GUILHERME DE ALMEIDA HORTA

Avaliação dos parâmetros físicos e fluídicos da facoemulsificação assistida por laser de femtossegundo

Tese apresentada à Faculdade de Medicina da Universidade de São Paulo, para obtenção do título de Doutor em Ciências

Programa de Oftalmologia

Orientador: Prof. Dr. Newton Kara José Junior

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Dados Internacionais de Catalogação na Publicação (CIP)

Preparada pela Biblioteca da
Faculdade de Medicina da Universidade de São Paulo

Horta, Guilherme de Almeida
Avaliação dos parâmetros físicos e fluídicos da facoemulsificação assistida por laser de femtossegundo / Guilherme de Almeida Horta. -- São Paulo, 2023.
Tese(doutorado)--Faculdade de Medicina da Universidade de São Paulo.
Programa de Oftalmologia.
Orientador: Newton Kara José Junior.

Descritores: 1.Cirurgia de catarata com femtolaser 2.Facoemulsificação 3.Solução salina 4.Córnea

USP/FM/DBD-390/23

Responsável: Erinalva da Conceição Batista, CRB-8 6755

DEDICATÓRIA

Dedico essa tese à minha futura esposa, **Isabela Coelho Guimarães**. Agradeço por todo apoio nos momentos que precisei. Pelo amor, parceria e por me ajudar no amadurecimento de vida. Você foi a maior inspiração para eu concluir essa tese.

Dedico ao meu pai, **Rogério Corrêa Horta**, por ser o meu maior mentor na oftalmologia e ter me ensinado tanto, além de dar os impulsos iniciais para a realização das pesquisas.

Dedico à minha mãe **Zilá de Almeida Guimarães**, pelo amor, incentivo e por investir na minha formação.

AGRADECIMENTOS

Agradeço ao Prof. Dr. Newton Kara Jose Jr., pela oportunidade única de desenvolver uma tese de pós-graduação pela Universidade de São Paulo. Serei eternamente grato pela aposta que fez em mim enquanto ainda era residente. Obrigado por extrair o melhor de mim e me fazer apaixonar por pesquisas científicas. Você é um grande exemplo de professor e espero ter chegado à altura da sua orientação.

Aos familiares e amigos, obrigado pelo apoio, carinho, e por fazerem parte da minha vida. Vocês são a motivação para eu tentar ser cada dia um pouco melhor.

Obrigado à equipe do Instituto Horta, pelo apoio e contribuição às pesquisas. Vocês foram fundamentais para o desenvolvimento dessa tese. Que eu possa ajudá-las com os seus sonhos assim como vocês me ajudaram a alcançar os meus.

Agradeço à Regina Ferreira de Almeida pela disponibilidade durante os mais de 4 anos e pelo trabalho ímpar. Sem você, a conclusão da tese não seria possível.

RESUMO

Horta GA. Avaliação dos parâmetros físicos e fluídicos da facoemulsificação assistida por laser de femtossegundo [tese]. São Paulo: Faculdade de Medicina, Universidade de São Paulo:2023.

Objetivos: Avaliar a eficiência da cirurgia de catarata pela facoemulsificação assistida por Laser de femtossegundo em comparação com a convencional, em termos do grau de manipulação cirúrgica intraocular e da qualidade de cicatrização da incisão principal. **Método:** Dois (2) estudos investigador-mascarado, consecutivos e não randomizados foram realizados. No estudo da manipulação cirúrgica, 160 participantes foram divididos em 4 grupos (Faco1, Faco2, Femto1 e Femto2) de acordo com a técnica cirúrgica (facoemulsificação convencional [Grupo Faco] ou cirurgia de catarata assistida por laser de femtossegundo [Grupo Femto]) e de acordo com o grau do *Lens Opacity Classification System III* (LOCS) (LOCS<11 [Grupo 1] ou LOCS≥11 [Grupo 2]). Os resultados medidos pelo facoemulsificador foram o tempo efetivo de facoemulsificação (EPT), indicando o uso de energia de ultrassom na cirurgia; e o consumo de solução salina balanceada (BSS), como forma de estimar o volume de líquido que entrou no olho por meio da irrigação. O estudo sobre a incisão foi um ensaio clínico que avaliou 37 olhos de 37 participantes com indicação de cirurgia de catarata, que foram divididos em 2 grupos: grupo Femto, com incisões automatizadas pelo laser de femtosegundo (18 olhos), e grupo Faco, com incisões por lâmina de bisturi (19 olhos). As incisões planejadas foram triplanares no grupo Femto e biplanares no grupo Faco, com 2.2 mm de largura e 1.65 mm de comprimento, de acordo com a sugestão da literatura. No período pós-operatório, avaliou-se as características das incisões em 2 exames com o Tomógrafo de Coerencia Óptica de Segmento Anterior (AS-OCT) (Cirrus, Carl Zeiss Meditec AG). Entre 2 e 4 dias (exame 1) e 1 e 3 meses (exame 2) foram avaliados o comprimento da incisão, e as prevalências de espaçamento endotelial, desalinhamento endotelial e descolamento localizado da membrana de Descemet (DMD). **Resultados**: Um total de 160 olhos foram incluídos no estudo da manipulação cirúrgica. Houve diferença de 53% entre o tempo efetivo de facoemulsificação (EPT) médio dos grupos Faco1 (5,80±2,86s) e Femto1 (2,73±1,88, 0,1 a 8,65s) P=0,00, e de 33% entre os grupos Faco2 (12,55±8,38s) e Femto2 (8,38±9,32s) P=0,00. Não houve diferenças significativas no uso de BSS entre os grupos Faco1 (55,73±12,45 ml) e Femto1 (59,37±10,93 ml) P=0,48, ou entre os grupos Faco2 (64,34±21,00 ml) e Femto2 (65,71±17,60 ml) P= 0,47. No estudo da morfologia das incisões, a média de comprimento da incisão foi estatisticamente maior no grupo Femto do que no grupo Faco, nos dois exames: 1.64 mm ± 0.16 vs. 1.43 mm ± 0.30 (P=.001), no exame 1, e 1.58mm ± 0.22 vs. 1.27mm ± 0.34 (P<.0001), no exame 2, respectivamente. A prevalência de espaçamento endotelial foi maior no grupo Femto do que no grupo Faco, no exame 1 (61.1% vs 42.1%, P=.24), enquanto nenhum olho apresentou essa alteração, no exame 2. O desalinhamento endotelial foi menos prevalente no grupo Femto, nos dois exames: 27.8% vs. 42.1% (P=.36), no exame 1, e 5.6% vs. 31.6% (P=.08), no exame 2, respectivamente. A presença de descolamento da membrana de

Descemet foi menor no grupo Femto do que no Grupo Faco, nos dois exames: 22.2% vs. 63.2% (P=.01), no exame 1, e 0.0% vs. 10.5% (P=.48), no exame 2. **Conclusões**: Em diferentes graus de catarata núcleo-cortical, a cirurgia assistida pelo laser de femtossegundo (FLACS) usou significativamente menos energia ultrassônica do que a facoemulsificação convencional. A redução da manipulação e do trauma intraocular subsequente tendem a atenuar o dano às células endoteliais e o edema corneano, no pós-operatório. As incisões automatizadas apresentaram comprimento médio mais próximo do planejado, e incidência significativamente menor de descolamento da membrana de Descemet (DMD), do que as incisões manuais. Sugerimos dar sequência à linha de investigação, estudando as implicações dos achados na velocidade de recuperação da acuidade visual.

Palavras-chave: Cirurgia de catarata com femtolaser. Facoemulsificação. Solução salina. Córnea.

ABSTRACT

Horta GA. Evaluation of the physical and fluidic parameters of femtosecond laser-assisted phacoemulsification [thesis]. São Paulo: “Faculdade de Medicina, Universidade de São Paulo”; 2023.

Objectives: To assess the efficiency of femtosecond laser-assisted cataract surgery compared to conventional surgery in terms of intraocular surgical manipulation and the healing quality of the main incision. **Method:** Two (2) consecutive, non-randomized investigator-masked studies were conducted. In the surgical manipulation study, 160 participants were divided into 4 groups (Faco1, Faco2, Femto1 and Femto2) according to the surgical technique (conventional phacoemulsification [Phaco group] or femtosecond laser-assisted cataract surgery [Femto group]) and according to the *Lens Opacity Classification System III* (LOCS) graduation (LOCS<11 [group 1] or LOCS≥11 [group 2]). The results measured by the phacoemulsifier were the effective phacoemulsification time (EPT), indicating the ultrasound energy used during surgery; and the balanced salt solution (BSS) use, to estimate the volume of liquid that entered the eye through irrigation. The study of the main incision was a clinical trial that evaluated 37 eyes of 37 participants with indication for cataract surgery, which were divided into 2 groups: Femto group, with automated incisions by femtosecond laser (18 eyes), and Phaco group, with scalpel blade incisions (19 eyes). The planned incisions were triplanar in Femto group and biplanar in Phaco group, with 2.2 mm width and 1.65 mm length, according to the literature suggestion. In the postoperative period, the characteristics of incisions were evaluated in 2 exams with the Anterior Segment Optical Coherence Tomography (AS-OCT) (Cirrus, Carl Zeiss Meditec AG). Between 2 and 4 days (exam 1) and 1 and 3 months (exam 2), the incision length was assessed, along with the prevalences of endothelial gap, endothelial misalignment, and localized Descemet membrane detachment (DMD). **Results**: A total of 160 eyes were included in the study of surgical manipulation. There was a 53% difference in the mean effective phacoemulsification time (EPT) between Phaco1 (5.80±2.86s) and Femto1 (2.73±1.88, 0.1 to 8.65s) groups, P=0.00, and a 33% difference between Phaco2 (12.55±8.38s) and Femto2 (8.38±9.32s) groups, P=0.00. There were no significant differences in the use of balanced salt solution (BSS) between Phaco1 (55.73±12.45 ml) and Femto1 (59.37±10.93 ml) groups, P=0.48, or between Phaco2 (64.34±21.00 ml) and Femto2 (65.71±17.60 ml) groups, P=0.47. In the study of incision morphology, the mean incision length was statistically greater in the Femto group than in the Phaco group at both examinations: 1.64 mm ± 0.16 vs. 1.43 mm ± 0.30 (P=.001) in exam 1, and 1.58 mm ± 0.22 vs. 1.27 mm ± 0.34 (P<.0001) in exam 2, respectively. The prevalence of endothelial gap was higher in the Femto group than in the Phaco group in exam 1 (61.1% vs. 42.1%, P=.24), while no eye presented this alteration in exam 2. Endothelial misalignment was less prevalent in the Femto group in both examinations: 27.8% vs. 42.1% (P=.36) in exam 1 and 5.6% vs. 31.6% (P=.08) in exam 2, respectively. The presence of Descemet membrane detachment was lower in Femto group than in Phaco Group, in both exams: 22.2% vs. 63.2% (P=.01) in exam 1 and 0.0% vs. 10.5% (P=.48) in exam 2. **Conclusions**: In different grades of nucleus-cortical cataract, femtosecond laser-assisted cataract surgery (FLACS) used significantly less ultrasonic energy than conventional phacoemulsification. Reduced intraocular manipulation and subsequent trauma tend to mitigate endothelial cell damage and corneal edema postoperatively. Automated incisions had an average length closer to the planned length and a significantly lower incidence of Descemet membrane detachment (DMD) than manual incisions. Further studies should investigate the implications of these findings on the visual acuity recovery time.

Keywords: Femtosecond laser-assisted cataract surgery. Phacoemulsification. Irrigation volume. Cornea.

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ESTUDO 2

LISTA DE ABREVIATURAS E SIGLAS

AS-OCT	Tomografia de Coerência Óptica de Segmento Anterior
BSS	Solução Salina Balanceada
C	Córtex
DMD	Descolamento da Membrana de Descemet
EPT	Tempo Efetivo de Facoemulsificação
FEMTOLASER	Laser de Femtossegundo
FLACS	Cirurgia de catarata assistida pelo laser de femtossegundo
HOA	Aberrações de Alta Ordem
LASIK	Laser-Assisted in Situ Keratomileusis
LIO	Lente Intraocular
LOCS	*Lens Opacity Classification System*
MS	Mean Standard (Média)
NC	Cor Nuclear
ND	Não Disponível
NO	Opalescência Nuclear
OVD	Ophthalmic Viscosurgical Device (Solução Viscoelástica Oftalmológica)
PIO	Pressão Intraocular
PPS	Pulsos por Segundo
SIA	Astigmatismo Induzido Cirurgicamente
SVE	Solução Viscoelástica

SUMÁRIO

1 INTRODUÇÃO

1 INTRODUÇÃO

No mundo, são realizadas aproximadamente 17.7 milhões de cirurgias de catarata por ano.[1] Atualmente, a técnica cirúrgica padrão-ouro e de melhor custo-efetividade para remoção da catarata é a facoemulsificação.[2]

O laser de femtossegundo é uma tecnologia que emite pulsos de luz ultracurtos, em femtossegundos (10^{-15} segundos), para gerar fotodisrupção do tecido [3]. O seu primeiro uso na oftalmologia foi na criação de cortes lamelares com a técnica de laser in situ keratomileusis (LASIK), em cirurgias refrativas de córnea [4]. Posteriormente, passou a realizar cortes de espessura total da córnea, possibilitando diferentes formatos de transplante corneano [5].

Em 2008, foi realizada a primeira cirurgia de catarata assistida pelo laser de femtossegundo (FLACS), que automatizou algumas etapas da facoemulsificação [6], como a incisão, a capsulotomia e a fragmentação do núcleo cristaliniano [3]. A curva de aprendizado da FLACS é de aproximadamente 100 casos [7], e o custo adicional do seu uso é de aproximadamente U$ 220 por olho [8].

A FLACS apresenta vantagens em relação à facoemulsificação convencional, incluindo a redução do uso de energia ultrassônica [9,10], diminuição do dano endotelial [9,10,11], redução do edema de córnea no pós-operatório [9], e a realização de capsulotomias [12] e incisões corneanas mais precisas [13,14].

Entretanto, a FLACS apresenta desvantagens em relação à técnica convencional, incluindo o aumento da concentração de prostaglandinas na câmara anterior [9], custo elevado [15], e posicionamento das incisões mais distantes do limbo em direção à córnea clara, podendo aumentar a indução de astigmatismo [16].

Metanálises apresentaram resultados clínicos de acuidade visual e taxa de complicações similares entre a FLACS e a facoemulsificação convencional [9,11].

O edema corneano após a facectomia atrasa a reabilitação visual.[17] O edema ocorre mais comumente devido à disfunção da bomba endotelial, causada por lesão mecânica, lesão química, inflamação ou doença ocular preexistente [18]. O trauma direto causado por instrumentos e fragmentos nucleares, o fluxo de irrigação e o aquecimento do líquido da câmara anterior danificam as células endoteliais [20]. A geração de calor é secundária à energia liberada pela oscilação longitudinal e torsional da ponteira de emulsificação em frequência ultrassônica, denominada energia ultrassônica.

A quantidade de energia ultrassônica utilizada, representada pelo tempo efetivo de facoemulsificação (EPT) indicado pelo aparelho, e o volume de solução salina balanceada (BSS) irrigado na câmara anterior durante a cirurgia podem estimar o grau de manipulação cirúrgica. Quanto maior o tempo de manipulação intraocular, o volume de irrigação de BSS e o EPT, maior o risco de edema de córnea [20,21].

A incisão corneana influencia a manipulação intraocular durante a cirurgia de catarata e o resultado visual do paciente [22]. A análise pós-operatória da morfologia das incisões, a partir de imagens capturadas com a Tomografia de Coerência Óptica de Segmento Anterior (AS-OCT), permite identificar o comprimento do corte e complicações, incluindo o selamento incompleto, descolamento da membrana de Descemet (DMD) e retração da face endotelial corneana próxima ao limbo [14,23].

O espaçamento endotelial está diretamente relacionado ao aumento do astigmatismo [22] e da espessura corneana [15]. O desalinhamento endotelial pode alterar o poder corneano e o astigmatismo [24]. O DMD impede o mecanismo de bomba endotelial, o que dificulta o selamento completo da ferida incisional e, consequentemente, aumenta o espaçamento endotelial e o edema de córnea no sítio da incisão, resultando em uma recuperação visual mais lenta [25,26]. A morfologia da incisão e a indução de astigmatismo e de aberrações corneanas são consideradas indicadores de qualidade do selamento e da cicatrização da incisão cirúrgica [22-29].

Devido à maior custo-efetividade da facoemulsificação convencional para o tratamento da catarata senil, ainda existem dúvidas sobre qual seria o valor do Laser de Femtossegundo na assistência a algumas etapas da cirurgia.

2 OBJETIVOS

2 OBJETIVOS

O intuito do projeto é acrescentar evidências à literatura sobre a cirurgia de catarata assistida pelo laser de femtossegundo ao avaliar o grau de manipulação cirúrgica intraocular, mensurado pelos parâmetros fluídicos da facoemulsificação, e a qualidade de construção e cicatrização da incisão principal.

3 ESTUDO 1

3 ESTUDO 1

Artigo sobre os parâmetros fluídicos em cirurgia de catarata assistida pelo laser de femtossegundo

CLINICS

ORIGINAL ARTICLE

Ultrasound power and irrigation volume in different lens opacity grades: comparison of femtosecond laser-assisted cataract surgery and conventional phacoemulsification

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Horta GA, Horta RC, Steinfeld K, Koch CR, Mello GR, Kara-Junior N. Ultrasound power and irrigation volume in different lens opacity grades: comparison of femtosecond laser-assisted cataract surgery and conventional phacoemulsification. Clinics. 2019;74:e1294

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OBJECTIVES: To compare the amount of ultrasound energy and irrigation volume in conventional phacoemulsification cataract surgery *versus* femtosecond laser-assisted phacoemulsification at different nuclear-cortical cataract grades.

METHOD: This was a prospective, consecutive, investigator-masked nonrandomized parallel cohort study. Patients were divided into 4 groups (Phaco1, Phaco2, Femto1 and Femto2) according to the surgical technique (conventional phacoemulsification [Group Phaco] or femtosecond laser-assisted cataract surgery [Group Femto]) and the Lens Opacity Classification System III (LOCS) grade (LOCS<11 [group 1] or LOCS⩾11 [group 2]). The measured outcomes were effective phacoemulsification time (EPT), indicating the ultrasound energy, and balanced salt solution (BSS) use, indicating the irrigation volume, to indirectly estimate the damage to the corneal endothelium caused by the cataract surgery.

RESULTS: A total of 160 eyes from 109 patients were included: 87 eyes in Group Phaco, 73 eyes in Group Femto, 76 eyes in group 1 and 84 eyes in group 2. The EPT mean in Femto1 was 53% less (2.73 ± 1.88, 0.1 to 8.65) than that in Phaco1 (5.80 ± 2.86) (p=0.00) and in Femto2 (8.38 ± 9.32) was 33% less than that in Phaco2 (12.55 ± 8.38) (p=0.00). No significant differences in mean LOCS grades between the Phaco1 (8.21 ± 1.44) and Femto1 (7.90 ± 1.90) groups (p=0.73) or between the Phaco2 (13.15 ± 2.55) and Femto2 (12.72 ± 2.18) groups (p=0.95) were found. There were no significant differences in the mean BSS use between the Phaco1 (55.73 ± 12.45) and Femto1 (59.37 ± 10.93) groups (p=0.48) or between the Phaco2 (64.34 ± 21.00) and Femto2 (65.71 ± 17.60) groups (p=0.47).

CONCLUSIONS: Compared to conventional phacoemulsification at different nuclear-cortical cataract grades, femtosecond laser-assisted cataract surgery provides an EPT reduction but does not influence the BSS use.

KEYWORDS: Femtolaser Cataract Surgery; Ultrasound Energy; Irrigation Volume; Balanced Salt Solution Use.

INTRODUCTION

Cataracts remain the most common potentially reversible cause of blindness, with an estimated 19 million phacoemulsification surgeries performed per year and a prospective 32 million surgeries projected in 2020 (1-3). Due to the increase in the population's life expectancy, it is essential to preserve corneal endothelial cells for long-term visual outcomes after cataract surgery (4-6). The proper functioning of these cells maintains the transparency of the cornea and avoids stromal edema (7-10).

Studies have shown that reducing the use of ultrasonic energy during phacoemulsification cataract surgery and reducing the volume of balanced salt solution (BSS) used can decrease endothelial cell loss (11-18). There is a shorter effective phacoemulsification time (EPT) and less endothelial cell loss in surgery assisted by a femtosecond laser than in conventional manual phacoemulsification (10-19). Since the femtosecond laser is still a new technology, long-term studies are necessary to analyze its real impact because innovations are constantly emerging, and many variables can influence endothelial cell loss (7-10). The present study compared the ultrasound power and BSS use in conventional manual

No potential conflict of interest was reported.

Received for publication on April 2, 2019. **Accepted for publication on** June 24, 2019

DOI: 10.6061/clinics/2019/e1294

phacoemulsification surgeries with those in femtosecond laser-assisted surgery.

■ MATERIAL AND METHODS

Study population

This investigation was a prospective, consecutive, investigator-masked, nonrandomized parallel cohort study performed at a single center. The study was performed in accordance with the Declaration of Helsinki. An appropriate written informed consent form was signed by all patients prior to surgery. Consecutive patients who had a cataract surgery indication and were older than 50 years were enrolled in the study. Eligible patients were included in the study after undergoing an extensive preoperative assessment. One hundred and sixty (160) patients were recruited between October 2015 and April 2016, and the sample calculation was based on similar studies comparing conventional phaco and femto cataract surgeries. All operations were performed by one experienced surgeon (IORH). Patients were excluded from the study if they had any preoperative ocular comorbidity (e.g., glaucoma, cornea guttata, corneal opacity), previous eye surgery, a posttraumatic cataract or intraoperative complications.

Each cataract was graded with the Lens Opacity Classification System (LOCS) scale by a masked investigator using a slit lamp. According to the LOCS, nuclear opalescence (NO), nuclear color (NC) and cortex (C) grading were considered in the sum ($NC+NO+C \geq 11$ or <11), and patients were divided into groups according to their LOCS grade: $LOCS<11$ (group 1) or $LOCS \geq 11$ (group 2). All eligible patients underwent a preoperative evaluation to determine the possibility of undergoing pretreatment with a femtosecond laser, with the added value being funded by the patient. Subsequently, they were divided according to the proposed surgical technique, specifically, conventional phacoemulsification (Group Phaco) or femtosecond laser-assisted cataract surgery (Group Femto).

Data collection

The data collected included sex, laterality, patient age at the time of cataract surgery, LOCS grade, the type of intraocular lens (IOL) implanted, the surgical technique, the EPT and the total BSS used in the surgery. The EPT represents the cumulative ultrasound energy used intraoperatively during the phaco procedure. The elapsed phaco is used to calculate the total energy delivered into the eye in one surgery. The BSS volume is an important fluid parameter for balancing aspiration and maintaining the anterior chamber during surgery. It measures the irrigation volume used during surgery and can be used to calculate the volume escaping through the surgical wounds. These parameters were informed by the Infiniti® Vision System (Alcon Laboratories, Inc.) in each surgery and were used to indirectly estimate the cataract surgery damage to the corneal endothelium. At the end of each surgery, these data were checked and then compared according to the technique of the cataract surgery performed and the LOCS grades.

Surgical technique

All operated eyes received topical moxifloxacin 30 minutes before the surgery. The pupils were dilated with phenylephrine, tropicamide and cyclopentolate. Anesthesia was used for conscious sedation and with topical 0.5% proparacaine hydrochloride and 0.75% bupivacaine hydrochloride, except in sensitive patients or those with very mature cataracts, who received peribulbar anesthesia with 2% lidocaine in combination with Hyalozima 50 IU/ml.

In Group Phaco, manual temporal incisions were made in the clear cornea; the main incision was 2.3 mm and the secondary incision was 1.2 mm, both in three planes and self-sealing. In group B, the LensX® (Alcon Laboratories, Inc.) interface contact lens (SoftFit®) system was used for coupling to the vacuum and ocular fixation. Approximately 5 minutes before the use of the laser, a drop of naphazoline hydrochloride 0.025% to 0.3% and pheniramine maleate (Claril, Alcon Laboratories, Inc.) was administered to decrease subconjunctival bleeding due to eye suction. The surgeon's predefined preferences for the use of the femtolaser were as follows: anterior capsulotomy of 4.7 mm; temporal clear corneal incisions (main - 2.3 mm; secondary - 1.2 mm); lens cube fragmentation pattern with 14 µJ, anterior capsule distance of 500 µm and posterior capsule distance of 800 µm, 20 µm spacing between the laser application points, 40 µm spacing between the horizontal layers, and a treated area 6 mm in diameter. After treatment with the laser, the surgery was immediately followed by phacoemulsification and IOL implantation. In all patients, after removing the anterior lens capsule, a full hydrodissection was performed with an ophthalmic viscosurgical device (OVD). Sodium hyaluronate 1.0% (DisCoVisc, Alcon Laboratories, Inc.) was injected to fill the anterior chamber.

The same parameters of phacoemulsification (Infiniti® Vision System, Alcon Laboratories, Inc.) were used for all groups: torsional ultrasound technology (Ozil® pen, mini Kelman® 30° flared tip) and linear mode. During phacoemulsification, the sculpture stage in the linear pulse mode had the following upper limits: a BSS bottle height equivalent to 100 cmH_2O, and aspiration rate of 30 ml/min, a vacuum level of 100 mmHg, a torsional amplitude of 90%, and 45 pulses per second (pps). The chop phase, in linear Burst mode, had the following upper limits: a BSS bottle height equivalent to 110 cmH_2O, an aspiration rate of 30 ml/min, a vacuum level of 300 mm Hg, and a torsional amplitude of 90% (30 ms on and 10 ms off). The technique used was called "Stop and Chop", which started with the sculpture of a central channel in the nucleus of the lens and then ended with the division with the phaco pen and a hook on the secondary incision. Emulsification was performed a half at a time, with the most suitable technique for the case. Cortical removal was conducted after the complete removal of the nucleus, and then the OVD was again injected into the anterior chamber. A foldable acrylic aspheric monofocal or diffractive multifocal IOL (AcrySof IQ and ReSTOR +3.0 [Alcon Laboratories, Inc], Tecnis monofocal and Tecnis multifocal +3.25 [Johnson & Johnson, NJ, USA], namely, a CT Asphina or an AT Lisa [Carl Zeiss Meditec AG]), was implanted into the capsular bag through the main incision, and then the OVD was removed. Corneal incision sealing was performed by stromal hydration, and if there was leakage, a bandage contact lens was used for one week.

Statistical analysis

Statistical analysis was performed with SPSS version 21.0 (SPSS, Inc., Chicago, IL) software. In comparative tests between the groups, a 95% significance level was used. The Mann-Whitney test was used to compare the LOCS and EPT grades between Groups Phaco and Femto. The BSS values were evaluated by *t* tests.

RESULTS

This prospective study included 160 eyes of 109 patients. There were 57 women (52.2%). Group Phaco (87 eyes) underwent conventional phacoemulsification, and Group Femto (73 eyes) underwent femtolaser-assisted cataract surgery. Eyes with cataracts graded at LOCS<11 were assigned to group 1 (76 eyes). Those with cataracts graded at LOCS≥11 were assigned to group 2 (84 eyes). Table 1 shows the number of eyes, average LOCS grade, EPT and BSS use in each group and the *p*-value of the statistical comparisons between group 1 and group 2. There was no significant difference between the average LOCS grade of Group Phaco1 (8.21 ± 1.44) and Group Femto1 (7.90 ± 1.90, *p*=0.73) or between that of Group Phaco2 (13.15 ± 2.55) and Group Femto2 (12.72 ± 2.18, *p*=0.95). Figure 1 shows that the average LOCS grade in group 1 was significantly lower than that in group 2. Therefore, it was possible to compare the groups (Phaco1 *vs.* Femto1 and Phaco2 *vs.* Femto2) without a bias in the results related to cataract grade.

There was a statistically significant reduction of 53% in the average EPT between Groups Phaco1 (5.80 ± 2.86, 1.82 range 14.52) and Femto1 (2.73 ± 1.88, 0.1 to 8.65) (*p*=0.00), and a 33% reduction between Groups Phaco2 (12.55 ± 8.38, 4.73 to 43.03) and Femto2 (8.38 ± 9.32, 1, from 66 to 57.00) (*p*=0.00). Figure 2 shows the EPT in each group: Phaco1 (5.33), Femto1 (2.65), Phaco2 (9.43), and Femto2 (5.44). There were similar EPT values in Groups Phaco1 and Femto2. Therefore, with similar degrees of LOCS classification, the Femto Groups had lower average EPTs than the Phaco Groups. There were no complications in either group. The results of BSS use show that the Phaco Groups had lower means than the Femto Groups when similar degrees of LOCS classifications were compared; however, there was no statistically significant difference in the BSS use between the groups (see Figure 3, Group Phaco1: 55.73 ± 12.45 *vs.* Group Femto1: 59.37 ± 10.93, *p*=0.48, and Group Phaco2: 64.34 ± 21.00 *vs.* Group Femto2: 65.71 ± 17.60, *p*=0.47).

DISCUSSION

The femtosecond laser was introduced in ophthalmology in 2001 for the purpose of creating a lamellar flap during laser in situ keratomileusis (LASIK). Subsequently, its use has been expanded to cataract surgery to create corneal incisions, perform capsulotomy and produce nucleus fragmentation (8,9). In cataract surgery, endothelial cells can be damaged by

Table 1 - Number of eyes and average LOCS grade, EPT and BSS used in each group as well as the *p*-value of the statistical comparisons between groups 1 and 2.

Groups	Phaco1	Femto1	*p*-value	Phaco2	Femto2	*p*-value
Eyes (n)	42	34	-	45	39	-
LOCS	13.15 ± 2.55	12.72 ± 2.18	0.95	8.21 ± 1.44	7.90 ± 1.90	0.73
EPT	5.80 ± 2.86	2.73 ± 1.88	0.00	12.55 ± 8.38	8.38 ± 9.32	0.00
BSS	56.09 ± 12.12	59.82 ± 10.75	0.48	63.53 ± 19.44	65.71 ± 17.60	0.47

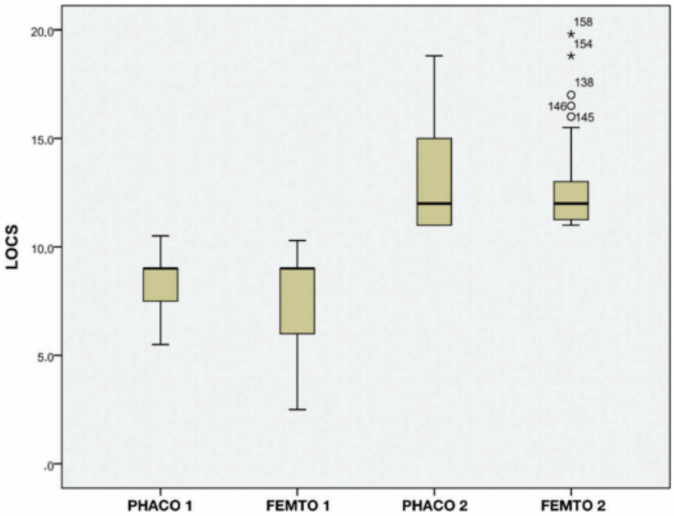

Figure 1 - LOCS by Group. LOCS=Lens Opacity Classification System III.

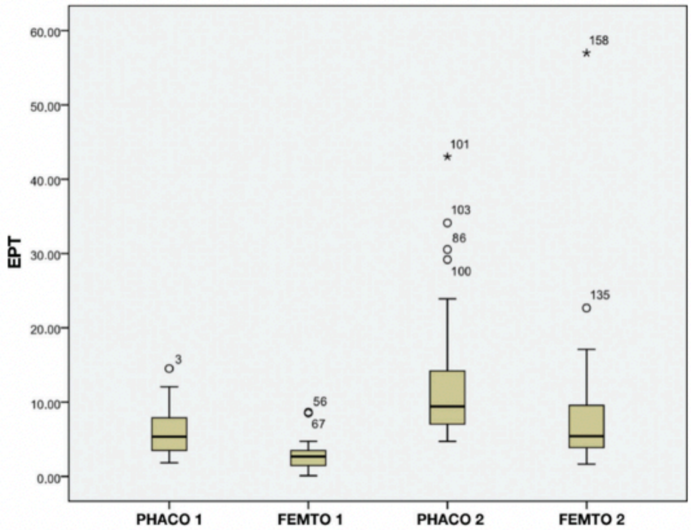

Figure 2 - EPT by Group. EPT=Effective phacoemulsification time.

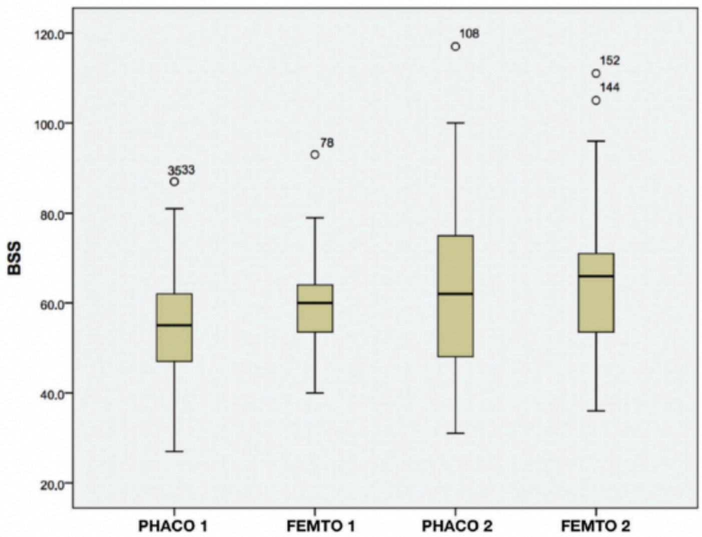

Figure 3 - BSS by Group. BSS=Balanced salt solution.

the contact of instruments or the IOL, irrigation turbulence, movements of the nucleus fragments, mechanical trauma of sonic waves and injury due to heat (7-10). Moreover, investigators have reported that a high nucleus grade, high infusion volume and high ultrasound energy are some of the variables correlated with the percentage of endothelial cell loss (7,20,21). In our study, two surgical techniques were compared in corticonuclear cataracts with different densities, and the EPT and BSS use were compared between the groups.

The phacoemulsification time is the most significant factor for endothelial cell damage (4). Abell et al. (22) showed a significant reduction in endothelial cell loss and corneal edema in the early postoperative period (1 day and 3 weeks) with the femtosecond laser. However, they showed no statistical evidence that the decrease in ultrasonic energy by the femtosecond laser reduced the endothelial cell loss at 6 months of surgery, except in cases where the EPT reached zero or in cases of femtosecond laser-assisted procedures without corneal incisions, showing that a large reduction in the energy used can bring benefits to the corneal endothelium. A possible explanation for laser corneal incisions causing greater endothelial cell damage than manual incisions could be due to the location of the corneal incisions (closer to the corneal center) and architecture. Moreover, even though the reduction in endothelial cell loss at the beginning of the postoperative period was the only clinically significant result, a reduction in endothelial cell loss can result in a rapid visual recovery (22).

The presented results are in line with those of other studies. Many contributions to the femtosecond laser cataract surgery came from Conrad-Hengerer et al. A study in 2012 that graded cataracts with the LOCS demonstrated a mean of 3.4 ± 0.9 in the femtosecond laser group and 3.1 ± 0.9 in the conventional group, and the average EPT was 0.16 (± 0.21) and 4.07 (± 3.14), respectively (9). There was a significant reduction in the EPT in the femtosecond laser group. Additionally, in 2012, another study compared fragmentation patterns with laser femtosecond in 160 eyes and showed a significant reduction in the ultrasound time in the group with a distance of 350 µm between the lines through the application of the laser (2.05 ± 3.08 seconds) than in the group with a distance of 500 µm (5.85 ± 5.55 seconds) as well as a statistically significant reduction in the EPT ($0{:}03 \pm 0{:}05$ seconds $0{:}21 \pm 0{:}26$ seconds, respectively) (23). In 2015, the EPTs in femtosecond laser-assisted surgery groups and conventional cataract surgery groups including brunescent cataracts with LOCS NO3 and NO5 (Phaco1 *vs*. Femto1 and Phaco2 *vs*. Femto2) were compared and showed no bias in the results related to cataract grade (24). The EPT in the femtosecond laser group was significantly lower than that in the conventional cataract surgery group for both grades, NO3 (0 ± 0 seconds *versus* 1.38 ± 1.35 seconds, respectively) and NO5 (1.35 ± 1.64 seconds *versus* 6.85 ± 3.83 seconds, respectively) ($p < 0.001$). The average EPT in the femtosecond laser group with LOCS NO5 was lower than that in the conventional surgery group with LOCS NO3, with a significant difference between groups (p=0.013). Daya et al. (25) showed an EPT of 9.89 ± 5.32 seconds in the conventional surgery group and an EPT of 8.58 ± 4.66 seconds in the femtosecond laser group, with a reduction of 13.2% (p=0.044) (24).

Reddy et al. (26), with the VICTUS® platform (Bausch + Lomb, New Jersey, USA), found a significantly lower EPT in the femtosecond laser group (5.2 ± 5.7 seconds) than in the conventional surgery group (7.7 ± 6.0) (p=0.025), and the BSS use was slightly higher in the femtosecond laser group (86.0 ± 25.8 ml) than in the conventional surgery group (84.6 ± 29.6 ml), but without a significant difference. The BSS use in our study was similar to that of Reddy et al., with no statistically significant differences between the groups, although the femtosecond laser group presented more BSS use than the conventional surgery group. To explain these results, we believe that the femtosecond laser-assisted group experienced less manipulation with the phaco tip and more manipulation with the aspiration pen, possibly because of an adventitious cortex due to laser bubbles, which caused great difficulty in hydrodissection. Therefore, fracture with a laser is more effective than the conventional technique since it consumes less EPT and the BSS is equivalent; moreover, due to the increased manipulation in the cortex aspiration phase but not in the phacoemulsification phase, regardless of BSS use, these results may be clinically significant. Nevertheless, additional randomized studies are required to establish the real, clinically significant benefits of femtosecond laser-assisted cataract surgery compared to conventional techniques. This study had limitations such as nonrandomization, a lack of safety data, a lack of postoperative results, and issues with refraction and reproducibility of the femtolaser technology; however, other studies cover these topics.

CONCLUSION

Cataract surgery assisted by a femtosecond laser is comparable to the conventional technique and can reduce postoperative complications. Compared to conventional cataract surgery, femtosecond laser-assisted surgery for different levels of corticonuclear cataracts significantly reduces the EPT and does not change the BSS use. Therefore, further research is needed to quantify the EPT reduction necessary to effectively protect the corneal endothelium and decrease cell death compared to these outcomes in the conventional technique. The technology and surgical techniques must continue to evolve to optimize cataract surgery results and lead to better incisions as well as reduced BSS use and EPTs.

AUTHOR CONTRIBUTIONS

Horta GA provided substantial contributions to the conception and design of the study, acquisition, analysis and interpretation of data, drafting and critical revision of the manuscript for important intellectual content and approval of final version of the manuscript. Kara-Junior N provided substantial contributions to the conception and design of the study, drafting of the manuscript and approval of the final version of the manuscript. Horta RC and Steinfeld K provided substantial contributions to the acquisition of data, critical revision of the manuscript for important intellectual content and approval of the final version of the manuscript. Koch CR and Mello GR provided substantial contributions to the conception and design of the study, analysis and interpretation of data, drafting and critical revision of the manuscript for important intellectual content and approval of the final version of the manuscript. All authors agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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4 ESTUDO 2

Artigo sobre as incisões corneanas na cirurgia de catarata assistida pelo laser de femtossegundo.

Enviado ao Journal of Refractive Surgery para publicação como artigo original.

EVALUATION OF CORNEAL INCISION IN FEMTOSECOND LASER-ASSISTED PHACOEMULSTIFICATION

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Conflict of interest: There are no conflict of interest to declare.

Funding: None.

Ethical Approval: The study was approved by the ethics committee of the Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, and all patients provided informed consent to participate in the study, following the guidelines established in the Declaration of Helsinki.

ABSTRACT

Purpose: This study aimed to evaluate the accuracy and quality of healing of main corneal incisions in femtosecond laser procedure in cataract surgery. Methods: A total of 37 eyes of 37 patients with indication for cataract surgery were separated into two groups in this prospective, nonrandomized study: Femto group, with incisions automated by femtosecond laser (18 eyes), and Phaco group, with incisions made using a keratome (19 eyes). The planned incisions were 2.2 mm wide and 1.65 mm long. The length of the incision and prevalence of endothelial gap, endothelial misalignment, and localized Descemet membrane detachment (DMD) were compared. Results: The mean incision length was statistically higher in the Femto group in two examinations: 1.64 mm ± 0.16 vs. 1.43 mm ± 0.30 ($p = 0.001$) in exam 1 (between 2 and 4 days) and 1.58 mm ± 0.22 vs. 1.27 mm ± 0.34 ($p < 0.0001$) in exam 2 (between 1 and 3 months). No eye presented endothelial gap in exam 2. The endothelial gap was higher in the Femto group in exam 1. In the two examinations, endothelial misalignment was lower in the Femto group, whereas the incidence of DMD was lower in the Femto group in the two examinations. Conclusions: Automated incisions with femtolaser presented a higher mean length and lower DMD incidence compared to manual incisions with a keratome.

INTRODUCTION

The femtosecond laser procedure in ophthalmology began with the performance of lamellar sections in laser in situ keratomileusis in refractive corneal surgeries[1]. Subsequently, its use expanded to perform full-thickness sections of the cornea, enabling different corneal transplant formats[2].

The first cataract surgery using femtolaser was performed in Hungary in 2008[3]. Currently, femtolaser is used in facectomy to perform corneal incisions, capsulotomy, and fragmentation of the lens nucleus[4,5,6].

Femtolaser-assisted cataract surgery has advantages over the conventional technique, including reduced use of ultrasonic energy[5,7], decreased endothelial damage[4,5,7], reduced corneal edema in the postoperative period[5], and performance of capsulotomy[8] and more precise corneal incisions[9,10].

However, the femtolaser procedure has some disadvantages in relation to the conventional technique, including increased prostaglandin levels in the anterior chamber[5]; high cost[6]; and positioning of the incisions farther from the limbus, toward the clear cornea, which may increase the risk of astigmatism[11].

The corneal incision influences the intraocular manipulation during cataract surgery and the patient's visual result[12]. Anterior segment optical coherence tomography (AS-OCT) obtains images of the cornea, measures the incision length, and is used to identify complications, such as incomplete sealing, Descemet membrane detachment (DMD), and retraction of the corneal endothelial face near the limbus[10,13].

This study aimed to evaluate the accuracy and quality of healing of main corneal incisions in femtosecond laser procedure in cataract surgery compared with keratome incisions in the conventional phacoemulsification technique.

PATIENTS AND METHODS

The study was approved by the ethics committee of the Hospital das Clínicas da Faculdade de Medicina da Universidade de São Paulo, and all patients provided informed consent to participate in the study, following the guidelines established in the Declaration of Helsinki.

All participants were submitted to preoperative ophthalmologic evaluation and allocated into two groups: the group submitted to incision using a keratome blade and conventional phacoemulsification (Phaco group) and the group with incisions, capsulotomy, and fracture of the lens core with femtosecond laser (Femto group).

Surgical technique

An experienced surgeon (R.C.H.) performed all surgeries with topical anesthesia. In the Femto group, the femtosecond laser platform (LensX®, *Alcon*

Laboratories, Inc.) was used. Approximately 5 min prior to laser use, a drop of 0.025%–0.3% naphazoline hydrochloride and pheniramine maleate (Claril, *Alcon Laboratories*, Inc.) was instilled to decrease subconjunctival bleeding due to eye suction. After sucking the eye, the main and accessory incisions were adjusted toward the clear cornea, anterior to the limbus. The standard configuration of the main incision was as follows: temporal axis, trapezoid triplanar architecture, 2.2 mm wide on the epithelial surface and 2.3 mm on the endothelial face, 1.65 mm long, and tunnel with entry angle of 70º and exit angle of 90º. After completion of the laser, the residual adhesions of the corneal stromal fibers were dissected with a spatula.

In the Phaco group, the 2.2-mm-wide main incision was made with a disposable keratome (Bisturi Medical 2.2M, *GeeEdge Medical Instrument* Co., Ltd., China), temporally, in a clear cornea. The planned architecture of the incision was biplanar arched, in the clear cornea, with an objective length of 1.65 mm. The definition of the programmed length was based on studies that demonstrated safety in rectangular-shaped incisions, with the tunnel long enough to generate a valvular effect and make it self-sealing, preventing the influx, and reflux of fluid from the anterior chamber.

The surgery proceeded with the traditional phacoemulsification and the *stop and chop* technique. At the end, the main and accessory incisions were hydrated with balanced saline, and a sponge (PVA *Eye Spear*, Cenefom Corp., Taiwan) used to press the anterior flap and check for leakage. In case of a positive Seidel sign, the hydration of the stroma was repeated until the leak was stopped.

As-oct

The images of corneal incisions were obtained by a single masked examiner who used the AS-OCT software (Cirrus, Carl Zeiss Meditec AG). The process occurred in two periods: between 2 and 4 days after surgery and between 1 and 3 months after surgery. The objective was to record images with the following characteristics: incision entry and exit site, main incision site with the largest corneal thickness, changes in the endothelial surface of the cut, and DMD.

Qualitative and quantitative evaluation of AS-OCT images

The AS-OCT images present a scale of dimensions defined by the equipment itself. The same investigator analyzed the images of each incision after exporting the images to the ImageJ software.

The evaluation of the architecture of the incisions included the incision length, endothelial gap, endothelial misalignment, and localized DMD. The characteristics described are considered indicators of sealing and healing quality[12-19].

Length was measured by tracing a line from the point of entry of the incision into the epithelium to the point of penetration into the anterior chamber. The comparison of the final measurement with the initially planned architecture is another quality indicator, since the length of the incision influences intraocular manipulation[20] and risk of astigmatism[21].

The endothelial gap is the apposition of the incisional edges of the posterior cornea[13] and characterizes an incomplete sealing. The longer the length of the incision and the more inclined the angle of entry into the anterior chamber, the larger the size, and area of the endothelial gap[12]. Another risk factor is low intraocular pressure[17,22].

Endothelial misalignment is defined by a misalignment of the edges of the incision in the posterior cornea and may occur by a combination of limbal margin contraction and central tissue thickening[15], indicating incomplete remodeling[15.] High intraocular pressure is significantly related to its presence, as well as stromal hydration[17].

The main risk factors for localized DMD are as follows: advanced age, preexisting endothelial diseases, prolonged surgical time, hard cataracts, irregular corneal incisions and inadvertent trauma with blunt instruments or phacoemulsification probe, and incisional trauma[18]. The longer the effective phacoemulsification time, the greater the risk of DMD[13].

Figure 1 shows an incision made with the femtolaser, and Figure 2 an incision with a keratome blade. Figures 3, 4, and 5 illustrate the concepts of endothelial gap, endothelial misalignment, and DMD, respectively.

Statistical analysis

Descriptive and exploratory data analyses were performed, and means, standard deviations, medians, and minimum, and maximum values were used for quantitative variables and absolute and relative frequencies for categorical variables. Next, the nonparametric Mann–Whitney test was used to compare the groups in relation to the time between surgery and examinations and the length of the incision. The chi-square and Fisher's exact tests were used to analyze the associations of the groups with the presence of endothelial gap, endothelial misalignment, and DMD. All analyses were performed with the aid of the R program, considering a significance level of 5%.

R Core Team (2023). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria.

RESULTS

The study included 37 eyes from 37 patients. Table 1 presents the results of the two groups, conventional phacoemulsification (Phaco group) and femtosecond laser-assisted phacoemulsification (Femto group), in relation to the characteristics of the participants and examinations. There was no significant difference between the groups regarding laterality, sex, and age of the patients ($p > 0.05$).

The mean length of the incisions was significantly higher in the Femto group than in the Phaco group ($p < 0.05$) (Table 2 and Figure 6). In the first examination, which was performed in the immediate postoperative period, the mean length of the incisions was 1.64 mm (range, 1.35–1.96) in the Femto group and 1.43 mm (range, 1.09–2.19) in the Phaco group. In the second examination, at 1 month postoperatively, the mean was 1.58 mm (range, 1.27–2.14) in the Femto group and 1.27 mm (range, 0.90–2.42) in the Phaco group. In all cases, the length of the incisions, manual, or automated, did not result in intraoperative technical difficulties or complications such as iris prolapse and incisional burn.

Table 3 shows that there was no significant association of the type of surgery to which the participants of both groups were submitted, in relation to the presence of endothelial gap and occurrence of endothelial misalignment ($p > 0.05$). The prevalence of endothelial gaps were 42.1% and 61.1% for the Phaco and Femto groups, respectively, in exam 1, and 0.0% in both groups in exam 2. The occurrence rates of endothelial misalignment were 42.1% and 27.8% for the Phaco and Femto groups, respectively, in exam 1, and 31.6% and 5.6% for the Phaco and Femto groups, respectively, in exam 2. In exam 1, the prevalence rate of DMD was significantly higher in the Phaco group (63.2%) compared to that in the Femto group (22.2%) ($p < 0.05$) (Figure 7). In exam 2, there was no significant association between the group regarding the presence of DMD ($p > 0.05$), and the prevalence rates were 10.5% and 0.0% in the Phaco and Femto groups, respectively.

Clinical data were also measured in the postoperative period. Significant corneal edema was identified in three eyes in the Phaco group (15.7%) and three eyes in the Femto group (16.6%) in exam 1 (between 2 and 4 days postoperatively). At 1 and 3 months after surgery, the mean best corrected visual acuity was 0.2 logMAR in both groups. The mean keratometry before (Kpre) and after surgery (Kpost) remained stable: Phaco group, Kpre = 42.22 and Kpost = 42.12, and Femto group, Kpre = 42.34 and Kpost = 42.22.

DISCUSSION

The corneal incision in cataract surgery has been widely studied in the literature and studies that evaluated postoperative results contributed to the understanding of the quality of the incisions. However, there is still no consensus that defines the ideal parameters for its construction.

Visibility[23] and freedom of intraocular movements[12,20], complete self-sealing that prevents the flow of fluid through the incision[24] and hypotonia[25], and refractive neutrality[21,26,27] can be considered the main qualities of an ideal incision.

There is no metric definition of a long or short incision in the literature. The presence of the following intraoperative challenges contribute to defining an excessively long incision: difficulty in the mobility of intraocular instruments, decreased visibility due to corneal striae and corneal hydration, and difficulty in the angle of access to cataracts[20].

About the architecture, the incision is safer when it presents a tunnel with a valve mechanism to prevent the influx and reflux of fluid from the anterior chamber[24,28]. Monica and Long demonstrated the safety and efficiency of 3-mm-wide and 2–3-mm-long self-sealing corneal incisions[29]. Sonmez and Karaca evaluated 2.8-mm-wide rectangular incisions and concluded that there was statistically greater risk of astigmatism in cases with a length of 1.5 mm than in cases with a length of 1.1 mm[21]. Conversely, in 2023, Wilczynski et al. found no significant difference in the risk of astigmatism between incisions with lengths of 1.4 mm, 1.8 mm, and 2.4mm[26].

Ernest et al. evaluated that incisions with a quadrangular shape, that is, equal width and length, are more stable in preventing leaks after external pressure than rectangular incisions[30]. Masket and Belani presented the safety of quadrangular self-sealing incisions of 2.2 mm and 3.0 mm in preventing leakage and hypotonia in the postoperative period[25].

From the analysis of the data on efficiency of both rectangular and quadrangular incisions, it is concluded that the planned incisions of 2.2 mm wide and 1.65 mm long, rectangular shape, triplanar with femtolaser, and biplanar with the keratome, used in the present study, present adequate quality parameters.

In the comparison between the incision models, Grewal et al. reported that the triplanar architecture was found in only 19% of the eyes with manual incisions and 100% of the incisions with femtolaser procedure[9]. The femtolaser enables the construction of automated corneal incisions reproducible in length, depth, and angle[9,10], positioned according to the planned axis[27], reducing the incidence of incomplete sealing, endothelial misalignment, DMD, and endothelial retraction[9,10]. There is morphological superiority of automated incisions over manual incisions, although the clinical relevance of these findings still needs to be studied[9].

The positioning of the incision with the femtolaser is, on average, farther from the limbus toward the center of the cornea than that of the manual incision[11]. The greater this distance, the greater the risk of astigmatism[11]. Therefore, the challenge for femtolaser platforms is to facilitate the identification of the limbus by the surgeon and penetrate the possible opacities present in the periphery of the cornea.

Nagy et al. concluded that manual incisions and those automated with the femtolaser increase high-order aberrations[27]. However, corneal incisions performed with both techniques are astigmatically neutral, as they induce minimal corneal astigmatism[31] and do not alter the topographic curvature of the cornea[32] and total corneal aberration[27].

Stromal hydration at the end of surgery decreases the inflow of fluid into the anterior chamber after surgery[14]. This technique generates greater local corneal edema[13] in relation to cases in which hydration was not performed[16], and the change in thickness remains for up to 2 weeks postoperatively. However, there is no significant difference in the cicatricial aspects of incisions with and without hydration[16].

Therefore, the choice of technique with stromal hydration and the period of 2 and 4 days after surgery for the first AS-OCT examination is adequate for the analysis of the incisions. The AS-OCT provides sensitive and detailed measurements of the incision in the clear cornea[13] and has been widely used for these purposes in the literature.

Between 5 and 9 weeks after an unsutured corneal incision, a cellular reactivation occurs in the stroma, characterizing a final phase of healing[33]. The endothelial gap and DMD appear in the early postoperative period and persist for up to 3 months[15]. Retraction of the posterior corneal flap at the incision site appears in 33.3% of the eyes between 2 and 3 weeks, 75% in 1 to 3 years, and 90.5% after 3 years[15]. Based on these results, it was decided to perform the second OCT test between 1 and 3 months after surgery.

The analysis of the causes and consequences of complications of endothelial gap, endothelial misalignment, and DMD has been extensively addressed in other studies.

Calladine and Parkard suggested that a longer incision would be less affected by the loss of coaptation because the removal of the margins of the posterior cornea would represent a smaller percentage of the entire incision[17]. Jin et al. reported a direct and significant relationship of incision length and angle of entry into the anterior chamber with increased endothelial gap area[12]. The changes in keratometry and spherical equivalent were statistically greater in the cases with endothelial gap[12].

In the results of the present study, femtolaser incisions were significantly longer than manual incisions, and there was a higher prevalence rate, although not significant, of endothelial gap in the Femto group. The clinical consequences of this incomplete sealing have been studied by some authors.

Bacteria present in the tear can reach the aqueous humor if there is a gap of the inner side of the incision, without needing a complete gap of the incisional tunnel[14]. In incisions with a 2.75-mm keratome blade, there was a significant increase in anterior corneal astigmatism in the group that presented endothelial gap, at the postoperative period of 1 week and 1 month, but not after 3 months[12]. Corneal thickening was statistically greater in patients with endothelial gap than in patients without it[13]. The functioning of the corneal endothelial pump could explain the improvement of this alteration over time. Thus, an endothelial gap delays a patient's visual and refractive rehabilitation time.

Endothelial misalignment may be caused by the combination of hydration and edema of the incision roof[16] with retraction of the posterior limbal margin. Its clinical effect is unknown, but it is supposed to induce changes in the anterior and posterior curvatures and, consequently, alter the power of the cornea and astigmatism[15]. Therefore, one hypothesis for the higher prevalence of endothelial misalignment in the Phaco group of the current study is the need for more vigorous stromal hydration.

In cataract surgery, DMD can occur, supposedly, during the construction of the main incision or in the insertion of surgical instruments.[17] Hypotonia is also correlated with its presence[17]. DMD impedes the mechanism of local endothelial pump, which hinders the complete sealing of the incisional wound and, consequently, increases the endothelial gap, and thickening of the cornea at the incision site, leading to slower visual recovery[18.19].

Table 4 presents the results of other studies that evaluated the characteristics of tunnel length, endothelial gap, endothelial misalignment, and DMD of major incisions in cataract surgery by means of AS-OCT examinations. Most studies did not analyze the incisions after 1 month. Thus, the evaluation, in the medium term, of incisions of 2.2 mm wide and 1.65 mm in length, with the femtolaser platform (LensX®, *Alcon Laboratories*, Inc.) is a novelty of the present study.

A study by Chaves et al. found no significant difference between the intended length and that achieved by femtolaser in 1.8-mm tunnel incisions. The authors evaluated the incisions immediately after femtolaser (18% gap and 0% DMD) and immediately after completing surgery (91% gap and 45% DMD). The results suggest that endothelial gap and DMD are more related to intraoperative manipulation than to laser energy[10].

Wang et al. evaluated endothelial misalignment at 2–3 weeks (33.3%), 1–3 years (75%), and 3 years (90.5%) after surgery. These dates are different from the ones they used to measure endothelial gap and DMD (1 day, 1–3 months, and 3 months). The data showed that the prevalence of misalignment increased over the years[15].

Grewal et al. found that endothelial gap, endothelial misalignment, and DMD were significantly less prevalent in femtolaser-generated incisions than in manual incisions[9]. The mean length of femtolaser incisions was 1.99 mm (1.86–2.13), which represents 94.9% of the intended 2.1 mm[9] and is in line with the result of the current study (95.7%). The mean length of the tunnel of manual incisions (1.43 mm) in our study was shorter than in other results in the literature[9,12,16,17,34]. The latter author also found a shorter incision length in the second exam[34], which possibly occurred due to the reduction of local corneal edema.

In the present study, two characteristics related to the quality and precision of the incisions were statistically favorable to the femtolaser technique: mean incision length in both exams and lower prevalence of DMD in exam 1. The observation of the cases at the postoperative period suggests that the eyes with DMD presented slower visual recovery, which would constitute a clinical advantage to the use of femtolaser.

However, there were no intraoperative complications related to the alterations, and the final visual acuity was similar between the groups. Both surgical techniques showed safe results. Thus, we conclude that, although, when submitted to microscopic evaluation, the quality of the incisions may vary according to the technique used, clinically, this difference was not highly significant.

Studies on corneal incisions include different equipment, parameters, and surgical techniques used in both femtolaser and conventional phacoemulsification, as well as diversity in tunnel architecture planning. The advancement of studies on the subject is necessary so that new data help define the currently vague concept of ideal incision.

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TABLES

Table 1 - Results of the analysis of the sample characterization variables according to the group

Variable	Category	[1]Group Phaco	Femto	p-value
		n (%)		
Sample	-	19 (100,0%)	18 (100,0%)	-
Eye	Right	12 (63,2%)	9 (50,0%)	[2]0,4194
	Left	7 (36,8%)	9 (50,0%)	
Sex	Female	14 (73,7%)	11 (61,1%)	[2]0,4142
	Male	5 (26,3%)	7 (38,9%)	
		Mean (standard deviation; minimum; maximum)		
Age (years)	-	70,6 (7,0; 58,0; 84,0)	67,8 (7,6; 55,0; 81,0)	[3]0,2875

[1]Phaco, conventional phacoemulsification; Femto, femtosecond laser-assisted phacoemulsification. [2]Chi-square test. [3]Mann–Whitney test.

Table 2 - Mean (standard deviation) and median (minimum and maximum value) incision lengths (mm) as a function of the group

[3]Exam	[1]Group				p-value
	Phaco		Femto		
	Mean (standard deviation)	Median (minimum and maximum value)	Mean (standard deviation)	Median (minimum and maximum value)	
Exam 1	1,43 (0,30)	1,36 (1,09-2,19)	1,64 (0,16)	1,64 (1,35-1,96)	[2]0,0016
Exam 2	1,27 (0,34)	1,18 (0,90-2,42)	1,58 (0,22)	1,53 (1,27-2,14)	[2]<0,0001

[1]Phaco, conventional phacoemulsification; Femto, femtosecond laser-assisted phacoemulsification. [2]Mann–Whitney test. [3]Exam 1, AS-OCT between 1, and 4 days after surgery; Exam 2, AS-OCT between 1, and 3 months after surgery

Table 3 - Presence of complications: endothelial gap, endothelial misalignment, and Descemet membrane detachment (DMD) depending on the group

[3]Exam	Variable	[1]Group		p-value
		I do	Femto	
		n (%)		
Exam 1	Endothelial gap	8 (42,1%)	11 (61,1%)	[2]0,2476
Exam 2	Endothelial gap	0 (0,0%)	0 (0,0%)	-
Exam 1	Endothelial misalignment	8 (42,1%)	5 (27,8%)	[2]0,3615
Exam 2	Endothelial misalignment	6 (31,6%)	1 (5,6%)	[3]0,0897
Exam 1	Descemet's membrane detachment	12 (63,2%)	4 (22,2%)	[2]0,0120
Exam 2	Descemet's membrane detachment	2 (10,5%)	0 (0,0%)	[3]0,4865

[1]Phaco, conventional phacoemulsification; Femto, femtosecond laser-assisted phacoemulsification. [2]Chi-square test. [3]Fisher's exact test. [3]Exam 1, AS-OCT 2–4 days after surgery; Exam 2, AS-OCT 1–3 months after surgery

Table 4 - Summary of studies reporting incision length and prevalence of endothelial gap, endothelial misalignment, and Descemet membrane detachment

Study	Eyes	Incision width (mm)	Post-op time	Incision length (mm)	Endothelial gap (%)	Endothelial misalignment (%)	DMD (%)
Horta	31	2.2	2-4 d	1.64 (femto)	61.1 (femto)	27.8 (femto)	22.2 (femto)
				1.43 (phaco)	42.1 (phaco)	42.1 (phaco)	63.2 (phaco)
			1-3 m	1.58 (femto)	0 (femto)	5.6 (femto)	0 (femto)
				1.27 (phaco)	0 (phaco)	31.6 (phaco)	10.5 (phaco)
Dupont-Monod[35]	35	2.2 and 2.75	1 d	ND	49	ND	51
			8 d	ND	9	ND	29
Can[34]	60	1.8	1 d	1.67	20	ND	66.6
			8 d	1.52	20	ND	36.6
			1 m	1.43	3.3	ND	3.3
Torres[36]	20	3.2	1 d	ND	25	45	ND
			1 m	ND	10	15	ND
Xia[13]	60	3.2	1 d	ND	70	ND	82
Calladine[17]	34	2.5	1 hour	1.61	41	65	62
Chaves[10]	11	2.5	1d	ND	82 (femto)	ND	36 (femto)
			1 m	ND	55 (femto)	ND	0 (femto)
Wang[15]	113	2.65 and 2.7	1 d	ND	85.7	ND	37.1
			1-3 m	ND	31.8	ND	4.5
			3 m	ND	3.3	ND	0
Grewal[9]	36	2.6	1 m	1.99 (femto)	ND	30 (femto)	0 (femto)
				2.04 (manual)	ND	38 (manual)	18 (manual)
Fukuda[16]	30	2.4	1 d	1.82	6.7	40	36.7
			1 s		0	13.3	3.3
			2 s		0	0	3.3
Mastropasqua[37]	60	2.75	1 s	1,67	85.7 (femto)	ND	ND
			1 m		36.7 (femto)	ND	ND
Jin[12]	80	2.75	1 s	1,67	70	ND	ND
			1 m		3.8	ND	ND
			3 m		0	ND	ND
Lyles[38]	25	2.75	1 d	ND	12	52	4
			1 s	ND	4	60	0
			1 m	ND	4	35	0

ND, not available *1st author d = day; s = week; m = month

FIGURES

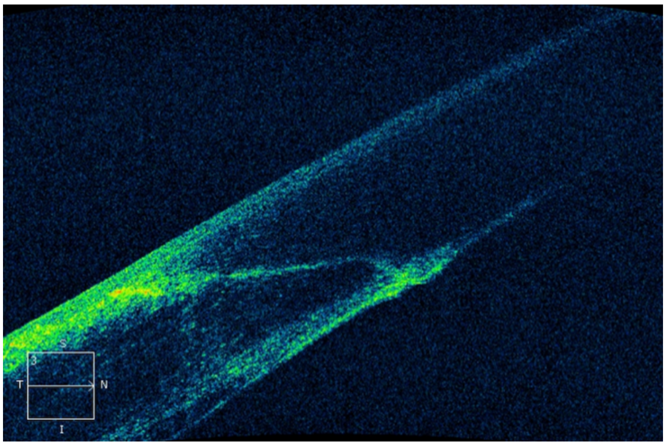

Figure 1 - Incision made by femtosecond laser (LensX®, *Alcon Laboratories*, Inc.)

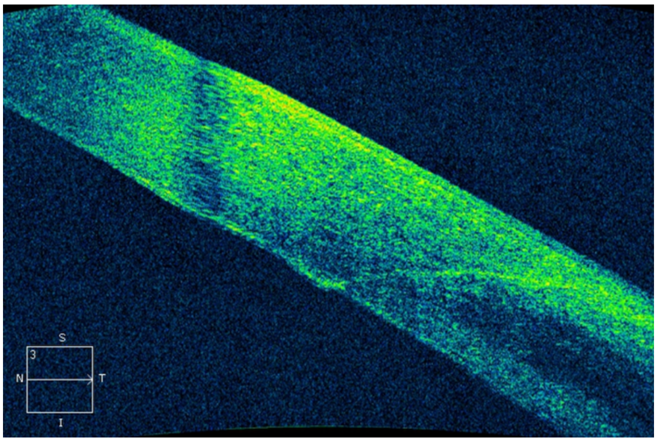

Figure 2 - Manual incision with a keratome blade

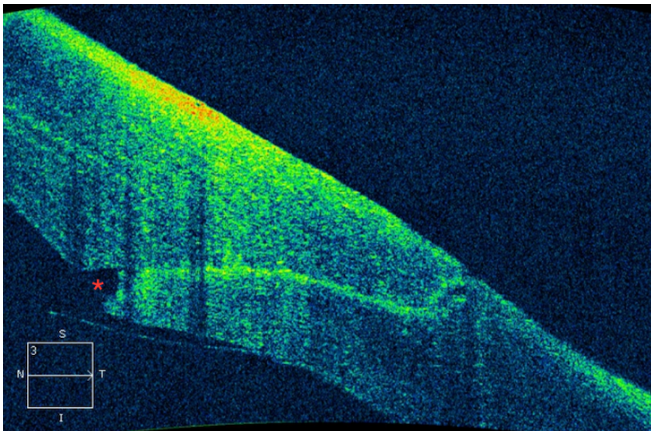

Figure 3 - Endothelial gap

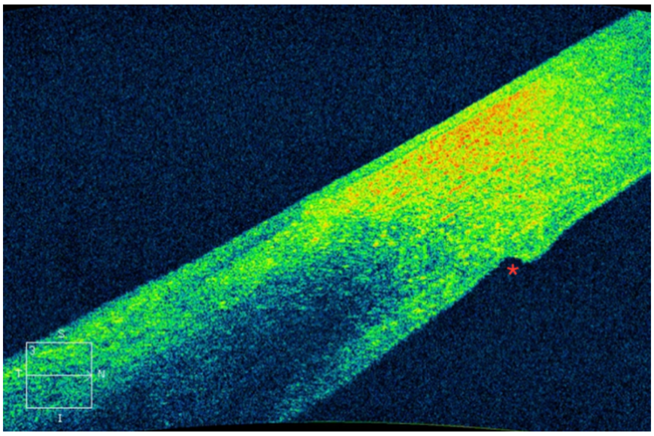

Figure 4 - Endothelial misalignment

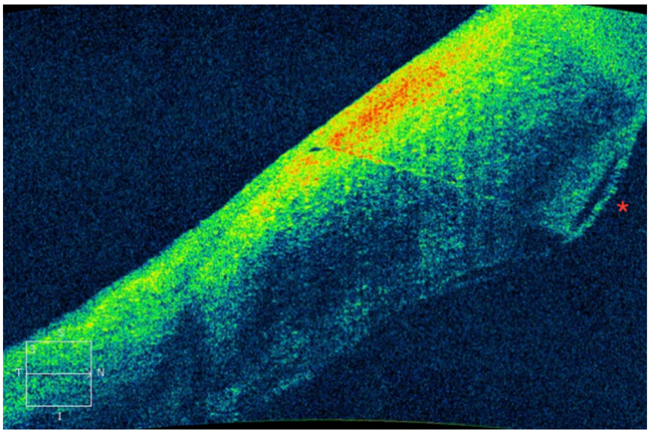

Figure 5 - Descemet membrane detachment

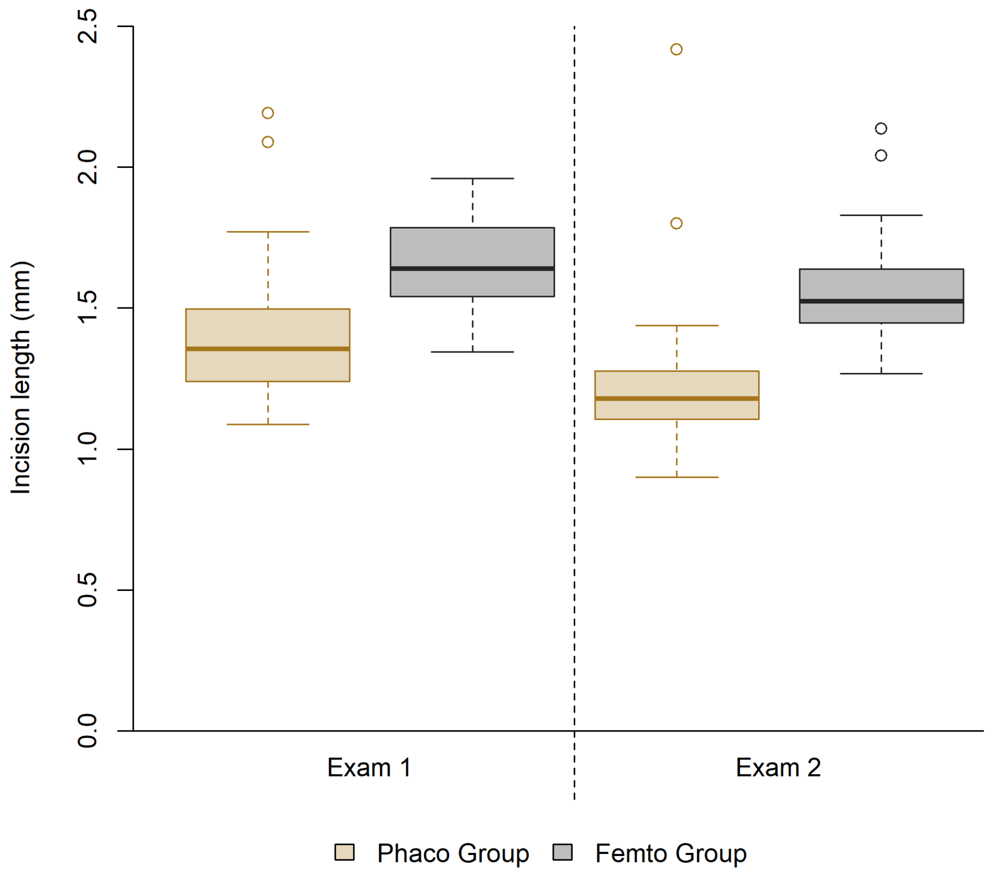

Figure 6 - Box plot of the incision length (mm) as a function of the group in both examinations. Exam 1, AS-OCT 2–4 days after surgery; Exam 2, AS-OCT 1–3 months after surgery

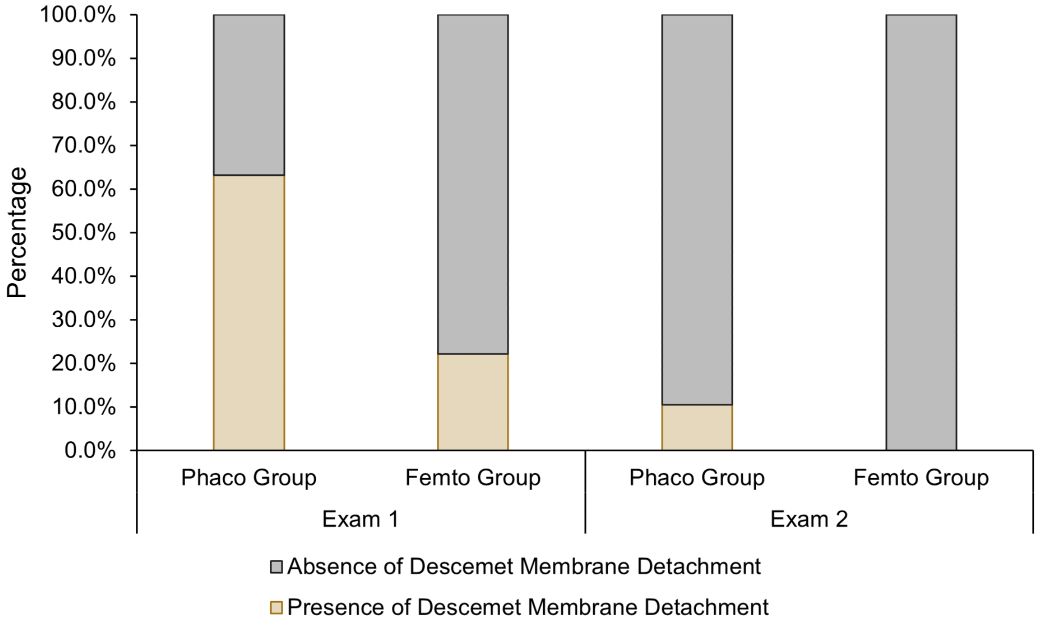

Figure 7 - Prevalence of Descemet membrane detachment as a function of the group in both tests

5 ESTUDO 3

Artigo de Revisão sobre a eficiência de incisões corneanas na cirurgia de catarata assistida pelo laser de femtossegundo.

Enviado ao Medical Research Archives para publicação como artigo de revisão.

FEMTOSECOND LASER-ASSISTED CATARACT SURGERY: AN INCISION EFFICACY REVIEW

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ABSTRACT

Purpose: This study aimed to review the scientific literature on corneal incisions in femtosecond laser-assisted cataract surgeries (FLACS) compared to keratome incisions in conventional phacoemulsification.

Conclusion: There are differences in the results of studies. Automated incisions seem to be more advantageous in the structure of the cut and incisional healing compared to manual incisions, in addition to astigmatism correction <1.0 D, with arcuate incisions. The induction of astigmatism and corneal aberrations are similar between techniques.

INTRODUCTION

The gold standard and highly cost effective technique for cataract removal is phacoemulsification,[1] which was developed in 1967 by Charles Kelman[2] and performed on approximately 17.7 million people annually.[3]

In 2008, femtosecond laser technology was used for the first time in cataract surgery.[4] Ultrashort pulses of light, in femtoseconds (10^{-15} s), generate a photodisruption of the tissue and enable the creation of corneal incisions and capsulotomy and fragmentation of the lens nucleus.[5]

The learning curve of femtosecond laser facectomy is approximately 100 cases,[6] and the additional cost of its use would be approximately $220 per eye.[7]

There is evidence that femtolaser-assisted cataract surgery presents advantages over the conventional technique, such as reduction in the use of ultrasonic energy,[8,9,10] reduction in endothelial damage,[8,9,11] decreased incidence of corneal edema in the postoperative period,[8] and more precise capsulotomy.[12]

However, the femtolaser has some disadvantages in relation to the conventional technique, including increased prostaglandin concentration in the anterior chamber[8]; cost-effectiveness[13]; and positioning of the incisions farther from the limbus, toward the clear cornea, which may increase the risk of astigmatism.[14]

Meta-analyses showed that the clinical results of visual acuity with and without correction and incidence of complications were similar between femtosecond laser-assisted cataract surgery (FLACS) and conventional phacoemulsification.[8,11]

Femtosecond laser platforms allow for various incision configurations. Still, there are surgeons who perform keratome incisions, even in FLACS.[15]

A literature review that compares the results of automated and manual incisions, with different equipment, and cutting methods, can support the choice of the technique used and elucidate the best path for future research. The present study aimed to evaluate the literature in relation to the quality and efficacy of corneal incisions with FLACS and conventional phacoemulsification, with different equipment.

INCISION MORPHOLOGY

The incision morphology (architecture, length, epithelial and endothelial gap, endothelial misalignment, Descemet membrane detachment (DMD), and corneal thickening) and the risk of astigmatism and corneal aberration are considered indicators of sealing quality and surgical incision healing.[16-23]

Endothelial gap is the apposition of the incisional edges of the posterior cornea[17] and indicates incomplete sealing of the incision. It is related to increased risk of astigmatism[16] and corneal thickness[13] and may delay visual rehabilitation.

Endothelial misalignment is the misalignment of the edges in the posterior cornea and caused by retraction of the limbar margin or thickening of the incision roof after hydration, indicating incomplete healing.[19] Its clinical effect is unknown, but it is supposed to induce changes in the anterior and posterior curvatures of the cornea and, consequently, alter corneal power, and astigmatism.[19]

The main risk factors for localized DMD are advanced age, preexisting endothelial diseases, prolonged surgical time, hard cataracts, irregular corneal incisions, and inadvertent incisional trauma with blunt instruments or phacoemulsification probe.[22] DMD impedes the endothelial pump mechanism, which hinders the complete sealing of the incisional wound and consequently increases endothelial gap and corneal thickening at the incision site, leading to slower visual recovery.[22,23]

Optical coherence tomography can be used to assess corneal features and guide treatment decisions[24] and was used in the following studies to investigate the morphological results of automated and manual incisions.

A prospective, nonrandomized case series study analyzed triplanar incisions, 2.5 mm wide and 1.8 mm tunnel length, in FLACS (LenSx, Alcon Laboratories, Inc., Fort Worth, TX) and compared the incisional changes in two periods in the surgery. The first examination was performed after the laser application but before the phacoemulsification phase, while the second examination was performed immediately after completion of the facectomy. The mean corneal thickness at the incision site was significantly higher in the second examination than in the first. The incidence rates of endothelial gap were 18% in the first exam and 91% in the second exam, while the incidence rates of DMD were 0% and 45%, respectively ($P < 0.05$). The data revealed that the complications did not occur due to the application of femtosecond laser but due to the surgical steps that followed it. Postoperatively, the prevalence rates of endothelial gap were 82%, at day 1 and 55% after 1 month. The prevalence rates of DMD were 36%, at day 1 and 0% after 1 month.[25]

Rodrigues et al. (2019) in a nonrandomized prospective cohort analyzed 2.75-mm incisions of the surgical groups with the Victus femtolaser (Technolas/Bausch & Lomb, Munich, Germany) and keratome and found the following results: prevalence rates of endothelial gap of 77.8% vs 100% ($P = 0.47$) at day 1 and 22% vs 75.6% ($P = 0.33$) after 30 days; DMD of 33.3% vs 66.7% ($P = 0.35$) after day 1 and 0.0% vs. 11.1% ($P = 0.99$) after 30 days; and corneal edema of 88.9% vs. 77.8% ($P = 0.99$) at day 1 and in no eye after 30 days. The femtolaser was used to perform triplanar cutting in all cases, while the manually constructed architecture varied between uniplanar (22.2%), biplanar (44.4%), and triplanar (33.3%) incisions, with a significant difference ($P = 0.009$). The incidence rate of <50% loss of total sealing was significantly higher with automated incisions (100% vs 44%, $P = 0.03$) on the first postoperative day, with no difference after 30 days (22.2 % vs. 22.2%, $P = 0.99$).[26]

A prospective nonrandomized study by Titiyal et al. (2018) identified that, on the first postoperative day, DMD was statistically more frequent in the conventional phacoemulsification group (49.35%), with a keratome incision of 2.2 mm in diameter, than in the FLACS group (9.61%), with the LenSx platform (Alcon Laboratories, Inc., Fort Worth, TX) ($P < 0.001$). This alteration occurred more frequently after the stromal hydration step (83.7%), and in all cases, it was resolved within 1 month after surgery.[27]

In a randomized study, incisions made by femtolaser showed less altered morphology (percentage of epithelial and endothelial gap and endothelial misalignment) than manual incisions. The increase in corneal thickness at the incision site was greater in the manual group than in the femto group, which was measured 30 and 180 days after surgery ($P < 0.05$).[28]

A series of cases compared incisions with femtolaser (Catalys, Johnson & Johnson, Santa Ana, CA) and 2.65-mm blade at 1 month after surgery. Triplanar incisions with a keratome were achieved in only 19% of cases. There was no difference in tunnel length (femto, 1.99 ± 0.07 mm, vs keratome, 2.04 ± 0.23 mm, P = 0.39). Some level of endothelial gap was found in all incisions; the gap ranged from 0.05 to 0.21 mm in the femto group and from 0.10 to 0.42 in the keratome group (P = 0.03). The femto group had a significantly lower prevalence of endothelial misalignment (P = 0.022) and DMD (0.0% vs 18.75%, P = 0.04).[29]

In 2018, a prospective review by Wang et al. evaluated the morphology of corneal incisions. Compared to the control group (steel blades), the femtolaser group (LenSx Alcon Laboratories, Inc., Fort Worth, TX) had a significantly lower incidence of endothelial gap at day 1 (P = 0.12) and lower incidence of DMD after 1 week (P=0.03), 1 month (0.048), and 3 months (0.048). Corneal thickening at the incision site decreased over time in both groups.[29]

Another prospective case series compared incisions with femtolaser (Catalys, Johnson & Johnson, Santa Ana, CA) and manual, 2.65 mm, without stromal hydration, at the end of surgery. He separated the eyes into three groups: group A with femtolaser and 110º entry angle, creating a greater valvular effect in the incision; group B with femtolaser and 70º angle; group C with manual incisions. The intraocular pressure (IOP) that would cause the incision to leak were tested at 1 day, 2 weeks, and 1 month; the mean IOP that caused fluid to leak through the incision was as follows: group A, 28.20 mm Hg ± 11.69; group B, 15.07 ± 10.64 mm Hg ($P = 0.005$), and group C, 9.93 ± 9.90 mm Hg ($P < 0.001$). On the first postoperative day, the Seidel test was positive in 0% of the cases in group A, 53% in group B, and 87% in group C. Therefore, the femtolaser created incisions with better integrity, especially when performed with a cutoff angle of entry into the larger cornea.[31]

Studies show significant differences in the morphology and healing time of incisions created by femtolaser and keratome blades. This difference in healing time can translate into greater speed of visual recovery.

Incisions with an angle of entry of 110º in the cornea, triplanar shape, and width < 2.65 mm, with the platforms LenSx (Alcon Laboratories, Inc., Fort Worth, TX) and Catalys (Johnson & Johnson, Santa Ana, CA), seem to have presented the best results.

RISK OF ASTIGMATISM AND CORNEAL ABERRATIONS

Fernandéz et al. (2018) concluded that temporal incisions, 2.5 mm wide and 1.5 mm long, with the femtolaser (Victus, Technolas/Bausch & Lomb, Munich), induced similar amount of astigmatism to those manual incisions with a 2.2-mm keratome. The mean surgically induced astigmatism (SIA) for right eyes was 0.14 D (manual) and 0.24 D (femto) ($P > 0.05$) and for left eyes 0.15 D (manual) and 0.19 D (femto) ($P > 0.05$).[32]

A prospective case series with FLACS (LenSx, Alcon Laboratories, Inc., Fort Worth, TX) found the following SIA results after 3 months of surgery: anterior cornea, 0.25 D ± 0.15 D ($P = 0.002$); posterior cornea, 0.16 ± 0.11 D ($P = 0.395$); and total cornea, 0.28 ± 0.17 D ($P = 0.013$).[33]

A study by Serrao et al. (2017) compared 2.75-mm triplanar incisions with a keratome and femtolaser (150 kHz Intralase iFS femtosecond laser). Both techniques induced minimal change in the amount of astigmatism of the anterior cornea ($P > 0.05$). However, the automated incisions induced less alteration in the direction of the astigmatism vector (P < 0.05) at 1 week and 1 month. Manual incisions significantly increased high-order aberrations (HOA) in 3.5-mm and 6.0-mm pupils, while automated incisions increased HOA only in 6.0-mm pupils. There was a significant difference between the techniques, in favor of femtolaser, in the induction of HOA in 3.5-mm pupils after 1, 3, and 6 months (P < 0.02), and 6.0-mm pupils after 3 and 6 months (P < 0.05).[34]

In a prospective case series with incisions 2.0 mm wide and 2.2 mm long, the SIA was statistically higher in the laser group (LenSx, Alcon Laboratories, Inc., Fort Worth, TX) than in the manual group at 1 day, 1 week, 1 month, and 3 months. There was a difference in mean corneal thickness at the incision site between the two groups at 1 day and 1 week (P = 0.001) but not after 1 month (P = 0.311) and 3 months (P = 0.749). The authors hypothesized that the inaccuracy of the incision positioning caused this result because the manual incisions were more peripheral than the automated ones (P = 0.001).[14]

Mastropasqua et al. (2014) did not find a difference in the induction of astigmatism and corneal aberrations between the two techniques. Keratometric astigmatism was significantly lower in the femtolaser incision group after 30 and 180 days (P < 0.05).[28]

A prospective randomized study compared 2.8-mm manual incisions and those with femtolaser (LenSx, Alcon Laboratories, Inc., Fort Worth, TX). The SIA was similar between the manual group (0.41 ± 0.14) and femto group (0.47 ± 0.13) (P = 0.218). The HOA significantly increased in both groups after cataract surgery (manual, 0.13 ± 0.05 to 0.15 ± 0.05, P = 0.025; femto, 0.13 ± 0.09 to 0.18 ± 0.12, P = .002) but with no statistical difference between the techniques. The values of low-order aberrations and total corneal aberration remained stable in both groups (P > 0.05).[36]

Triplanar incisions with femtolaser, 2.2 mm wide and 1.50 mm long, did not alter the HOA of the cornea at 1 month postoperatively. Additionally, the prevalence rate of endothelial gap was 0% at 1 day, and that of endothelial misalignment was 5%, at 1 month.[36]

The data on risk of astigmatism and corneal aberrations allow us to conclude that, with the configurations of incisions and laser platforms, one technique had no advantage over the other. Smaller incisions seem to have induced less astigmatism. Updates that allow better identification of the corneal limb and tests with different patterns of incision architecture can optimize the results with femtolaser technology.

ARCUATE INCISIONS

Residual astigmatisms >0.75 D may reduce visual acuity and increase patient visual dissatisfaction.[37,38]

The effects of astigmatism correction by corneal arcuate incisions increase according to length[40], depth, distance from the limbus, patient's age,[39,40,41] and all predictors of SIA.[42] The correction stabilizes between 3 and 6 months after surgery.[39,43]

Femtosecond laser platforms allow you to control the positioning, width, and depth of arcuate incisions. Penetrating and intrastromal cuts (do not open anteriorly) with femtolaser are effective in reducing the incidence of corneal astigmatism.[44]

Corneal biomechanics and the astigmatism meridian are independent predictors of the effectiveness of intrastromal incisions.[45] Intrastromal arcuate keratotomy is more predictable[46] and potentially leads to a lower risk of complications, such as infection, tunnel gap, and epithelial ingrowth in the anterior chamber.[39.47]

Penetrating and intrastromal cuts with femtolaser have been effective in correcting mild and moderate astigmatisms.[46,48] A literature review by Chang et al. (2018) with automated incisions in virgin eyes concluded that penetrating incisions reduced astigmatism between 26.8% and 58.62%, and intrastromal cuts reduced between 36.3% and 58%. In posttransplant eyes, the results ranged between 35.4% and 84.77% with penetrating incisions and between 23.53% and 89.42% with intraestromal incisions.[47] Femtolaser has been effective in correcting astigmatism in corneas after penetrating transplantation or deep anterior lamellar keratoplasty.[49]

Visco et al. (2019) found that 85.2% of cases had corneal astigmatism >0.50 D preoperatively. After treatment with femtolaser arcuate keratotomy (LENSAR Laser System, LENSAR, Inc.), 95.8% of cases had astigmatism ≤0.50 D. The mean total change in corneal astigmatism was 0.72 ± 0.51. Compared to the preoperative corneal cylinder of 0.92 ± 0.34 D, postoperative refractive astigmatism significantly decreased to 0.14 ± 0.23 D ($P < 0.001$).[50]

In a case series published by Day and Stevens (2016), femtolaser-arcuate incisions (Catalys, Johnson & Johnson, Santa Ana, CA) corrected, on average, 0.71 ± 0.43 D of the intended astigmatism of 1.24 ± 0.44 D or 59% ± 31% of the total.[45]

A retrospective study analyzed penetrating arcuate incisions with femtolaser (LenSx, Alcon Laboratories, Inc., Fort Worth, TX). The mean preoperative astigmatism was 1.36 ± 0.44 D, and the mean SIA was 0.82 ± 0.43 D (60% correction) postoperatively.[42]

An interventional clinical study evaluated cases of corneal astigmatism >0.50 D treated with femtolaser-arcuate incisions (LenSx, Alcon Laboratories, Inc., Fort Worth, TX). The mean astigmatism significantly decreased from 1.65 ± 0.83 D to 0.59 ± 0.54 D (P < 0.001) after 3 months of surgery, resulting in an SIA of 1.05 ± 0.44 D (64% correction). No complications were reported, and the eyeglass independence rate was 82.3%.[51]

In a randomized case-control study, with target astigmatism of 1.50 D in the group of limbar relaxing incisions and 1.38 D in the group of intrastromal arcuate incisions with the femtolaser (LenSx, Alcon Laboratories, Inc., Fort Worth, TX), the SIA was 1.02 D versus 1.23 D (P = 0.21), and the index correction was 0.48 versus 0.73 (P = 0.02). The percentage of cases that reached a postoperative cylinder <0.50 D was 20% and 44%, with the manual, and automated technique, respectively (P = 0.01).[52]

A prospective case series evaluated femtolaser treatment (LenSx, Alcon Laboratories, Inc., Fort Worth, TX) to correct astigmatisms between +0.75 and +2.50 D. The mean astigmatism decreased by 47%, from 1.31 ± 0.41 D, preoperatively, to 0.69 ± 0.34 D, after surgery ($P < 0.01$).[53]

Sanmillan et al. (2023) developed an algorithm that considered the corneal biomechanics to improve the predictability of arcuate incisions with the LDV Z8 femtolaser (Ziemer Instruments, Port, Switzerland) and managed to reduce preoperative refractive astigmatism by 38% (−1.39 ± 0.79 D–−0.86 ± 0.67 D, P = 0.02).[54]

Ahn et al. (2022) compared the conventional phacoemulsification group with the arcuate incision group (80% deep) with FLACS (LenSx, Alcon Laboratories, Inc., Fort Worth, TX) for treatment of corneal astigmatism up to 3.00 D. The mean preoperative astigmatism was 0.85 ± 0.58 D in both groups, while the SIA was significantly higher after femtolaser treatment (0.82 D) than with the limbar relaxing incisions (0.63 D) (P < 0.001). However, when treating astigmatism <0.75 D, there was hypercorrection in 58.9% of cases with femtolaser and 48.8% with manual incisions.[55]

After arcuate incisions in cataract surgeries with astigmatisms <1.0 D, more eyes achieved a result of ≤0.5 D in the FLACS group (Catalys Precision Laser System, Johnson &Johnson & Johnson, Irvine, CA) (89%) than in the conventional surgery group (71%) (P = 0.001). The preoperative cylinder decreased from 0.61 ± 0.18 D in the FLACS group and 0.57 ± 0.20 D in the conventional group to 0.43 ± 0.4 D and 0.26 ± 0.28 D, respectively, with a significant difference between the groups (P < 0.001). The percentage of patients with uncorrected visual acuity of 20/20 was 62% and 48%, respectively (P = 0.025). [56]

A prospective study concluded that manual penetrating incisions and femtolaser incisions (LenSx, Alcon Laboratories, Inc., Fort Worth, TX) are efficient for correction of corneal astigmatism, between 0.50 D and 1.75 D, with no statistical difference between the techniques. Mean corneal astigmatism in the manual group decreased from 0.98 ± 0.39 D preoperatively to 0.70 ± 0.40 after 3 months and from 1.05 ± 0.33 D to 0.63 ± 0.34 D in the femto group. The residual cylinder significantly decreased in both groups, from 1-month postoperative exam to the 3-month postoperative exam. Moreover, 95% of the eyes in the femto group and 89% in the manual group achieved refractive astigmatism ≤0.50 D after 3 months. Uncorrected visual acuity was similar between the groups, at 1, and 3 months.[57]

A literature review by Gonzáles-Cruces et al. (2022) evaluated manual arcuate incisions versus femtolaser incisions. The mean correction of astigmatism was similar between the groups (manual = 0.77 ± 0.18, femto = 0.79 ± 0.17). The mean uncorrected visual acuity was 0.19 ± 0.12 and 0.15 ± 0.05 logMAR, for manual incisions with keratome and arcuate with FLACS, respectively (P = 0.39). Refractive stability occurred at 3 month.[43]

The accuracy of femtolaser to correct astigmatisms from 1.25 to 3.0 D is less than that of toric intraocular lenses. The mean astigmatism at 3-month postoperative period was −0.63 ± 0.55 D in the toric lens group and −0.90 ± 0.53 D in the femtolaser group (*P* = .037) against a preoperative total corneal astigmatism of 2.16 ± 0.39 and 1.96 ± 0.55, respectively. Residual cylinder of up to 1.00 D was achieved in 84% and 64% of cases, respectively. Therefore, toric intraocular lenses are the best option for correction of astigmatisms >1.0 D.[58]

Manual and femtolaser arcuate keratotomies are safe and effective, but the latter is more accurate and predictable,[43] as well as fast, adjustable, and safe to reduce mild and moderate corneal astigmatisms.[39,53] The development of new nomograms can further improve the results.[39]

CONCLUSIONS

The femtosecond laser proved to be efficient in the construction of precise and safe corneal incisions, with faster healing than keratome incisions. However, the general data show that the techniques are similar in inducing astigmatism and corneal aberrations. Some studies have shown statistical relevance in favor of automated arcuate incisions in relation to manual ones for astigmatism correction. Toric intraocular lenses are still the best alternative for treating cylinders >0.75 D.

To determine the best incision configuration with the femtosecond laser, further studies will be able to test different cutting angles in the anterior and posterior regions of the cornea, depth of the lamellar cut, level of energy used, and spacing between the points and layers of laser application.

Studies of new technologies and techniques for facectomy should include, in the future, in addition to traditional data (incision, capsulotomy, ultrasound energy, visual acuity, and complications), secondary data related to health (physical and mental well-being), quality of life (independence of glasses), and visual function (dysphotopsies).[59]

Conflicts of interest statement: There are no conflicts of interest to declare.

Funding: None.

Acknowledgments: None.

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6 Comentários Conclusivos

6 COMENTÁRIOS CONCLUSIVOS

Os estudos avaliaram a incisão principal e o grau de manipulação intraocular da facoemulsificação convencional em comparação com a cirurgia de catarata assistida pelo laser de femtossegundo (FLACS).

O uso do femtolaser (LenSx, Alcon Laboratories, Inc., Fort Worth, TX), com padrão de fragmentação em cubos, diminuiu significativamente a necessidade de energia ultrassônica na facoemulsificação de cataratas com diferentes graduações núcleo-corticais, sugerindo que o trauma intraocular teria sido menor nos casos de FLACS. Embora não tenha sido o escopo dos estudos, parece que o resultado clínico final foi similar entre as técnicas. Indica-se a realização de mais pesquisas que avaliem a preservação das células endoteliais corneanas, o edema de córnea e a velocidade de recuperação visual pós-operatórios.

O laser de femtossegundo se mostrou eficiente na construção de incisões corneanas precisas e seguras, com cicatrização mais rápida do que as incisões por bisturi. As incisões automatizadas apresentaram comprimento médio mais próximo do planejado, e incidência significativamente menor de descolamento da membrana de Descemet (DMD) do que as incisões manuais.

As plataformas atuais de femtolaser permitem diversas configurações de uso, incluindo a construção incisional com diferentes ângulos e profundidade de corte na córnea, formatos de fratura do cristalino, nível de energia usada, distância entre os pontos e entre as camadas de aplicação de laser. Sugerimos que novas investigações testem distintas incisões corneanas e fragmentações de núcleo do cristalino com os equipamentos de laser e técnicas cirúrgicas disponíveis.

As evidências apresentadas no presente projeto, em conjunto com outros achados descritos na literatura e com as futuras pesquisas, poderão contribuir para o entendimento do verdadeiro potencial da tecnologia do femtolaser na cirurgia de catarata. O conhecimento advindo dos estudos pode levar ao avanço da técnica da FLACS e, possivelmente, a melhores resultados visuais e recuperação mais rápida para os pacientes.

7 REFERÊNCIAS

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8 Anexo

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

DADOS DE IDENTIFICAÇÃO DO PARTICIPANTE DA PESQUISA OU RESPONSÁVEL LEGAL

1. NOME: .:... ....

DOCUMENTO DE IDENTIDADE Nº : .... SEXO : .M ☐ F ☐

DATA NASCIMENTO: ..../......../......

ENDEREÇO... Nº.................... APTO: ....

BAIRRO: .... CIDADE ....

CEP:....................................... TELEFONE:DDD (............) ....

2.RESPONSÁVEL LEGAL ....

NATUREZA (grau de parentesco, tutor, curador etc.) ....

DOCUMENTO DE IDENTIDADE :....................................SEXO: M ☐ F ☐

DATA NASCIMENTO.: ....../......./......

ENDEREÇO: .... Nº .... APTO: ....

BAIRRO:...CIDADE: ....

CEP:..TELEFONE:DDD (...........)..

DADOS SOBRE A PESQUISA

1. TÍTULO DO PROTOCOLO DE PESQUISA: Facoemulsificação Convencional Versus Facoemulsificação Assistida pelo Laser de Femtossegundo: Avaliação de Eficácia e Segurança

PESQUISADOR : GUILHERME DE ALMEIDA HORTA

CARGO/FUNÇÃO: PÓS-GRADUANDO

INSCRIÇÃO CONSELHO REGIONAL Nº: 520113538-4

UNIDADE DO HCFMUSP: Departamento de Oftalmologia FMUSP

2. AVALIAÇÃO DO RISCO DA PESQUISA:

RISCO MÍNIMO	□	RISCO MÉDIO	□
RISCO BAIXO	X	RISCO MAIOR	□

3.DURAÇÃO DA PESQUISA : 10/01/20 até 30/07/21

4 – Apresentação:

Convidamos o(a) senhor(a) a participar de uma pesquisa científica. Pesquisa é um conjunto de procedimentos que procura criar ou aumentar o conhecimento sobre um assunto. Estas descobertas embora frequentemente não tragam benefícios diretos ao participante da pesquisa, podem no futuro ser úteis para muitas pessoas.

Para decidir se aceita ou não participar desta pesquisa, o(a) senhor(a) precisa entender o suficiente sobre os riscos e benefícios, para que possa fazer um julgamento consciente. Inicialmente explicaremos as razões da pesquisa. A seguir, forneceremos um termo de consentimento livre e esclarecido (TCLE), documento que contém informações sobre a pesquisa, para que leia e discuta com familiares e ou outras pessoas de sua confiança. Uma vez compreendido o objetivo da pesquisa e havendo seu interesse em participar, será solicitada a sua rubrica em todas as páginas do TCLE e sua assinatura na última página. Uma via assinada deste termo deverá ser retida pelo senhor(a) ou por seu representante legal e uma cópia será arquivada pelo pesquisador responsável.

5A) Justificativa, objetivos e procedimentos:

O objetivo da pesquisa é comparar a eficácia e segurança da cirurgia de catarata pela facoemulsificação convencional com a facoemulsificação assistida pelo laser de femtossegundo em diferentes graus de catarata.

5B) Desconfortos, riscos e benefícios

Os benefícios virão para a comunidade em médio prazo pois permitirão ampliarmos a base de informações que comparam os resultados das técnicas cirúrgicas de catarata por facoemulsificação convencional e facoemulsificação assistida pelo laser de femtossegundo.

Não há riscos diretos da sua participação em relação à pesquisa. O senhor(a) pode apenas sentir um leve desconforto ao realizar os exames de imagem no pós-operatório.

5C) Forma de acompanhamento e assistência

O(A) senhor(a) será acompanhado pela equipe médica durante o estudo e após o término do mesmo.

Em qualquer etapa do estudo, o(a) senhor(a) terá acesso aos profissionais responsáveis pela pesquisa. O investigador principal é o Dr. Newton Kara-Junior. O investigador executante é o pós-graduando Guilherme de Almeida Horta, que pode ser encontrado no Telefone (21) 99963-7990. Se você tiver alguma consideração ou dúvida sobre a ética da pesquisa, entre em contato com o Comitê de Ética em Pesquisa da Faculdade de Medicina da Universidade de São Paulo (**CEP-FMUSP**): Av. Dr. Arnaldo, 251 - Cerqueira César - São Paulo - SP -21º andar – sala 36- CEP: 01246-000, horário de atendimento: 8:00-17:00h; Tel: (11) 3893-4401/4407 E-mail: cep.fm@usp.br

5D) Liberdade de recusar-se e retirar-se do estudo

A escolha de entrar ou não nesse estudo é inteiramente sua. Caso o(a) senhor(a) se recuse a participar deste estudo, o(a) senhor(a) receberá o tratamento habitual, sem qualquer tipo de prejuízo ou represália. O(A) senhor(a) também tem o direito de retirar-se deste estudo a qualquer momento e, se isso acontecer, seu médico continuará a tratá-lo(a) sem qualquer prejuízo ao tratamento ou represália.

5E) Manutenção do sigilo e privacidade

Os seus dados serão analisados em conjunto com outros pacientes, não sendo divulgado a identificação de nenhum paciente sob qualquer circunstância.

Solicitamos sua autorização para que os dados obtidos nesta pesquisa sejam utilizados em uma publicação científica, meio como os resultados de uma pesquisa são divulgados e compartilhados com a comunidade científica.

5F) O (A) senhor(a) receberá uma via deste Termo de Consentimento Livre e Esclarecido.

5G) Garantia de Ressarcimento

O(A) senhor(a) não terá qualquer custo, pois o custo desta pesquisa será de responsabilidade do orçamento da pesquisa. O (A) senhor(a) tem direito a ressarcimento em caso de despesas decorrentes da sua participação na pesquisa.

5H) Garantia de indenização

O (A) senhor(a) tem direito à indenização diante de eventuais danos decorrentes da pesquisa.

Acredito ter sido suficientemente informado a respeito das informações que li ou que foram lidas para mim, descrevendo o estudo Facoemulsificação Convencional Versus Facoemulsificação Assistida pelo Laser de Femtossegundo: Avaliação de Eficácia e Segurança**.**

Eu discuti com o pós-graduando Guilherme de Almeida Horta sobre a minha decisão em participar nesse estudo. Ficaram claros para mim quais são os propósitos do estudo, os procedimentos a serem realizados, seus desconfortos e riscos, as garantias de confidencialidade e de esclarecimentos permanentes. Ficou claro também que minha participação é isenta de despesas e que tenho garantia do acesso a tratamento hospitalar, quando necessário. Concordo voluntariamente em participar deste estudo e poderei retirar o meu consentimento a qualquer momento, antes ou durante o mesmo, sem penalidades ou prejuízo ou perda de qualquer benefício que eu possa ter adquirido, ou no meu atendimento neste Serviço.

Assinatura do paciente/representante legal	Data ___/___/

Assinatura da testemunha	Data ___/___/

para casos de pacientes menores de 18 anos, analfabetos, semi-analfabetos ou portadores de deficiência auditiva ou visual.

(Somente para o responsável do projeto)

Declaro que obtive de forma apropriada e voluntária o Consentimento Livre e Esclarecido deste paciente ou representante legal para a participação neste estudo.

Assinatura do responsável pelo estudo	Data ___/___/