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The Efficacy of Improved Phacoemulsification Needle Use in High Dense Lens Nuclei (a Clinical-Experimental Study)

Skuteczność zastosowania ulepszonej igły do fakoemulsyfikacji jąder soczewki o podwyższonej gęstości (badanie kliniczno-eksperymentalne)

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Abstract: Background: To study the efficacy of the developed phacoemulsification needle with the most dense lens nuclei in experimental and clinical conditions.

Material and Methods: An experimental study was conducted on 15 isolated lenses of 15 patients. In clinical part of the study patients were divided into 2 groups: PE using a standard needle (30 eyes) and PE using an improved needle (30 eyes) with senile cataract. Two PE needles were used in the course of the experiment and clinical study (PE needle in the INTREPID® Micro--Coaxial System and the improved needle).

Results: In experimental study it was found that using a standard needle the maximum values of the force were 104.1 ± 4.3 g and improved needle – 65.4 ± 3.6 g. This proves a better introduction of an improved needle into the lens. In clinical study, the use of an improved needle for PE in patients with a high degree of lens density allowed to reduce the total ultrasonic energy (CDE) by 41.69%. A statistically significant decrease in postoperative edemas and burns of the cornea in the postoperative period was also noted.

Conclusions: The improved needle for PE, differs from standard needles in that the butt end surface of the bell-shaped part contains equilateral teeth. This can significantly reduce the force required for needle introduction for PE into the lens and reduce the amount of ultrasonic energy for lens emulsification. From a practical point of view, this allows to reduce the rehabilitation of patients after cataract surgery.

Key words: needle for phacoemulsification, phacoemulsification, cataract.

Abstrakt: Cel: Badanie efektywności rozwiniętych igieł dla fakoemulsyfikacji z jądrem najgęstszych soczewek w warunkach eksperymentalnych i klinicznych.

Materiał i metody: Badanie eksperymentalne przeprowadzono na 15 soczewkach odizolowanych, które należały do 15 pacjentów. W części klinicznej badania pacjentów podzielono na 2 grupy: PE przy użyciu standardowej igły do fakoemulsyfikacji (30 oczu) i PE przy użyciu ulepszonej igły (30 oczu) z zaćmą związaną z wiekiem. Zaćma dojrzała (brązowa) została zdiagnozowana u wszystkich pacjentów. W trakcie eksperymentu i badania klinicznego użyto dwóch igieł PE (igła PE w systemie mikroosiowym INTREPID® i ulepszona igła).

Wyniki: W badaniach eksperymentalnych stwierdzono, że przy użyciu standardowej igły maksymalne wartości siły wyniosły 104,1 ± 4,3 g, a przy użyciu ulepszonej igły – 65,4 ± 3,6 g. To świadczy o lepszym wprowadzeniu ulepszonej igły do soczewki. W badaniu klinicznym zastosowanie ulepszonej igły do PE u pacjentów o wysokim stopniu gęstości soczewki pozwoliło zmniejszyć całkowitą energię ultradźwiękową (CDE) o 41,69%. Odnotowano również statystycznie istotny spadek obrzęków pooperacyjnych i oparzeń rogówki w okresie pooperacyjnym.

Wnioski: Ulepszona igła do PE różni się od standardowych igieł tym, że powierzchnia czołowa części w kształcie dzwonu zawiera zęby równoboczne. Może to znacznie zmniejszyć siłę wymaganą do wprowadzenia igły do PE do soczewki i zmniejszyć ilość energii ultradźwiękowej do emulgowania soczewki. Z praktycznego punktu widzenia pozwala to ograniczyć rehabilitację pacjentów po chirurgicznym leczeniu zaćmy.

Słowa kluczowe: igła do fakoemulsyfikacji, fakoemulsyfikacja, zaćma.

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Relevance

Ultrasonic phacoemulsification (PE) is a widely used method for removing cataracts in various degrees of lens density. Particularly it is relevant to conduct PE in the lens nuclei with high density.

When removing the lens nuclei with high density, difficulties are known that are associated with the impossibility of a complete breakdown of a lens nucleus, which can lead to the complications development. Thus, the development of transient edema of the cornea in patients with mature cataract can occur in 24.4%,

burns of the cornea in 27.3% (1, 2, 3), incomplete capsulorhexis associated with the strain of the anterior lens capsule in 28.3% of cases, posterior capsule rupture – in 1.9% (4), respectively. According to some authors, the loss of endothelial cells in the center of the cornea after PE is 8.5 to 11.7% (5, 6, 7).

Due to that, for more effective PE in dense nuclei of the lens, new PE systems are applied (combined ultrasound, torsion ultrasound, «Intelligent Phaco»), in which, owing to the lower consumption of ultrasound energy and a higher rate of aspiration of fragments, the loss of corneal endothelial cells decreases, and the number and severity of postoperative complications associated with it are reduced.

We have developed a needle for PE to be used with the most dense lens nuclei, which was tested in experimental and clinical conditions at the State Institution "Filatov Institute of Eye Diseases and Tissue Therapy of the National Academy of Medical Sciences of Ukraine".

Based on literature data on the possibility of conducting experimental work for evaluation of the mechanical properties of the lens, determination of the effort required to introduce needles of various designs for the PE under experimental conditions is an urgent task.

Purpose

To study the efficacy of the developed phacoemulsification needle with the most dense lens nuclei in experimental and clinical conditions.

Materials and Methods

An experimental study was conducted on 15 isolated lenses of 15 patients aged 65–74 years old with a diagnosis: 10 – mature senile cataract, 5 – overripe senile cataract, which were removed with extracapsular cataract extraction method. Lens samples were obtained by performing extracapsular cataract extraction in patients with severe subluxation of the lens, where ultrasound phacoemulsification was not advisable in the period from 2015 to 2018.

Data on the density characteristics of the lens were confirmed by preoperative ultrasound B-scan with the determination of the acoustic density in different layers of the lens. All lenses were among the densest, as confirmed by the US study and biomicroscopic examination.

A clinical study was conducted in a group of 40 patients (60 eyes) with senile cataract. A mature (brown) cataract (5 degree of density) was diagnosed in all patients by biomicroscopic examination using classification Buratto (6).

Criteria for inclusion of patients in the clinical study:

- no complications during surgery and in the postoperative period;
- absence of concomitant ocular pathology of the anterior part of the eye (corneal scars, corneal dystrophy, keratoconus, lens subluxation, etc.);
- absence of common systemic diseases (diabetes mellitus, rheumatoid arthritis);
- absence of previous surgical interventions on the examined eye.

The selection of patients for the study was conducted taking into account the criteria of statistical identify.

In accordance with the clinical task, the patients were divided into 2 groups:

Group 1 (30 eyes) – PE operation with an IOL using a standard needle in the INTREPID® Micro-Coaxial System for the INFINITI system;

Group 2 (30 eyes) – PE operation with IOL using improved needle.

The obtained data are correctly processed by modern methods of statistics and carefully analyzed. The methods of descriptive statistics and methods of graphical visualization were used in the work. At the same time, following indicators were calculated: the number of studied in groups (n), the average values of the parameters (M), their standard deviations (SD) and standard errors (Standard Error).

To evaluate the differences between the comparison groups, a parametric test – Student's t-test was used and a 95% confidence interval was calculated. Accordingly, differences with significance level of $p < 0.05$ by Student's t-test for related or independent groups were considered significant.

The work envisages measures for the safety and health of patients, observance of their rights, human dignity, moral and ethical standards in accordance with the principles of the Helsinki Declaration of Human Rights, set out in the document «Condition of Bioethics of the Declaration of Ethical Regulation of Medical Research», Convention if the Council Europe on Human Rights and Biomedicine and the relevant Laws of Ukraine. Patients gave their consent to conduct research.

Visual acuity (VA) before surgery was 1.69 ± 0.20 logMAR. PE with intraocular lens implantation was performed in all patients. All operations were performed by one surgeon on an Infiniti Vision System device with specified parameters using the «phacochop» procedure for breaking and emulsifying the lens.

Two PE needles were used in the course of the experiment (the standard PE needle in the INTREPID® Micro-Coaxial System and the improved needle (the Ukrainian patent for utility model 64851). The improved PE needle differs from the standard needle in that the butt end surface of the bell-shaped part contains equilateral teeth, which makes it possible to more effectively penetrate into the deeper layers of the lens nucleus with a high degree of density (Fig. 1).

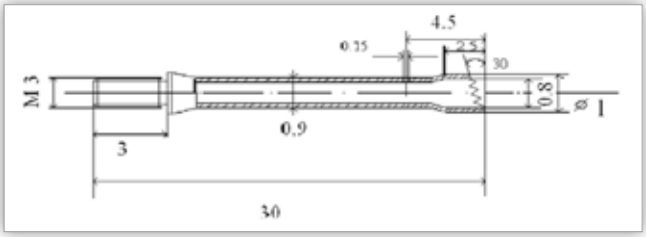

Fig. 1. Draft of improved PE needle (mm).
Ryc. 1. Projekt ulepszonej igły PE (mm).

Samples of the lens were stored in a balanced solution at a temperature of 5–7 degrees.

We have developed a test stand designed to measure the force applied when a needle penetrates into the lens substance (Fig. 2).

The test stand included the following modules:

1) Driving element with programmed speed;
2) Fixing part in which the handle for PE is screwed;

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3) The system of adjusting the handle position (the ability to change the angle at which the tool will be embedded into the lens substance);
4) The system of monitoring and recording the obtained data.

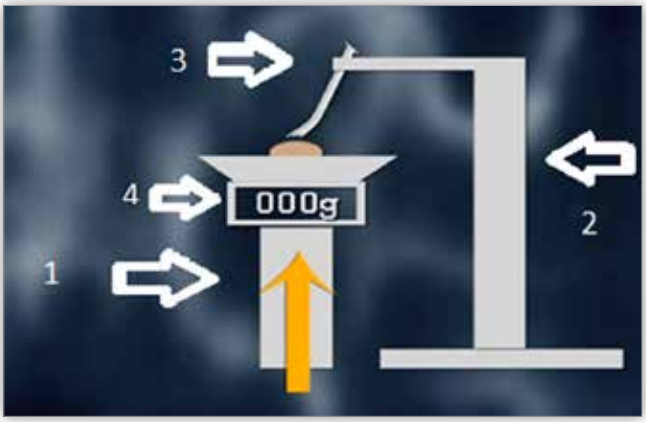

Fig. 2. Schematic representation of the experimental stand.
Ryc. 2. Schematyczne przedstawienie stanowiska doświadczalnego.

To determine the depth of needle penetration, notches with a discreteness of 2 mm were applied on the lateral surface of the needle. The study consists in measuring the force that occurs when the butt end surface of the needle contacts with the lens material under the action of the same strain. During the experimental study, the sample should not be completely destroyed.

The container with the lens was mounted on electronic analytical balance with a resolution of 0.1 g. The lens substance was fixed in a Petri dish (Fig. 3).

The phacotip was fixed in a special device. The container

Fig. 3. Lens fixation in a Petri dish.
Ryc. 3. Mocowanie soczewki na szalce Petriego.

with the lens was located on the moving element of the original device, in a position that ensures its linear movement in the direction of the fastened tip of the PE system, with a speed of 1 mm/22 s (Fig. 4).

Upon contact of the needle, operating in 100% longitudinal and 100% torsion ultrasound mode, the weight of the container with the lens was reflected on the control panel of the balance, which increased over time and was corresponded to the force applied to the lens substance.

At the same movement speed of the container, the weight of the structure depended on the needle pressure on the lens substance and the speed of the needle penetration.

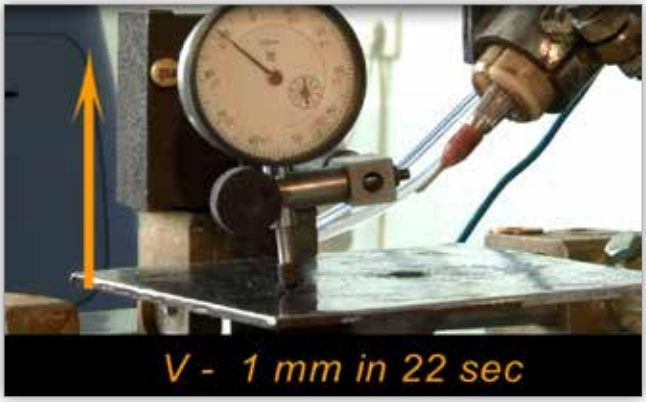

Fig. 4. The original design provides a forward movement at a speed of 1 mm in 22 seconds.
Ryc. 4. Oryginalna konstrukcja zapewnia ruch do przodu z prędkością 1 mm w 22 sekundy.

Results

According to the color gradations and the lack of reflex from the fundus of the eye, the nuclei of the lens belonged to the 5 degree of density. During ultrasound study, it was found that the relative acoustic resistance parameter was in the range of 0.35 to 0.42 conventional units (cu), which can be attributed to the most mechanically solid lenses. During the experiment, it was found that at the moment of contact of the standard needle with the anterior sections of the lens, the force indicator was 44.0 ± 2.3 g. Further immersion of the PE needle into the lens nucleus was characterized by plastic deformation of the lens nucleus with formation of multiple cracks in the radial directions and subsequent destruction of the lens substance. The maximum force indicator was 104.1 ± 4.3 g and corresponded to the moment of reaching the densest layers of the lens nucleus.

During contact of the improved needle with the anterior layers of the lens, the force indicator was 30.2 ± 2.5 g. This is primarily due to the fact that in the course of the needle operation, its contacts with flat surfaces oriented perpendicular to the motion vector were excluded, which contributed to a decrease in total level of pressure on the lens. Upon reaching the dense structures of the lens, this indicator was 65.4 ± 3.6 g (Fig. 5).

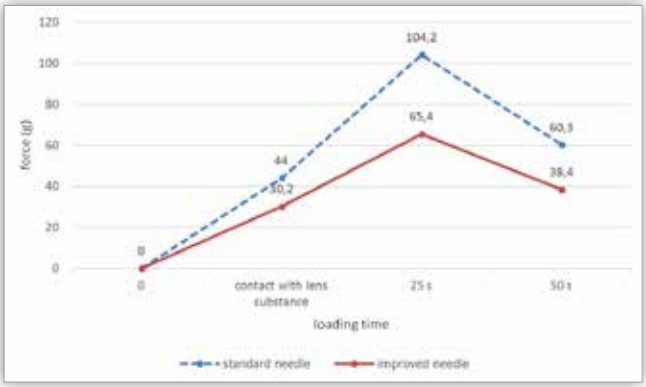

Fig. 5. The value of the force parameter depending on the loading time.
Ryc. 5. Wartość parametru siły w zależności od czasu ładowania.

As follows from the analysis of the obtained data, when using a standard needle (group 1), the contact with the lens surface, which was 44.0 ± 2.3 g, was statistically significan-

tly higher than in the group with an improved needle (group 2) 30.2 ± 2.5 g (p = 0.01). Student's test (t) was 11.12. Upon reaching the maximum values of the force, the parameters were 104.1 ± 4.3 g and 65.4 ± 3.6 g, respectively. Student's test (t) was 18.78.

To assess the efficacy of introduction and the rate of emulsification of the lens substance in the course of the PE, the total ultrasonic load "Cumulative Dissipated Energy – CDE" was registered, which was calculated by the formula:

CDE = (phaco time * average phaco power) + (torsional time * 0.4 * average torsional amplitude).

It can be seen from this formula that the CDE indicator, ceteris paribus (the technique of performing the operation, qualification of the surgeon) directly depends on the mechanical density of the lens substance. This indicator is automatically fixed in the operating system "Infiniti Vision System".

Groups of patients/ Grupy pacjentów	CDE indicator (conventional units)/ Wskaźnik CDE (jednostki konwencjonalne)	Number of examinations (n)/ Liczba badań (n)
Group 1/ Grupa 1	67.54±14.32	30
Group 2/ Grupa 2	39.38±12.71	30

Tab. I. Dependence of CDE indicator on the type of needle used for phacoemulsification.

Tab. I. Zależność wskaźnika CDE od rodzaju igły użytej do fakoemulsyfikacji.

It was found that in the group 1 of patients using a standard needle for PE, the average cumulative disparate energy at the end of the operation was 67.54 ± 14.32 conventional units, while in the group 2 of patients where an improved needle was used for PE, this indicator was statistically lower and amounted to 39.38 ± 12.71 conventional units (Tab. I). It was established during the operations that the use of an improved needle for the PE allowed to penetrate into the lens substance more effectively and perform a complete break of the lens.

The use of an improved needle for PE in patients with a high degree of lens density allowed to reduce the total ultrasonic energy (CDE) by 41.69%. A statistically significant decrease in postoperative edemas and burns of the cornea in the postoperative period was also noted.

Best corrected visual acuity (BCVA) logMAR in the first 3 days after surgery in the examined patients was 1.0 ± 0.22 in the first group, and 0.43 ± 0.11 in the second group. Subsequently, an increase in VA to -0.004 ± 0.22 in 1–3 months in both groups after surgery was noted. In 4 cases (13.3%), a burn of the cornea in the area of the main incision was observed in the first group in the early postoperative period, requiring the imposition of an additional corneoscleral suture. In the first group, in 9 cases (30.0%) there was diffuse corneal edema with burns in the area of the main incision, which increased the period of rehabilitation of patients. In the second group, in 2 cases (6,6%), a local burn of cornea was observed. All operations were unremarkable.

The average density of the endothelial cells (DEC) of the cornea in the preoperative period was 2590 ± 341 cells/mm^2 in the first group and 2623 ± 325 cells/mm^2 in the second group. In the postoperative period, this indicator was 2233 ± 367 cells/mm^2 and 2489 ± 275 cells/mm^2, respectively. The average loss of endothelial cells was 13.7 ± 4.3% and 5.1 ± 1.2%, respectively (Tab. II). The development of epithelial-endothelial dystrophy of the cornea was not observed in any of the cases in the studied groups.

Groups/ Grupy	DEC before the operation M±SD (cells/mm^2)/ DEC przed operacją M ± SD (komórki/ mm^2)	DEC after the operation M±SD (cells/mm^2)/ DEC po operacji M ± SD (komórki / mm^2)	Dynamics, %/ Dynamika, %
1	2590±341	2233±367	-13.7±4.3
2	2623±325	2489±275	-5.1±1.2

Tab. II. Dynamics of changes in the density of endothelial cells in groups (p<0.05).

Tab. II. Dynamika zmian gęstości komórek śródbłonka w grupach (p <0,05).

Discussion

Nowadays surgeons performing PE focus on minimal use of US energy and shorten the phaco time in hard grades of cataracts. The density of the nucleus determines the amount of US energy required for the emulsification of the nuclear material. Most complications of phacoemulsification result from US energy and power.

To date, the needles for PE differ in the inclination angle of the inlet (0°, 30°, 45° and 60°) and the standard dimensions of the inner diameter of the needle – 0.9 and 1.2 mm. In study by Rajesh S., Sonal J. (2017), was concluded that mean CDE rate in patients using 30-degree phaco tips was less than in 0-degree group (8). In the last decade, in connection with the transition to microinvasive seamless surgery, attempts have been made to minimize the diameter of the tubular part of the needle, which reduces the risk of intraocular aberrations and increases the control of the operation. However, on the other hand, there have been described cases of needle occlusion for PE in the emulsification of the superdense lens of the lens, which lead to an increase in the time of surgery and the number of manipulations in the anterior chamber of the eyeball.

The disadvantages of existing needles for PE include a large contact area of the working end surface with the lens nucleus, which requires additional effort when introducing the needle into the nucleus.

However, there are certain types of needles for PE that have tried to eliminate this drawback by changing the end surface in contact with the lens. E.R. Zaleski (1997), proposed a needle for PE with a modified flat end surface, which is made in the form of a step (9). J.F. Gravlee (1996) developed a needle with small sharpening angles of the cutting edge of the working part of the needle, made by sharpening the outer or inner surfaces of the tubular portion of the needle (10).

Modifications of the working part of the needle described above are aimed at reducing the force for introducing the needle into the lens core by reducing the contact area of the working end surface with the lens core or by sharpening the cutting edges.

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The disadvantages of the needles described above include the presence on the end surface of a plane, perpendicular to the needle's motion vector, that impedes the introduction of the needle into the lens nucleus. On known needles, the cutting edges are extended in nature, which increases the size of the cut off particles of the lens of the eye and complicates the process of aspiration.

We described here the effectiveness of using an advanced phacoemulsification needle in experimental and clinical conditions.

A study conducted by us on routine cataract cases in the grade of 4 and 5 of Buratto classification. The mean CDE in the 1 group with a standard needle 67.54 ± 14.32 c.u. was bigger than in the 2 group with an improved needle 39.38 ± 12.71 c.u. The US power was 100% in linear mode for all cases. The side of the phaco tip helps in cutting the nucleus.

The use of an improved needle for PE in patients with a high degree of lens density allowed to reduce the total ultrasonic energy (CDE) by 41.69%. A statistically significant decrease in postoperative edemas and burns of the cornea in the postoperative period was also noted. We used phaco chop technique with sharp chopper in both the groups. The sharp chopper helps in cutting the nucleus when placed perpendicular to the nucleus.

Less CDE in phacoemulsification of the cataract translates to less US energy use and is considered better for corneal recovery (11). High CDE reading is equated with statistically significant corneal endothelial cell loss with one surgeon, one technique and one setting (12).

The mean BCVA was little better in the 2 group 0.43 ± 0.11 against 1.0 ± 0.22 in the first group. Subsequently, an increase in VA to -0.004 ± 0.22 in 1–3 months in both groups after surgery was noted.

We think that using an improved needle could reduce mechanical and ultrasonic loading, which led to a decrease in postoperative corneal edema and a decrease in the rehabilitation time of patients. In future we will present the results of using an improved needle in patients with cataract using a femtosecond laser.

Conclusion

We have improved the needle for PE, which differs from standard needles in that the butt end surface of the bell-shaped part contains equilateral teeth, which makes it possible to more effectively penetrate into the deeper layers of the lens nucleus with a high degree of density. In this case we can significantly reduce the force required for introduction needle for PE into the lens and reduce the amount of ultrasonic energy for emulsification of the lens.

In clinical practice, the use of an improved needle for PE in patients with a high degree of lens density allowed to reduce the total ultrasonic energy (CDE) by 41.69%, which leads to a statistically significant decrease in postoperative edemas and corneal burns in the postoperative period. This allows reducing the rehabilitation of patients after surgical treatment of cataract.

Due to the development of femtosecond cataract surgery, an additional reduction in ultrasonic energy can significantly reduce ultrasound exposure and achieve the planned result in the shortest time.

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