

Evaluation of efficacy of new lens nucleus fragmenting forceps in cataract surgery

Avaliação da eficácia de uma nova pinça fragmentadora de núcleo do cristalino para cirurgia de catarata

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The authors Marco Antônio Rey de Faria and Francisco Irochima Pinheiro applied for patent for forceps no. BR 10 2018 001342-4. The other authors declare no conflict of interest.

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ABSTRACT

Objective: To evaluate the efficacy of low-cost nucleus fragmenting forceps designed to reduce the use of ultrasound during phacoemulsification.

Methods: A total of 60 pig eyes enucleated 10 hours before were placed in the microwave oven, at maximum power for 10 seconds, to form cataracts with hardness comparable to a grade IV nucleus in the Lens Opacities Classification System III. Cataract extraction was performed using the Centurion® phacoemulsifier (Alcon Laboratories, Geneva, Switzerland) and Leica M620 microscope. All eyes were submitted to the pre-chop technique dividing the nucleus into four parts. After the pre-chop, the quadrants in 30 eyes were phacoemulsified with the torsional mode and were fragmented in the remaining 30 eyes after the pre-chop was with the fragmentation forceps before torsional mode phacoemulsification. The device was calibrated for all eyes by applying the following parameters: 40% linear torsional phacoemulsification; intraocular pressure of 65 mmHg; the linear vacuum of 600 mmHg; aspiration flow of 40 ccs/minute. After each procedure, the following was recorded: cumulative dissipated energy; equivalent average torsional amplitude; equivalent average ultrasonic power; estimated aspirated fluid; ultrasound total time; and total aspiration time. Statistical analysis was performed using the Kruskal-Wallis test and the IBM Statistical Package for Social Sciences. The p-value <0.05 was considered statistically significant.

Results: There was a statistically significant reduction favoring the use of the nucleus fragmenting forceps in all parameters, except for the average torsional amplitude.

Conclusion: The use of the nucleus fragmenting forceps contributed to improving the efficacy of torsional phacoemulsification in enucleated pig eyes.

RESUMO

Objetivo: Avaliar a eficácia de uma pinça fragmentadora de núcleo, de baixo custo, desenvolvida para reduzir o uso de ultrassom durante a emulsificação do núcleo.

Métodos: Sessenta olhos de porco com 10 horas de enucleação foram colocados no forno de micro-ondas, em potência máxima por 10 segundos, para a formação de catarata com dureza comparável à de um núcleo grau IV na *Lens Opacities Classification System III*. A extração da catarata foi realizada com o facoemulsificador Centurion® (Alcon Laboratories, Genebra, Suíça) e microscópio Leica M620. Todos os olhos foram submetidos a técnica de *pre-chop*, dividindo o núcleo em quatro partes. Em 30 olhos, após o *pre-chop*, foi feita a facoemulsificação dos quadrantes com o modo torsional e, nos outros 30 olhos, após o *pre-chop*, cada quadrante foi fragmentado com a pinça antes da facoemulsificação com o modo torsional. O aparelho foi calibrado para todos os olhos com os seguintes parâmetros: faco torsional linear 40%; pressão intraocular 65 mmHg; vácuo linear 600mmHg e fluxo de aspiração 40cc/ minuto. Após cada procedimento, verificaram-se energia dissipada acumulada; média da amplitude do faco torsional; média equivalente do poder ultrassônico; líquido aspirado estimado; tempo total de ultrassom e tempo total de aspiração. A análise estatística foi realizada utilizando o teste de Kruskal-Wallis com o IBM *Statistical Package for Social Sciences*. Valor de p<0,05 foi considerado estatisticamente significante.

Resultados: Houve redução estatisticamente significante em favor do uso da pinça fragmentadora de núcleo em todos os parâmetros, menos na média de amplitude do faco torsional.

Conclusão: O uso da pinça fragmentadora de núcleo contribuiu para melhorar a eficácia do faco torsional em olhos de porco enucleados.

INTRODUCTION

Globally, it is estimated that approximately 100 million eyes have a cataract, causing a visual acuity less than 6/60, and this figure is probably three- to four-fold greater for cataracts causing a visual acuity of less than 6/18.

⁽¹⁾ These estimates are projected to double in the next 20 years if service delivery does not improve¹. To reduce the backlog of cataract blindness and 'operable' cataract, it is necessary to annually operate at least all eyes that developed a cataract.⁽³⁾ Highly developed countries usually perform between 4,000 and 6,000 cataract surgeries per million population per year.⁽³⁾ According to data from the Ministry of Health, 346,125 cataract surgeries were performed in Brazil in 2010, through the Unified Health System (SUS). In 2011, 2014 and 2016, a total of 413,416, 469,820, and 452,893 surgeries were performed, respectively⁴. Brazil is estimated to perform less than 5,000 cataract operations per million population per year.⁽⁴⁾ Also, according to data from the Ministry of Health, of the total number of individuals examined aged 60 years or older (estimated today as 13.2% of the Brazilian population), 28.7% were diagnosed with cataracts, with higher figures in the Midwest (33.7%) and Northeast (31.9%) regions. In the North, it was 26.7%. Of the total number of patients diagnosed with cataracts in Brazil, 72.7% were submitted to surgery. Of these, 47.6% of procedures were carried through the public health system (SUS) and 37.9% were paid by health insurance plans. Of those aged over 60 years, 27.7% had cataract surgery indications but, for some reason, did not undergo the procedure.⁽⁴⁾

These data show cataract surgery is an important and growing public health problem in Brazil, and it is imperative that we seek increasingly safe and low-cost methods for surgery, always bearing in mind the risk/benefit and cost-effectiveness ratios.^(4,5)

Introduced in 1967, ultrasonic phacoemulsification has undergone a slow evolution. Due to the revolutionary concept for the time it was developed, the long learning curve, the good results with the planned extracapsular extraction, and mainly due to the ineffectiveness and poor performance of the first devices, phacoemulsification only became the method of choice for most cataract surgeries in the 1990s.

⁽⁶⁾ It was found that the corneal endothelium could be damaged during phacoemulsification, and would be caused by several factors, such as flow of the irrigation fluid, turbulence and movement of liquid in the anterior chamber, air bubbles, direct trauma by instruments or nucleus fragments in the endothelium, and time and ultrasound power required for emulsification of the nucleus.⁽⁷⁾ To avoid these

complications, several techniques were developed to improve the efficiency of lens nucleus removal with less endothelial damage, fewer thermal lesions in incisions and reduced complication rates; less zonular weakness and capsular tension, within a shorter time and the amount of ultrasonic energy required for nucleus emulsification.⁽⁸⁻¹¹⁾ These techniques aim to divide the lens nucleus into multiple fragments to make them more accessible, thus decreasing the amount of ultrasonic energy, as well as the endothelial and thermal lesions resulting from their use.

Introduced in the last decade, the femtosecond laser has been suggested to decrease the time and power of ultrasound used in cataract surgery.⁽¹²⁾ However, due to its high cost, it has not been available for use in our public healthcare service.

In the present study, the efficacy of a new low-cost lens nucleus fragmenting forceps⁽¹³⁾ was evaluated in pig eyes, to further reduce (and probably abolish) the use of ultrasound in phacoemulsification technique, aiming to make it safer, with little ocular damage, and not rising the cost of cataract surgery. The objective was to evaluate the efficacy and safety of low-cost nucleus fragmenting forceps designed to reduce the use of ultrasound during phacoemulsification.

METHODS

The research started with the approval of the Animal Use Ethics Committee of the Medical School, University of São Paulo, São Paulo (SP), Brazil, based on the proper and ethical use of laboratory animals, according to the guidelines of the National Centre for the Replacement, Refinement, and Reduction of Animals in Research (NC3Rs).

The research was performed using 60 pig eyes within 10 hours of enucleation. The pig eyes were placed in a microwave oven, at maximum power for 10 seconds, to form cataracts with hardness compared to a nucleus classified as IV in Lens Opacities Classification System (LOCS) III.⁽¹⁴⁾ The procedures for cataract extraction were performed using the Centurion[®] phacoemulsification apparatus (Alcon Laboratories, Geneva, Switzerland) under microscopy (Leica Microscope model M620).

Initially, all eyes were submitted to the pre-chopper technique to divide the lens nucleus into four parts. Next, in 30 eyes, the division of the lens nucleus was followed by fragmentation of each part using the fragmenting forceps (Figure 1) and conquer of fragments was made with the phacoemulsification apparatus in a torsional mode. In the other 30 eyes, the division of the lens nucleus into four parts was followed by conquering nuclear fragments with the same phacoemulsification apparatus in torsional mode, but not using the fragmenting forceps.

The phacoemulsification apparatus was calibrated for torsional mode as follows: 40% linear torsional phaco from 0%; intraocular pressure of 65 mmHg, continuous; vacuum of 600 mmHg, linear starting at 200 mmHg; aspiration flow 40 cc/minute starting at 20 ccs/minute.

The following parameters were recorded at the end of each procedure: cumulative dissipated energy, average torsional amplitude, equivalent average ultrasonic power;

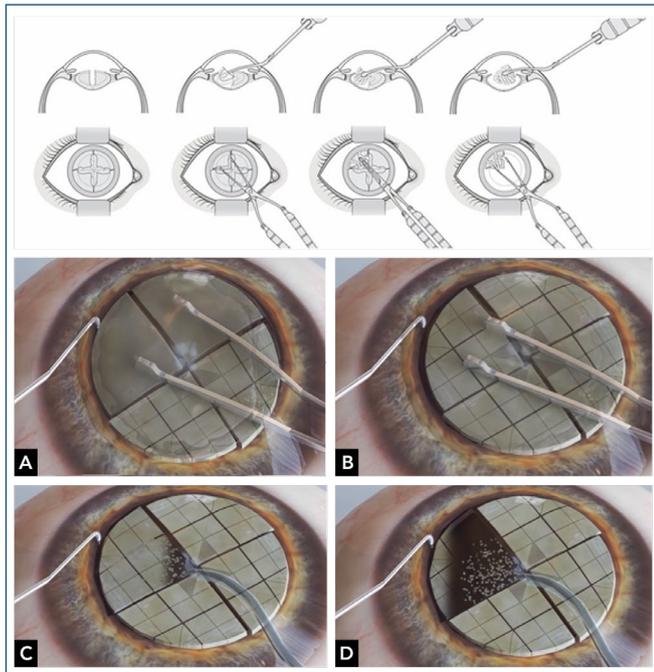


Figure 1. (A) From left to right, the sequence of the technique using the lens nucleus fragmenting forceps. (B) In (1), the introduction of the fragmenting forceps in the anterior chamber after dividing the nucleus into four parts; (C) each quadrant of the lens nucleus is trapped and fragmented by the forceps; (D) aspiration of multiple nucleus fragments.

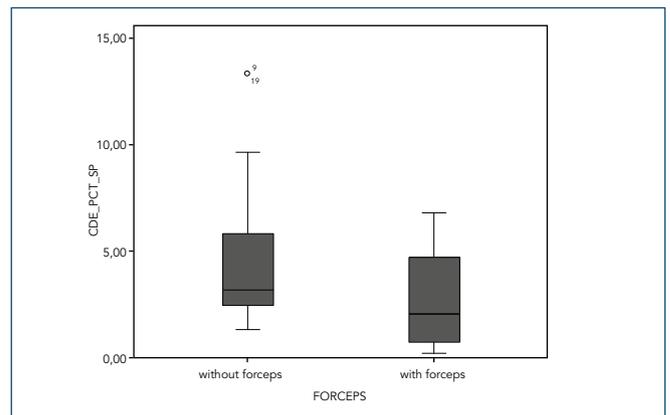
estimated aspirated fluid; ultrasound total time; and total aspiration time.

Statistical analysis was performed using the Kruskal-Wallis test with the statistical package IBM Statistical Package for Social Sciences (SPSS). A p-value <0.05 was considered statistically significant.

RESULTS

Table 1 shows the mean values, differences in the mean, standard error of the difference between means, lower and upper values of 95% confidence interval of the mean difference, and p-value of the variables evaluated during cataract extraction by the phacoemulsification technique, using or not the lens nucleus fragmenting forceps 60 pig eyes of the study.

Figures 2 to 7 show the box plots created for the variables studied.



CDE: cumulative dissipated energy.

Figure 2. Comparative box plot of cumulative dissipated energy with and without the use of the lens nucleus fragmenting forceps for pre-chop in the torsional mode phaco.

Table 1. Variables evaluated during cataract extraction by the phacoemulsification technique and results

Variables	n	Average	Mean difference (MD)	Standard error (SE)	95% confidence interval (MD)	p-value
Cumulative dissipated energy						
No forceps	30	4.80	2.50	0.71	1.09-3.91	0.004*
With forceps	30	2.30				
Equivalent average torsional amplitude						
No forceps	30	0.27	0.07	0.02	0.03-0.12	0.134
With forceps	30	0.20				
Equivalent average ultrasonic power						
No forceps	30	0.11	0.01	0.01	-0.01-0.04	0.014*
With forceps	30	0.09				
Estimated aspirated fluid						
No forceps	30	27.40	11.13	3.16	4.81-17.45	<0.0001*
With forceps	30	16.27				
Ultrasound total time (US)						
No forceps	30	2,627.37	1,206.73	299.08	608.06-1,805.40	<0.0001*
With forceps	30	1,420.63				
Total aspiration time						
No forceps	30	4,156.00	1,134.00	519.55	94.00-2,174.00	0.001*
With forceps	30	3,022.00				

*Statistically significant at 5%. MD: mean difference; US: ultrasound.

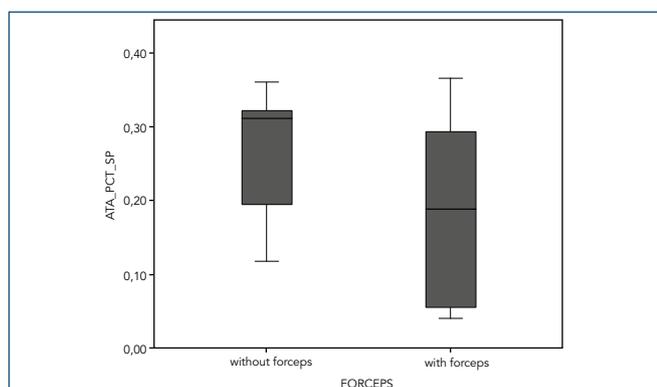


Figure 3. Comparative box plot of the average torsional amplitude with and without the use of the lens nucleus fragmenting forceps for pre-chop in torsional mode phaco.

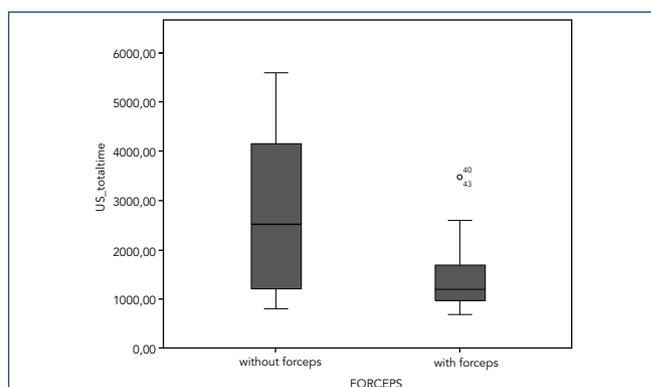


Figure 6. Comparative box plot of ultrasound total time with and without the use of the lens nucleus fragmenting forceps for pre-chop in the torsional mode phaco.

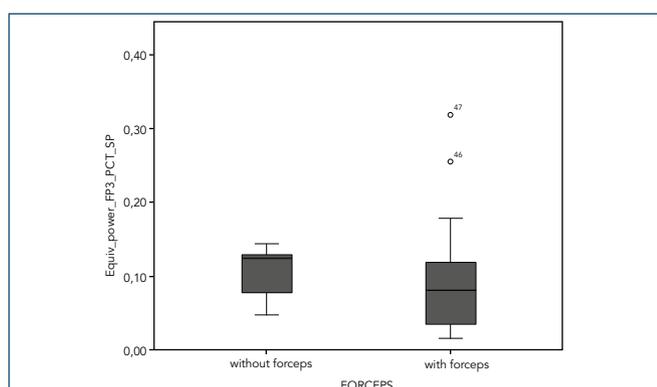


Figure 4. Comparative box plot of equivalent average ultrasonic power with and without the use of the lens nucleus fragmenting forceps for pre-chopper in torsional mode phaco.

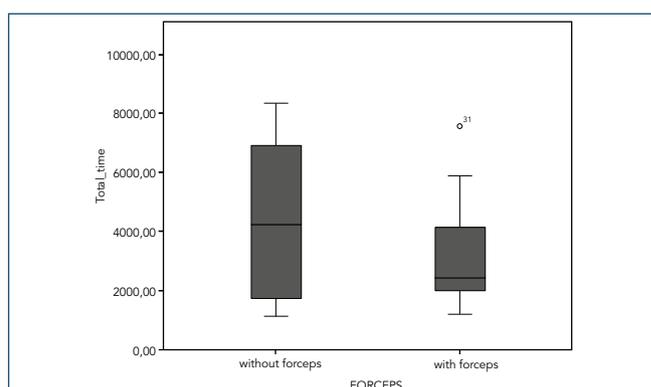


Figure 7. Comparative box plot of total aspiration time with and without the use of the lens nucleus fragmenting forceps for pre-chop in the torsional mode phaco.

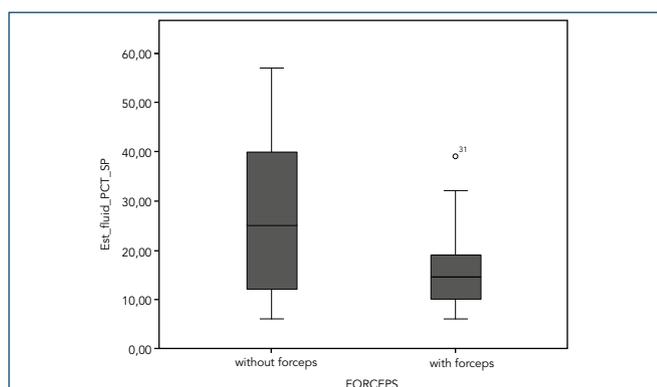


Figure 5. Comparative box plot of the estimated aspirated fluid with and without the use of the lens nucleus fragmenting forceps for pre-chop in the torsional mode phaco.

DISCUSSION

Due to the benefits achieved, such as rapid visual recovery and few complications, phacoemulsification is currently the predominant technique for cataract surgery worldwide.⁽¹⁵⁾ However, studies reported endothelial loss between 4% and 15%, even when surgery is performed by experienced surgeons.⁽¹⁶⁾ Phacoemulsification can damage

the corneal endothelium by several factors, such as corneal deformation during surgery; turbulence of the irrigation fluid; overuse of ultrasonic energy, and mechanical trauma during surgery by instruments, poorly performed maneuvers, and even by lens nuclear fragments.⁽¹⁷⁾ With endothelial loss and the inability of residual endothelial cells to maintain their function, there is an accumulation of fluid in the stroma, leading to low visual acuity, caused by edema and consequent opacity of the cornea.⁽¹⁸⁾

The recent use of femtosecond laser for cataract surgery, where corneal incision, capsulorhexis, and fragmentation of the lens nucleus are performed by laser, has reduced the time of use of ultrasound in phacoemulsification, and been shown to be a safe procedure in patients with Fuchs endothelial dystrophy.⁽¹⁹⁾

Bascaran et al⁽²⁰⁾ compared intraoperative phacoemulsification parameters (cumulative dissipated energy, total time of intraocular surgery, total ultrasound time, total phacoemulsification time, total torsion time, total aspiration time, ultrasound energy, torsional amplitude, and estimated aspirated fluid) in the eyes submitted to

conventional phacoemulsification (INFINITI® Vision System platform) and femtosecond laser-assisted cataract surgery (VICTUS femtosecond laser platform). The values of the parameters accumulated dissipated energy, total ultrasound time, torsional energy time, and estimated aspirated fluid were significantly lower in cataract surgery assisted by femtosecond laser. The other parameters evaluated did not present significant differences in the comparison between the two surgical techniques.

In the present study, in the pig eyes in which the researcher used phaco in torsional mode, there were statistically significant reductions favoring the use of lens nucleus fragmenting forceps; in that, by 47.9% in cumulative dissipated energy (from 4.80 to 2.30); 81.8% in equivalent average torsional amplitude (from 0.11 to 0.09); 59.4% in estimated aspirated fluid (from 27.40 to 16.27); 54.1% in ultrasound total time (from 2,627.37 to 1,420.63); and 72.7% in total aspiration time (from 4,156.00 to 3,022.00).

Higher values of cumulative dissipated energy are related to longer operative and recovery times, while lower values correlate with more efficient surgeries.⁽²¹⁾ Reductions in other parameters evaluated add more favorable evidence to perform more efficient surgery. In a broader analysis, the reduction of estimated aspirated fluid and total aspiration time also add favorable evidence, since an excessive volume of intraoperative irrigation solution could increase hydrodynamic flow and turbulence in the anterior chamber, potentially damaging endothelial cells.⁽²²⁾ The reduction in the volume of irrigation solution required can be explained by the use of the lens nucleus fragmenting forceps, which avoids the need for manipulation (with associated leakage of wounds) and the ineffective phacoemulsification of the nucleus fragments. Ultrasound and the dynamic energy of fluids have the worst effect on eye structures.⁽²³⁾ Ultrasound time has been related to the loss of endothelial cells.⁽²⁴⁻²⁶⁾

Femtosecond laser-assisted cataract surgery has gradually become more popular, showing advantages for anterior capsulotomy, self-sealing incisions, fragmentation of the nucleus into small pieces, as well as for the correction of corneal astigmatism. However, due to the significant increase in the cost of surgery, its use has been more limited, especially for individuals with lower purchasing power.⁽¹⁵⁾ In addition to the significant increase in surgery costs, there are important accidents with the use of femtosecond laser in cataract surgery, such as total dissection of the Descemet membrane and its accidental aspiration.⁽²⁷⁾ Thus, some techniques for the mechanical division of the nucleus, such as pre-chopper have become

an interesting alternative, mainly by not traumatizing the zonular complex.⁽²⁸⁾ Bearing this in mind, and aiming to make cataract surgery by phacoemulsification safer for patients, while not raising costs, the researcher designed new lens nucleus fragmenting forceps to break each quadrant into small pieces, resulting from mechanical cracking of the lens nucleus.⁽¹³⁾

Under the conditions of this study, there was a statistically significant reduction favoring the use of the lens nucleus fragmenting forceps in terms of cumulative dissipated energy; equivalent average torsional amplitude; equivalent average ultrasonic power; estimated aspirated fluid; ultrasound total time, and total aspiration time.

Study limitations

Although the use of the lens nucleus fragmenting forceps showed a significant improvement in surgical efficacy of cataract extraction in enucleated pig eyes, a possible decreased damage to corneal endothelium was not evaluated.

CONCLUSION

The use of the lens nucleus fragmenting forceps contributed to improving the efficacy of cataract surgery in enucleated pig eyes with the use of torsional mode phaco.

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