatism during phacoemulsification. J Refract Surg. 2007;23:499-504.
4. Kamiya K, Shimizu K, Ohmoto F, Amano R. Evaluation of corneal biomechanical parameters after simultaneous phacoemulsification with intraocular lens implantation and limbal relaxing incisions. J Cataract Refract Surg. 2011;37:265-70.
5. Mendicute J, Irigoyen C, Aramberri J, Ondarra A, Montés-Micó R. Foldable toric intraocular lens for astigmatism correction in cataract patients. J Cataract Refract Surg. 2008;34:601-7.
6. Alpins N. A new method of analyzing vectors for changes in astigmatism. J Cataract Refract Surg. 1993;19:524-33.
7. Alpins N, Goggin M. Practical Astigmatism Analysis for Refractive Outcomes in Cataract and Refractive Surgery. Surv Ophthalmol. 2004;49:109-22.
8. Geggel HS. Arcuate Relaxing Incisions Guided by Corneal Topography for Postkeratoplasty Astigmatism: Vector and Topographic Analysis. Cornea. 2006;25(5):545-57.

9. Kaufmann C, Krishnan A, Landers J, Esterman A, Thiel MA, Goggin M. Astigmatic neutrality in biaxial microincision cataract surgery. J Cataract Refract Surg. 2009;35:1555-62.
10. Silva EF, Trindade F. Surgical correction of astigmatism during cataract surgery. Arq Bras Oftalmol. 2007;70(4):609-14.
11. Wang L, Misra M, Koch DD. Peripheral corneal relaxing incisions combined with cataract surgery. J Cataract Refract Surg. 2003;29:712-22.
12. Hoffmann PC, Auel S, Hütz WW. Results of higher power toric intraocular lens implantation. J Cataract Refract Surg. 2011;37:1411-8.
13. Visser N, Nuijts R, deVries NE, Bauer NJC. Visual outcomes and patient satisfaction after cataract surgery with toric multifocal intraocular lens implantation. J Cataract Refract Surg. 2011(37):2034-42.
14. Mingo-Botín D, Muñoz-Negrete F, Kim HRW, Morcillo-Laiz R, Rebolleda G, Oblanca N. Comparison of toric intraocular lenses and peripheral corneal relaxing incisions to treat astigmatism during cataract surgery. J Cataract Refract Surg. 2010;36:1700-8.
15. Ferrer-Blasco T, García-Lázaro S, Albarrán-Diego C, Belda-Salmerón L, Montés-Micó R. Refractive lens exchange with a multifocal diffractive aspheric intraocular lens. Arq Bras Oftalmol. 2012;75:192-6.
16. Behndig A, Montan P, Stenevi U, Kugelberg M, Zetterström C, Lundström M. Aiming for emmetropia after cataract surgery: Swedish National Cataract Register Study. J Cataract Refract Surg. 2012;38:1181-6.
17. Goggin M, Moore S, Esterman A. Outcome of Toric Intraocular Lens Implantation After Adjusting for Anterior Chamber Depth and Intraocular Lens Sphere Equivalent Power Effects. Arch Ophthalmol. 2011;129(8):998-1003.

18. Razali NM, Wah Y. Power comparisons of Shapiro-Wilk, Kolmogorov-Smirnov, Lilliefors and Anderson-Darling tests. Journal of Statistical Modeling and Analytics. 2011;2(1):21-33.
19. Shi R, Conrad S. Correlation and regression analysis. Annals of Allergy, Asthma & Immunology. 2009;103(4):S35-S42.
20. Carpenter J, Bithell J. Bootstrap confidence intervals: when, which, what? A practical guide for medical staticians. Stat Med. 2000;19:1141-64.
21. Gudmundsdottir E, Jonasson F, Jonsson V, Stefánsson E, Sasaki H, Sasaki K. “With the rule" astigmatism is not the rule in the elderly - Reykjavik Eye Study: A population based study of refraction and visual acuity in citizens of Reykjavik 50 years and older. Acta Ophthalmol Scand. 2000;78:642-6.
22. Ganekal S, Dorairaj S, Jhanji V. Limbal relaxing incisions during phacoemulsification: 6-month results. J Cataract Refract Surg. 2011(37):2081-2.
23. Alió JL, Piñero D, Tomás J, Alesón A. Vector analysis of astigmatic changes after cataract surgery with toric intraocular lens implantation. J Cataract Refract Surg. 2011;37:1038-49.
24. Goggin M, Moore S, Esterman A. Toric Intraocular Lens Outcome Using the Manufacturer’s Prediction of Corneal Plane Equivalent Intraocular Lens Cylinder Power. Arch Ophthalmol. 2011;129(8):1004-8.
25. Arraes JC, Cunha F, Arraes TA, Cavalcanti R, Ventura M. Limbal relaxing incisions during cataract surgery: one-year follow-up. Arq Bras Oftalmol. 2006;69(3):361-4.
26. Coloma-Gonzáles I, Gonzáles-Herrera M, Megual-Verdú E, Hueso-Abancens JR. Limbal Relaxing Incisions and Cataract Surgery: Our Experience. Arch Soc Esp Oftalmol. 2007;82:551-4.

27. Cristóbal JA, delBuey M, Ascaso FJ, Lanchares E, Calvo B, Doblare M. Effect of Limbal Relaxing Incisions During Phacoemulsification Surgery Based on Nomogram Review and Numerical Simulation. Cornea. 2009;28:1042-9.

28. Gills JP, Wallace R, Miller K, Fine HI, Friedlander M, McFarland M, Zhang X, Granet NS. Reducing Pre-Existing Astigmatism with Limbal Relaxing Incisions. In: A Complete Surgical Guide for Correcting Astigmatism. 2003; Thorofare, NJ. Slack Inc:99-119.

29. Ahmed IIK, Rocha G, Slomovic AR, Climenhaga H, Gohill J, Greagore A, Ma J. Visual function and patient experience after bilateral implantation of toric intraocular lenses. J Cataract Refract Surg. 2010;36:609-16.

30. Bauer NJC, deVries N, Webers CAB, F Hendrikse, Nuijts RMMA. Astigmatism management in cataract surgery with the AcrySof toric intraocular lens. J Cataract Refract Surg. 2008;34:1483-8.

31. Buckhurst PH, Wolffsohn J, Naroo SA, Davies LN. Rotational and centration stability of an aspheric intraocular lens with a simulated toric design. J Cataract Refract Surg. 2010;36:1523-8.

32. Correia RJB, Moreira H, Lago-Netto SU, Pantaleão GR. Visual performance after toric IOL implantation in patients with corneal astigmatism. Arq Bras Oftalmol. 2009;72(5):636-40.

33. Debois A, Nochez Y, Bezo C, Bellicaud D, Pisella PJ. Refractive precision and objective quality of vision after toric lens implantation in cataract surgery. J Fr Ophthalmol. 2012;35:580-6.

34. Ernest P, Potvin R. Effects of preoperative corneal astigmatism orientation on results with a low-cylinder-power toric intraocular lens. J Cataract Refract Surg. 2011;37:727-32.

35. Forseto AS, Nosé R, Nosé W. Toric Intraocular Lens Misalignment Inducing Astigmatism After Refractive Surgery. J Refract Surg. 2011;27(9):691-3.
36. Koshy JJ, Nishi Y, Hirnschall N, Crnej A, Gangwani V, Maurino V, Findl O. Rotational stability of a single-piece toric acrylic intraocular lens. J Cataract Refract Surg. 2010;36:1665-70.

TERCEIRO TRABALHO

Status: Manuscrito aceito pela RBO em 06/06/2013.

Comparison of clinical outcomes between limbal relaxing incisions and toric intraocular lenses in eyes with astigmatic corneas

Comparação de resultados clínicos entre incisões relaxantes limbares e lentes intraoculares tóricas em olhos com córneas astigmáticas

Giuliano de Oliveira Freitas, M.D., Research Fellow at the Federal University of Minas Gerais, Belo Horizonte-MG, Staff of Cataract Surgery Department at ISO Olhos – Instituto de Saúde Ocular, Uberlândia-MG, Brazil.

Joel Edmur Boteon, Ph.D., M.D., Ophthalmology Professor at the Federal University of Minas Gerais, Belo Horizonte-MG, Brazil.

Mario Jose Carvalho, M.D., Head of Cataract Surgery Department at ISO Olhos – ISO Olhos – Instituto de Saúde Ocular, Uberlândia-MG, Brazil.

Rogerio de Melo Costa Pinto, D.A., Biostatistics Professor at the Federal University of Uberlândia, Uberlândia-MG, Brazil.

Financial Contributors

- Private: Alcon Labs. of Brazil (São Paulo-SP) provided all intraocular lenses, at no cost, for scientific purposes.
- Public: Municipal Health Authority of Uberlândia-MG funded surgical procedures as regular governmental assistance policy.

Financial Disclosure: No author has a financial or proprietary interest in any material or method mentioned.

Corresponding author: Giuliano O. Freitas

Address: ISO Olhos, R. Eduardo Marquez 50, Martins

Uberlândia-MG/Brazil, ZIP Code 38.400-442

Phone: +55 (34) 3230-5050

Fax: + 55 (34) 3230-5055

E-mail: gofreitas@ufmg.br

Abstract

Objective: To compare refractive and vectorial outcomes of limbal relaxing incisions (LRI) versus toric intraocular lenses (IOL) in the treatment of preexisting corneal astigmatism at the time of phacoemulsification.

Methods: This longitudinal observational case series assessed 62 eyes of 31 consecutive cataract patients with preoperative corneal astigmatism between 0.75 and 2.50 diopters in both eyes. Patients were randomly assorted in two groups: one assigned to receive AcrySof Toric^{TM} IOL in both eyes, and another one assigned to have AcrySof Natural^{TM} IOL associated with LRI, also in both eyes. All patients were re-evaluated, postoperatively, at 1, 3 and 6 months, when refractive astigmatism analysis was performed using vectorial methods proposed by Thibos. Variability of outcomes within each group and between groups were assessed and compared.

Results: Manifest refractive cylinder, in diopters (D), as means ± standard deviation, in the LRI group for 1-month, 3-month and 6-month re-evalutions were respectively -0.66 ± 0.30; -0.70 ± 0.21 and -0.74 ± 0.26 when compared to -0.58 ± 0.24; -0.63 ± 0.20, and -0.62 ± 0.17 in the toric IOL group. (P value ≥ 0.06). Vectorial analysis evidenced greater astigmatism reduction in the toric IOL group in the 6th postoperative month, when postoperative mean astigmatic power vector was 0.31 D, when compared to 0.37 D in the LRI group (P value = 0.00).

Conclusions: A trend of slightly better refractive outcomes favoring toric IOL group was seen, although such a trend was not statistically significant. Vectorial analysis, however, suggests that the use of toric IOL may constitute a more advantageous approach

in the treatment of pre-existing corneal astigmatism, simultaneously with phacoemulsification.

Keywords

Cataract, astigmatism, limbal relaxing incisions (LRI), toric intraocular lens (toric IOL), vector.

Resumo

Objetivo: Comparar os resultados refracionais e de análise vetorial, das incisões relaxantes limbares (IRL) versus lentes intraoculares (LIO) tóricas no tratamento do astigmatismo corneano pré-existente por ocasião da facoemulsificação.

Método: Estudo observacional longitudinal (série de casos) no qual foram avaliados 62 olhos de 31 pacientes consecutivos de catarata com astigmatismo corneano pré-operatório entre 0,75 e 2,50 dioptrias para ambos os olhos. Os pacientes foram aleatoriamente distribuídos entre 2 grupos: um submetido a implante de LIO AcrySof Toric™ em ambos os olhos e outo grupo no qual seriam implantas LIO AcrySof Natural™ complementada por IRL, também em ambos os olhos. Todos os pacientes foram reavaliados com 1, 3 e 6 meses de pós-operatório, sendo feitas análises do astigmatismo refracional pelo métodos vetorial proposto por Thibos, interessando a variação de resultados dentro de cada grupo e entre os grupos.

Resultados: O cilindro refracional manifesto, em dioptrias, expresso como média ± desvio padrão, para o grupo IRL, nas avaliações de 1, 3 e 6 meses, foram respectivamente -0,66 ± 0,30; -0,70 ± 0,21 e -0,74 ± 0,26 em comparação aos -0,58 ± 0,24; -0,63 ± 0,20 and -0,62 ± 0,17 do grupo LIO tórica (valor de P ≥ 0,06). A análise vetorial evidenciou maior redução no astigmatismo no grupo LIO tórica no 6º mês pós-operatório, para o qual vetor de poder astigmático médio foi de 0,31 D, comparado ao de 0,37 D do grupo IRL (valor de P = 0,00).

Conclusões: Tendência a melhores resultados refracionais favorecendo o grupo LIO tórica foi encontrada, entretanto, significância estatística não foi evidenciada ao longo do estudo. A

análise vetorial, sugere que o uso de LIO tóricas possa se constituir em modalidade vantajosa no tratamento do astigmatismo corneano pré-operatório por ocasião da facoemulsificação.

Descritores

Catarata, astigmatismo, incisões relaxantes limbares (IRL), lente intraocular tórica (LIO tórica), vetor.

Introduction

Corneal astigmatism is an issue of major concern in modern cataract surgery. (1) At least 15% to 20% of cataract patients have 1.50 diopters (D) or more of corneal astigmatism at preoperative evaluation. (2) Suboptimum vision, due to cataract and astigmatism, is associated with impaired quality of life and increased number of falls in the elderly. (3) One popular approach to correct corneal astigmatism simultaneously to cataract surgery is to treat pre-existing cylinder by creating limbal relaxing incisions (LRI). (4-6) Toric intraocular lens (IOL) implantation is another valuable option in the treatment of corneal astigmatism in cataract patients. (7) To ascertain which approach constitutes a better surgical option remains under debate. (8) This study compared both techniques by means of pre and postoperative cylinder refraction and Thibos vectorial analysis. (9, 10)

Patients and methods

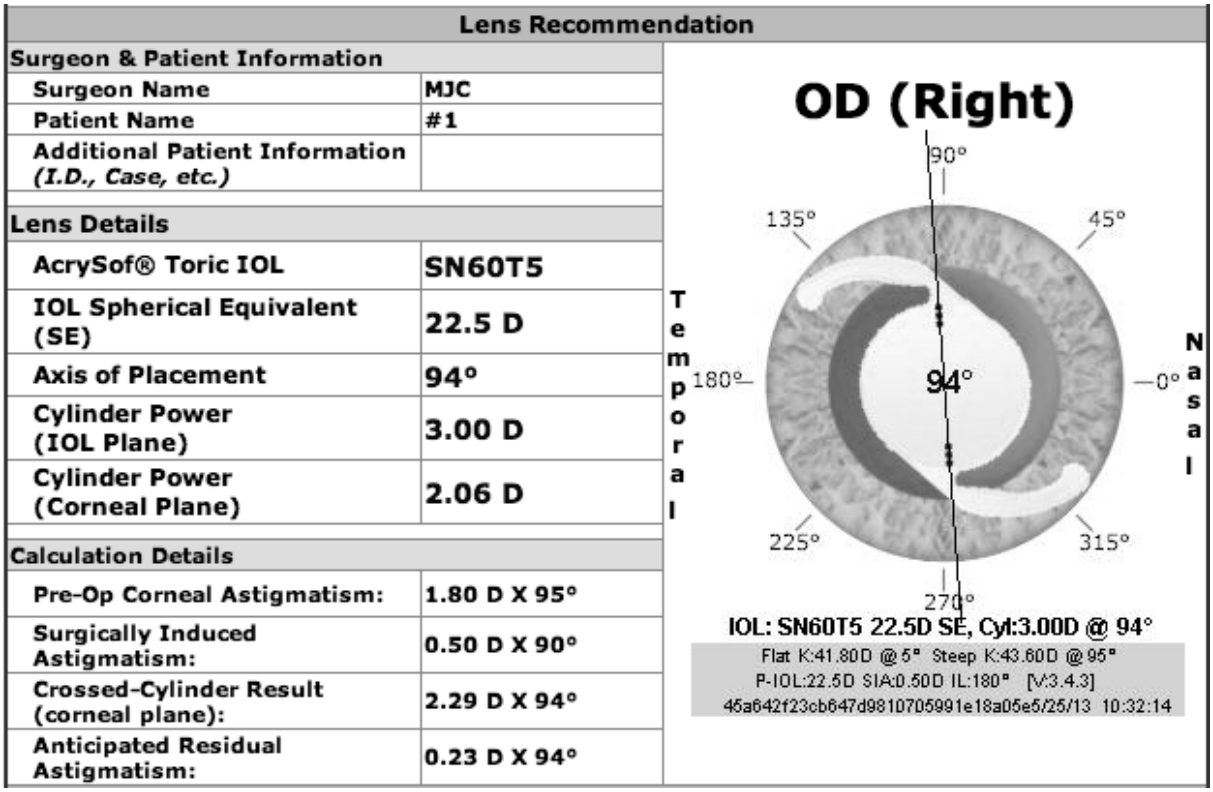
This longitudinal observational case series, designed as part of an ongoing Doctorate Thesis of one of the authors (*G.F.*) at Federal University of Minas Gerais (UFMG), assessed 31 consecutive cataract patients with preoperative corneal astigmatism between 0.75 and 2.50 diopters (D) in both eyes. Patients were randomly assorted, employing Microsoft Excel™ "***ƒ*=RANDBETWEEN(1;2)**" function, in two phacoemulsification groups: "1" for toric IOL group, assigned to receive toric IOL in both eyes (model AcrySof Toric™, Alcon™, Inc.), and "2" for LRI group, assigned to have spherical IOL (AcrySof Natural™, Alcon™, Inc.) associated with LRI, also in both eyes. All patients provided a written informed consent, after they had received an explanation about the nature of the study and its potential complications, in accordance with the tenets of the Declaration of Helsinki and the UFMG's institutional ethics committee protocol (ETIC 341/09). All surgeries were performed, between May 2010 and June 2012, at ISO Olhos, Instituto de Saude Ocular, Uberlândia-MG, Brazil.

Inclusion criteria were age older than 40 years and, for both eyes, visually significant cataract (best corrected visual acuity worse than LogMAR 0.3), regular corneal astigmatism between 0.75 D and 2.50 D, and pharmacologic mydriasis of at least 6.0 millimeters to allow proper intraoperative visualization of axis marks on the toric IOL.

The following were exclusion criteria: previous surgery in the eye under study, pterygium, ocular disease that would lead to poor postoperative corrected visual acuity (corneal scarring, uveitis, advanced glaucoma, neuro-ophthalmic disease, significant macular disease or other retinopathy), zonule or pupil abnormalities and any irregular corneal astigmatism.

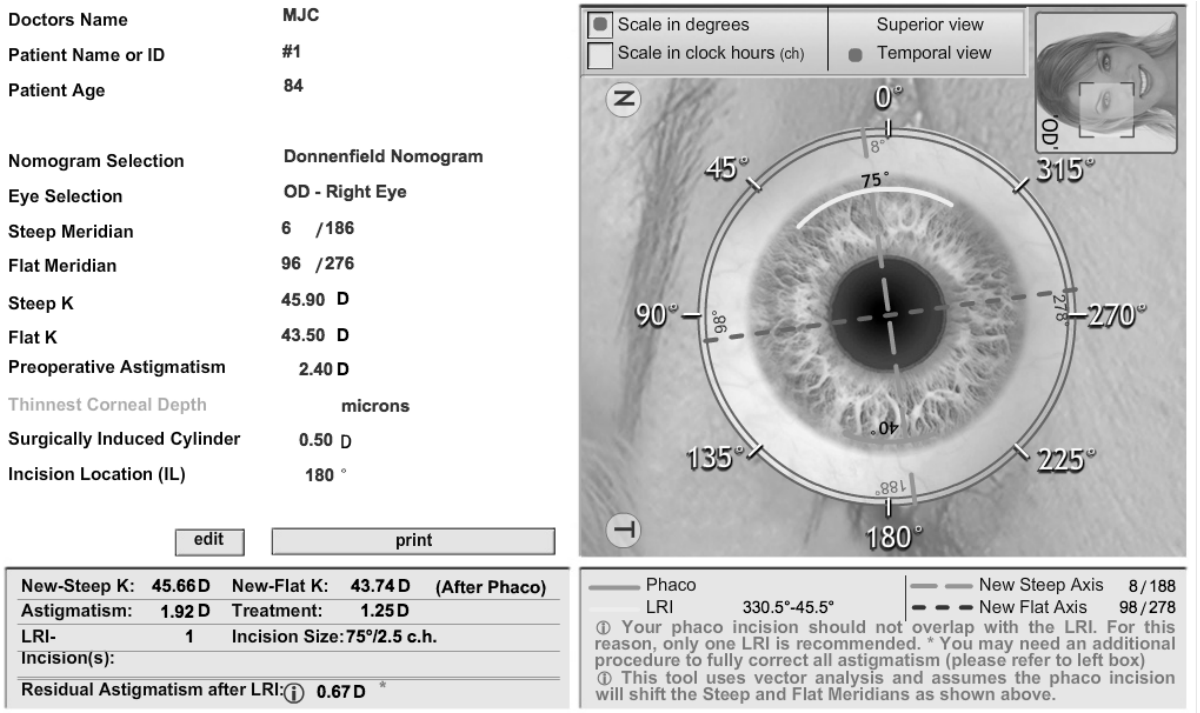
Preoperatively, every patient had a complete ophthalmic evaluation performed by an examiner other than the surgeon (*G.F.*), including logMAR best distance corrected visual acuity, manifest refraction, slit lamp examination, applanation tonometry, and fundoscopy under pharmacological mydriasys, in addition to corneal topography (Orbscan™ II, Bausch&Lomb™, Inc.) and ultrasound immersion biometry (OcuScan™, Alcon™, Inc.). Hoffer Q formula was used in eyes with an axial length shorter than 22 mm, and SRK/T formula was used for all other cases.

Toric IOL cylinder power and axis placement were determined using the IOL manufacturer's online calculator (www.acrysoftoriccalculator.com). Size and location of LRI were also determined via online application (www.lricalculator.com), according to Donnenfeld's nomogram. For both Toric IOL and LRI groups, biometry, simulated keratometry (one reading per eye), main incision location, and surgeon's expected surgically induced astigmatism (-0.50 D) were entered into the calculators, with emmetropia as the goal postoperative refraction, i.e., zero sphere and the smallest residual cylinder possible. (11, 12) Figures 1 and 2 show examples of toric IOL and LRI surgical plannnings, respectively.



Lens Recommendation	
Surgeon & Patient Information	
Surgeon Name	MJC
Patient Name	#1
Additional Patient Information *(I.D., Case, etc.)*	
Lens Details	
AcrySof® Toric IOL	SN60T5
IOL Spherical Equivalent (SE)	22.5 D
Axis of Placement	94°
Cylinder Power (IOL Plane)	3.00 D
Cylinder Power (Corneal Plane)	2.06 D
Calculation Details	
Pre-Op Corneal Astigmatism:	1.80 D X 95°
Surgically Induced Astigmatism:	0.50 D X 90°
Crossed-Cylinder Result (corneal plane):	2.29 D X 94°
Anticipated Residual Astigmatism:	0.23 D X 94°

Figure 1. Example of toric IOL surgical planning (http://www.acrysoftoriccalculator.com - accessed May 1st , 2012).



Doctors Name	MJC
Patient Name or ID	#1
Patient Age	84
Nomogram Selection	Donnenfield Nomogram
Eye Selection	OD - Right Eye
Steep Meridian	6 /186
Flat Meridian	96 /276
Steep K	45.90 D
Flat K	43.50 D
Preoperative Astigmatism	2.40 D
Thinnest Corneal Depth	microns
Surgically Induced Cylinder	0.50 D
Incision Location (IL)	180 °

edit print

New-Steep K:	45.66 D	New-Flat K:	43.74 D	(After Phaco)
Astigmatism:	1.92 D	Treatment:	1.25 D	
LRI-Incision(s):	1	Incision Size:	75°/2.5 c.h.	
Residual Astigmatism after LRI:	0.67 D *			

Figure 2. Example of LRI surgical planning (http://www.lricalculator.com - accessed May 1st , 2012).

The same surgeon (*M.C.*) performed all surgeries under mild sedation and topical anesthesia. Just before surgery, a sterile ink pen was used to make two marks on the corneal limbus at the 0-degree and 180-degree positions, with the patient sitting upright at the slit lamp, to avoid ocular torsion.

For both groups, phacoemulsification, followed by IOL implantation, was performed through a temporal 2.75 mm wide corneal incision. In the toric IOL group, the IOL was rotated to align with the planned axis. LRI were created inside the limbus using a calibrated diamond knife with the blade depth set at 600 μm.

In the postoperative period, patients were given an eye-drop combination of moxifloxacin and dexamethasone q.i.d. for a week and, then, prednisolone q.i.d. tapered throughout another 3 weeks. All patients were evaluated at 1, 3 and 6 months postoperatively by an examiner other than the surgeon (*G.F.*). Postoperative manifest refraction (sphere and cylinder) and visual acuity (uncorrected and corrected) were obtained. Calculations of Thibos vectors (9, 10), for refractive astigmatism, were performed using Microsoft Excel™ for MacIntosh spreadsheets (version 12.2.7, Microsoft Corp.). Shapiro-Wilk normality tests of data set were performed using IBM™ SPSS™ for Microsoft Windows™ software (version 20.0.0). A *p* value of 0.05 or less was considered statistically significant. (13) Wilcoxon test was used to analyze statistical non-parametric differences within the same group throughout the follow up period and Mann-Whitney U test was used to determine differences between Toric IOL and LRI groups at each reevaluation. (5)

Results

The study enrolled 62 eyes of 31 consecutive eligible patients. All surgeries were uneventful. None of the eyes required a second intervention. No potentially sight-threatening complications, such as persistent corneal edema, pupillary block, retinal detachment or endophthalmitis were observed.

Patient demographics and preoperative data are presented in Table 1.

Table 1. Patient demographics and preoperative data.

	Group		
	LRI	Toric IOL	*P* value*
Patients (n)	16	15	-
Eyes (n)	32	30	-
Sex (F/M)	8/8	11/4	-
Age (y)			
Mean ± SD	71.75 ± 8.87	65.67 ± 6.28	.01
Topographic astigmatism (D)			
Mean ± SD	1.32 ± 0.47	1.41 ± 0.54	.60
Range	0.75 to 2.40	0.80 to 2.50	-
Steepest topographic 180º-semimeridian angle (n)			
0 to 30º or 151º to 180º	18	5	-
61º to 120º	8	24	-
31º to 60º or 121º to 150º	6	1	-

F = females; D = diopters; IOL = intraocular lens; M = males; LRI = limbal relaxing incisions; mm = millimeters; n = number; SD = standard deviation; y = years; (*) Mann-Whitney U test.

All patients have accomplished the follow up period of 6 months.

Table 2 shows preoperative, 1-month, 3-month and 6-month postoperative manifest cylinder refraction of both groups.

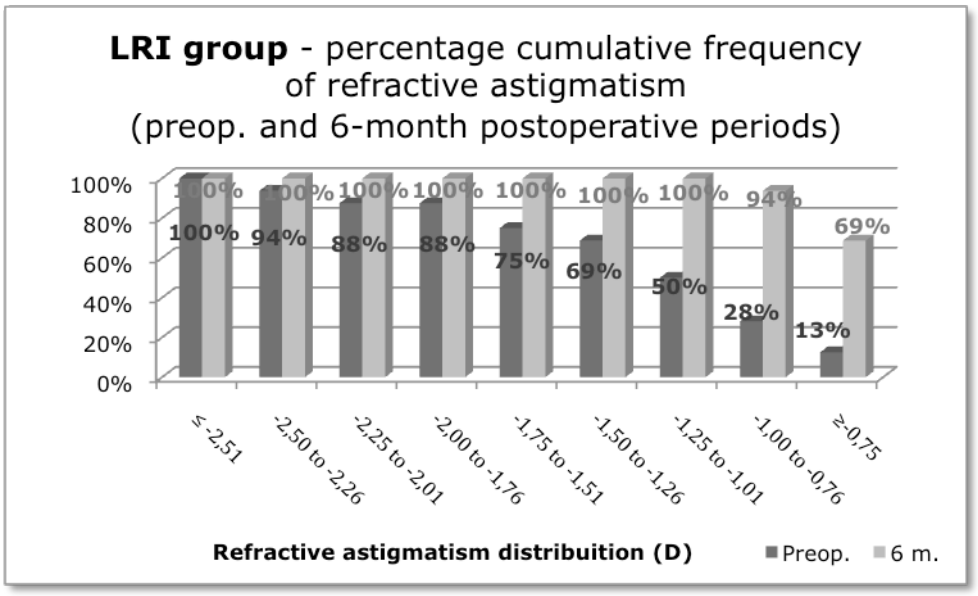
Table 2. Preoperative, 1-month, 3-month and 6-month postoperative manifest cylinder refraction.

	Group		
Cylinder diopters	LRI	Toric IOL	*P* value*
Preoperative			
Mean ± SD	-1.48 ± 0.60	-1.40 ± 0.73	.73
Range	-2.75 to -0.50	-2.75 to -0.25	-
1-month postoperative			
Mean ± SD	-0.66 ± 0.30	-0.58 ± 0.24	.25
Range	-1.25 to 0.00	-1.00 to 0.00	-
P value$_1$	.00	.00	-
3-month postoperative			
Mean ± SD	-0.70 ± 0.21	-0.63 ± 0.20	.17
Range	-1.00 to 0.00	-1.00 to -0.25	-
P value$_3$	.00	.00	-
6-month postoperative			
Mean ± SD	-0.74 ± 0.26	-0.62 ± 0.17	.06
Range	-1.25 to -0.25	-1.00 to -0.25	-
P value$_6$	.00	.00	-

IOL = intraocular lens; LRI = limbal relaxing incisions; SD = standard deviation; (*) Mann-Whitney U test; Wilcoxon test – preoperative cylinder x 1-month($_1$), 3-month($_3$) and 6-month($_6$) postoperative cylinder.

Figure 3 compares percentage cumulative frequency of refractive astigmatism between LRI and toric IOL groups.

A)



B)

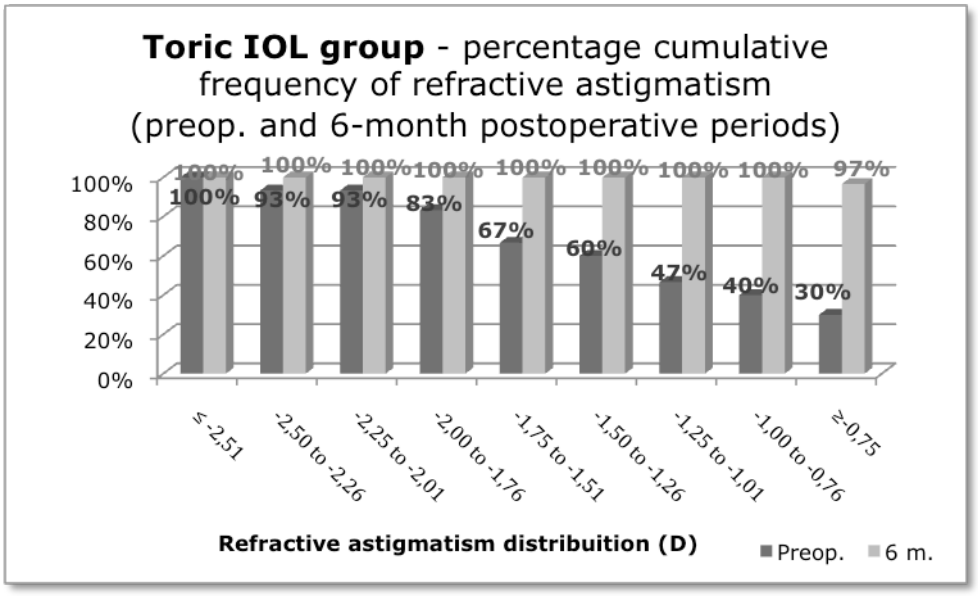


Figure 3. Percentage cumulative frequency of astigmatism distribution in the LRI (A) and toric IOL (B) groups at the preoperative and 6-month postoperative periods (IOL = intraocular lens; LRI = limbal relaxing incisions; Preop. = preoperative period; 6 m. = 6-month postoperative period).

Figure 4 compares mean magnitudes of astigmatic power vectors (APV), preoperatively, 1-month, 3-month and 6-month between LRI and Toric IOL groups.

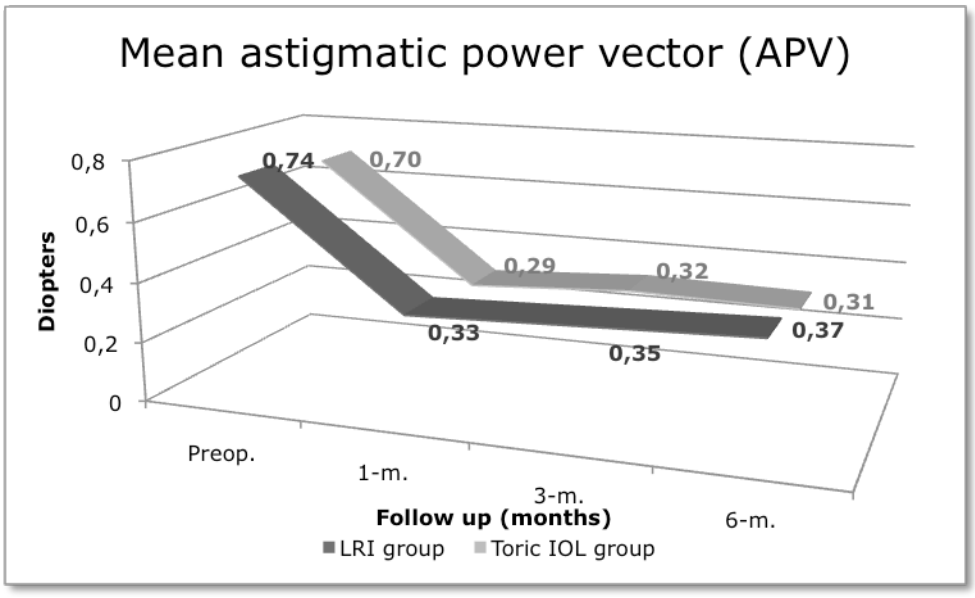


Figure 4. Mean magnitudes of preoperative, 1-month, 3-month and 6-month postoperative mean astigmatic power vector (APV). Between groups, there was no statistical difference through out the periods studied, except for the 6-m., when it was lower in the Toric IOL group*. Within each group, preoperative APV was greater than any postoperative APV, remaining stable on† (APV = astigmatic power vector; IOL = intraocular lens; LRI = limbal relaxing incisions; m. = *n*-month postoperative; Preop. = preoperative period; *Mann-Whitney U test, P value = 0.05; †Wilcoxon test – pre- and postoperative periods, P value = 0.00).

Figure 5 compares pre- and 6-month postoperative APV in the LRI and toric IOL groups.

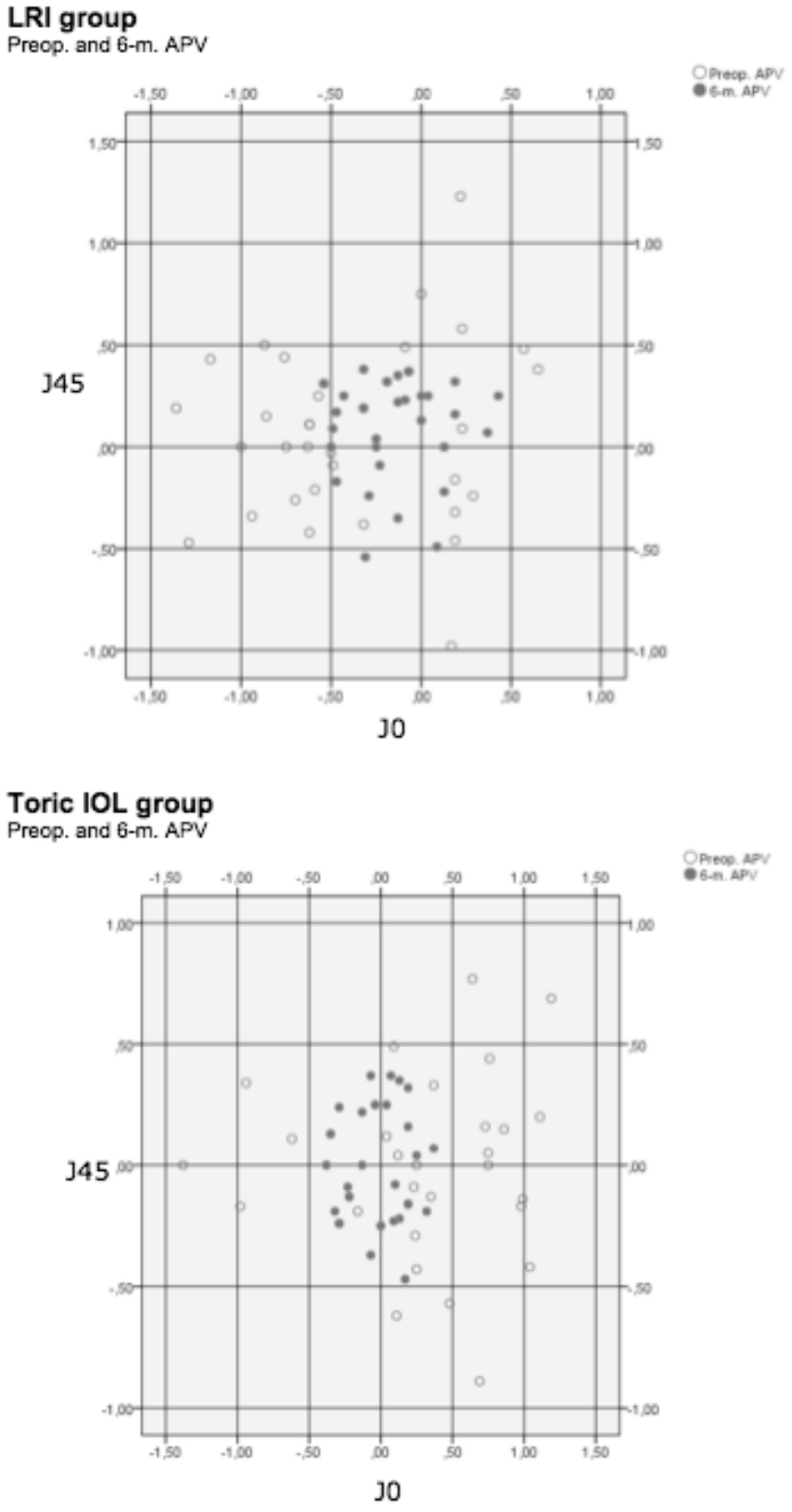


Figure 5. Scatterplot of astigmatic vectors J0 and J45 preoperatively and 6 months postoperatively in the LRI group *(top)* and the Toric IOL group (*bottom*) (LRI = limbal relaxing incisions; IOL = intraocular lens).

Discussion

In this study, both LRI and toric IOL groups presented comparable preoperative characteristics for most aspects of interest, as shown in Table 1, in accordance with randomization design of our study. However, in the LRI group the mean age of patients was statistically higher, if compared to toric IOL group. It is well known that both oblique and against-the-rule astigmatism increase in occurrence as age increases (14, 15). Accordingly, it can be seen, in table 1, that oblique and against-the-rule astigmatism forms were more frequently found in the LRI group. Both of these forms of corneal astigmatism seem to respond somewhat poorly to LRI. (16, 17) Overall capacity of LRI to treat pre-existing corneal astigmatism may have been undervalued to an uncertain extent, and outcomes might have been different, if there were no such discrepancies in mean age between groups.

Manifest pre and postoperative refractive cylinders, shown in table 2, for both LRI or toric IOL groups, are in accordance with current literature. (18, 19) Differences between pre and postoperative refractive cylinders were statistically significant within each group throughout the follow up period (*P* value = 0.00). Between groups, however, they were not (*P* value > 0.05). A trend of lower mean values favoring the toric IOL group was observed, although such trend was, at most, close to statistical significance at 6^{th} postoperative month. Toric IOL group, in the last postoperative visit, had 97% of eyes with refractive astigmatism between -0.75 D and zero; 100% of eyes between -1.00 D and zero. The LRI group had 69% of eyes between -0.75 D and zero of refractive astigmatism, and 94% of eyes between -1.00 and zero, as can be seen in figure 3. Again, a trend in outcomes predictability, favoring toric IOL group, can be noticed.

Thibos and coworkers (9, 10) have proposed a scalar termed astigmatic power vector (APV) that may be used to determine statistical differences between datasets, whenever astigmatism magnitude is the primary concern. (20) Such vectorial astigmatism analysis is gaining popularity in literature in recent years, as an increasing number of articles employ it as analytical instrument. (1, 4, 7, 8, 21, 22) Figure 4 compares mean magnitudes of pre and postoperative APV within each group and between groups. A statistically significant reduction in APV, considering preoperative and any postoperative APV, was found within each group (*P* value = 0.00). Between groups, toric IOL group exhibited lower APV mean magnitude at 6-month postoperatively; the difference to LRI group was statistically significant (*P* value ≤ 0.05). The trend suggested by non-vectorial analysis of refractive astigmatism, so far, is now highlighted by objective data given by APV vectorial differences between groups.

Figure 5 shows components of APV, J0 and J45, plotted on a two-dimensional Cartesian plane. Spread of 6-month postoperative APV, in both groups, deviate nearly ±0.50 D from origin (x=0; y=0). However, APV (the vector between origin and each data point) is more homogeneously concentrated around origin in the toric IOL plot than in the LRI plot, which is suggestive of lower postoperative astigmatism in the toric IOL group. (20)

Conclusion

In conclusion, satisfactory refractive astigmatism reduction was obtained in both groups. However, our results suggest that the use of toric IOL may be slightly advantageous, from vectorial standpoint, in the treatment of pre-existing corneal astigmatism during phacoemulsification. The main limitation of our study was the greater amount of eyes with oblique or against-the-rule astigmatism present in LRI group, which introduced a bias to the analysis of LRI group of unknown extent. It is also possible that longer follow up periods might undercover statistical significance in the differences of manifest refractive cylinder means between groups.

References

1. Srivannaboon S, Soeharnilla C, Chirapapaisan C, Chonpimai P. Comparison of corneal astigmatism and axis location in cataract patients measured by total corneal power, automated keratometry, and simulated keratometry. J Cataract Refract Surg. 2012;38:2088-93.

2. Alió JL, Agdeppa M, Pongo VC, Kady BE. Microincision cataract surgery with toric intraocular lens implantation for correcting moderate and high astigmatism: Pilot study. J Cataract Refract Surg. 2010;36:44-52.

3. Wolffsohn JS, Boghal G, Shah S. Effect of uncorrected astigmatism on vision. J Cataract Refract Surg. 2011;37:454-60.

4. Muftuoglu O, Dao L, Cavanagh HD, McCulley JP, Bowman RW. Limbal relaxing incisions at the time of apodized diffractive multifocal intraocular lens implantation to reduce astigmatism with or without subsequent laser in situ keratomileusis. J Cataract Refract Surg. 2010;36:456-64.

5. Carvalho MJ, Higashitani-Suzuki S, Lemes-Freitas L. Limbal relaxing incisions to correct corneal astigmatism during phacoemulsification. J Refract Surg. 2007;23:499-504.

6. Kamiya K, Shimuzu K, Ohmoto F, Amano R. Evaluation of corneal biomechanical parameters after simultaneous phacoemulsification with intraocular lens implantation and limbal relaxing incisions. J Cataract Refract Surg. 2011;37:265-70.

7. Mendicute J, Irigoyen C, Aramberri J, Ondarra A, Montés-Micó R. Foldable toric intraocular lens for astigmatism correction in cataract patients. J Cataract Refract Surg. 2008;34:601-7.

8. Mingo-Botín D, Muñoz-Negrete F, Kim HRW, Morcillo-Laiz R, Rebolleda G, Oblanca N. Comparison of toric intraocular lenses and peripheral corneal relaxing incisions to treat astigmatism during cataract surgery. J Cataract Refract Surg. 2010;36:1700-8.

9. Thibos LN, Wheeler W. Power vectors: an application of Fourier analysis to the description and statistical analysis of refractive error. Optom Vis Scie. 1997;74:367-75.

10. Thibos LN, Horner D. Power vector analysis of the optical outcome of refractive surgery. J Cataract Refract Surg. 2001;27:80-5.

11. Behndig A, Montan P, Stenevi U, Kugelberg M, Zetterström C, Lundström M. Aiming for emmetropia after cataract surgery: Swedish National Cataract Register Study. J Cataract Refract Surg. 2012;38:1181-6.

12. Goggin M, Moore S, Esterman A. Outcome of Toric Intraocular Lens Implantation After Adjusting for Anterior Chamber Depth and Intraocular Lens Sphere Equivalent Power Effects. Arch Ophthalmol. 2011;129(8):998-1003.

13. Razali NM, Wah Y. Power comparisons of Shapiro-Wilk, Kolmogorov-Smirnov, Lilliefors and Anderson-Darling tests. Journal of Statistical Modeling and Analytics. 2011;2(1):21-33.

14. Goto T, Klyce S, Zheng X, Maeda N, Kuroda T, Ide C. Gender- and Age-ralated differences in corneal topography. Cornea. 2001;20(3):270-6.

15. Gudmundsdottir E, Jonasson F, Jonsson V, Stefánsson E, Sasaki H, Sasaki K. “With the rule" astigmatism is not the rule in the elderly - Reykjavik Eye Study: A population based study of refraction and visual acuity in citizens of Reykjavik 50 years and older. Acta Ophthalmol Scand. 2000;78:642-6.

16. Silva EF, Trindade F. Surgical correction of astigmatism during cataract surgery. Arq Bras Oftalmol. 2007;70(4):609-14.

17. Ganekal S, Dorairaj S, Jhanji V. Limbal relaxing incisions during phacoemulsification: 6-month results. J Cataract Refract Surg. 2011(37):2081-2.

18. Visser N, Nuijits R, deVries NE, Bauer NJC. Visual outcomes and patient satisfaction after cataract surgery with toric multifocal intraocular lens implantation. J Cataract Refract Surg. 2011(37):2034-42.

19. Alió JL, Piñero D, Tomás J, Alesón A. Vector analysis of astigmatic changes after cataract surgery with toric intraocular lens implantation. J Cataract Refract Surg. 2011;37:1038-49.
20. Statham M, Apel A, Stephensen D. Comparison of the AcrySof SA60 spherical intraocular lens and the AcrySof Toric SN60T3 intraocular lens outcomes in patients with low amounts of corneal astigmatism. Clin Exper Ophthalmology. 2009;37:775-9.
21. Mendicute J, Irigoyen C, Ruíz M, Illarramendi I, T Ferrer-Blasco, Montés-Micó R. Toric intraocular lens versus opposite clear corneal incisions to correct astigmatism in eyes having cataract surgery. J Cataract Refract Surg. 2009;35:451 - 8.
22. Sheppard AL, Wolffsohn J, Bhatt U, Hoffmann PC, Scheider A, Hütz WW, Shah S. Clinical outcomes after implantation of a new hydrophobic acrylic toric IOL during routine cataract surgery. J Cataract Refract Surg. 2013;39:41-7.

QUARTO TRABALHO

Status: Manuscrito aceito pela RBO em 09/05/2013.

Alpins and Thibos vectorial astigmatism analyses – proposal of a linear regression model between these methods

Análises vetoriais de Alpins e Thibos para o astigmatismo – proposta de modelo de regressão linear entre estes métodos

Giuliano de Oliveira Freitas, M.D., Research Fellow at the Federal University of Minas Gerais, Belo Horizonte-MG, Staff of Cataract Surgery Department at ISO Olhos – Instituto de Saúde Ocular, Uberlândia-MG, Brazil.

Joel Edmur Boteon, Ph.D., M.D., Ophthalmology Professor at the Federal University of Minas Gerais, Belo Horizonte-MG, Brazil.

Mario Jose Carvalho, M.D., Head of Cataract Surgery Department at ISO Olhos – ISO Olhos – Instituto de Saúde Ocular, Uberlândia-MG, Brazil.

Rogerio de Melo Costa Pinto, D.A., Biostatistics Professor at the Federal University of Uberlândia, Uberlândia-MG, Brazil.

Financial Contributors

- Private: Alcon Labs. Brazil (São Paulo-SP) provided all intraocular lenses, at no cost, for scientific purposes.
- Public: Municipal Health Authority of Uberlândia-MG funded surgical procedures as regular governmental assistance policy.

Financial Disclosure: No author has a financial or proprietary interest in any material or method mentioned.

Corresponding author: Giuliano O. Freitas

Address: ISO Olhos, R. Eduardo Marquez 50, Martins

Uberlândia-MG/Brazil, ZIP Code 38.400-442

Phone: +55 (34) 3230-5050

Fax: + 55 (34) 3230-5055

E-mail: gofreitas@ufmg.br

Abstract

Purpose: To determine linear regression models between Alpins descriptive indices and Thibos astigmatic power vectors (APV), assessing the validity and strength of such correlations.

Methods: This case series prospectively assessed 62 eyes of 31 consecutive cataract patients with preoperative corneal astigmatism between 0.75 and 2.50 diopters in both eyes. Patients were randomly assorted among two phacoemulsification groups: one assigned to receive AcrySof Toric intraocular lens (IOL) in both eyes and another assigned to have AcrySof Natural IOL associated with limbal relaxing incisions, also in both eyes. All patients were reevaluated postoperatively at 6 months, when refractive astigmatism analysis was performed using both Alpins and Thibos methods. The ratio between Thibos postoperative APV and preoperative APV (APV_{ratio}) and its linear regression to Alpins percentage of success of astigmatic surgery, percentage of astigmatism corrected and percentage of astigmatism reduction at the intended axis were assessed.

Results: Significant negative correlation between the ratio of post- and preoperative Thibos APV_{ratio} and Alpins percentage of success ($\%_{Success}$) was found (Spearman's ρ=-0.93); linear regression is given by the following equation: $\%_{Success} = (-APV_{ratio} + 1.00)x100$.

Conclusion: The linear regression we found between APV_{ratio} and $\%_{Success}$ permits a validated mathematical inference concerning the overall success of astigmatic surgery.

Key-words

Phacoemulsification; Astigmatism; Limbus corneae/surgery; Lens implantation, intraocular; Diagnostic techniques, ophthalmological.

Resumo

Objetivo: Estabelecer modelos de regressão linear entre os índices propostos por Alpins com os vetores astigmáticos de Thibos, avaliando a validade e a força dessas correlações.

Método: Série de casos na qual foram avaliados prospectivamente 62 olhos de 31 pacientes de catarata com astigmatismo corneano pré-operatório entre 0,75 e 2,50 dioptrias para ambos os olhos. Os pacientes foram aleatoriamente distribuídos entre 2 grupos: um submetido a implante de lente intraocular (LIO) AcrySof Toric™ em ambos os olhos e outro grupo, no qual seriam implantas LIO AcrySof Natural™ complementada por incisões relaxantes limbares, também em ambos os olhos. Todos os pacientes foram reavaliados aos 6 meses de pós-operatório, sendo feitas análises do astigmatismo refracional tanto pelo método vetorial proposto por Alpins, quanto pelo proposto por Thibos. A razão entre os vetores astigmáticos pós- e pré-operatórios de Thibos ($VA_{pós/pré}$), bem como a correlação linear com o percentual de sucesso da cirurgia do astigmatismo, o percentual de astigmatismo corrigido e o percentual de redução do astigmatismo no eixo pretendido, propostos por Alpins, foram avaliados.

Resultados: Foi encontrada correlação negativa significativa entre a $VA_{pós/pré}$ de Thibos e o percentual de sucesso da cirurgia do astigmatismo ($\%_{Sucesso}$), de Alpins (ρ de Spearman=-0.93); regressão linear dada pela seguinte equação: $\%_{Sucesso} = (-VA_{pós/pré} + 1{,}00)x100$.

Conclusões: A regressão linear encontrada entre $VA_{pós/pré}$ e $\%_{Sucesso}$ permite uma inferência matemática validada a respeito do sucesso de cirurgia do astigmatismo em termos gerais.

Descritores

Facoemulsificação; Astigmatismo; Limbo da córnea/cirurgia; Implante de lentes intraoculares; Técnicas de diagnóstico oftalmológico.

Introduction

Vectors are mathematical expressions that combine values for magnitude and direction. A given vector has specified values for each of these parameters. Astigmatism, with cylinder power and axis (refractive) or magnitude and meridian (corneal), fits such a description (1, 2). Manipulation of vectors follows certain rules and can yield resultant vectors from combinations of others. Similarly, the combination of a known preoperative astigmatism and planned surgical effect on that astigmatism can yield desired postoperative astigmatism (1).

The Alpins method is a vectorial analysis that allows determination of the effectiveness of a specific astigmatic treatment. It considers both magnitude and orientation of astigmatism. Three fundamental vectors are used in the analysis: target-induced astigmatism (TIA) – the astigmatic change the surgery was intended to induce, surgically induced astigmatism (SIA) – the astigmatic change the surgery actually induced and difference vector (DV) – the induced astigmatic change that would enable the initial surgery to achieve its intended target. Various relationships between these vectors, such as correction index (SIA/TIA), flattening index ([SIA x Cos 2 x angle between SIA and TIA]/TIA), index of success (DV/TIA) among others, provide a complete description of the astigmatic correction achieved with a specific modality of treatment. It can be determined whether the treatment was on axis, or off axis and whether too much, or too little effect was achieved. The Alpins method has been used by several authors to analyze the astigmatic changes induced with different surgical and nonsurgical options (1), including limbal relaxing incisions (1, 3-7), excimer laser refractive surgery, toric intraocular lens implantation, vitrectomy or orthokeratology (8).

If, however, astigmatism is represented in rectangular vector form, conventional scalar methods can be applied to each vector component. Furthermore, standard multivariate statistics can be used to compute population means and variances, define confidence intervals, and test hypotheses. Thibos and Horner have proposed such an approach (9, 10). According to this method, power vectors are geometrical representations of spherocylindrical refractive errors in three fundamental dioptric components. The first component is a spherical lens with power M equal to the spherical equivalent of the given refractive error (M = sphere + cylinder/2). The remaining two components come from a Jackson crossed cylinder, equivalent to a conventional cylinder of positive power J at axis α + 90° (α = the meridian of maximum positive power or angle of astigmatic prescription) crossed with a cylinder of negative power $-J$ at axis 90°. Thus, a power vector is that vector drawn from the coordinate origin of this space to the point (M, J_0, J_{45}) (7, 9). The magnitude of the asigmatic power vector (APV) on the astigmatic plane is defined by $(J_0^2+J_{45}^2)^{1/2}$ and represents a non-signed scalar that may be used to determine statistical differences in the magnitude of astigmatism between two datasets (11, 12).

To our knowledge, Alpins and Thibos analyses are not readily interchangeable to one another, when it comes to their mathematical results and interpretation. The aim of the present article is to determine if linear regressions between Alpins indices and Thibos APV are strong enough to be considered clinically relevant.

Patients and methods

This case series, designed as part of an ongoing Doctorate Thesis of one of the authors (*G.F.*) at the *Federal University of Minas Gerais* (UFMG), prospectively assessed 31 consecutive cataract patients with preoperative corneal astigmatism between 0.75 and 2.50 diopters (D) in both eyes. Patients were randomly assorted between two phacoemulsification groups: toric intraocular lens (IOL) group, assigned to receive toric intraocular lenses (model AcrySof Toric, Alcon, Inc.) in both eyes and limbal relaxing incisions (LRI) group, assigned to have spherical IOL (AcrySof Natural, Alcon, Inc.) associated with LRI also in both eyes. All patients provided a written informed consent, after they received an explanation of the nature of the study and its potential complications, in accordance to the tenets of Declaration of Helsinki and UFMG's institutional ethics committee protocol. All surgeries were performed between May 2010 and June 2012 at ISO Olhos, Instituto de Saúde Ocular, Uberlândia-MG, Brazil.

Inclusion criteria were age older than 40 years and, for both eyes, visually significant cataract (best corrected visual acuity worse than LogMAR 0.3), regular corneal astigmatism between 0.75 D and 2.50 D, pharmacologic mydriasis of at least 6.0 milimeters to allow proper intraoperative visualization of axis marks on the toric IOL.

The following were exclusion criteria: previous surgery in the eye under study, pterygium, ocular disease that would lead to poor postoperative corrected visual acuity (corneal scarring, uveitis, advanced glaucoma, neuroophthalmic disease, significant macular disease or other retinopathy), zonule or pupil abnormalities and any irregular corneal astigmatism.

Preoperatively, every patient had a complete ophthalmic evaluation, by an examiner other than the surgeon (*G.F.*), including logMAR best corrected distance visual acuity, manifest refraction, slitlamp examination, applanation tonometry, and fundoscopy under pharmacological mydriasys. In addition to corneal topography (Orbscan II, Bausch&Lomb, Inc.) and ultrasound immersion biometry (OcuScan, Alcon, Inc.). *Hoffer Q* formula was used in eyes with an axial length shorter than 22 mm, and SRK/T formula was used for all other cases.

Toric IOL cylinder power and axis placement were determined using the IOL manufacturer's online calculator (www.acrysoftoriccalculator.com). Size and location of LRI were also determined via online application (www.lricalculator.com), according to Donnenfeld's nomogram. For both Toric IOL and LRI groups, biometry, keratometry, main incision location, and surgeon's expected surgically induced astigmatism (-0.50 D) were entered into the calculators, with emmetropia as the goal postoperative refraction, *i.e.*, zero sphere and the smallest residual cylinder possible.

Surgical Technique

The same surgeon (*M.C.*) performed all surgeries under mild sedation and topical anesthesia. Just before surgery, a sterile ink pen was used to make two marks on the corneal limbus at the 0-degree and 180-degree positions with the patient sat upright at the slitlamp, to avoid ocular torsion.

For both groups, phacoemulsification, followed by IOL implantation, was performed through a 2.75 mm temporal corneal incision.

In the toric IOL group, the IOL was rotated to align with the

planned axis.

For LRI group patients, LRI were created inside the limbus using a calibrated diamond knife with the blade depth preset at 600 µm.

Postoperative Follow up

All patients were reevaluated at 6 months postoperatively by an examiner other than the surgeon (*G.F.*). Postoperative manifest refraction was obtained and analysis of refractive astigmatism, comparing pre- and postoperative periods, was performed using both Alpins and Thibos methods.

Statistical Analysis

Both Alpins and Thibos calculations were performed using Microsoft Excel® for MacIntosh spreadsheets (version 12.2.7, Microsoft Corp.). Shapiro-Wilk normality tests of data set were performed using IBM SPSS® for Microsoft Windows® software (version 20.0.0). A p value of 0.05 or less was considered statistically significant. The ratio between Thibos 6-month postoperative APV and preoperative APV (APV_{Ratio}) and its linear regression with Alpins percentage of success of astigmatic surgery ($\%_{Success}$), percentage of astigmatism corrected ($\%_{Corrected}$) and percentage of astigmatism reduction at the intended axis ($\%_{Reduction}$) were assessed. Pearson's (r) or Spearman's (ρ) linear correlation coefficients, for parametric and non-parametric regressions respectively, were used. Considering each of these coefficients, as modulus, if it was equal to, or less than 0.4, it was regarded as a weak correlation indicator, if between 0.4 and 0.8 the correlation was considered as moderate and if greater then, or

equals to 0.8, it was indicative of a strong linear correlation evidence (13, 14). Bootstrapping (95% confidence interval) was also taken into account for each non-parametric regression (15).

Results

The study enrolled 62 eyes of 31 consecutive eligible patients (12 men and 19 women). Patients' mean age was 68.81 years (with a standard deviation of ± 8.20 years), ranging from 51 to 84 years. None of the eyes required a second intervention. No potentially sight-threatening complications, such as persistent corneal edema, pupillary block, retinal detachment or endophthalmitis were observed.

Data set concerning APV_{ratio} and $\%_{Success}$ generated from these case series have clearly deviated from normal distribuition, hence Spearman's ρ was used for non-parametric regression analisys.

Thibos and Alpins analises are depicted in tables 1 and 2, respectively, as follows:

Table 1. Preoperative and 6-month postoperative Thibos APV.

	Group		
Diopters	LRI	Toric IOL	p value*
Preoperative			
Mean ± SD	0.74 ± 0.30	0.70 ± 0.37	0.74
Range	0.25 to 1.38	0.13 to 1.38	-
6-month postoperative			
Mean ± SD	0.37 ± 0.13	0.31 ± 0.09	0.05
Range	0.13 to 0.63	0.13 to 0.50	-
P value†	0.00	0.00	-

APV = Thibos astigmatic power vectors; LRI = limbal relaxing incisions; SD = standard deviation; (*) Mann-Whitney U test; (†) Wilcoxon test – preoperative APV x 6-month postoperative APV.

Table 2. Six-month postoperative Alpins indices.

	Groups		
	LRI	Toric IOL	*p* value*
6-month postoperative IoS			
Geometric mean ± SD	0.53 ± 0.25	0.37 ± 0.24	0.01
Range	0.31 to 1.42	0.03 to 1.14	-
p value†	0.07	0.99	-
6-month postoperative FI			
Geometric mean ± SD	0.62 ± 0.46	0.81 ± 0.36	0.00
Range	0.08 to 1.74	0.10 to 1.68	-
p value†	0.43	0.44	-
6-month postoperative CI			
Geometric mean ± SD	0.64 ± 0.31	0.94 ± 0.31	0.00
Range	0.17 to 1.58	0.51 to 1.69	-
p value†	0.29	0.81	-

CI = Alpins correction index; FI = Alpins flattening index; IoS = Alpins index of success; LRI = limbal relaxing incisions; SD = standard deviation; (*) Mann-Whitney U test; (†) Wilcoxon test – 1-month postoperative IoS x 6-month postoperative IoS.

Figure 1 depicts a statistically significant negative correlation between AVP_{ratio} and $\%_{Success}$ 6-month postoperatively.

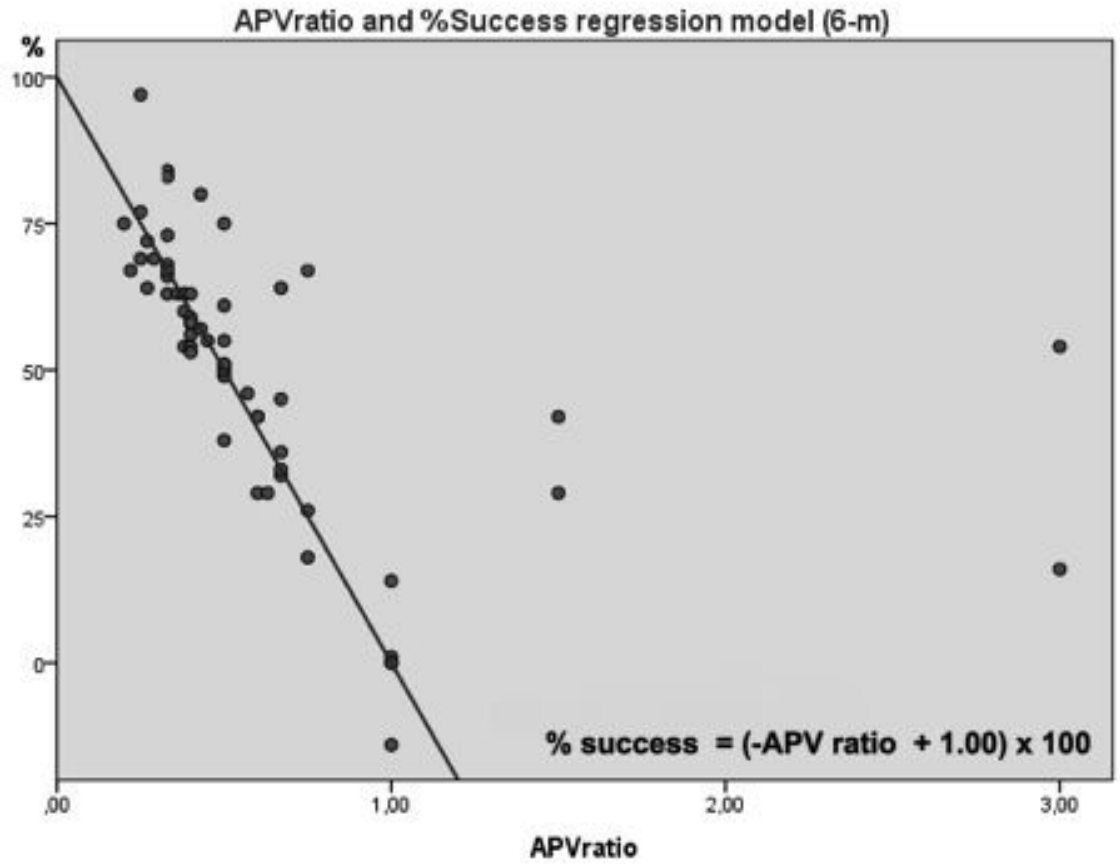


Figure 1. Scatterplot showing a regression model between AVP_{ratio} and $\%_{Success}$ 6-month postoperatively (APV_{ratio}=astigmatic power vector ratio, defined as 6-month postoperative astigmatic power vector divided by preoperative astigmatic power vector; $\%_{Success}$=percentage of success of astigmatic surgery; 6-m=6-month postoperative follow up period).

We found a Spearman's ρ coefficient for the regression model between AVP_{ratio} and $\%_{Success}$ 6-month postoperatively equals to -0.83. Employing bootstrapping calculation, *r* coefficient increased even further to -0.93. Four eyes deviated remarkably from the trendline. Such eyes were considered as outliers, but they were kept in the study roll.

Spearman's ρ coefficient, even employing bootstrapping, was too low for both AVP_{ratio} and $\%_{Corrected}$ and AVP_{ratio} and $\%_{Reduction}$. Respectively: -0.31 and -0.44.

Discussion

Although it provides a sophisticated analysis on astigmatism description and treatment for both refractive and keratometric aspects (1), Alpins method, relies on somewhat complex sequential equations in order to complete its calculations, making its routine use often unpractical. Computer softwares designed to perform such calculations in a amenable manner, may be cost prohibitive for many cataract surgeons as a routine tool.

Thibos method on its turn, requires a much simpler design to carry out its calculations, not demanding any specific software to be accomplished. As a drawback, Thibos method offers essencialy a straightforward comparison between preoperative and postoperative refractive power vectors (9, 10) fairly related to the success achieved by the astigmatic surgery.

Hence the idea of trying to make these two methods interchangeable, taking advantage of mathematical simplicity from Thibos and the valuable indices from Alpins. To our knowledge, this is the first article, on the literature, to employ both Alpins and Thibos methods to the same patient series, in order to try to correlate their results.

Since both APV_{ratio} and $\%_{Success}$ data deviated from normal distribution (16), non-parametric analises were performed (14).

In statistics, outlier is an observation that is numerically distant from the rest of the data set, clearly deviating from other members of the sample in which it occurs. Occurrence of outliers may be by chance in any distribution, but they are often indicative either of measurement error or a heavy-tailed distribution. Identifying outliers is important both for improving the quality of

original data and for reducing the impact of anomalous values in the process of knowledge discovery in databases. Analysis of outliers and their influential points is an important step of the regression analises (18). Since outliers are not generated via any predictable model, any rule for removing outliers, or not, has to be somewhat arbitrary, With such an informal approach, it is impossible to be objective or consistent, or to generalize their elimination process. If the threshold is too strict, some rogue points will remain. If the threshold is not strict enough, too many good points will be eliminated (19). We kept, within our data set, 4 cases presumed as outliers (farthest 4 cases to the right side of the trendline) because Spearman's ρ coefficient, used in our analisys, is not consistently affected by outliers (17, 19).

Our findings, summarized in tables 1 and 2, suggest a very strong statistical negative correlation between APV_{ratio} and $\%_{Success}$ (ρ=-0.83 what implies a negative correlation strength of 83% and its bootstrapping of 0.93 implies, on its turn, a calculated correlation strength even greater of 93%) (16). However, correlations between APV_{ratio} and $\%_{Corrected}$ or $\%_{Reduction}$ cannot be promptly assumed as well. APV_{ratio} and $\%_{Corrected}$ correlation is only negatively weak (ρ=-0.31, what implies a correlation strengh of nearly 31%). APV_{ratio} and $\%_{Reduction}$ correlation is moderately waek (ρ=-0.44, implying a correlation strengh of 44%). For the latter two correlations, statistical significance is irrelevant (14). The rationale behind this finding is that both $\%_{Success}$ and APV_{ratio} provide relative measures of surgical success. It is important to notice that both $\%_{Corrected}$ or $\%_{Reduction}$ are influenced by any misalignment between intended and actual treatment, such influence is not present on Thibos analisis, hence their weak correlation.

Alpins index of success (IoS) is a suitable parameter for astigmatism treatment assessment (1). Alpins $\%_{Success}$ is an

expression of IoS in percentage terms: $\%_{Success}=(1–IoS)x100\%$. APV_{ratio} correlates to $\%_{Success}$, as shown by our model. So, it implies that APV_{ratio} also correlates to IoS. In the same manner, APV_{ratio} could be used as a validated alternative assesment tool with more than 90% certainty. It seems reasonable to us the regression formula we found: $\mathbf{\%_{Success}=(-APV_{Ratio}+1.00)x100}$ is appropriate for success analysis of an individual surgical case. It may be converted by several softwares to an easy-to-use, unexpensive application with potencial to assist cataract and refractive surgeons an assesment tool of refractive results. Figure 2 shows an example of an Excel spreadsheet where our regression equation was set as a function for which inputs of preoperative and postoperative data render outputs of Alpins $\%_{Success}$.

	A	B
1	**Preoperative astigmatism**	
2	Cylinder power (*≠ 0; -/+ diopters*)	-1.25
3	Cylinder axis (*degrees*)	85
4	**Postoperative astigmatism**	
5	Cylinder power	-0.25
6	Cylinder axis	90
7	***Calculated* % Success of Astigmatism Surgery**	**80%**

Figure 2. Example of an Excel spreadsheet where the regression formula was set as a function for which inputs of preoperative and postoperative refractive astigmatism render outputs of Alpins $\%_{Success}$.

Analysis of aggregated cases, such as in comparative studies among techniques might be influenced by the uncertainty inherent to the regression formula, limiting the usage of our formula to individual analises.

The main limitation of our study is our data set limited to 62 eyes. Larger patient cohorts, specialy if a normal data distribution

is present, might further refine our findings, possibly expanding the usage of our formula. The comparison of which technique, toric IOL or LRI, provided better outcomes is beyond the scope of this study, such an analisys is going to be presented in a related study of the same patient series.

In conclusion, linear regression we found between APV_{ratio} and $\%_{Success}$ permits a validated mathematical inference concerning the overall success of astigmatic surgery for individual patients.

References

1. Alpins N, Goggin M. Practical Astigmatism Analysis for Refractive Outcomes in Cataract and Refractive Surgery. Surv Ophthalmol. 2004;49:109-22.

2. Alpins N. Astigmatism analysis by the Alpins method. J Cataract Refract Surg. 2001;27:31-49.

3. Carvalho MJ, Higashitani-Suzuki S, Lemes-Freitas L. Limbal relaxing incisions to correct corneal astigmatism during phacoemulsification. J Refract Surg. 2007;23:499-504.

4. Arraes JC, Cunha F, Arraes TA, Cavalcanti R, Ventura M. Limbal relaxing incisions during cataract surgery: one-year follow-up. Arq Bras Oftalmol. 2006;69(3):361-4.

5. Silva EF, Trindade F. Surgical correction of astigmatism during cataract surgery. Arq Bras Oftalmol. 2007;70(4):609-14.

6. Hida, Wilson Takashi et al. Incisões relaxantes limbares ou incisões no meridiano mais curvo associadas a facoemulsificação com implante de lente intra-ocular multifocal: relato de três casos. Arq Bras Oftalmol. 2008;71(2):273-7.

7. Ambrósio Jr, Renato et al. Implante de segmentos de anel estromal em ceratocone: resultados e correlações com a biomecânica corneana pré-operatória. Rev Bras Oftalmol. 2012;71(2):89-99.

8. Alió JL, Piñero D, Tomás J, Alesón A. Vector analysis of astigmatic changes after cataract surgery with toric intraocular lens implantation. J Cataract Refract Surg. 2011;37:1038-49.

9. Thibos LN, Horner D. Power vector analysis of the optical outcome of refractive surgery. J Cataract Refract Surg. 2001;27:80-5.

10. Thibos LN, Wheeler W. Power vectors: an application of Fourier analysis to the description and statistical analysis of refractive error. Optom Vis Scie. 1997;74:367-75.

11. Koshy JJ, Nishi Y, Hirnschall N, Crnej A, Gangwani V, Maurino V, Findl O. Rotational stability of a single-piece toric acrylic intraocular lens. J Cataract Refract Surg. 2010;36:1665-70.
12. Statham M, Apel A, Stephensen D. Comparison of the AcrySof SA60 spherical intraocular lens and the AcrySof Toric SN60T3 intraocular lens outcomes in patients with low amounts of corneal astigmatism. Clin Exper Ophthalmology. 2009;37:775-9.
13. Mingo-Botín D, Muñoz-Negrete F, Kim HRW, Morcillo-Laiz R, Rebolleda G, Oblanca N. Comparison of toric intraocular lenses and peripheral corneal relaxing incisions to treat astigmatism during cataract surgery. J Cataract Refract Surg. 2010;36:1700-8.
14. Correa S. Probabilidade e estatística. 2a. Edição. ed: PUC Minas Virtual.; 2003.
15. Shi R, Conrad S. Correlation and regression analysis. Annals of Allergy, Asthma & Immunology. 2009;103(4):S35-S42.
16. Carpenter J, Bithell J. Bootstrap confidence intervals: when, which, what? A practical guide for medical staticians. Stat Med. 2000;19:1141-1164.
17. Razali NM, Wah Y. Power comparisons of Shapiro-Wilk, Kolmogorov-Smirnov, Lilliefors and Anderson-Darling tests. Journal of Statistical Modeling and Analytics. 2011;2(1):21-33.
18. Rahman SMAK, Sathik M, Kannan KS. Multiple linear regression models in outlier detection. International Journal of Research in Computer Science. 2012;2(2):23-8.
19. Motulsky HJ, Brown RE. Detecting outliers when fitting data with nonlinear regression – a new method based on robust nonlinear regression and the false discovery rate. BMC Bioinformatics. 2006;7(123).

Anexo A – Parecer do Comitê de Ética em Pesquisa da UFMG (ETIC 341/09).

UNIVERSIDADE FEDERAL DE MINAS GERAIS
COMITÊ DE ÉTICA EM PESQUISA - COEP

Parecer nº. ETIC 341/09

Interessado(a): Prof. Joel Edmur Boteon
Departamento de Oftalmologia e Otorrinolaringologia
Faculdade de Medicina - UFMG

DECISÃO

O Comitê de Ética em Pesquisa da UFMG – COEP aprovou, no dia 02 de setembro de 2009, o projeto de pesquisa intitulado **"Comparação entre utilização de incisões relaxantes limbares e implante de lentes intraoculares tóricas no controle intra-operatório do astigmatismo corneano pré-existente"** bem como o Termo de Consentimento Livre e Esclarecido.

O relatório final ou parcial deverá ser encaminhado ao COEP um ano após o início do projeto.

Profa. Maria Teresa Marques Amaral
Coordenadora do COEP-UFMG

Av. Pres. Antonio Carlos, 6627 – Unidade Administrativa II - 2º andar – Sala 2005 – Cep:31270-901 – BH-MG
Telefax: (031) 3409-4592 - e-mail: coep@prpq.ufmg.br

Anexo B – Cópia da Ata de Defesa da Tese (21 de novembro de 2013).

UNIVERSIDADE FEDERAL DE MINAS GERAIS

PROGRAMA DE PÓS-GRADUAÇÃO EM CIÊNCIAS APLICADAS À CIRURGIA E À OFTALMOLOGIA

UFMG

ATA DA DEFESA DE TESE DO ALUNO
GIULIANO DE OLIVEIRA FREITAS

Realizou-se, no dia 21 de novembro de 2013, às 09:00 horas, Sala 018 (Fac. Medicina/UFMG - andar térreo)., da Universidade Federal de Minas Gerais, a defesa de tese, intitulada *COMPARAÇÃO ENTRE O USO DE INCISÕES RELAXANTES LIMBARES E LENTES INTRAOCULARES TÓRICAS NO TRATAMENTO DO ASTIGMATISMO CORNEANO PRÉ-EXISTENTE NA FACOEMULSIFICAÇÃO*, apresentada por GIULIANO DE OLIVEIRA FREITAS, número de registro 2010654093, graduado no curso de MEDICINA, como requisito parcial para a obtenção do grau de Doutor em CIÊNCIAS APLICADAS À CIRURGIA E À OFTALMOLOGIA, à seguinte Comissão Examinadora: Prof(a). Joel Edmur Boteon - Orientador (UFMG), Prof(a). Homero Gusmao de Almeida (UFMG), Prof(a). Luiz Carlos Molinari Gomes (UFMG), Prof(a). ROBERTO PEDROSA GALVÃO FILHO (IOR - Instituto de Olhos do Recife), Prof(a). ADROALDO DE ALENCAR COSTA FILHO (UFRJ).

A Comissão considerou a tese:

(X) Aprovada

( ) Reprovada

Finalizados os trabalhos, lavrei a presente ata que, lida e aprovada, vai assinada por mim e pelos membros da Comissão.
Belo Horizonte, 21 de novembro de 2013.

Prof(a). Joel Edmur Boteon (Doutor)

Prof(a). Homero Gusmao de Almeida (Doutor)

Prof(a). Luiz Carlos Molinari Gomes (Doutor)

Prof(a). Roberto Pedrosa Galvão Filho (Doutor)

Prof(a). Adroaldo De Alencar Costa Filho (Doutor)

Anexo C – Cópia da Declaração de Aprovação da Tese (21 de novembro de 2013).

UNIVERSIDADE FEDERAL DE MINAS GERAIS

PROGRAMA DE PÓS-GRADUAÇÃO EM CIÊNCIAS APLICADAS À CIRURGIA E À OFTALMOLOGIA

UFMG

FOLHA DE APROVAÇÃO

COMPARAÇÃO ENTRE O USO DE INCISÕES RELAXANTES LIMBARES E LENTES INTRAOCULARES TÓRICAS NO TRATAMENTO DO ASTIGMATISMO CORNEANO PRÉ-EXISTENTE NA FACOEMULSIFICAÇÃO

GIULIANO DE OLIVEIRA FREITAS

Tese submetida à Banca Examinadora designada pelo Colegiado do Programa de Pós-Graduação em CIÊNCIAS APLICADAS À CIRURGIA E À OFTALMOLOGIA, como requisito para obtenção do grau de Doutor em CIÊNCIAS APLICADAS À CIRURGIA E À OFTALMOLOGIA, área de concentração RESPOSTA INFLAMATÓRIA À AGRESSÃO

Aprovada em 21 de novembro de 2013, pela banca constituída pelos membros:

Prof(a). Joel Edmur Boteon - Orientador
UFMG

Prof(a). Homero Gusmao de Almeida
UFMG

Prof(a). Luiz Carlos Molinari Gomes
UFMG

Prof(a). Roberto Pedrosa Galvão Filho
IOR - Instituto de Olhos do Recife

Prof(a). Adroaldo De Alencar Costa Filho
UFRJ

Belo Horizonte, 21 de novembro de 2013.

Apêndice A – Modelo de Termo de Consentimento Livre e Esclarecido (TCLE).

Termo de Consentimento Livre e Esclarecido

A moderna cirurgia de catarata tem por objetivo não somente a restauração da visão, mas também diminuir a dependência dos pacientes em relação ao uso de óculos ou lentes de contato no pós-operatório. Neste sentido, o controle do astigmatismo pré-existente é de fundamental importância. Esse controle pode ser conseguido, por ocasião da cirurgia de catarata, pelo uso de lentes intraoculares tóricas ou pela realização de incisões relaxantes limbares.

Este estudo pretende comparar essas alternativas em termos da eficiência da redução do astigmatismo.

CONVIDAMOS o senhor a participar deste estudo, face à ocorrência, em seus olhos, de catarata e astigmatismo corneano passíveis de abordagem cirúrgica, quer seja pelo implante de lente intraocular tórica, ou pela realização de incisões relaxantes limbares.

É importante que o senhor saiba que ambas as opções são rotineiramente utilizadas com a finalidade de diminuir o astigmatismo em pacientes submetidos à cirurgia de catarata. Os riscos possíveis são os mesmos de qualquer cirurgia de catarata realizada pelo método da facoemulsificação, bem como são os mesmos os cuidados pré e pós-operatórios. Vale enfatizar que não está descartada a possibilidade de reintervenções cirúrgicas, ou mesmo, da necessidade de uso de óculos ou lentes de contato no pós-operatório.

Serão prestadas orientações para o reconhecimento dos principais sinais de complicações e oferecida a opção de entrar em contato, pelo telefone a qualquer hora, com algum dos pesquisadores, ainda que seja para o esclarecimento de eventuais dúvidas.

Sua participação é **VOLUNTÁRIA** e não acarretará em ônus adicionais.

Os dados obtidos a partir deste estudo são de interesse **exclusivamente científico**, estando garantida a privacidade dos pacientes envolvidos. **Se decidir, por qualquer razão, deixar de fazer parte do grupo de pacientes relacionados no estudo, NÃO** haverá qualquer mudança no seu tratamento ou em sua relação com a equipe assistente. A qualquer momento, o(senhor poderá abandonar o grupo de estudo, com total respeito à liberdade de escolha e preservação dos dados obtidos durante a sua participação. Seu tratamento e acompanhamento continuarão sendo realizados no mesmo local e pela mesma equipe.

O presente estudo encontra-se respaldado pelo Comitê de Ética em Pesquisa da Universidade Federal de Minas Gerais.

Estaremos sempre à disposição para o esclarecimento de quaisquer dúvidas.

Resumo Técnico do Estudo

Título do Projeto: **Comparação entre utilização de incisões relaxantes limbares e implante de lentes intraoculares tóricas no controle intra-operatório do astigmatismo corneano pré-existente**.

Instituição a que pertencem os Pesquisadores Responsáveis: Universidade Federal de Minas Gerais (UFMG).

Pesquisadores Responsáveis:

Dr. Giuliano de Oliveira Freitas, Oftalmologista.
Membro do Corpo Clínico do ISO – Olhos, Instituto de Saúde Ocular.
End.: R. Eduardo Marquez 50, B. Martins. CEP 38.400-442.
Uberlândia-MG.
Contato: (34) 3230-5050 - (34) 9976-8583.
E-mail: giuliano@isoolhos.com.br

Dr. Joel Edmur Boteon, Oftalmologista.
Coordenador do Curso de Pós-Graduação do Departamento de Oftalmologia e Otorrinolaringologia da Faculdade de Medicina da UFMG
End.: Universidade Federal de Minas Gerais Faculdade de Medicina, Departamento de Oftalmologia e Otorrinolaringologia. Av. Prof. Alfredo Balena, 190 - Sala 3005 B. Santa Efigênia 30.130-100.
Belo Horizonte- MG.
Contato: (31) 3248-9767 – E-mail: botteon@medicina.ufmg.br

Comitê de Ética em Pesquisa da Universidade Federal de Minas Gerais

Av. Antônio Carlos, 6627
Unidade Administrativa II - 2º andar - Sala 2005
Campus Pampulha
Belo Horizonte, MG - Brasil
CEP 31270-901
E-mail: coep@prpq.ufmg.br
Telefax: (31) 3409-4592

Dados de Identificação do Paciente (Voluntário do Estudo)

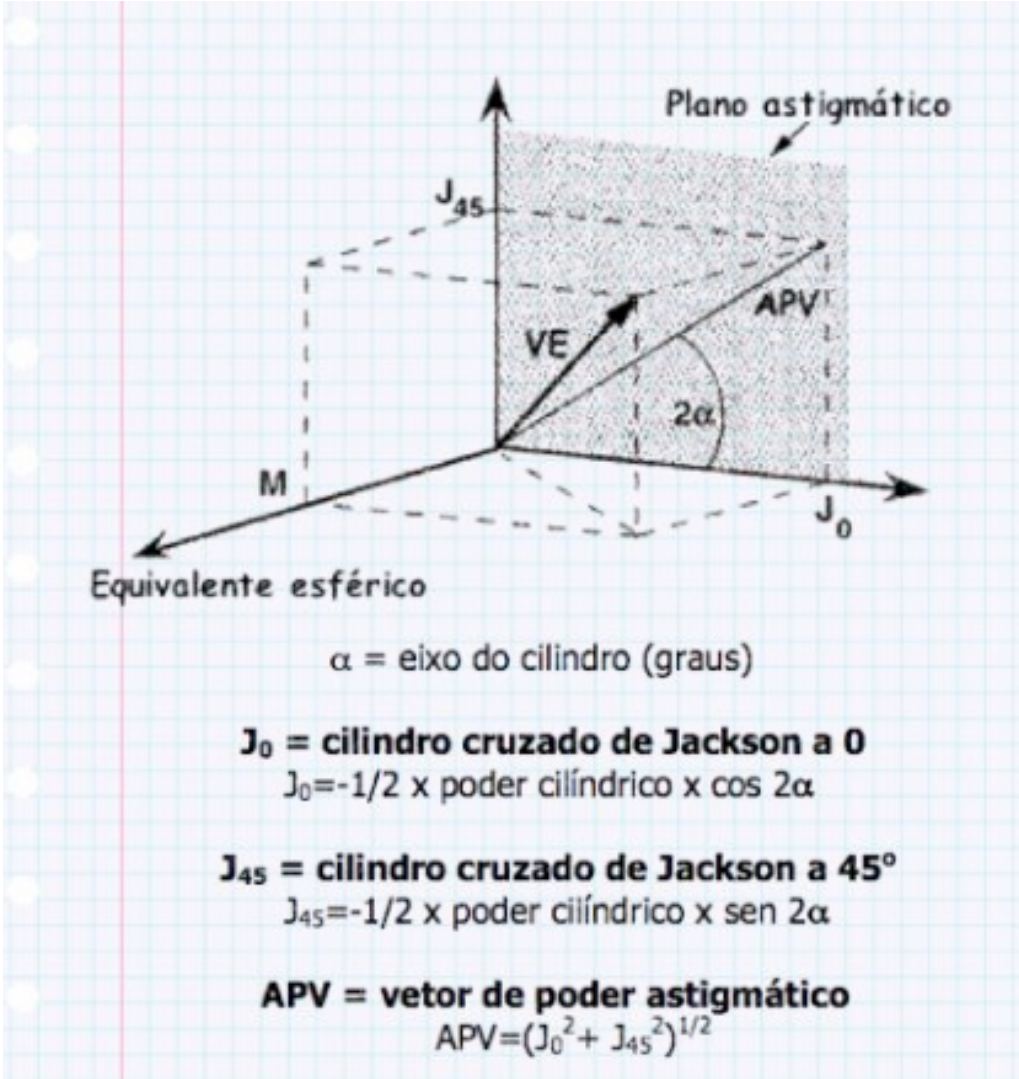
Nome do Voluntário:_____
Idade:____ anos.
R.G.:_____

Testemunha:_____
Idade:____ anos.
R.G.:_____

Apêndice B – Banco de dados gerado pela pesquisa (arquivo "**Planilhas IRL x LIO tórica.xlsx**" em CD-ROM). São apresentados os dados, por grupo, ao longo do período estudado, bem como as fórmulas matemáticas, com as respectivas expressões, para que o *software* Microsoft Excel™ pudesse efetuar os cálculos necessários.

Estes dados podem servir tanto para a confirmação das análises apresentadas, como também, para originar novos trabalhos cinetíficos a partir dos olhos estudados, mesmo por outros autores que eventualmente se interessarem por nossa pesquisa.

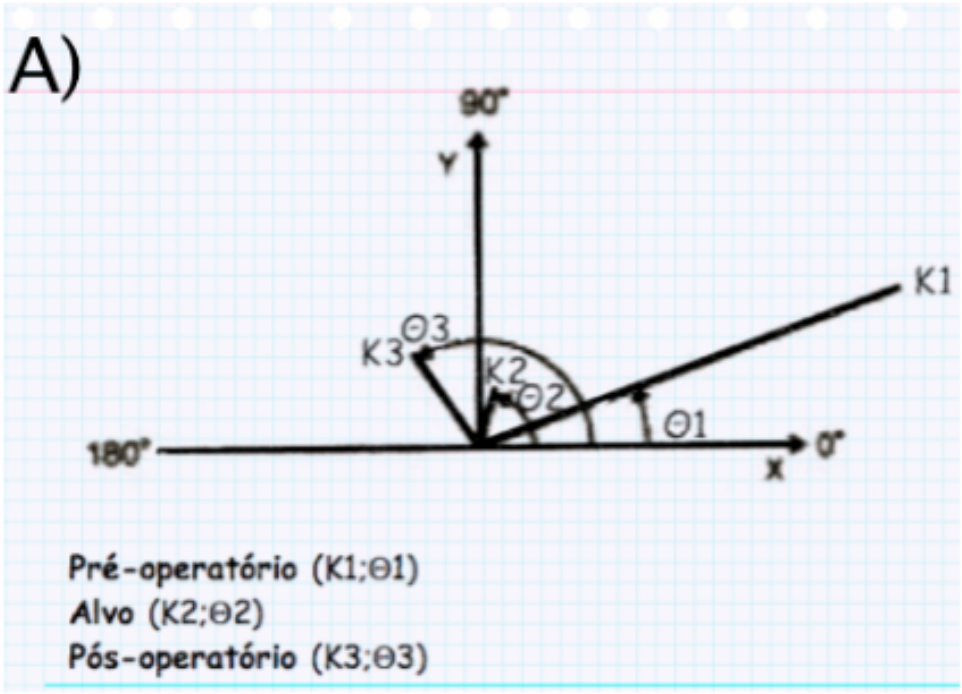
Apêndice C – Representação esquemática da análise vetorial de Thibos.

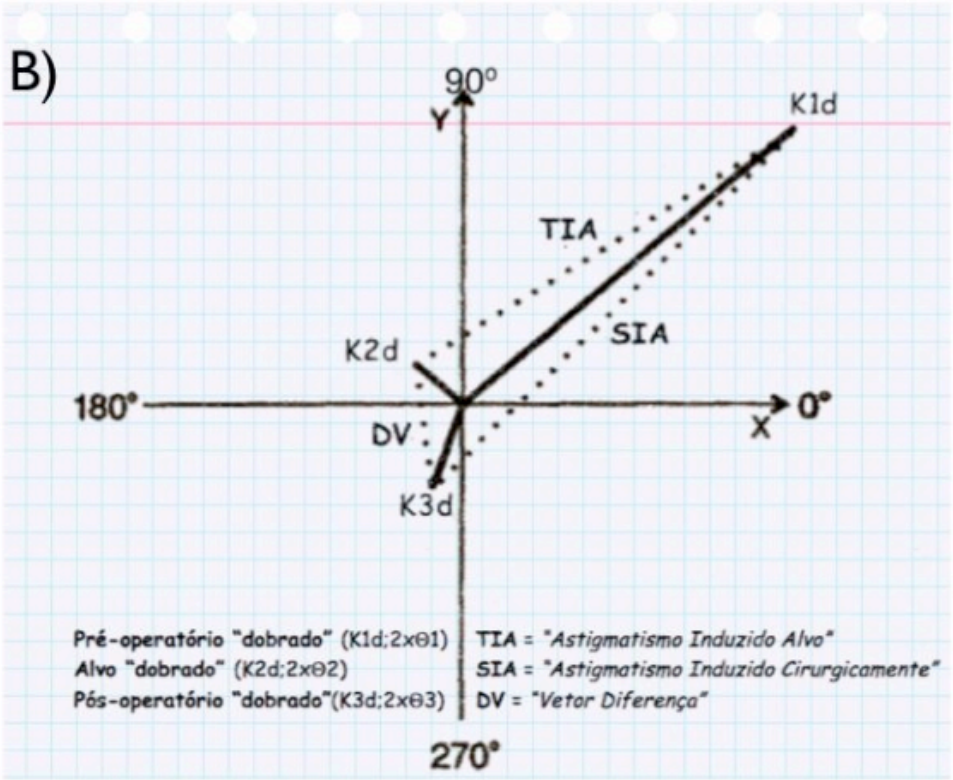


Adaptado de: Thibos LN, Wheeler W. Power vectors: an application of Fourier analysis to the description and statistical analysis of refractive error. Optom Vis Scie. 1997;74:367-75.

O esquema apresenta a representação bidimensional do vetor astigmático (APV) cuja origem econtra-se na interseção dos eixos e a extremidade no cruzamento das coordenadas J0 e J45.

Apêndice D – Representação esquemática da análise vetorial de Alpins.





Adaptado de: Alpins N. A new method of analyzing vectors for changes in astigmatism. J Cataract Refract Surg. 1993;19:524-33.

A análise de Alpins toma por base os astigmatismos pré-operatório (K1), alvo (K2) e pós-operatório (K3), com os

respectivos ângulos (ø1, ø2 e ø3), dispostos num diagrama polar de 180^{o} mostrado na figura A.

Em seguida, o diagrama é transposto para 360^{o}, mantendo-se os valores, em módulo, do astigmatimo (K1d, K2d e K3d), mas dobrando-se os valores dos ângulos originais (2ø1, 2ø2 e 2ø3), como se vê na figura B. Nesse novo diagrama, representam-se os vetores astigmatismo induzido alvo (TIA), com origem em K1d e extremidade em K2d, vetor astigmatismo induzido cirurgicamente (SIA), com origem em K1d e extremidade em K3d e vetor diferença (DV), com origem em K2d e extremidade em K3d. Todos os índices propostos por Alpins são calculados a partir de relações estabelecidas entre TIA, SIA e DV.