

Developing Informed Consent Tool for the Cataract Operation

Oh Gi-Dong*, Okazaki Akira**, Hattori Junko***

*Tokyo Kasei Gakuin University, gidong270@mac.com

**Takushoku University, zak@kansei-design.com

***Aichi Prefectural University, hattori@nrs.aichi-pu.ac.jp

Abstract: The risk of cataract is very high for the elderly. It is said that most people over 80 years old have some symptoms connected with cataract.

We tried to find out what is necessary to promote patients' understanding for the operation of cataract so that we will develop the informed consent tool exclusively for the operation of cataract.

We received content information from Kugayama Hospital concerning the cause of cataract, its therapy, method of the operation, and care after the operation.

We found out that we should solve these three points in order to make new tools: 1. How we tell patients through Videos that the operation is painless. 2. How we offer convincing information. 3. How we relieve patients' unpleasant feeling.

Key words: *Informed Consent, Kansei, Cataract Operation, Unpleasant feeling, Fear and Anxiety*

1. Foreword

In medical treatment scene, preparations for treatment given to children and informed consents for adults are very different. In the preparation we help children be ready for the treatment, while in the informed consent we help patients' understanding. Because of this difference, explanatory tools for the preparation and for the informed consent are also very different.

We have developed several tools for the preparation for children, and have proposed ways of relieving their fear and anxiety. Then we have tried to discuss what is necessary to help adult patients understand their treatment and to develop informed consent tools.

We chose the tool for the cataract because the risk of getting cataract is very high for the elderly people. It is said that most people over eighty years old show some symptom related to cataract, so its necessity will be very high.

2. Object of Our Study

We tried to find out what is necessary to promote patients' understanding for the operation of cataract so that we will develop the informed consent tool exclusively for the operation of cataract.

This study is part of "Research about Developing Informed Consent Tool for Relieving Fear against Cataract Operation".

Supported by Grant-in-Aid for Exploratory Research 2012-2013

3. Making Prototypes

We made movies of real operation scenes. Then we made two prototype tools for explaining the treatment based on these movies. Out of the two prototype tools, one used the Video of the operation and the other used CG.

3-1. Process of Operation of Cataract

The operation of cataract mainly follows this process nowadays.

- 1) Wash around the eye cleanly and put clean cloth on the eye.
- 2) Anesthetize the eye.
- 3) Cut around the iris of the eye for about 3 millimeters.
- 4) Insert a tool through the cut and gouge out the shell of crystalline lens.
- 5) Insert a thin pipe through the cut.

Break the inside of crystalline lens and suck up the broken pieces through the pipe.

- 6) Insert the artificial lens.
- 7) Sew up the cut.
- 8) Apply the eye bandage.

3-2. The Video of the Operation

In cooperation with Kugayama Hospital, we took video of operations from three viewpoints, one being the doctors' (microscope picture), and the other two being observers' (Video taken by two cameras) (Figure. 1).



Figure.1 Taking Films of the Operations of Cataract

We made movies of four operations, and chose the third operation considering the length of time and camera angle.

The operation took 23 minutes and 43 seconds. Out of the three viewpoints we selected scenes, which were easily understandable and arranged them.

Then we made 6 minute long explanatory movie using the arranged scenes.



Figure.2 Making movies of operations

3-3. Explanatory Tool using Adobe Flash

We made the explanatory tool (for cataract) using Adobe Flash. The contents are “What is cataract?”, “The treatment of cataract”, “Time needed for the operation”, ”Preparation for the operation”, “The process of operation”, “The care after the operation”.

The explanatory movie can be seen by two ways. One is just to start the tool, and it runs automatically. It takes 1 minute 10 seconds and deals with the process of the operation. The other is to use interactive operation system.

If we click the menu we can see the tool as many times as we like (Figure. 3).



Figure. 3 The Explanatory Tool for Cataract using interactive operation system

4. Verification Experiment

We showed the 6 minute long explanatory movie and part of the explanatory tool dealing with the process of the operation to four subjects and measured their reaction using multi-sensor Operational Bioinstrumentation System NeXus 4 (NAC Image Technology Inc.).

The sensors we used were BVP/HR (Blood Volume Pulse/ Heart Rate Variability) and SC/GSR (Skin Conductance/Galvanic Skin Response).

First we measured BVP/HR and SC/GSR of the subjects in their relaxed condition for 1 minute.

Then we measured their BVP/HR and SC/GSR showing the operation movie and explanatory tool. Then we interviewed them.

The BVP/HR and SC/GSR are as follows.

The wave of BVP is in proportion to the amount of blood flow. The amplitude of BVP increases as the amount of blood flow increases. (Vasodilatation)

When the amplitude decreases the amount of blood flow decreases (Hemadostenosis).

The distance between each peak shows HR, or heart beat rate (Figure. 4).

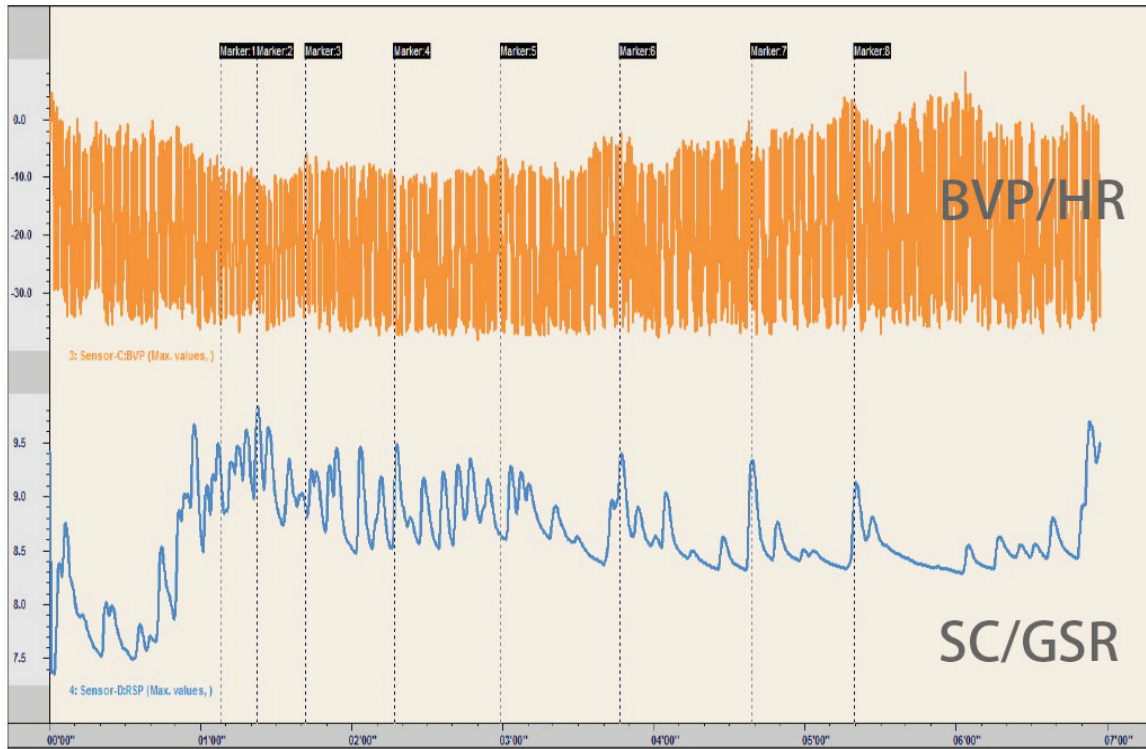


Figure. 4 The Analytical data of BVP/HR and SC/GSR

SC/GSR: (psychogenic sweating) means that our hands sweat when we feel tense. Psychogenic sweating reflects the levels of tension of sympathetic nervous system and the levels of arousal. Skin conductance sensor measures the increase of conductance (reciprocal number of resistance) due to sweating.

5. Results and Comment

We analyzed the data we got using Bio Trace+ Software for Nexus-4. We converted the raw data from SC/GSR.

The column 1 in Fig5 shows the measured data in the relaxed condition. The wave of SC/GSR shows composure of subjects. Column 2 is the part measured during the time the subjects are shown the explanatory tool. We marked points where big changes could be seen and synchronize with the explanatory tool.

Column 3 is the part measured during the time the subjects are shown the explanatory movie. We marked points where big changes could be seen and synchronize with the explanatory movie.



Figure. 5 Measured data of experiment

We marked points where big changes could be seen and synchronize with the explanatory movie. As the result, we found that the subjects displayed strong reactions to the numbers 1, 5, 4, 2, 6 in the process of the cataract operation. The order of these figures shows not only the order in the operation process but also the order of the degree of their reactions. Number 1 is the highest, and number 6 is the lowest.

The strongest reaction to the number 1 in the process seems to show subjects' tension just before the operation starts.

Also it may be because we feel bigger fear when something is put on or applied to the eye than to the hands or legs. Numbers 2, 4, 5, 6 are direct treatments to the eye, that is, to pierce, break and insert (Fig6).

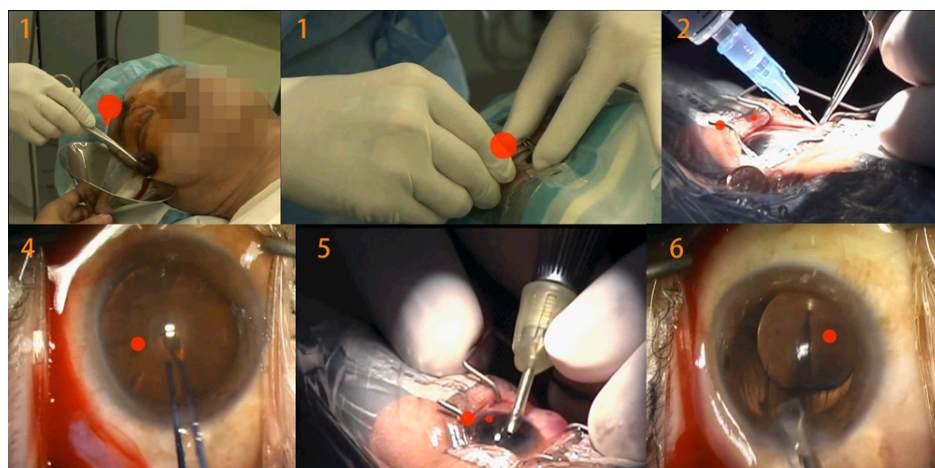


Figure. 6 Scenes in the explanatory movie to which many subjects displayed reactions

In the explanatory movie degree of reactions to scenes changed greatly, while in the explanatory tool change of degree of reactions was not so great as in the explanatory movie.

In the explanatory movie the subjects displayed big reactions to the deed of treatment, while in the explanatory tool many of them displayed reactions to the picture of the section of the eye rather than to the deeds of treatment.

We also found that the wave of SC/GSR goes down gradually. This seems to show the increase of the level of understanding of the subjects. This is more clearly seen in the reactions to the explanatory tool (Fig 7).



Figure. 7 The analytical data using Bio Trace+ Software for Nexus-4

After the experiment we asked the subjects questions about the explanatory movie and the explanatory tool. Out of the four subjects, one had the experience of cataract, one had the experience of the operation to the eye (Lasik Operation), one was interested in the operation to the eye (Lasik Operation) One was the person whose family had experienced the operation of cataract.

The subject who had experienced the cataract operation answered, “I didn’t feel shocked so much to see the explanatory movie because I have the experience of the operation,” “To see the movie it seems we feel pain when some operation tool is put into the eye, but in fact we don’t feel pain because we are applied anesthetic many times during the operation,” “In the explanatory tool details are not shown, so we don’t feel scared.” To see the movie the operation seems to be painful, but according to doctors and patients it is not painful actually. From this we got the suggestion that in order to relieve patients’ fear we need means to tell them understandably that they will not feel pain.

The subject whose family had the experience of cataract operation and the subject who had had the eye operation (Lasik Operation) answered, “We didn’t feel scared because we have the experience or

previous knowledge (information from the family).” From this we got the suggestion that in order to relieve patients’ fear it is important how we give correct information in advance.

The subject who is thinking of taking the eye operation answered, “At first I was scared to see the operation movie, but not so scared as I shut my eyes,” “I was scared, but could see the movie more calmly than I had expected,” “Eye operation is scary, so actuality film, which is more realistic, is more convincing than the explanatory tool, which is less realistic. The explanatory tool will not relieve fear against the operation,” “I’m thinking of eye operation so I want more concrete information,” “The eye in the film looks big and slippery, and its movement and changing form is unpleasant.”

From these answers we found out that we should solve these three points in order to make new tools:

- 1) How we tell patients through Videos that the operation is painless
- 2) How we offer convincing information
- 3) How we relieve patients’ unpleasant feeling.

6. Future Prospect of Our Study

We should put stress on realistic impression in making informed consent tools for adults. We have already explained necessary elements for more realistic impression, so we are going to use these elements and make new tools and do experiments.

7. References

- [1] “Preparation for operation for Hospitalized Children” (O Creation, 2006), which got Good Design Special Award from the Director General of Small and Medium Enterprises Agency in 2007.
- [2] “Interface Design for Assisting Explanation to the Parents of Invalid Children before Kidney Biopsy” International Service Innovation Design Conference, 389-399, 2008
- [3] “Development of a preparation tool for CV catheter with a grade indicator of perceived pain” 2010 KOSES & JSKE Cooperative Symposium, Emotion Research in Practice, 198-199, 2010
- [4] “A Research about Developing Informed Consent Tool for Relieving Fear for Cataract Operation” ISAE2013, CD-ROM
- [5] “The Research Related to KAN- SEI Stimulation Elements in Cyber – Space” 2001 Spring Conference of Emotion and Human Sensibility, KSES (Korean Society for Emotion & Sensibility), CD-ROM, May 2001