Original article

Design and validation of a simulator for training in continuous circular capsulotomy for phacoemulsification

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ABSTRACT

Introduction: To design and validate a simulator for learning and training in the capsulorrhexis technique. Methods: The system consists of a methacrylate support inclined 15° for the surgeon’s hand, an area of commercially available aluminum foil, and another one of similar characteristics, where the student performs the technique through some slots that are previously made in the support. In order to evaluate the feasibility of this simulator, data were collected from 65 ophthalmologists performing the technique during training activities. The ophthalmologists were randomly divided into one group of 30 specialists who start their learning on the eyes of an animal cadaver, and into another of 35 specialists who previously started with this simulator.

Results: A simulator is developed for training in the capsulorrhexis technique. The students from the simulator group achieved a reduction in the use of cadaver eyes, and a higher efficiency in correct capsulorrhexis, unlike the group who started directly on the cadaver eyes.

Conclusions: This simulator is an innovation in training of the capsulorrhexis technique as regards simplicity, cost, and reuse, as compared to other virtual simulators with more expensive computer equipment (CE) equipment that are more difficult to transport. It is an important step prior to the use of cadaver parts and experimental animals, decreasing the number of both, and therefore the teaching costs.

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Diseño y validación de un simulador para el entrenamiento en la capsulotomía circular continua en la facoemulsificación

Resumen

Introducción: Diseñar y validar un simulador para el aprendizaje y entrenamiento de la técnica de la capsulorrhexis.
Introduction

According to the World Health Organization cataracts continue to be the main cause of blindness all over the world, except in the most developed countries. The most usual form is age-related cataract, the epidemiology of which has been estimated at over 48% of global blindness cases, about 18 million people. Age is considered to be the main risk factor although there are other causes such as inheritance, trauma, particularly of the perforating type, certain diseases such as diabetes mellitus, galactosemia, Lowe syndrome, Fabry disease, etc., as well as the use of some medications (particularly those induced by corticoids and chlorpromacín, miotics, amioradone, gold salts). It could also be secondary to other diseases, the most frequent being chronic anterior uveitis, and syndromes such as Down and Werner or miotonic dystrophy.

The objective is to prevent or delay the development of cataracts and, in the case of already formed cataracts (excepting cataracts secondary to systemic diseases or caused by toxic agents), the only treatment is surgery. Phacoemulsification is the most modern technique for cataract surgery, first described by Kelman in 1967. Subsequently, the development and improvement of devices and the use of more bonds to surgery techniques facilitated significant improvements in the technique and reduction of post surgery complications. At present, cataract surgery is carried out with a microincision which has reduced the size of the incision to 1.5 mm and lowered the risks for the patient.

During training for cataract surgery, surgeons must approach a critical step which is considered to be one of the most complicated procedures which can determine the final results of the surgery: capsulorhexis. This technique consists in breaking the anterior lens in order to approach the nucleus thereof. It presents some difficulties, mainly tears during extraction or lens emulsification, which can extend to the posterior capsule. The ongoing quest for improving this specific stage of phacoemulsification produced results in 1990 when Gimbel and Neuhann published a joint paper describing what to this date still is the biggest advantages for cataract surgery: anterior continuous circular capsulorhexis (CCC), with guidelines for successful execution.

The references below include several models for learning and practicing this technique, such as rabbit, corpse eyes and even artificial eyes. To this we must add the development of virtual and 3-D simulators that reproduce actual situations that may arise during surgery.

Even though the phacoemulsification technique is difficult to perform in animal eyes because pig or rabbit capsules are more elastic than human capsules, our experience after giving teaching 30 courses on phacoemulsification techniques have provided sufficient results and information to state that animal models are adequate and appropriate. On the same grounds, we believe that simulators must be utilized as part of the learning process of this technique before practicing on animal models.

Material and methods

Simulator description and use

The methacrylate simulator is 22 cm wide and 30 cm long, with a height between 3 cm and 5 cm. It has an inclination of 15° that provide support for the surgeon to avoid trembling and fatigue. This area is inserted in a methacrylate support to improve support for the surgeon hands and hold the simulator steady on the surgical table (Fig. 1).

The simulator for performing CCC designed in our hospital includes a section in which the student executes the technique on a sheet of aluminum or the like having similar characteristics (Fig. 1). It also includes a lower section which supports the simulator and a top part comprising a lid with 2 rulers (one below and the other above the lid) for stretching the material on which capsulorhexis will be performed. In front of the sheet on the lower simulator section there is an opening through which a PVC sheet protrudes for making slits simulating the incisions made at the beginning of
phacoemulsification and through which the student passes the cystotome and the rhexis tweezers (Fig. 2). In front of these slots and in the upper section of the simulator there are 5 fixed thumbtacks imitating the lens, all of which allow the students to carry out all the maneuvers required in CCC.

An aluminum sheet is placed between the 2 rulers, with the 5 thumbtack heads protruding from the sheet simulating the anterior capsules. This allows the student to perform a small incision with the cystotome over the thumbtack in order to subsequently execute the technique.

After a theoretical session in which the basics of capsulorhexis and its complications are explained, students begin to work on the simulator. In the first stages of training tears occur which prevent successful capsulorhexis.5 Through the slits a cystotome is introduced to make a small mark on the aluminum sheets over one of the thumbtack heads, as that made in the anterior capsule of the lens, to initiate the CCC maneuvers (Fig. 2). All these manipulations are evaluated by the experts in charge of the course who have over 20 years of practicing and teaching ophthalmology. As this is a blind study, the experts do not know the group to which the students belong.

Within a reasonable period of time and meticulous training according to schedule, the student is able to achieve sufficient ability and dexterity to execute the technique adequately and obtain good results. The training activities scheduled described in the following section conclude with practicing and perfecting the surgical technique in experimentation animals.

**Simulator feasibility. Scientific and technical parameters of the study**

Our training system for performing CCC has been tested and approved by the excellent results achieved with this technique by 65 ophthalmologists (professionals and trainees) who attended phacoemulsification courses of one and a half days in which said technique is practiced in 2 h sessions over pig eyes. A statistical study was carried out with 35 specialists who assessed the “simulator” learning method and a further 13 who learned the method directly with “animal (pig) eyes”. Said specialists were divided randomly in 2 groups: Group 1 (without simulator) began their learning practicing capsulorhexis and phacoemulsification in animal corpse eyes during the 2 sessions of the first day, while Group 2 (with simulator) comprised students who performed capsulorhexis in the simulator during the first session and on animal eyes in the second session. For these 65 specialists the number of eyes utilized in each session was counted, as well as the adequacy of the capsulorhexis.

**Statistical analysis**

For the statistical analysis the SPSS® v.10.0 for Windows (SPSS Inc., Chicago, Illinois, USA) was utilized. Data are expressed as mean ± SD. The differences between the groups were analyzed by means of ANOVA, followed by the U Mann–Whitney test for analyzing differences between the groups. The percentages were compared by means of the Z test. In both cases, the significance level required was of p < 0.05.

**Results**

**Statistical study: group 1 (without simulator)**

In this group an increase in the number of eyes was observed (from 206 in the first session to 237 in the second one) (Table 1). Each student used a mean of 6.87 ± 1.28 eyes in the first session whereas in the second this value increased to 7.90 ± 0.71. This increase was significant (p < 0.001).

The students of this group utilized 443 eyes, a mean of 14.77 ± 1.71 eyes per student in the 2 sessions.
Table 1 - Comparative table of groups 1 and 2.

<table>
<thead>
<tr>
<th></th>
<th>Group 1 (without simulator)</th>
<th>Group 2 (with simulator)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>First session</td>
<td>Second session</td>
</tr>
<tr>
<td>No. of eyes/session</td>
<td>6.87 ± 1.28</td>
<td>7.90 ± 0.71</td>
</tr>
<tr>
<td>Adeq. Rhexis/session</td>
<td>1.27 ± 0.69</td>
<td>5.00 ± 0.87</td>
</tr>
<tr>
<td>Overall No. of eyes</td>
<td>206</td>
<td>237</td>
</tr>
<tr>
<td>No. of eyes/student</td>
<td>14.77 ± 1.71</td>
<td></td>
</tr>
<tr>
<td>Overall No. of adeq. rhexis</td>
<td>98</td>
<td>150</td>
</tr>
<tr>
<td>Adeq. Rhexis (%) (Efficiency) (%)</td>
<td>47.57</td>
<td>63.29</td>
</tr>
<tr>
<td>Cost/student (€)</td>
<td>41.20 ± 7.67</td>
<td>47.4 ± 4.27</td>
</tr>
</tbody>
</table>

The number of capsulorhexis considered to be adequate also increased significantly from 3.27 ± 0.69 to 5.00 ± 0.87 (p < 0.0001). These results evidenced a significant increase in the number of eyes utilized by students between the first and second session and of the number of adequate CCC. Taking into account the number of adequate CCC with the sum of utilized eyes (Table 1), in the first session of this group 47.57% of CCC were adequate whereas in the second session this percentage increased significantly up to 62.29% (p < 0.0001).

Statistical study: group II (with simulator).

In the first session, this group practiced capsulorhexis with some previous notions on the simulator, without utilizing animal eyes. In the second session 243 eyes were utilized, with the mean number of eyes for students being of 6.94 ± 1.35. This matches the total number utilized by each student in both sessions. In what concerns the number of adequate rhexis in the second session, a value of 5.71 ± 1.13 was achieved (Table 1).

Considering the overall number of correct rhexis, it is observed that this group exhibited 82.30% of adequate rhexis (Table 1).

Comparative statistical study on the execution of continuous circular capsulorhexis applying different methods (group without simulator and group with simulator)

Significant differences were observed between the 2 groups in the parameters of the study.

For the comparative study the first step was to study the first session of group 1 and the second session of group 2. This comparison was made to verify whether practicing with the simulator produces a substantial improvement in the studied parameters when compared to a group of students that were not initiated in the practice of capsulorhexis. On the other hand, the results obtained in the second session are also analyzed after performing capsulorhexis directly in pig eyes (group 1) or after learning in the simulator (group 2). This comparison is made to verify which of the 2 learning methods is more effective, on the capsulorhexis simulator or directly on pig eyes.

Session 1-Group I/Session 2-Group II

In what concerns the number of utilized eyes, the group 1 utilized a mean of 6.87 ± 1.28 eyes and the group of it utilized a mean of 6.94 ± 1.35 eyes. No statistical difference was found (p = .855).

On the contrary, in what concerns the number of executed capsulorhexis which were assessed as adequate, the first group obtained 3.27 ± 0.13 and the second one 5.71 ± 1.13. A significant increase was observed (p < 0.0001) (Table 1). In addition, as outlined above, the percentage of adequate CCC in the first group was of 47.57% while in the second group said percentage increased significantly to 82.30% (p < 0.0001) (Table 1).

Session 2-Group 1/Session 2-Group 2

In what concerns the number of eyes utilized, the number diminished from 7.90 ± 0.71 eyes utilized by the first group to 6.94 ± 1.35 utilized by the second group. This difference was significant (p < 0.001) (Table 1).

As regards the number of capsulorhexis assessed as adequate, the first group achieved 5.00 ± 0.87 and the second 5.71 ± 1.13, a significant difference (p = 0.013) (Table 1). In addition and as described above, the percentage of adequate CCC in the first group was of 63.29% while in the second group it increased significantly to 82.30% (p < 0.0001) (Table 1).

Overall, the number of eyes utilized by each group 1 surgeon was 14.77 against 6.94 eyes utilized by the members of the group of students who previously trained with the simulator.

Technical results: costs and efficiency

In training activities the ethical implications of utilizing experimentation animals for learning phacoemulsification must be considered, together with the expense involved in what concerns anesthesia and qualified personnel for maintaining anesthesia. This study has only considered the costs involved in training specialists taking into account the number of dead animal eyes utilized without considering other expenses.

According to the following formula:

Mean expense per specialist (MES) = (eye price x number of eyes) (expressed in €)

The following differences were found in the expense per student and 1.5 days of training between both groups according to the number of eyes that were utilized.

As can be seen in Table 1, in the first session the group without simulator incurred a mean expense of 41.20 ± 7.67€ against 47.40 ± 4.27€ of the second session. This increase was significant (p < 0.001).
As regards the cost, calculated on the basis of the above formula, in the second session the cost of group 1 was of \(47.4 \pm 4.27\)€ against \(41.65 \pm 8.09\)€ of the group trained with the simulator. This difference was significant (\(p < 0.001\)).

Taking into account that during the first session the second group did not utilize eyes for training, the above results involved a reduction of costs of almost 6% (5.75%) against the costs of the first group.

Comparing the overall cost between both groups, the group without simulator exhibited a cost of \(88.6 \pm 10.29\)€, whereas the group that had previously used the simulator the cost was \(41.66 \pm 8.09\)€. This difference was significant (\(p < 0.0001\)).

**Discussion**

One of the stages that the referenced studies consider to be very difficult in cataract surgery is continuous circular capsulotomy,\(^3\)\(^4\) without evidence of tears or anomalies. In this regard, this technique can be considered as key in the learning curve of phacoemulsification because significant and potentially severe complications could arise in its execution. The surgeon must acquire sufficient dexterity and precision to execute the technique adequately. For this reason obtaining experience directly with patients is not adequate.

Despite being a simple and easy model, the use of cadaver eyes for learning the capsulorhexis technique\(^6\)–\(^9\) involves added costs, mainly when human corpses are used. In any case, the potential, preparation and maintenance of cadavers increases the price of training for ophthalmology students and specialists.

On the other hand, the use of virtual simulators for training, with the support of 3-D Images\(^15\)–\(^14\) is a significant development in learning because, in addition to training in the CCC technique, simulators are able to produce complications in the technique, thus enhancing the extrapolation of training in live surgery. However, the drawback of this type of simulators is high cost in computer equipment and the increased cost of implementing it in training activities for students.

On the basis of the results obtained in group 2 (with simulator), a favorable evolution has been observed in learning and executing CCC using less eyes than the group without simulator in the same session. This suggests that the use of the simulator during the first session enhanced dexterity and diminished the number of cadaver eyes utilized in the second session. Therefore, it would be necessary to use less eyes of live animals, which is the pursued objective for training specialists according to the ethical principles of our Microsurgery Units. On the other hand, it has been observed that even when the number of cadaver eyes consumed by the second group is lower, simulator training translates in improved execution of capsulorhexis because higher efficiency is achieved (82.30 against 47.57 and 63.29%) in the execution of adequate capsulorhexis. This demonstrates the usefulness and significance of a simulator for a crucial procedure as CCC.

Accordingly and on the basis of the results obtained in this study, the authors consider that the development of said simulator for practicing capsulorhexis is a novelty because to date such simple, cheap and reusable simulators have not been described. The advantage provided by this simulator in what concerns the number of cadaver eyes makes it an indispensable tool for training surgeons in the execution of CCC, or as practice for ophthalmology students. On the other hand, said simulator is easy to carry and therefore students can use it in their workplace as well as in the training center.

In accordance with the new tendencies in surgical technique training, this simulator can be considered as the step prior to the use of cadavers and experimentation animals, diminishing their number and accordingly reducing training costs. Comparing the overall cost of both groups, a significant difference is obtained in the reduction of the costs of the group that practiced with the capsulorhexis simulator.

The simulator of this article has recently been granted a patent by the Patent Office of Spain under number P200601475, which confirms the usefulness and originality of said device.

**Conflict of interests**

No conflict of interests has been declared by the authors.

**References**

