MEASUREMENT OF VISION FUNCTION AND QUALITY OF LIFE IN THE PATIENTS UNDER PHACOEMULSIFICATION WITH THE INTRAOCULAR LENSES OF DIFFERENT PRICES

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A Thesis Submitted in Partial fulfillment of the Requirements

for the Degree of Master of Science in Health Economics

Department of Economics

Faculty of Economics

Chulalongkorn University

Academic Year 2001

ISBN 974-17-0819-6

การวัดการทำหน้าที่ของสายตาและคุณภาพชีวิตของผู้ป่วยที่เข้ารับการผ่าตัดต้อกระจกแบบ Phacoemulsification โดยใช้เลนส์ตาเทียมที่มีราคาต่างกัน

นายสมเกียรติ ศรไพศาล

วิทยานิพนธ์ฉบับนี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตร
ปริญญาวิทยาศาสตรมหาบัณฑิตสาขาวิชาเศรษฐศาสตร์สาธารณสุข
คณะเศรษฐศาสตร์
จุฬาลงกรณ์มหาวิทยาลัย
ปีการศึกษา 2544

ISBN 974-17-0819-6

Thesis Title : Measurement of Vision Function and Quality of Life in the Patients under Phacomulsification with the Intraocular Lenses of Different Prices

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438 59077 29 MAJOR HEALTH ECONOMICS
KEY WORD: VISION FUNCTION / QUALITY OF LIFE / CATARACT SURGERY / INTRAOCULAR LENS

SOMKIAT SORNPAISARN: MEASUREMENT OF VISION FUNCTION AND QUALITY OF LIFE IN THE PATIENTS UNDER PHACOEMULSIFICATION WITH THE INTRAOCULAR LENSES OF DIFFERENT PRICES. THESIS ADVISOR: ASSOC. PROF. SIRIPEN SUPAKANKUNTI,Ph.D. THESIS CO-ADVISOR: VIROJ TANGCHAROENSATHIEN, M.D., Ph.D. 117 pp. ISBN 974-17-0819-6

This study was the starting point of the study of the effectiveness in the Phacoemulsification treatment with the intraocular lenses (IOLs) of different prices: IOLs Brand A cost THB 2,000 (USD 44.97) /Lens, IOLs Brand B cost THB 600 (USD 13.49)/Lens and IOLs Brand C cost THB 900 (USD 20.45)/Lens. These were the prices in the year 2001. By the way, all of them basically had the same characteristics : 6 ─ millimeter diameter, modified C-loop with 1 piece of haptic under the same treatment method which was the mentioned Phacoemulsification. This particular method was one of the most preferable among the opthalmologists for the cataract surgery because of the low rate complication. It was implemented at Lampang Hospital,Ministry of Public Health, Thailand.

The objective of the study was to compare the vision function (VF) and the quality of life (QOL), first developed by Fletcher et al, with the scores gained after the surgery by using the 3 brands of polymethyl methacrylate (PMMA) IOLs as well as the risk factors of the complication from the surgery.

This study was a cohort study based on the primary data. The cataract patients who were registered for the surgery were selected by the established criteria. Phacoemulsification with intraocular lens implantation was performed by post-graduate opthalmologists who had at least 5 years' experience in the cataract surgery. And those particular selected subjects would be interviewed with the vision function (VF) and quality of life (QOL) questionnaires. In addition to VF and QOL, the other 3 measurements in the thesis were standard gamble (SG), visual analogue scale (VAS) and time trade off (TTO)] .

The analysis consisted of 2 stages. The first stage was the validity test of the tools by partial correlation and regression analysis. From this first stage, it was found that the best tool was QOL. The middle ranks were VF and VAS, and the worst was TTO. The second stage was the means comparing of the scores gained from "before" to "2 weeks after surgery" of vision function and quality of life among the 3 brands of PMMA IOLs by using t-test

As for comparing means, the result showed that the VF scores gained from "before" to "2 weeks after surgery" of IOLs Brand A was significantly more than the ones of IOLs Brand B, and the significance (2-tailed) was .002. And the VF scores gained of IOLs Brand A was significantly more than the ones of IOLs Brand C, and the significance (2- tailed) was .089. This meant that IOLs Brand A had the highest mean of VF scores gained more than IOLs Brand B and IOLs Brand C.

This study could be concluded that the intraocular lenses of different brand names or different prices had unequal outcome. Accordingly a further study would be needed to seek a cost-effectiveness analysis of cataract surgery to provide the efficiency aspect for decision making.

Department……Economiccs……Student's signature……...

Field of study…….Health Economics……..Advisor's signature……..

Academic year……2001……...Co-advisor's signature…….

สมเกียรติ ศรไพศาล : การวัดการทำหน้าที่ของสายตาและคุณภาพชีวิตของผู้ป่วยที่เข้ารับการผ่าตัดต้อกระจกแบบเฟโกอิมัลซิฟิเคชั่นโดยใช้เลนส์ตาเทียมที่มีราคาต่างกัน(MEASUREMENT OF VISION FUNCTION AND QUALITY OF LIFE IN THE PATIENTS UNDER PHACOEMULSIFICATION WITH THE INTRAOCULAR LENS OF DIFFERENT PRICES) อ.ที่ปรึกษา : รศ. ดร. ศิริเพ็ญ ศุภกาญจนกันติ, อ.ที่ปรึกษาร่วม : น.พ.วิโรจน์ ตั้งเจริญเสถียร 117 หน้า ISBN 974-17-0819-6

วิทยานิพนธ์ฉบับนี้เป็นจุดเริ่มต้นของการศึกษาประสิทธิผลของการรักษาโรคต้อกระจก ด้วยวิธีผ่าตัดแบบ Phacoemulsification ซึ่งใช้เลนส์ตาเทียมที่มีราคาต่างกัน โดยให้ลักษณะพื้นฐานที่เหมือนกันคือ ขนาดเส้นผ่าศูนย์กลาง 6 มิลลิเมตร ตัวและขาของเลนส์ตาเทียมเชื่อมต่อเป็นชิ้นเดียวกัน โดยขาของเลนส์แก้วตาเทียมเป็นรูปตัว C ประกอบด้วยเลนส์ตาเทียมชนิด A ซึ่งมีราคา 2,000 บาทต่อเลนส์ เลนส์ตาเทียมชนิด B ซึ่งมีราคา 600 บาท ต่อเลนส์ และเลนส์ตาเทียมชนิด C ซึ่งมีราคา 900 บาท ต่อเลนส์ ราคาของเลนส์ตาเทียมเป็นราคาที่ตั้งไว้ในปี 2001 โดยนำมาใช้ในวิธีการรักษาแบบเดียวกัน ซึ่งก็คือวิธีผ่าตัดต้อกระจกแบบ Phacoemulsification ดังกล่าวซึ่งเป็นวิธีที่นิยมใช้ในกลุ่มจักษุแพทย์ เนื่องด้วยมีภาวะแทรกซ้อนต่ำ การผ่าตัดดังกล่าวนี้กระทำที่โรงพยาบาลประจำจังหวัดลำปาง

การศึกษาครั้งนี้มีวัตถุประสงค์เพื่อเปรียบเทียบการทำหน้าที่ของสายตา (Vision function / VF) และคุณภาพชีวิต (Quality of life / QOL) ก่อนและหลังการผ่าตัดโดยใช้เลนส์ตาเทียมที่มีราคาและเครื่องหมายการค้าต่างกันรวม 3 ชนิด สำหรับ VF และ QOL นี้ได้รับการพัฒนาเป็นครั้งแรกโดย Fletcher และคณะ นอกจากนี้ยังมีวัตถุประสงค์เพื่อศึกษาอัตราเสี่ยงในเรื่องภาวะแทรกซ้อนจากการผ่าตัดด้วย

การศึกษานี้เป็นแบบการศึกษาไปข้างหน้าโดยอาศัยพื้นฐานข้อมูลปฐมภูมิ ผู้ป่วยต้อกระจกที่ลงทะเบียนเข้ารับการผ่าตัด จะได้รับการคัดเลือกโดยใช้เกณฑ์ตามที่ได้ตั้งไว้แล้ว และผู้ป่วยจะได้รับการผ่าตัดโดยจักษุแพทย์ผู้มีประสบการณ์ในการผ่าตัดอย่างน้อย 5 ปี โดยผู้ป่วยจะได้รับการสัมภาษณ์โดยใช้แบบสอบถามการทำหน้าที่ของสายตา (VF) และคุณภาพชีวิต (QOL) นอกเหนือจาก VF และ QOL แล้วยังมีการสัมภาษณ์ผู้ป่วยอีก 3 วิธี คือวิธี Standard gamble (SG), วิธี Visual analogue scale (VAS) และวิธี Time trade off (TTO)

การวิเคราะห์ประกอบด้วย 2 ขั้นตอน กล่าวคือขั้นตอนที่ 1 ได้แก่ การทดสอบความเที่ยงตรงของเครื่องมือแต่ละชนิดโดยการวิเคราะห์สัมประสิทธิ์สหสัมพันธ์เชิงส่วนและสมการถดถอย จากขั้นตอนที่1 นี้พบว่าเครื่องมือที่ดีที่สุดคือ QOL เครื่องมือระดับปานกลางคือ VF และ VAS และเครื่องมือที่มีประสิทธิภาพน้อยที่สุดคือ TTO และขั้นตอนที่ 2 คือการเปรียบเทียบความแตกต่างของค่าเฉลี่ยของคะแนนของการทำหน้าที่ของสายตา (VF) และคุณภาพชีวิต (QOL) “ก่อนการผ่าตัด” จนถึง “หลังการผ่าตัด 2 สัปดาห์” โดยเปรียบเทียบเลนส์ตาเทียมทั้ง 3 ชนิด ซึ่งใช้วิธี t-test

จากการเปรียบเทียบความแตกต่างของค่าเฉลี่ย ปรากฏผลว่าคะแนนการทำหน้าที่ของสายตา (VF) “ก่อนการผ่าตัด” จนถึง “หลังการผ่าตัด 2 สัปดาห์” ของเลนส์ตาเทียมชนิด A มีมากกว่าคะแนนของเลนส์ตาเทียมชนิด B อย่างมีนัยสำคัญทางสถิติที่ระดับ 99% และคะแนนของเลนส์ตาเทียมชนิด A ยังมีคะแนนมากกว่าเลนส์ตาเทียมชนิด C อย่างมีนัยสำคัญทางสถิติที่ระดับ 90% คะแนน ซึ่งสรุปได้ว่าเลนส์ตาเทียมชนิด A มีค่าเฉลี่ยของคะแนน VF สูงสุดเมื่อเทียบกับเลนส์ตาเทียมชนิด B และเลนส์ตาเทียมชนิด C

จากการศึกษาครั้งนี้สรุปได้ว่าเลนส์ตาเทียมต่างชนิดหรือต่างราคากันให้ผลลัพธ์การทำหน้าที่ของสายตาต่างกัน ดังนั้นในลำดับต่อไปสมควรที่จะมีการศึกษาวิเคราะห์เรื่องประสิทธิภาพของการใช้เลนส์ตาเทียม เช่น ศึกษาวิเคราะห์ในเรื่องของต้นทุน-ประสิทธิผลเพื่อเป็นข้อมูลประกอบการตัดสินใจของแพทย์ในการเลือกใช้เลนส์ตาเทียม อันเป็นข้อมูลในระดับนโยบายของประเทศต่อไป

ภาควิชา เศรษฐศาสตร์	ลายมือชื่อนิสิต…….
สาขาวิชา เศรษฐศาสตร์สาธารณสุข	ลายมือชื่ออาจารย์ที่ปรึกษา…….
ปีการศึกษา2544	ลายมือชื่ออาจารย์ที่ปรึกษาร่วม……..……..

Acknowledgements

As for this full-of-attention thesis of mine, I am greatly indebted to my thesis advisor, **Associate Professor Siripen Supakankunti** and to my thesis co-advisor, **Dr. Viroj Tangcharoensathien** for their expert advice, their encouragement to me and the guidance at every step of my thesis from the beginning to the end with all their capability, realizing that this thesis might be beneficial to the country development in terms of health economics.

I am also extremely grateful to the thesis committee members: **Assistant Professor Paitoon Kraipornsak**, **Associate Professor Wattana S. Janjaroen, Assistant Professor Somchai Suksiriserekul** and all lecturers in the Health Economics Program, from whom I have learnt various kinds of such knowledge as a research job, disciplines and ways of thinking, etc. which can be applied in my career and in my daily life.

I also would like to express my sincere thanks to **Dr. Suchint Wongchoosie, Director of Lampang Hospital** and her staff for their kind welcoming of my visits, providing me with useful information and collecting data by questionnaire for this study, and especially the opthalmologists at Lampang Hospital who performed the cataract surgery in the subjected patients.

I am also grateful to **the staff of Pranangklao Hospital** (in Nonthaburi Province) and **Nan hospital** (in Nan Province) for their cooperation in doing and compiling some questionnaire pre-tests.

And I would like to thank to **all my friends and the staff of the Health Economics Program** for their help and cooperation during my studying there.

Moreover, I would really like to give special thanks to **Dr. watanee T. Jenchitr, Director of Thai Eye Institute** and her staff who gave me the knowledge of cataract, which is the core part of this thesis, from the beginning to the end, and to the **Thai Eye Institute** and especially **Dr. Pichat Pojanasomboon** who supported the operating cost of this study. And I herein thank to those who are parts of my accomplishment whose names I cannot all mention.

Last but not least, I would like to thank wholeheartedly to my parents who always give mental support in every step of my life; to my wife: Mrs. Panchathip Sornpaisarn who have also helped me to edit my English in the thesis; and to my son who always shows understanding that his father was creating the hard task and had less time for him during the past year.

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Abbreviation

VARIABLE	MEANING
Decimal	Dividing the numerator of the Snellen fraction by the denominator
EDU	Education
FAMINC	Family in come per year
IOL	Intra ocular lens
LogMAR	The logarithm of the reciprocal of the decimal visual acuity
PMMA	Poly methyl methacrylate
QOL	Quality of life (questionnaire developed by Aravind Eye Hospital staff, India)
QOL_1	QOL score before surgery
QOL_3	QOL score of 2 weeks after surgery
QOL_{13}	Gain of QOL score from before to 2 weeks after surgery
SES	Socio-economic status
SG	Standard gamble
Time loss	Time of visual loss
TTO	Time trade off
TTO_1	TTO score before surgery
TTO_3	TTO score of 2 weeks after surgery
TTO_{13}	Gain of TTO score from before to 2 weeks after surgery
VA	Ranking of visual acuity from 1-14, while 20/20 is 14
VAS	Visual analog scale
VAS_1	VAS score before surgery
VAS_3	VAS score of 2 weeks after surgery
VAS_{13}	Gain of VAS score from before to 2 weeks after surgery
VF	Vision function (questionnaire developed by Aravind Eye Hospital staff, India)
VF_1	VF score before surgery
VF_3	VF score of 2 weeks after surgery
VF_{13}	Gain of VF score from before to 2 weeks after surgery

CHAPTER 1

INTRODUCTION

1.1 BACKGROUND AND RATIONALE

Blindness and visual impairment are the major problems in developing countries. In 1978 the World Health Organization found that there were 28 million blinds. Among this amount, 14-17 million were blind from cataract. In Thailand, the epidemiological survey of eye diseases by the Ministry of Public Health in 1987 found that the prevalence of the blind who had visual acuity lower than 20/400 were 0.6% of Thai population. The most common cause of blindness was cataract which was equal to 74% of total blindness. Therefore, there were 230,880 people (from total 52 million Thai population) who were blind from cataract in Thailand. (Srisupan et al, 1993)

In Thailand during the age of 52-85, the prevalence of senile cataract was 15% (Samsen,1999). It is accordingly clear that senile cataract is a very important health problem, in terms of impact on both the affected individual and society overall.

Senile cataract is not a preventable disease but treatable by the surgery with intraocular lens (IOL) implantation. There are many kinds of surgery and many kinds of lens used. The Phacoemulsification is one of the most preferable method for opthalmologists to use in cataract surgery because of its low complication.

Among many types of IOLs, Polymethyl metacrylate IOLs (PMMA IOLs) are the most widely used.

There are 3 brands ,of PMMA IOLs, which are in popular use :

Brand 1 : **IOLsA**, from USA., THB 2,000(USD 44.97) / lens (Price in the year 2001)

Brand 2 : **IOLsB** from Nepal, THB 600(USD13.49) / lens (Price in the year 2001)

Brand 3 : **IOLsC** from USA., THB 900(USD20.24) / lens (Price in the year 2001)

In health service, the efficiency of resource allocation and the equity need to be taken into account. The cost-effectiveness analysis is a kind of instrument to help the administrators in decision making for the most efficiency and equity. For this reason, it is accordingly interesting to find out the comparison between the Phacoemulsification with IOLs implantation using the PMMA IOLs brand 1 (IOLsA) , brand 2 (IOLsB) and brand 3 (IOLsC) which have the same characteristics : 6 millimeter diameter, modified C-loop, one piece of haptic. The objective is to prove which one provides more quality of life and/or vision function scores gained. Moreover, the risk factor of complication from each lens type will be concerned.

1.2 Research question

To find out which of the 3 brands of PMMA IOLs provides more vision function (VF) and/or quality of life (QOL) scores gained in the Phacomulsification.

1.3 Research objective

1. ***The general objective*** is to compare VF and QOL scores gained between the Phacoemulsification with the intraocular lens implantation using the PMMA IOLs group 1,2 and 3. And to find out the risk factor of complication from the surgery.
2. ***The specific objectives are :***

1) To compare VF gained between the Phaecomulsification with the intraocular lens implantation using the PMMA IOLs group 1,2 and 3
2) To compare QOL gained between the Phaecomulsification with the intraocular lens implantation using the PMMA IOLs group 1,2 and 3
3) To find out the relative risk from the 3 lens types ; intraoperative and postoperative complication within 2 weeks (Using prospective study)

1.4 Scope of Study

This study is to measure VF and QOL gained in 150 senile cataract patients at Lampang Hospital (free of charge) with the same surgical technique : the Phaecomulsification which is common and preferable to the opthalmologists and has low rate of complication, by using the 3 lens types :

The PMMA IOLs Group 1 are used in the 1st patient group

The PMMA IOLs Group 2 are used in the 2nd patient group

The PMMA IOLs Group 3 are used in the 3rd patient group

1.5 Possible benefits

This study is to find out the quality of life and vision function of all the 3 patient groups above. It may accordingly provide some policy implication for decision making in choosing which lens types between the 3 groups to be used , for the effectiveness, in the cataract patients in Thailand. This is hoped to be beneficial, in terms of budget, not only to the patients themselves but also to the hospital and eventually to the country's economy.

CHAPTER 2

LITERA TURE REVIEW

In this chapter, literature review is organized and divided into 22 parts as follow :

2.1 Concept, Definition and Classification of Cataract

2.2 Cataract Surgery

2.3 Intraocular Lens

2.4 The Visual Acuity

2.5 New visual Acuity Charts for Clinical Research

2.6 Converting Snellen Visual Acuity to Decimal Visual Acuity for Statistical Analysis

2.7 Cost-Effectiveness and Decision Analysis of Cataract Surgery

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2.9 Cost-Utility Analysis

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2.12 Cost-Utility Analysis and Economic Welbeing

2.13 Measuring Preferences and Multi-Attributes Status Classification System

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2.15 Choosing of Scaling Methods

2.16 Methodology for Measuring Health-State Preferences : Population and Context Effects

2.17 Measurements of Vision Function and Quality of Life in Patients with Cataract surgery in Southern India

2.18 Visual Functioning and Quality of Life Outcomes among Cataract Operated and Unoperated Bind Population in Nepal

2.1 Concept, Definition and Classification (petawanich, 1985)

Lenses are organs in the orbital cavity which exists behind the corneas. Normally, they are transparent. So they enable humans to have good visual acuity. While the lenses are opaque, which we call "cataract", the visual acuity (VA) is decrease.

Cataract can be classified into 3 groups :

1. *Congenital Cataract :* This type of cataract partly derives from genetic cause or congenital rubella infection from mothers who get rubella infection during pregnant within the first 3 months.
2. *Senile Cataract :* It is degenerative change of the lens, found in adults over 45 years old

   Classification by lens opacity into 4 stages :

   1) Incipient cataract
   2) Immature cataract
   3) Mature cataract
   4) Hyper-mature cataract
3. *Secondary Cataract :*

   Classification by causes divided into 4 groups :

   1) Traumatic cataract

2) Complicated cataract : This type derives form diseases in the orbit such as chronic panuveitis, glaucoma, retinitis pigmentosa, retinal detachment and high myopia.
3) Disease-associated cataract such as diabetic cataract
4) Irradiation cataract

2.2 Cataract Surgery

Presently there are 3 most common operations *(Buranapong, 1999) :*

1) ***Intracapsular Cataract Extraction (ICCE)*** which is a surgery that extract all of cataract and lens capsule.
2) ***Extracapsular Cataract Extraction (ECCE)*** which is surgery that extract part of anterior capsule, nucleus and cortex except the posterior capsule and zonular fiber.
3) ***Phacoemulsification*** that is surgery in which the ultrasound is used to emulsify lens material, then vacuums them out and the posterior lens capsule is left.

2.3 Intraocular lenses

Cataract surgery with IOL implant, first operated on 29 November 1940 by Harold Ridley for Moorstield and St. Thomas Hospital in London, England. In U.S.A., IOL implantation first operated in 1960-1970 by ophthalmologist in Miami, in Thailand first operated in 1980.

Intraocualr lens materials.

1. Polymethylmethacrylate (PMMA) is a form of plastic, softened and enable to be formed any model while heated. When let it cool, it will be solidity and not change.

2. Other material

2.1 Glass provide higher refractive index than PMMA but it will crack by Neodymium Yag laser that used in treatment of posterior capsular opacitication.So it is not preferred by optermologist. (No used Now)

2.2 Silicone provide lower refractive index than PMMA. The advantage of silicone lens is its compressibility so it needs only 3 mm. Surgical wound. Nowaday it is commonly used in the Thailand too, but more expensive.

UN-absorbing lenses.

Ultraviolet absorbing materials are dirived from benzotriozoles and benzophenones, are used in the production of lenses of any factory, in order to prevent retinal damage from UV.

2.4 The visual Acuity (Petawanich, 1985)

How to measure the visual acuity (VA)

The patient would be asked to hold the kind of the above card in good light, at al distance of 35 cm. (14 inches) from the patient's eyes. Then, the patient reads the numbers on the chart starting from the biggest ones to the smallest ones. The visual acuity, that is the fraction number on the right side would be recorded, record at the smallest number the patient can read.

Figure : Near vision chart.

Source : Near vision chart in clinical practice

If the patient cannot read even the biggest number, the following method will be used :

- The patient will be asked to count the fingers of the investigator at a distance of 1-2 feet. If the patient can count the fingers correctly, the patient visual acuity is ***Fc 1 foot (Finger count 1 foot)***
- If the patient can't count the fingers, the investigator should move his hand in front of the patient sight. If the patient can tell that there is something movable, his visual acuity is ***Hm (Hand motion)***
- If the patient can't see the hand movement, the light will be projected from several directions to the patient's eyes. If the patient can tell the direction correctly, his visual acuity is ***Pj (Light projection)***
- If the patient can't tell the direction correctly but can only perceive the light, the visual acuity is ***Pl (Light perception)***. If the patient can't perceive the light, the visual acuity is ***No Pl (NPL)*** or absolute blindness.

2.5 NEW VISUAL ACUITY CHARTS FOR CLINICAL RESEARCH

Ferris, Kassoff, Brensnick (1982) recommended three new visual acuity charts facilitate quantitative use of visual acuity test results. (Applying from the Early Treatment Diabetic Retinopathy Study.) The charts have high-contrast lettering on washable white polystyrene. Each line has five Sloan letters; the lines are of equal difficulty, and there is a geometric progression in letter size from line to line. This provides a similar task for each line on the chart with the letter size being the only variable. Charts with different letter sequences are used for testing right and left eyes. (Fig. 1)

NEW VISUAL ACUITY CHARTS

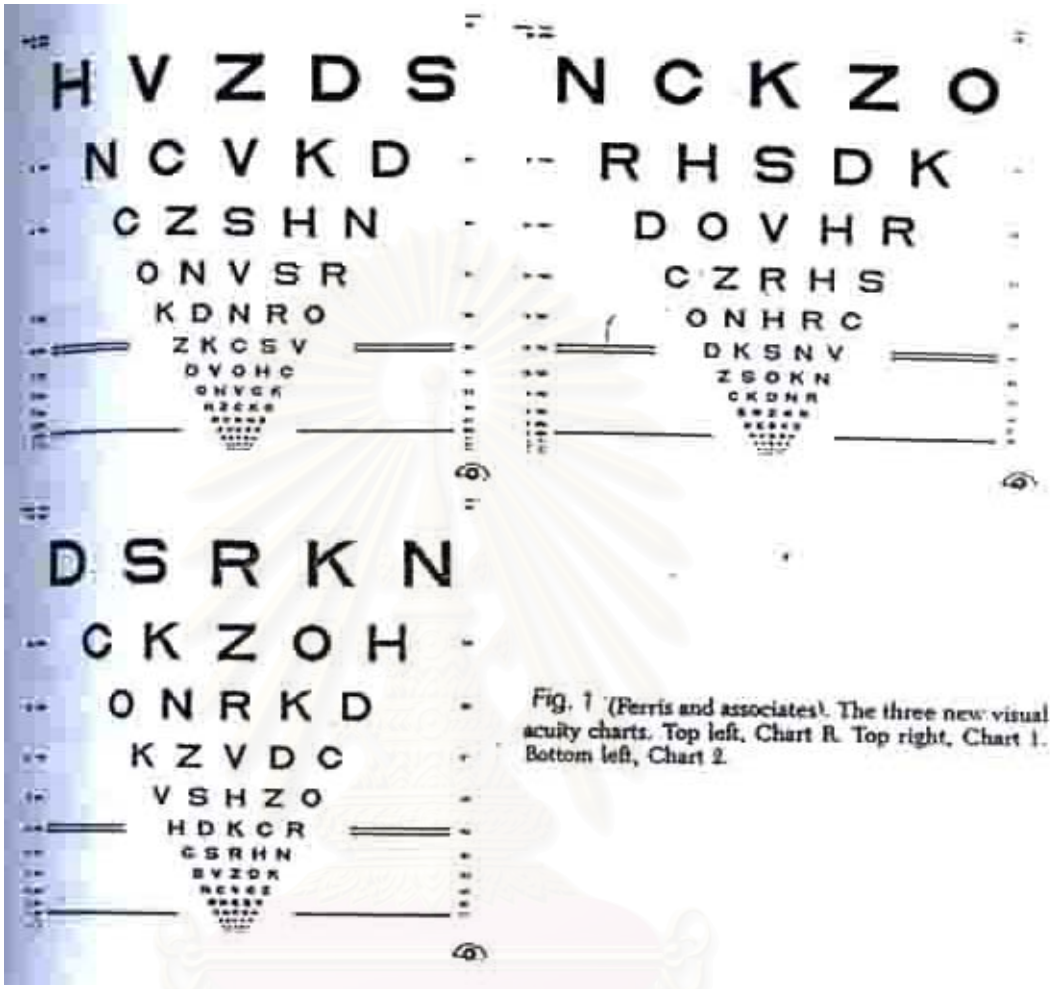

Fig. 1 (Ferris and associates). The three new visual acuity charts. Top left, Chart R. Top right, Chart 1. Bottom left, Chart 2.

Source : Ferris, kassoff, Brensnick (1982), new visual acuity charts for clinical research.

They also suggested that visual acuity can be specified with several different scales. Two commonly used scales are the decimal visual acuity and the logarithm of the minimal angle of resolution (LogMAR) [Table 1]. Decimal visual acuity is obtained by dividing the numerator of Snellen fraction by the denominator. The logarithm of the reciprocal of this decimal visual acuity approximates the logarithm of the minimal angle of resolution. Table 1 shows that the decimal visual acuity is nonlinear, whereas the LogMAR score is linear, decreasing by 0.1 unit of each lower line on the chart.

TABLE 1

EQUIVALENT VISUAL ACUITY MEASUREMENTS

Snellen Visual Acuites			Fraction Decimal	LogMAR
4 Meters	6 Meters	20 Feet		
4/40	6/60	20/200	0.10	1.0
4/32	6/48	20/160	0.125	0.9
4/25	6/38	20/125	0.16	0.8
4/20	6/30	20/100	0.20	0.7
4/16	6/24	20/80	0.25	0.6
4/12.6	6/20	20/63	0.32	0.5
4/10	6/15	20/50	0.40	0.4
4/8	6/12	20/40	0.50	0.3
4/6.3	6/10	20/32	0.63	0.2
4/5	6/7.5	20/25	0.80	0.1
4/4	6/6	20/20	1.00	0.0
4/3.2	6/5	20/16	1.25	-0.1
4/2.5	6/3.75	20/12.5	1.60	-0.2
4/2	6/3	20/10	2.00	-0.3

Source : Ferris, Kassoff, Brthsnick (1982), New visual acuity charts for clinical research

2.6 Converting Snellen visual acuity to decimal visual acuity for statistical analysis

Ober, et al (2000) Investigated the long-term outcomes of silicone versus acrylic intraocular lens (IOL) implantation in phacotrabeculectomy (PT) with special emphasis on posterior capsular opacification. This study is to determine whether there are differences in long-term outcomes between the two foldable IOLs with respect to the rate of posterior

capsular opacification (PCO) and best-corrected visual acuity (BCVA) as well as IOP control, medical dependency, and filtration success rate.

Corrected Snellen visual acuity were recorded before surgery and at regualr intervals after surgery. Snellen visual acuity figures were converted to decimal visual acuity values for statistical analysis. BCVA (Best corrected visual acuity) improved significantly after surgery for both groups (all $P < 0.0001$), whereas there was no significant difference between their values during and postoperative period (all $P > 0.05$; Table 1).

Table 1. Preoperative and Postoperative Mean Decimal Visual Acuity

	Visual Acuity		
Time	**Acrylic**	**Silicone**	**P***
Preoperative	0.42 ± 0.20 (43)	0.38 ± 0.24 (93)	0.08
1-4 mos	0.52 ± 0.25 (43)	0.55 ± 0.26 (99)	0.04
6-9 mos	0.59 ± 0.27 (43)	0.64 ± 0.27 (88)	0.26
12-15 mos	0.61 ± 0.27 (43)	0.65 ± 0.29 (88)	0.35
18-21 mos	0.60 ± 0.26 (43)	0.62 ± 0.28 (85)	0.53
24-27 mos	0.55 ± 0.26 (43)	0.62 ± 0.27 (63)	0.06
30-36 mos	0.54 ± 0.29 (43)	0.63 ± 0.27 (81)	0.10
P†	0.0001	0.0001	

Number in parentheses denote the number of patients.

*Mann-Whitney U test.

†Repeated measures analysis of variance.

Source : Ober et al. (2000), Posterior capsular opacification in Phacotrabeculectomy

In addition, the authors examined for any difference in age, sex, the presence of diabetes or hypertension between both groups.

2.7 Cost-Effectiveness and Decision Analysis of Cataract Surgery

Brown et al. (2000) stated that value from an interventional therapy occurs when it positively affects quality of life and/or length or life. Therapies that do not accomplish at least one of these goals have a questionable role in the fight against disease.

The length of life component can often be extracted from evidence-based medical information in the literature. However, quality-of-life information is not so readily available. Why ? Because the many mechanisms for measuring quality have not been standardized, are inapplicable across diverse medical specialties, and are far from uniformly accepted.

In 1977, Weinstein and Stasson reported a methodology for ascertaining the cost-effectiveness of interventional medical therapies. Based upon utility theory, it has been modified to incorporate: (i) evidence-based medicine, (ii) patient-based preferences, (iii) decision analysis, and (iv) econometric modeling with discounting to account for the time value of money. A brief explanation of each of these components follows:

1. Evidence-Based Medicine

Evidence-based medicine incorporates the highest quality of medical information available. Because of the high standards and confidence in the methods, the information obtained is typically reproducible, thereby giving clinicians conviction in the therapies they provide for patients.

2. Patient-Based Preferences (utility analysis)

Utility values have been obtained from physicians, administrators, researchers, and the general public, but increasing numbers of researchers believe those obtained from patients are the most valuable.

A number of methodologies are available to measure utility values, including the standard gamble technique, the willingness-to-pay technique and the time tradeoff technique. The latter seems to be the most reproducible and valid.

As an example, the average patient with counting fingers vision in the better eye by time tradeoff method is 0.50.

Utility values are not necessarily static, and improvement of visual acuity by an interventional therapy often yields an improvement in utility value. For example, a patient with counting fingers vision in the better seeing eye from a cataract who achieves 20/40 vision after cataract extraction typically improves from a utility value of 0.50 to 0.80. Therefore, there is a gain of 0.3 utility points from the surgery.

In addition to improvement gained from an interventional therapy, the duration of improvement also contributes to the value conferred by the therapy. The duration can be taken into account by using the quality-adjusted life-year (QALY), which is derived by multiplying the utility value gain obtained from an interventional therapy by the years of benefit conferred by the therapy. The patient with cataracts who improves from a utility value of 0.50 before surgery to 0.80 after surgery, and who experiences the benefit for the remaining 20 years of life, would therefore gain a total of 6.0 (0.3 x 20) QALYs from the surgery.

Although this is not typically the case in ophthalmology, a therapy that improves length of life will also yield more QALYs since duration of the benefit effect is in the equation used to derive the number of QALYs gained.

It should be noted that vehicles other than utility analysis are available for measuring quality of life. Most, such as the VF-14 and MOS short form-36 are scaling systems that ask a number of set questions that are particularly task-oriented. Although valuable in their own right, these vehicles are often not applicable across all specialties in medicine. Additionally, because of the specific number of set questions, they may miss

variables related to the quality of life associated with a health state that are of unique importance to a patient.. Utility analysis, in contrast, is believed to encompass more because it incorporates more aspects, including those that are task-specific, psychosocial, economic, etc.

3. Decision Analysis

When various treatment options are available, decision analysis allows one to determine the optimal treatment strategy, based on the maximization of utility values.

Decision analysis is necessary because many variables contribute to an outcome. In the case of cataract surgery, the treatment can be complicated by macular edema, endophthalmitis, retinal detachment, and other adverse variables. These all have an effect upon the final mean visual acuity (and therefore the utility value) obtained after surgery. When the utility value associated with a visual acuity is used in a decision analysis tree, the mean difference in utility points gained from a therapy can be ascertained.

4. Cost-Effectiveness

Amalgamating the costs associated with an interventional therapy with the number of QALYs gained from the therapy yields the cost per QALY.

It has been suggested that interventional therapies costing less than $20,000/QALY gained are likely to be cost-effective, whereas those costing more than $100,000/QALY gained should not be considered particularly cost-effective.

Case Scenario

A 70-year-old executive presented to the ophthalmologist with a history of gradually decreasing in vision in both eyes over the past 2 years. His medical history is unremarkable. Ocular examination revealed a visual acuity of : OD-20/70, and OS-20/70. Anterior segment examination disclosed no evidence of inflammation in either eye and a posterior subcapsular lens opacity bilaterally. The fundus examination was normal

bilaterally. Before contemplating surgery, the patient asked specifically what the most likely visual result was, as compared to no treatment.

The most likely result and the quality-of-life can both be obtained by decision analysis. In this model, the values located at the right side of the decision tree (Figure) represent utility values corresponding to those of patients with the following visual acuity in the better-seeing eye:

20/20 = 0.92

20/25 = 0.87

20/30 = 0.84

20/40 = 0.80

20/50 = 0.77

20/70 = 0.74

20/100 = 0.67

20/200 = 0.66

20/400 = 0.64

Counting fingers = 0.52

Interpretation

The final utility value with no cataract surgery is unchanged at 0.74 (20/70). With cataract surgery, the probable utility outcome, despite the potential complications, is 0.91 (just less than 20/20). Surgery is

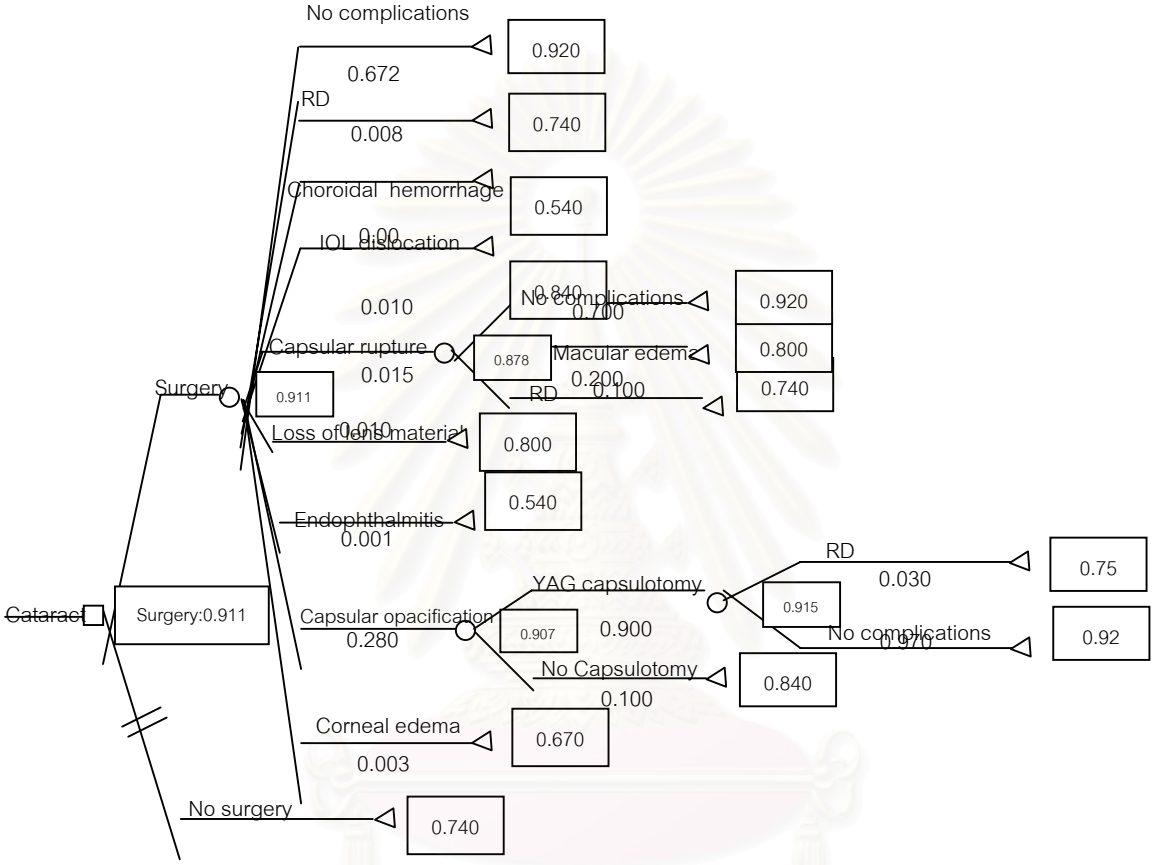

Figure. Decision tree for cataract surgery. RD = retinal detachment, IOL = intraocular lens, YAG = yttrium-aluminum-garnet. Square = decision node, Circle = chance node, Triangle = terminal node. Utility values are the numbers in the rectangular boxes at the terminal nodes and within the sub-trees. Numbers below the lines represent proportions. Proportions indicate likelihood (probability) of the particular health state. Proportions within each subtree must equal 1.0.

Source: Brown et al. (2000), Cost-effective analysis, thevalue component of evidence-based medicine

Therefore selected as the alternative delivering the most value to the patient.

Cost-Effectiveness Implications

The anticipated improvement in utility value is therefore 0.17 (0.91-0.74). Because this patient has a life expectancy of approximately 13 year, the number of quality-adjusted life-years (QALYs) gained from the treatment would be 2.21 (13 x 0.17). These QALYs are then discounted at a 3% yearly rate to account for the time value of money, yielding 1.50 QALYs gained from the therapy.

The quality-adjusted life-years can then be combined with the total cost of the cataract surgery and the weighted cost of the complications associated with the surgery to yield the cost-effectiveness in $/QALY (cost per quality-adjusted life-year) gained.

Assuming the costs of cataract surgery and the weighted costs of its associated complications to be $2,100, the cost per QALY is $2,100 per 1.5 years or $1,400/QALY gained.

Theoretical Benefits of Cost-Effective Analysis

The cost-effective methodology described herein has the following advantages when assessing the value of an interventional therapy:

1. It allows a comparison across all medical specialties using the common denominator of cost per QALY.

2. It incorporates patient-based preferences for the quality of life into the value.

3. It takes into account evidence-based medicine, which is most reproducible and reliable.

4. It highlights therapies that are highly effective and also points out those are not effective so they can be improved or discarded.

5. It allows all stakeholders in health care a mechanism by which they can measure and compare the value of interventional therapies.

2.8 Complication, patients' Satisfaction, Working Efficiency and Acceptance of IOL/Spectacles Associated with Cataract Surgery

In 1992, Raiyawa and Wattanachote studied in ling term comparison between the ECCE with IOL implantation and the ICCE with spectacles correction in 232 subjects in rural area of Udonthani province in the cataract surgery campaign, and followed up the result at 1, 6, 12 -month interval in terms of visual acuity, satisfaction, problems during surgery, post-operative complication, post-operative working efficiency of the patients and spectacles/lens acceptance. There are some interesting results found as follows :

1. Visual Acuity of the Post-Operative Eye

Surgical technique	**Visual acuity**			
	Less than 20/200	**20-200-20/70**	**Better than 20/70**	**Total**
ECCE with IOL	5 (3.88%)	42 (32.56%)	82 (63.56%)	129 (100%)
ICCE with spectacles	15 (14.56%)	55 (53.40%)	33 (32.04%)	103 (100%)
Total	20	95	115	232

CHI-SQUARE = 25.02, 2 DEGREE OF FREEDOM, p-value = 0.00000369 (< 0.05)

Source : Raiyawa, Watnachote (1992) Comparative study of cataract surgery between ICCI with spectacle correction and ECCE with lens implantation in rural Thailand

2. Surgical complication

Surgical technique	Complication		
	No	Yes	Total
ECCE with IOL	122 (94.57%)	7 (5.43%)	129 (100%)
ICCE with spectacles	97 (94.12%)	6 (5.83%)	103 (100%)
Total	219 (74.40%)	13 (5.60%)	232 (100%)

OR = 1.08

95%CI = (0.31-3.72)

p-value = 0.90

Source : Raiyawa, Watnachote (1992) Comparative study of cataract surgery between ICCI with spectacle correction and ECCE with lens implantation in rural Thailand

3. Post-operative complications

Complication	ECCE with IOL	ICCE with spectacle
1. Increase in intraocular pressure	3 (2.33%)	4 (3.88%)
2. IOL displacement	2 (1.55%)	-
3. Corneal edema	4 (3.10%)	3 (2.91%)
4. After cataract	21 (16.28%)	-
5. Retinal detatchment	-	2 (1.94%)
6. Diplopia	1 (0.77%)	-
7. No complication	98 (75.97%)	94 (91.27%)
Total	**129 (100%)**	**103 (100%)**

Source : Raiyawa, Watnachote (1992) Comparative study of cataract surgery between ICCI with spectacle correction and ECCE with lens implantation in rural Thailand

4. Satisfaction of visual acuity improvement after cataract surgery

Surgical technique	Satisfaction			
	Increase	Same	Decrease	Total
ECCE with IOL	4 (3.1%)	37 (28.67%)	88 (68.23%)	129 (100%)
ICCE with spectacles	12 (11.65%)	44 (42.71%)	47 (54.63%)	103 (100%)

CHI-SQUARE = 14.32, 2 degree of freedom, p-value = 0.0008 (< 0.05)

Source : Raiyawa, Watnachote (1992) Comparative study of cataract surgery between ICCI with spectacle correction and ECCE with lens implantation in rural Thailand

5. Working efficiency in the group with income (95 cases)

Surgical technique	**Working efficiency**			
	Increase	**Same**	**Decrease**	**Total**
ECCE with IOL	3 (5.90%)	8 (15.67%)	40 (78.43%)	51 (100%)
ICCE with spectacles	9 (20.46%)	14 (31.87%)	21 (47.67%)	44 (100%)
Total	**12**	**22**	**61**	**95**

CHI-SQUARE = 10.05, 2 degree of freedom, p-value = 0.006 (< 0.05)

Source : Raiyawa, Watnachote (1992) Comparative study of cataract surgery between ICCI with spectacle correction and ECCE with lens implantation in rural Thailand

6. Working efficiency in the group with no income (137 cases)

Surgical technique	**Working efficiency**			
	Increase	**Same**	**Decrease**	**Total**
ECCE with IOL	2 (2.56%)	16 (20.52%)	60 (76.62%)	78 (100%)
ICCE with spectacles	2 (3.39%)	26 (44.60%)	31 (52.54%)	59 (100%)
Total	**4**	**42**	**91**	**137**

CHI-SQUARE = 9.16, 2 degree of freedom, p-value = 0.01

Source : Raiyawa, Watnachote (1992) Comparative study of cataract surgery between ICCI with spectacle correction and ECCE with lens implantation in rural Thailand

7. Acceptance or familiarization with spectacles or IOL

Surgical technique	Complication		
	No	Yes	Total
ECCE with IOL	123 (95.35%)	6 (4.65%)	129
ICCE with spectacles	65 (63.11%)	38 (36.89%)	103
Total	188	44	232

OR = 11.98
95%CI = (4.54-33.42)
p-value = < 0.05

Source : Raiyawa, Watnachote (1992) Comparative study of cataract surgery between ICCI with spectacle correction and ECCE with lens implantation in rural Thailand

This study provides some applicable knowledge of cataract complication, the patients' satisfaction, the measurement of working efficiency and acceptance of IOL or spectacles that might influence the quality of life.

2.9 Cost-Utility Analysis

2.9.1 Utility Values and Age-Related Macular Degeneration

Brown et al (2000) would like to find out the utility values associated with age-related macular degeneration and varying the degree of visual loss. They divided 80 white patients with unilateral or bilateral age-related macular degeneration into 5 groups according to the visual acuity (VA) in the better-seeing eye, they found that the mean utility value for the total group with age-related macular degeneration was 0.72 (95% confidence interval (CI), 0.66-0.78) using the time trade-off method and 0.81 (95%CI,0.76-0.86) using the standard gamble method. Using the time trade-off method correlated with the visual acuity in the better-seeing eye, the results were as follows :

group 1 (VA20/20 to 20/25), 0.89 (95% CI, 0.82-0.96)

group 2 (VA20/30 to 20/50), 0.81 (95% CI, 0.73-0.89)

group 3 (VA20/60 to 20/100), 0.57 (95% CI, 0.47-0.67)

group 4 (VA20/200 to 20/400), 0.52 (95% CI, 0.38-0.66)

group 5 (FC to PI), 0.40 (95% CI, 0.29-0.50)

2.9.2 Cost-Utility Analysis of the Cochlear Implant in Children

Cheng et al. (2000) used cost-utility analysis to study in 78 profoundly deaf children (average age = 7.5 years old) who received cochlear implant. Using the time-trade-off (TTO), visual analog scal (VAS), and Health Utilities Index-Mark III (HUI). Parents rated their child's health state at the time of the survey and immediately before and 1 year after implantation. They found that cochlear implant cost $9029 per QALY using the TTO, $7500 per QALY using the VAS, and $5197 per QALY using the HUI.

2.9.3 Cost-Utility Analysis of Unruptured Cerebral Aneurysms

Johnston SC, Gress, Kahn JG. (1999) performed a cost-utility analysis comparing surgical clipping and endovascular coil embolization (2 common treatments) for asymptomatic unruptured cerebral aneurysms of a hypothetical cohort of 50-year-old women. They found that for an asymptomatic unruptured aneurysm less than 10 mm in diameter in patients with no history of SAH from a different aneurysm, both procedures resulted in a net loss in QALYs, and confidence intervals (CI) were not compatible with a benefit from treatment (clipping, loss of 1.6 QALY [95% CI 1.1 to 2.1]; coiling, loss of 0.6 QALY [95% CI 0.2 to 0.8]). For larger aneurysms (> or = 10 mm), those producing symptoms by compressing neighboring nerves and brain structures, or in patients with a history of SAH from a different aneurysm, treatment was cost-effective. Coiling appeared more effective and cost-effective than clipping but these differences depended on relatively uncertain model parameters.

2.9.4 Routine Neonatal Circumcision : A Cost-Utility Analysis

Ganiats TG. Et al (1991) performed a cost-utility analysis to evaluate the relative importance of each of the various elements in the current circumcision debate.

Elements used in the analysis included the cost of the procedure, the procedure, the pain associated with the procedure, the risk of urinary tract infections, and the risk of penile cancer. The net, discounted lifetime dollar cost of routine circumcision is $102 per person, while the net, discounted lifetime health cost is 14 hour of healthy life. These results suggest that the financial and medical advantages and disadvantages of routine neonatal circumcision cancel each other and that factors other than cost or health outcomes must be used in decision making.

2.9.5 Cost-Effective Use of Antiemetics

Grunberg (1998) performed a pilot study to determine objectively the utility scores for various states of emesis using decision analysis techniques in 30 patients completing a cycle of chemotherapy were asked to fill out a brief questionnaire. They were asked to assume that any other toxicities experienced (mucositis, alopecia, etc.) had remained the same, and to relate their overall quality of life of a rating scale (visual analog scale) based on the assumption that there either had or had not been a minimal amount of nausea and vomiting. A marked difference was noted, with 27 of 30 patients stating that quality of life would have been better without vomiting. Moreover, the magnitude of this difference was striking. The mean increase in rating scale score when nausea and vomiting were removed was 52 mm out of a total scale of 100 mm.

2.10 Distortion of Utility Judgment

The usual methods of utility assessment may overstate the disutility of mild or moderate health conditions, they may overstate the benefit of curing or preventing such conditions. For example, Uble et al. Asked subjects. Who has a ganglion cyst on one hand that occasionally causing mild pain, however she is able to do everything normally. “On a scale from 0 to 100, where 0 is as bad as death and 100 is perfect health, how would you rate this condition?” The mean answer was 92. The cyts was judged about 1/12 as bad as

death. This seem too high, too far from 100. The reason of the answer is that these conditions will get priority in the final ranking than they deserve.

Baron et al found the rating scale judgment yield smaller disutilityies for health conditions and are more consistent with which each other when subjects are first asked. For example, a subject who rates blindness as 40 on a scale from 0 (death) to 100 (normal) may revises this number upward after judging that blindness is closer to normal health than to death. These results suggest that, indeed, conditions tend to be rated as close to death than they ought to be, and that bias can be corrected by instructions to consider the mid point of the scale.

2.11 Cost-Utility Analysis and the Calculation Method

In cost-utility analysis the aggregation across subjects is achieved by measuring all individual utilities on the common 0-1 dead-health scale and taking the arithmetic mean. The central basis for this method is that the difference in utility between being dead and being healthy is set equal across people. In this way the method is egalitarian with in the health domain; that is, each individual's health is count equally. (Torrance, 1985)

2.12 Cost utility Analysis and Economic Wellbeing

The utility measurement should be uncomfounded by the subject's economic wellbeing. Thus, it is important to assure the subject that all treatment and all outcomes will be costless to him and to his family-that is, the subject is to assume full-coverage health insurance and salary continuation insurance (Torrance, 1985)

2.13 Measuring preferences and Multi-attribute status classification systems

2.13.1 Distinctive features of the Qaly method : The egalitarian assumption

The egalitarian assumption is a fundamental feature of the qualy approach. It is both a statement of social philosophy concerning the unique importance of health in people's lives and a technical step designed to permit the aggregation of utilities. Different authors have emphasized one or another aspect of the egalitarian assumption.

Emphasizing the social-values perspectives, Chen and Bush (1976) say "that days and well-years in everyone's life are of equal value, regardless of the individual's age, sex, socio-economic status, or other characteristics." Kaplan and Bush (1982) state that an "egalitarian basis for comparing the lives and preferences of different persons…...treats days in all lives as of equivalent social value." (These authors also recognize the role that their position plays in aggregation.)

Emphasizing the role of the egalitarian assumption in the adding up of utilities, Torrance and Feeney (1989) say, "The central basis for the aggregation is that the difference in utility between these two outcomes is set equal across people. In this way the method is egalitarian; a full healthy life for each individual carries the same weight." The authors also state that this aggregation approach embodies a "fundamental ethical judgment" Zeckhauser and Shepard (1976) adopt the egalitarian assumption as an explicit principle of aggregation ("QALYs returning to different individuals should be weighted equally" They add that a health state may affect different years differently, so that utilities would have to be scaled separately. Age is cited as and example.

A person's economic position is, of course, a circumstance that may not be permitted to influence the important of a person's health status in comparison with others.

The irrelevance of economic position is underscored by a corollary to the egalitarian assumption. Torrance (1986) says “the utility measurement should be unconfounded by the subject’s economic well-being. Thus, it is important to assure the subject that all treatment and all outcomes will be costless to him and to his family”

The corollary on cost is particularly important in that it ensures that poor people have an equal voice and weight in the determination of health policy. It also illustrates that calibrating or scaling utilities to account for income or other variables to satisfy the egalitarian assumption is not and easy matter.

2.13.2 Health state descriptions

Each unique possible health outcome for the program under evaluation and for the comparison program must be defined as a health state for utility measurement. Depending on the study there may be only a few health states or there may be many hundreds. For example, a study of kidney dialysis and transplantation required only four states because there were only four distinct health outcomes-kidney transplant, hospital dialysis, home dialysis and death [Torrance et al. (1973)]. On the other hand, a study of neonatal intensive care required 960 states because there was a vast array of possible outcomes [Torrance et al. (1982), Boyle et al. (1983)]

The health states should be described in functional, as opposed to clinical terms. That is, the description should focus on how well or poorly a person in this health state is able to function, rather than on his clinical diagnosis or his laboratory test results. A comprehensive description should include a statement on the level of physical functioning, the level of emotional functioning and the level of social functioning.

The utility for a health state is affected by is duration [Torrance et al. (1972), Sackett and Torrance (1978)]. Thus, it is important to specify the duration of the health state either as part of the description itself or as part of the measurement process.

The utility of health state should be unconfounded by utilities for other states that may or may not follow this one. Thus, it is important that the prognosis for the health state not be left unspecified or vague for each subject to interpret differently. Usually this is handled by making no mention of prognosis in the health state description itself, and then specifying a clear and certain prognosis as part of the measurement process. In measuring the utility of a chronic condition, the prognosis should be stated as no change other than the normal aging process until death with the age of death specified. In the case of a temporary condition, it should be no change until the end of the temporary duration specified at which point the person returns to normal health. (Torrance, 1985)

2.13.3 Utility measurement

Fundamentally, utility measurement simply consists of presenting a subject with descriptions of several health states and eliciting directly or indirectly the subjects' relative preferences for the states. Each description of a health state should be functionally oriented and comprehensive. Further, the description of the state or the measurement process should specify ***the age of onset*** fo**r** the state, and whether or not the state applies to the subject himself or to someone else. Normally, the health states should be of ***the same duration, same age of onset, and same prognosis***-otherwise the results are difficult to interpret (Torrance, 1985).

2.13.4 Whom should you ask ?

The answer can be determined, in part, from the purpose and the viewpoint of the study. Most cost-utility are undertaken to influence public policy decisions and, accordingly, are conducted from the societal viewpoint. In this case, the appropriate utilities are those of and informed member of the general public or community representative. Informed means that the subjects truly understands what the health state is like. This is the sticking point. How do you describe, in a complete and yet unbiased manner, a particular dysfunctional health state (for example, kidney dialysis) to a healthy

individual who has no experience with the condition ? And how do you know when you have done it right ? Issues to be considered here include the style and detail of the health state description (discussed earlier), the reliability and validity of different procedures (discussed later) and the extent of differences in measurements made on different types of subjects such as patients, physicians and the general public (discussed below).

Patients are appropriate subjects to ask regarding the utility of their condition in clinical trials as described earlier. This is particularly true when the focus is on comparisons of alternatives within the trial, as it generally is, rather that comparisons beyond the trial. That is, a trial comparing two methods of treating arthritis can properly.

Health professionals, such as physicians and nurse, have also been used as the source of health state utilities. This has many of the same advantages and disadvantages as the use of patients. It minimizes the problems of describing the states, but at the expense of possible bias due to conflict of interest and due to the special age, sex and socio-economic status of health professionals.

Who you should ask is only an issue if different groups are known to give different results. With interval scale cardinal utilities this has generally not been the case. Most investigations have found no difference among different groups-age, sex, socio-economic status, ethnic background, religious affiliation, general public, physicians, nurses, patients [Kaplan and bush (1982), Sackett and Torrance (1978), wolfson et al. (1982)]; a few have found small differences [Sackett and Torrance (1978)]; none have found large differences. (Torrance, 1985)

2.13.5 Quality of life measures in health care : *Sensitivity of change*

Measures of quality of life that can distinguish between patients at a point in time are not necessarily as sensitive to changes in patients over time when repeated. However, sensitivity to change, sometimes referred to as responsiveness, is a crucial requirement for most applications, especially in clinical trials, evaluation research, or cost-utility analyses.

There are several reasons why instruments may be intensive to change in quality of life. One reason is that larger more generic instruments may include several items not relevant to the particular disease or treatment group. A second related factor is that instruments may include items that assess areas that are relatively static or not a feasible target of the health care intervention-for example, patterns of social relationships. "A third problem is that quality of life measures may be subject to ceiling or floor effects. For patients with very poor quality of life who obtain minimum scores before treatment there may be no scope to register any further deterioration." Finally, some quality of life instruments still contain too few broad categories to be sensitive to subtle but important changes in patients. It is not surprising therefore that when patients complete several quality of life instruments a different impression of quality of life changes over time may be obtained with different measures.

The absence of a standard against which to assess the measurement properties of a quality of life instrument as a particular problem when examining instruments' sensitivity to change. One approach is to examine the associations between quality of life change scores and other changes in health status. The alternative is to examine the sensitivity and specificity of quality of life change scores against an external criterion such as the view of the clinician or the patient that a significant change has occurred. However, one of the most important areas for further development is in making quantitative change scores for quality of life more clinically meaningful (Fitzpatrick et al. 1992)

2.13.6 The reliability of the outcome

The reliability of the measure, its consistency in reproducing repeated measures of a phenomenon by the same individual or across different groups of observers, provides evidence that a concept is understood readily enough by a wide enough range of people to provide stable information. As such, it is necessary, but insufficient, for assessing validity. The reliability of a measurement strategy is evaluated in different ways. "Intrarater

reliability" is a measure of the stability of the rating an individual judge gives to the same question that is presented more than once during the same or subsequent administrations. "Test-retest reliability" is a test of reliability may be a useful indicator of task comprehension in providing preference weights: concordance of two ratings at separate times can provide evidence that people have constantly in their understanding of the measurement technique as well as of the health state. However, test-retest reliability may be confounded by real changes in preferences for health states that are occasioned by the experience of them. For example, women's preferences for anesthesia during childbirth varied considerably depending on whether the measures were taken during labor or 1 month pre-or postpartum: Test-retest reliability was high for the measures unassociated with labor (Chritensen-Szalanski, 1984). Finally, "Interrater reliability," a measures of consistency among multiple judges, is generally felt to be less germane as a test of preference reliability, given that preferences, by definition, vary across people. (Gold et al)

2.13.7 Method for assigning preferences to health states

Method of preference weighting have been developed primarily from two theoretical tradition: expected utility theory and psychophysical or psychological scaling methods.

Utility approaches

The methods derives form expected-utility theory include the standard gamble and time trade-off techniques. The standard gamble approach, which is based on the axioms of expected utility theory, has been widely used to measure health state preferences (Torrance, 1986). The technique begins with asking the respondent to consider a hypothetical choice between the certainty of continued life in the health state of interest (one of less than optimal health) and a gamble. The gamble has two possible outcomes. The positive outcome is usually a state of full health (assigned a utility of 1). The negative outcome is usually death (assigned a utility of 0). The probabilities in the gamble are systematically altered (visual aids such as a probability wheel or a chance board are used to illustrate the

probabilities) until the respondent is indifferent between the choice of the certainty of continued life in the health state of interest and the gamble. The expected value of the gamble at this point is, by substitution, the utility for the health state of interest relative to full health and death. The standard gamble will accommodate states worse than death. Here the certain state is death, and the choices for which the probability is varied are between cure and a chronic state worse than death.

The time trade off method presents the respondent with the task of determining what amount of time they would be willing to give up to be in a better versus a poorer health state (Torrance et al., 1972). Here the choice is between two certain outcomes rather than the certain outcome of the described health state and a gamble between life and death. The time trade off method, also performed with visual aids, asks judges to value the alternative of being in a less desirable health state (A) for a longer period of time followed by death, versus being in a more desirable state (B) for a shorter period of time followed by death. The time in state B is decreased to a point where the judge becomes indifferent in between the alternatives. The preference for state A is calculating as life expectancy at the point of indifference in state B divided by the life expectancy in state A. Time trade off can also provide weights for health states worse than death.

Decision theorists and economists have favored either the standard gamble method, because it follows directly from the axioms of expected utility theory, or the time trade off method, which also has theorical roots in decision theory. They hold that the standard gamble is valid by implication if the basic assumptions of expected utility theory are accepted (Torrance, 1987). In addition, it is argued that preferences are gathered in a setting that mirrors many clinical decisions where judges must take choices under conditions of uncertainty (Ben Zion and Gafni, 1983; Gafni and Birch, 1995 : Torrance et al., 1995b). Others have argued that the standard gamble does not correspond to the typical decision-making task in health, where multiple potential outcomes are possible and the

choice of two options as certain as death or perfect health are not scenarios that typically confront people (Richardson, 1994). Critics of the technique also argue that the predictions of expected utility theory have not been borne out in empirical trials (Llwellyn-Thomas et al., 1982 ; Kahneman and Tversky, 1983 ; Anderson, 1979 ; Shoemaker, 1982). There is debate also as to whether, when performing CEAs for purposes of information resource allocation (where preferences for health states are collected from representative populations rather than from patients), considerations of risk are, in fact, germane.

Coefficients of intrarater reliability (0.77) and test-retest reliability (0.80) have been reported for the standard gamble (Froberg and Kane, 1989b). For time trade off, intrarater reliability has been reported to range from 0.77 to 0.88 and test-retest reliability in the short term has shown coefficients ranging from 0.63 (at 6 weeks) to 0.87 at 1 week or less (Froberg and Kane, 1989b; Nease et al., 1995). Correlations between standard gamble and time trade off have been reported to range from 0.31 (Hornberger et al., 1992) to 0.65 (Read et al., 1984) .

There is significant contention with repect to the feasibility of collecting preference weights using the standard gamble. Investigators favoring the approach have argued that when the standard gamble is collected properly, with appropriately designed visual aids and measurement props, it is feasible in general and patient populations (Torrance, 1986). Others have found the approach cognitively demanding for patients and argue that the method is unnatural for many people who are unused to formulating their preferences in terms of gamble. The difficulty with the task is held by some to reduce the validity of the approach.

Both the standard gamble and time trade off methods are structured so that respondents make their choices involving the three health states on an interval-level scale, thereby directly producing preference weights with interval-level scaling properties. Weights derived from both techniques tend to be higher than those generated with many of

the other preference-weightings techniques. Empirical work has shown that when individuals are asked to choose between a gain and a loss of similar magnitude, the preference for the gain is much less that the desire to avoid the loss (Kahneman and Tversky, 1983). In the case of the standard gamble, people will almost always choose to remain in a lower state of health-no matter how undesirable it is-rather than accept any substantial risk of death. This conservatism in gambling with respect to death usually results in numerically higher utilities being derived with the standard gamble relative to other techniques.

The time trade off method collapses considerations of quantity of life directly into the measure of health-related quality of life. It thereby directly measures the number of healthy years that are equivalent to a given time in a particular health state. Because this mean that the two measurements from which a QALY is formed (effectiveness and value for a particular health state) are done in the same metric, some authors believe that time trade off has a theoretical advantage when compared with other methods of preference elicitation (Nord, 1992b; Richardson, 1994). It has recently been noted that the time trade off question confounds preferences for the health states themselves with time preference; this is because the years of life that are "sacrificed" in the time trade off come at the end of the life span and, therefore, may be valued less because they are farther in the future.

Time trade off and standard gamble have been used in collecting weights for a number of component health states in versions of the HUI. Time trade off is currently being used in collecting weights for the EuroQol (Williams, 1995 a,b).

Psychophysical approaches

Methods derived from the psychophysical tradition include the paired-comparison approach, *rating scale* methods (including *category scaling* and *visual analogue scales*), and *magnitude estimation.*

Direct rating methods, including category rating and visual analogue scales, require judges to assign each health state to one number, usually on a scale from 0 (least desirable to death) to 100 (most desirable to prefect health). Visual aids such as a "felling thermometer" are used to support this task. Judges are instructed to place health state along the scale according to their relative desirability, typically with the additional instruction that the spacing between each point in the scale should be regarded as equivalent. The preference value for each of the states is simply the value associated with its placement on the scale. States worse than death can be accommodated.

Direct rating methods are referred to as category rating when the scale is divided into discrete points, one of which must be chosen (e.g., 0.1,0.2,0.3,etc.); they are known as visual analogue scales when the scale contains no internal markings and raters are required to place a mark at some point between the two anchor states.

Intrarater reliability of rating scale technique has ranged from 0.70 to 0.94 with comparable ranges for magnitude estimation (Froberg and Kane, 1989b). Correlation of test-retest reliability at 1 week using a rating scale approach has been reported as 0.77 (O'Connor et al., 1987); at 1 year, another study reported a correlation of 0.49 comparing unfavorably with test-retest reliability of the time trade off technique (Torrance, 1976).

Rating scale methods are higher familiar to most people from a variety of everyday experiences in which they are asked to provide information on an array of experiences (e.g., sporting events, movies, level of pain) using this technique. It is widely agreed that the cognitive burden of respondents is less than with other techniques. However, empirical work has shown that people have difficulty directly assigning a number to feelings about health states (Patrick et al., 1994). In addition, some investigators have found that individuals are unable to provide and explanation of the relationship of their responses on a rating scale to the concepts of welfare or utility that would be the foundation of decisions about resource allocation (Richardson, 1994).

Rating scales are held to produce interval-level values when respondents are instructed to place the health states on the line such that the intervals between their placement reflect the differences they perceive between the health states. Concerns regarding scaling characteristics of the visual analogue and category rating scales have been raised by the observation that difficulty in making absolute judgements results in the avoidance of the extreme categories of a scale, resulting in a clustering of values that acts to reduce the range of possible responses (Streiner and Norman, 1989). Other empirical work suggests that rating scales provide and reliable results when the response continuum is made explicit to subjects (Kaplan and Ernst, 1983).

2.14 METHODOLOGY FOR MEASURING HEALTH-STATE

Froberg, et al. (1989) stated that preferences or utilities refer to levels of subjective satisfaction, distress, or desirability that people associate with a particular health state. Other synonyms for this level of subjective satisfaction are quality of life, weight, or rating of the health state .

In general, various approaches to obtaining health-state preferences have included these three steps: (1) defining a set of health states of interest, (2) indentifying a judge or group of judges to provide judgments of the desirability of each health state, and of necessary, (3) aggregating across the judges to determine scale values for each health state .

The appropriateness of making interpersonal comparisons of utility lies at the heart of the controversy over aggregating preferences. Resnick, for example, describes how individuals scales can be recalibrated such that a unit on one person's scale in the same as a unit on another person's scale. On the other hand. Torrance handles the problem by establishing two clearly defined outcomes, one good and one bad, as anchor points, but not necessarily end points, for the utility scale. The central basis for aggregation is that the

difference in utility between these two outcomes of ‘a normal healthy life’ and ‘death’ is set equal across people. In addition to the controversy surrounding interpersonal comparison of utility, using the arithmetic mean raises questions of equity, since the same mean value can arise if, for example, three people all give a health state a rating of 20 utility points as when two people give it 30 utility points and one person gives it 0 points. These issues cannot be thoroughly discussed and resolved here, but they should be considered whenever preferences are aggregated for applied purposes.

2.15 CHOOSING OF SCALING METHODS

Froberg et al. (1989) stated that three scaling methods used in studies of health-state preferences require subjects to respond in terms of an interval scale: the standard gamble, time trade-off and category ratings . The other scing methods (magnitude estimation, equivalence, and willingness-to-pay) require ratio-level responses.

The standard gamble is complex and not intuitively obvious to most respondents. The time trade-off method was developed by Torrance and his colleagues specifically for use in health research as a simple-to-administer alternative to the standard gamble. Like the standard gamble, it presents the respondent with a choice. However, in the time trade-off technique the respondent is asked to choose between to alternatives of certainty rather than between a certain outcome and gamble.

Originating in psychometrics, the rating scale consists of a line on a page with clearly defined endpoints or anchors. The rating scale is the most frequently used method for measuring health-state preferences.

Evaluation of scaling methods

In international review articles there is some hesitancy about answering this question . Williams writes expressly that ‘‘the valuation part can be handled by a variety of methods…No one of these--….is clearly superior or inferior to the others’’

Decision theorists have historically favored the standard gamble because it is built on a set of fundamental axioms underlying the expected utility model and it forces the respondent to make preference judgments under conditions of uncertainty some decision theorists have turned to other methods because the standard gamble is so difficult to explain to respondents. Further, recent evidence suggests that people exhibit patterns of preference that are incompatible with expected utility theory. For example, Llewellyn-Thomas et al. found that changes in the gamble outcomes significantly influenced reported values for health states, a finding that both contradicts expected utility theory and indicates that the standard gamble is internally inconsistent. Shoemaker presents extensive evidence that people violate the axioms of EUT. At the individual level, EU maximization is more the exception than the rule, at least for the types of decision tasks examined. These theoretical developments raise questions concerning the validity of the standard gamble technique.

In particular, utilities derived from the standard gamble may be biased by risk aversion. Economists generally accept the hypothesis that individuals are risk averse when evaluating a sure gain against a gamble with an equal or higher expected gain. However, psychological research indicates that when people are faced with a sure loss vs a gamble with a substantial probability of an even grater loss, they are often risk-seeking and choose the gamble. Putting these two pieces together, Kahneman and Tversky studied risky prospects that involved both positive and negative outcomes. The standard gamble, with a certain health state evaluated against a gamble with a certain health state evaluated against a gamble with some probability of perfect health and some probability of death, is an example of a risky prospect with both positive and negative outcomes. Kahneman and Tversky found that the pleasure of a gain is much less intense than the pain of a similar-sized loss. This finding suggests that people will usually choose to remain in a less-than-perfect health state rather than risk ending up sicker or dead. In particular, a health state would have to be extremely undesirable before a person would accept an operation with even a moderate risk

of death. This conservatism with respect to risk taking would have a tendency to inflate utilities derived from the standard gamble relative to other scaling methods that do not involve gambles.

The time trade-off technique was recently developed by Torrance expressly for the scaling of health preferences. It was designed to produce the same results as the standard gamble at less cost and with less burden on the respondent.

Reliability

A measure is reliable if it is relatively free of measurement error. Reliability concerns the extent to which a scaling method produces consistent results. With respect to the scaling of health states, reliability can be assessed in three ways: intra-rater reliability refers to a single rater's consistency when an item is presented more than once; test-retest reliability refers to stability of scale values over short periods of time; and inter-rater reliability is consistency among judges regarding scale values. Table I presents available data on each type of reliability for the different scaling methods.

Table 1. Reliability of scaling methods

Reliability	SG	TTO	RS	ME	EQ	WTP
Intra-rater reliability	0.77	0.77-0.88	0.70-0.94	0.74-0.83		
	[38]	[38.52]	[16. 49. 52]	[16]		
Intra-retest agreement (%)				97.2%		
				[15]		
Test-retest reliability						
1-week or less	0.80	0.87	0.77			
	[51]	[51]	[51]			
4-week		0.81				
		[42]				
6-week		0.63-0.80				
		[50]				
1-year	0.53	0.62	0.49			0.25
	[38]	[38]	[38]			[21]
Inter-rater reliability			0.75-0.77	0.75-0.79	0.60	
			[16]	[16]	[16]	
Inter-rater agreement(%)				88%		
				[15]		

SG = standard gamble: TTO = time trade-off: RS = rating scale; ME = magnitude estimation; EQ = equivalence; WTP = willingness-to-pay.

All are correlations unless otherwise indicated.

Source: Froberg et al. (1989), Methodology for measuring health state preference-II:scaling methods

In general, intra-rater reliability is acceptable for all scaling methods for which these data are available. Test-retest reliability coefficients up to 6 weeks are also satisfactory with the possible exception of 0.63, the lower range value for the time trade-off method at 6 weeks. Interpretation of the low test-retest reliability for measurements taken a year apart is ambiguous; the low coefficients probably reflect true preference changes as well as measurement error. Inter-rater reliability appears to be acceptable except for the rather low coefficient of 0.60 reported by Patrick el al. for the equivalence method. Overall, these data are encouraging, but the gaps in the table indicate a need for further research. Also, comparisons among the studies are limited by the fact that a frequently used statistic, the Pearson Product Moment Correlation Coefficient, is dependent upon variability across subjects. Thus, correlation form studies using different subjects and sample sizes are not directly comparable.

Validity

A scaling method is valid if it accurately measures what it is intended to measure. Validity is generally thought to be of three types: content, criterion, and construct. Applied to health-state preferences, content validity refers to the adequacy of the health-state descriptions in representing health status. Content validity is achieved by careful selection of artributed and presentation of sufficient detail.

Criterion-related validity does not apply to health-state preferences since there exists no criterion embodying individuals ‘’true’’ preferences.

Many approaches to construct validation are possible, two of which have been taken in the validation of health preference scaling methods; (1) examining the degree to which results of different scaling methods converge, and (2) examining the degree to which predicted relationships between preferences and other variables are empirically supported. Considerably more work has been done using the first approach than the second.

Three studies have compared the standard gamble, time, trade-off, and rating scale. Torrance viewed the standard gamble as the criterion technique, arguing that the standard gamble is valid by definition since it is based directly on intuitively appealing axioms of utility theory for decisions made under uncertainty. (Note, however, that Shoemaker presents considerable with these axioms.) He found a correlation of 0.65 between the time trade-off and standard gamble and a correlation of 0.36 between category ratings and the standard gamble. He also reported that individual and population mean values of the standard gamble and time trade-off appeared to be equivalent while category ratings were clearly different.

Wolfson et al arrived at a different conclusion after comparing the same three scaling methods. They found that values obtained for the standard gamble were consistently higher than those obtained for category ratings, or time trade-off. The latter two were more similar than either was to the standard gamble. The authors speculate that scale values from the standard gamble are contaminated by and ‘’aversion to gambling’’. Despite their contradictory findings both Torrance and Wolfson et al. Recommend the use of the time trade-off method because it appears valid and is easier to administer than the standard gamble.

Read et al. found moderately high correlations between the standard gamble, time trade-off and category rating methods (r = 0.56-0.65) for both single-attribute and multi-attribute health states. However, the standard gamble generated consistently higher preference scores than the other two method. In addition, for multiattribute health states there was a significant interaction between survival, using category scaling, but not using the standard gamble. These authors stress that high correlations among scaling methods do not guarantee that the methods produce equivalent ratings. Two additional studies compared only the standard gamble and category ratings. Both found standard gamble

values to be significantly higher than category rating values], and one also reported nonsignificant correlations between the two methods.

Churchill et al. found only a low correlation (0.22) between the time trade-off method and a visual analogue rating scale.

Table 2 summarizes the studies that have compared the results of different scaling methods. A ‘’yes’’ in the table indicates that the investigators found at least one of three conditions: (1) a linear relationship between scaling methods. (2) a significant correlation between scaling methods (Which doesn’t necessarily imply a strict linear relationship) or (3) that the mean values were not statistically different. Even using this liberal criterion, the table shows that these studies have produced mixed results. A substantial amount of convergence is evident, but no clear patterns emerge concerning which methods do and do not converge. Perhaps the most that can be concluded is that while correlations between methods are usually moderately high, the different methods do not necessarily produce equivalent scale values.

Table 2. Reliability of scaling methods[a]

Study	SG	TTO	RS	ME	EQ	WTP
Patrick et al. [16]			Yes	Yes	No	
Kaplan et al. [14]			No	No		
Haig et al. [17]			Yes	Yes		
Torrance [38]	Criterion	Yes	No			
Wlofson et al. [39]	No	Yes	Yes			
Read et al. [34]	Yes	Yes	Yes			
Llewellyn-Thomas et al. [40]	No		No			
O'Connor et al. [36]	No		No			
Detsky et al. [41]		Yes	Yes			
Churchill et al. [42]		No	No			
Miles [43]			yes		Yes	

SG = standard gamble; TTO = time trade-off: RS = rating scale; ME = magnitude estimation; EQ = equivalence; WTP = willingness-to-pay.

[a]A '' yes'' in the table indicates that investigators found at least one form of convergence: a linear relationship a significant correlation, or mean values that were not significantly different.

Source: Froberg et al. (1989), Methodology for measuring health state preference-II:scaling methods

However, in the psychosocial measurement literature, it is generally accepted that although different scaling methods should produce the same rank ordering, they should not necessarily be expected to produce identical results. The exact scale values produced by different methods will differ because the methods ask respondents to perform different

tasks. The author also suggested that selection of an appropriate scaling method thus depends upon the way in which the results will be used.

Feasibility

To be useful, scaling methods must be both economical and acceptable to respondents. The standard gamble and time trade-off are inherently expensive due to their reliance on a lengthy interview with well-trained interviewers using elaborate branching procedures. Further, because people find it difficult to work with probabilities and may also have an aversion to taking risks, they often do not give consistent and sensible answers to standard gamble questions even under standardized conditions.This is particularly problematic in population studies with large numbers of subjects.

The standard gamble appears to be more successful with highly educated respondents. The time trade-off method, while expensive, has been found to be easier for respondents than the standard gamble. In general, the category ratings methods are least expensive and easiest to understand.

One indication of a scaling method's acceptability to respondents is response rate, although response rate is influenced by other variables as well. High response rates have been achieved with all methods. Both the likelihood of response and plausibility of response increased with education.

Torrance reports that participation rates were lowest for the general public (70-80%) and highest for those with a special interest in research, like patients or clinicians (83-100%)

CONCLUSIONS

Based on data concerning their reliability, validity, and feasibility, the most promising scaling methods are the category ratings, magnitude estimation, and the time

trade-off methods. The category ratings method is easiest to administer, and appears to yield scale values that are as valid as any other method. Thus, in large-sample studies, this would seem to be the method of choice.

The time trade-off method is more expensive and difficult to administer than the other two methods, but several studies support its validity. Unlike the category ratings and magnitude estimation methods, it asks respondents to make a decision. Having to make a decision about the number of years one would give up to be in a healthy state may lead to more thoughtful consideration of each health state. However, a potential difficulty with the time trade-off is that individuals probably discount years in the future, viewing them as less important than current year. Thus, it cannot be assumed that every year ''trade off'' has the same value.

When the decision problem under study involves uncertainty, as do most clinical decisions, the standard gamble may have particular value due to its risk orientation, but it is not recommended for population studies because it is complex, expensive and difficult to administer.

However, decision-oriented methods, particularly the time trade-off and standard gamble, may be more effective in small-scale investigations and individual decision making.

2.16 METHODOLOGY FOR MEASURING HEALTH-STATE PEFERENCES: POPULATION AND CONTEXT EFFECTS

Evidence suggests that certain characteristics of the rater, such as medical knowledge or experience with and illness, may influence his or her judgments. Also, the way health states are defined, labeled, and presented has been demonstrated to influence rater judgments; even subtle changes in wording can produce preference reversals. A

question that has arisen in this context is whose valuations should be incorporated into an index.

Demographic characteristics

Numerous studies have found no differences in preferences attributable to sex or age. The only exception is Sackett and Torrance's finding that the utility values associate with 6 of their 15 disease-specific health states were associated with age. Older persons assigned lower utility to dialysis and transplantation, but higher utility to hospital confinement for and unnamed contagious disease.

Neither SES nor professional status appears to influence preferences , nor do other demographic variables such as race, nationality, marital status, political persuasion, or religion. Additional studies with adequate power to detect differences are needed to increase confidence that preferences do not depend upon demographic characteristics.

Medical knowledge experience with illness

Sackett and Torrance found that the health state of the respondent was related to utilities for some but not all heath states; for example, home dialysis patients assigned higher utility to kidney dialysis than did the general public. This finding has prompted speculation that most patients with a particular disease or disability learn to cope with it, and therefore the general public's fear of and disutility for a condition may be exaggerated. In a more recent study. Llewellyn-Thomas et al. reported that the rater' s own health status did not influence ratings.

Carter et al. compared the ratings of a group of health professionals (physicians, nurses and health administration students) with those of a random sample of enrollees of a prepaid health plan. Although the ordering of item did not differ, the consumer judges tended to assign higher scale values than the health professional. In a study of nursing

home outcomes. Kane et al. reported that the importance attributed to a particular health domain varied substantially with the type of respondent. In particular, significant differences were noted between nursing home residents; of the nonresident groups, family member ratings deviated most from the overall mean ratings.

Among Wolfson et al. S 840 pairwise comparisons among physicians. Physical and occupational therapists, family members of stroke patients, and stroke patients, only 15 pairs were statistically significant. Rosser and Kind performed 14 pairwise comparisons among patients, nurses, physician, and healthy volunteers and found two significant differences; medical patients vs physicians and medical patients vs psychiatric patients.

At this time, reports of no differences among rater groups outweigh those showing significant differences.

On the whole, the literature on rater differences suggests that while age and experience with the health state being rated (not general health status) may influence raters valuations, the effects of most other demographic and experiential/medical variables are small or nonexistent. Torrance's conclusion that ''differences in valuations attributable to the personal characteristics of respondents are trivial when compared with the differences that might arise from the alternative methodologies used to create an index in the first place''

It should be emphasized that this does not mean people always express similar preferences for health states. In fact, Sackett and Torrance reported a standard deviation of 0.30 for a distribution of health preferences on a 0-1 scale, indicating that respondents differed greatly in their preferences. Since empirical evidence suggests that these individual differences cannot be adequately explained by variables such as age, sex, socio-economic status, religion, illness, and other personal characteristics, the more important questions may involve the implications of using an average weight to represent a particular population.

Perhaps, we should be as concerned about the variability of preferences within groups as we have been about variability between groups.

Fortunately, the bulk of the evidence points to no systematic preference differences among rater groups due to demographic characteristics. However, the finding that age and experience with the health state being rated are associated with preference values suggests that, in some cases.

INCONSISTENCIES DUE TO LIMITATIONS IN HUMAN JUDGMENT

Most inconsistencies in preferences for health states that are due to limitations in human judgment arise when the same objective alternatives are viewed in relation to different points of reference. Tversky and Kahneman have analyzed this phenomenon on a variety of situations, calling these inconsistencies ‘’framing effects’’. For example, they show that when respondents are given a choice between two programs, they preferr one program when outcomes are defined in terms of the number of lives the program will save, but a different program when the same outcomes are defined in terms of the number of lives that will be lost. This reversal of preferences occurs despite the fact that the two situations are effectively identical. ‘’Because of imperfections of human perception and decision.

Anchoring effects

Sutherland et at. found that values assigned to health states using rating scales were strongly influenced by the anchors on the scale. Even the standard gamble has been shown to be internally inconsistent. In one study, the standard gamble yielded inconsistent results when other outcomes were substituted for the outcomes of perfect health and death. Hershey et al. Provide further evidence that variations in probabilities and outcome levels as well as other variations in the way the standard gamble is applied induce systematic bias in utility functions.

Labeling effects

Torrance [9] found that labels had a significant effect on preferences; specifically, tuberculosis was preferred to an unnamed contagious disease and mastectomy for injury was preferred over mastectomy of breast cancer. However, one could argue that in both of these studies, labeling had the effect of providing more information to subjects about the health state; thus the resulting change in preferences should not be considered bias or error.

Outcome description effects

Several studies have shown that variations in the way outcomes are described can affect preferences. Twice it has been demonstrated that framing a clinical decision making problem in terms of the probability of dying produces different preferences that framing it in terms of probability of surviving. By using various combinations of positive, negative, and mixed frames, O'Connor et al. concluded that the negative frame (probability of dying) appeared to be the biased one.

INCONSISTENCIES DLE TO SITUATION-SPECIFIC VARIABLES

Prognosis and duration

Unfortunately, the field of health status measurement has been hampered by differences in the way investigators have handled prognosis in the way investigators have handled prognosis and duration. Because of these differences, scale values for various multiattribute health indexes are not directly comparable. For example, scale values for the Sickness Impact Profile were obtained by asking judges to rate the severity of dysfunction described in an item without regard for what may be causing it. No mention is made of prognosis or duration. On the other hand, Torrance et al. asked subjects to imagine being in each state for a lifetime.

Rosser and kind found that changing the prognosis from treatable to permanent had very minor effiects on scale values. In contrast, Sackett and Torrance demonstrated that the utility as signed to a health state decreased as the duration of time in the state increased. Since these two studies were methodologically so different, particularly with respect to health-state description and scaling methods, we cannot speculate about reasons for the contradictory findings.

Mode of presentation

Body et al. Compared the preference values assigned to health states for (1) scenarios relating to laryngeal cancer patients ability to carry out various activities and (2) a combination of the scenario and a voice recording. They found that scores assigned to the scenarios alone differed significantly from those assigned to the combination. In some cases scenarios alone were rated higher than the combined scenario/voice recording, whereas in other cases the reverse was true. In as another study the information contained in the narrative form was more specific than in the outline form, and it also included more problems.

This leaves the question which type of format produces the most valid preference values. In the absence of such information, we surmise that moderately detailed health-state descriptions yield more accurate judgments of preference than either very scant descriptions or very lengthy descriptions that run the risk of overloading the rater's information processing capacity.

WHAT TO DO ABOUT CONTEXT EFFECTS

When inconsistencies result from judgment errors, interviewers can help raters to resolve them. When inconsistencies result from the effects of situation-specific variables, we can attempt to standardize conditions across studies, or if that is not desirable or

feasible, we should view preferences as having validity only within the context in which they were measured.

2.17 Measurements of Vision Function and Quality of Life in Patients With Cataracts in Southern India

Fletcher et al. (1997) developed and validated vision function (VF) and quality of life (QOL) instruments in patients with cataracts in the context of large volumes surgery in a developing country. The instruments were developed using a consensus approach. One hundred patients who were undergoing cataract surgery at Aravind Eye Hospital, Madurai, India, were interviewed preoperatively and 3 and 12 months postoperatively. Standard clinical procedures were followed, including measurement of visual acuity. They found that visual acuity was measured by use of the Early Treatment of Diabetic Retinopathy Study (ETDRS) tumbling E charts with the logarithm of the minimal angle of resolution (longMAR) scores. The logMAR score is closely approximated by the logarithm of the reciprocal of the traditional Snellen visual acuity. The ETDRS logMAR scale is linear with a 0.1 difference between lines on the chart..

The levels of visual acuity that were classified as counting fingers, hand movements, and light perception were assigned visual acuity values of 1/200 (2.3), 0.5/200 (2.6), and 0.25/200 (2.9).

Preoperative scores from the VF and QOL instruments were significantly associated with visual acuity (r = 0.4),which were demonstrated in table 1

Table 1. Vision Function and Quality of Life Scale Scores Preoperatively and 3 and 12 Months Postoperatively*

	Score, Mean (SD)			
		Postoperatively		
Category	Preoperatively	3 mo	12 mo	Est
Vision function				
General	9.8 (15)	66.3 (20)	66.7 (12)	3.7
Visual perception	20.4 (17)	83.6 (18)	83.9 (22)	3.6
Peripheral vision	19.3 (21)	77.9 (24)	80.7 (24)	2.8
Sensory adaptation	21.5 (18)	79.4 (16)	76.8 (21)	2.9
Depth perception	29.5 (31)	89.1 (20)	86.3 (23)	1.8
Total	20.5 (17)	80.5 (17)	79.8 (20)	3.5
Quality of life				
Self-care	53.2 (27)	92.9 (13)	92.7 (17)	1.4
Mobility	32.9 (24)	86.0 (19)	85.4 (23)	2.2
Social	45.1 (33)	87.2 (22)	85.9 (27)	1.2
Mental	58.0 (30)	86.3 (21)	87.6 (25)	1.0
Total	48.0 (23)	88.9 (15)	88.5 (20)	1.7

** CV indicates coefficient of variation (adjusted for age,gender,literacy,and treatment);logMAR,logarithm of the minimal angle of resolution*

source: Fletcher et al. (1997), Measurements of vision function and quality of life in patients with cataracts in Southern India

Internal reliability (Cronbach α) was greater than .9. Both instruments showed large changes after surgery, with effect sizes of 3 or greater for most VF scales (range, 1.8-

3.7) and 1 or greater for QOL scales (range, 1.0-2.2). Changes in visual acuity after surgery were correlated with changes in the VF (r = 0.44) and QOL (r = 0.41) scale scores. Between interviewer reproducibility was acceptable (total VF scale, Spearman r = 0.74). They mead the conclusions that the study provided strong evidence for the validity, reproducibility, and responsiveness of the instruments, and for the feasibility of using them in the setting of a large volume of cataract surgery in a developing country.

INSTRUMENT DEVELOPMENT

VF QUESTONNAIRE (Table 2)

The following areas were assessed by the VF questionnarie: general, a single question that assessed overall VF (question 1); visual perception, limitation in everyday activities and visual acuity (question 6); sensory adaptation, light-dark adaptation, visual search, color discrimination, and glare disability (questions 7a , 7b, 8, 9, 11a, and 11b); and depth perception, a single-question scale (question 10).

QOL QUESTIONNAIRE (Table 3)

The following areas were assessed by the QOL questionnaire: self-care (ie, bathing, dressing, and toileting); mobility (ie, walking to the homes of neighbors, walking to shops, and doing household chores); social (ie, attending social functions and meeting with friend); and mental (ie, feelings of a burden on others, dejection, and loss of confidence). The questions with regard to the help that a patient received were not used to modify the scoring system but to provide additional descriptive information.

SCORING OF VF QOL QUESTIONNAIRES

For both the VF and QOL questionnaires, the subscales were defined on the basis of best judgment. Simple scoring schemes were used for both questionnaires. For each

response, the 4-point rating scale was scored from 1 (no problems) through 4 (maximum problems), with 2 and 3 for the intermediate rankings. For each subscale, the score was calculated as the cumulative total of individual item responses expressed as a percentage of the maximum score possible. For questions 7a, 7b, 11a, and 11b in the VF questionnaire, the subscale score was based on the represented the greater degree of a problem. Scales were calibrated between 100 (''best'' possible score, ie, no problems in performing any of the functions in that subscale) and 0 (''worst'' possible score, ie, maximum disability on every item in the subscale). The overall VF and QOL scale scores were calculated by aggregating across all items in each scale. Additionally, satisfaction with treatment was measured by 3 questions on a 5-point rating scale: overall satisfaction, visual acuity compared with that before surgery, and recommendation to a close relative regarding surgery.

Table 2. Vision Function Questionnaire*

Question No.	Question	Rating			
		Not at All	A Little	Quite a lot	A Lot
1	In general, would you say your vision (with glasses of you wear them) is:	1 (very good)	2 (good)	3 (fair)	4 (poor)
2	To what extent does your sight limit you in your daily activities ?	1	2	3	4
3	How much problem do you have recognizing people across the street ?	1	2	3	4
.4	How much problem do you have recognizing The face of a person standing near you ?	1	2	3	4
5	How much problem do you have recognizing small or minute objects (such as grains or the lines in your hand) ?	1	2	3	4
6	When you are walking along, how much problem do you have noticing objects off to the side ?	1	2	3	4
7a	How much problem do you have adjusting to darkness after being in bright light ?	1	2	3	4
7b	How much problem do you have adjusting to brightness after being in dark place ?	1	2	3	4
8	How much problem do you have locating something when it is surrounded by a lot of other things (like finding a specific food item on your plate) ?	1	2	3	4
9	How much problem do you have in recognizing colors ?	1	2	3	4
10	When you reach for an object (eg, to take a glass), how much problem do you have in finding it, because it is further away or closer than you thought?	1	2	3	4
11a	How much problem do you have in recognizing a person when you are in bright light?	1	2	3	4
11b	How much problem do you have seeing with bright lights shining on your eyes (such as from an oncoming bus or car)?	1	2	3	4

source: Fletcher et al. (1997), Measurements of vision function and quality of life in patients with cataracts in Southern India

Table 3. Quality of Life Questionnaire*

Activity	Rating				Does Someone Help You?	
	Not at All	A Little	Quite a lot	A Lot	Reply1	Reply 2
Self-care						
How much problem do you have because of you vision in doing the following activities unaided?						
Bathing	1	2	3	4	yes	No
Eating	1	2	3	4	yes	No
Dressing	1	2	3	4	yes	No
Toileting	1	2	3	4	yes	No
Mobility						
How much problem do you have because of your the following activities unaided ?						
Walking to neighbors	1	2	3	4	yes	No
Walking to shops	1	2	3	4	yes	No
Doing your usual household chores	1	2	3	4	yes	No
Social						
Because of your visual problems, do you feel less inclined to participate in the following?						
Attending social functions like weddings, funerals, festivals	1	2	3	4	yes	No
Meeting with friends and relatives	1	2	3	4	yes	No
Mental						
Because of your vision problem do you feel:						
A burden on others	1	2	3	4	.....	.....
Dejected	1	2	3	4	.....	.....
Loss of confidence in doing usual activities	1	2	3	4	.....	.....

source: Fletcher et al. (1997), Measurements of vision function and quality of life in patients with cataracts in Southern India

In univariate analyses, no effect of sex or age was seen. Literacy was significantly related to the sensory adaptation subscale and the total VF scale score, with illiterate patients reporting poorer VF than literate patients. Illiterate patients also reported significantly more problems with self-care. Multivariate analyses, including literacy, age, sex, and the logMAR score, confirmed the highly significant influence of visual acuity on the VF and QOL scales, with the exception of peripheral vision where the relationship was weaker ($P < .1$). Nineteen percent of the variance in the total VF scale score and 16% of the total QOL scale score were explained by the model, with visual acuity being the major explanatory variable. Postoperative scores at 3 and 12 months were almost identical, suggesting that no further improvement or deterioration took place during the longer follow-up period. More than 90% of the patients reported that they were highly satisfied with the results of their surgical procedures. Changes in the VF and QOL scale scores between baseline and 1 year were highly correlated with changes in visual acuity (Figure 1 and Figure 2).

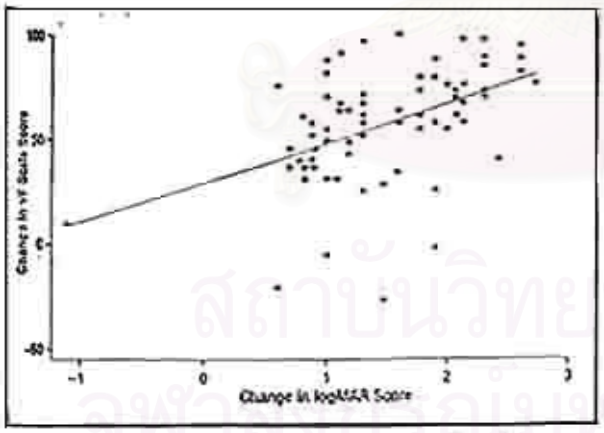

Figure 1. Change in vision function (VF) scale score vs change in logarithm of the minimal angle of resolution (logMAR) score. Seventy-one points are shown; 12 points represent more than 1 patient (n=63; r=0.4476; P<.01).

Source : Fletcher et al (1997), Measurement of vision function and quality of life in patients with cataract in Southern India

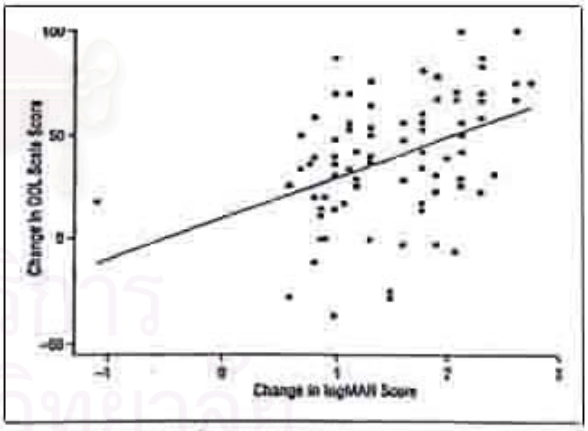

Figure 2. Change in the quality of life (QOL) scale score vs change in the logarithm of the minimal angle of resolution (logMAR) score. Eighty-two points are shown; 1 point represents more than 1 patient (n=63; r=0.4069; P<.01).

Source : Fletcher et al (1997), Measurement of vision function and quality of life in patients with cataract in Southern India

In the VF questionnaire, the strongest relationships were found for visual perception and depth perception, with visual acuity explaining 18% and 21% of the variance, respectively, in those subscales. The association with sensory adaptation was weaker, with visual acuity explaining 11% of the variation in the subscale a correlation coefficient of 0.34. The weakest association with visual acuity was for peripheral vision, with visual acuity explaining only 1% of the variability and a correlation coefficient of 0.2. The association of visual acuity with the QOL scales was strongest for the self-care and mobility subscales and weaker for the social and mental subscales. Nineteen percent of the variance in self-care and 15% of the variance in mobility were explained by visual activities and independent mobility, while social and mental functioning may also be determined by the individual's own personal reaction and adaptation to loss of vision.

Both the VF and QOL questionnaires were highly responsive to cataract surgery. Changes in visual acuity were associated with changes in the VF and QOL scale scores, explaining 17% and 12% of the variance in these total scores, respectively, with correlations of 0.44 and 0.41. This compares with a correlation of 0.07 in 1 study.[15] Our results suggest that visual acuity alone does not capture the full impact of cataract surgery on patients' everyday activities. Visual acuity did not explain the large ES for peripheral vision and sensory adaptation or for social and mental functioning.

Effect size is a method for interpreting changes in scores by examining the relationship of the change in score to its SD at baseline when patients are in a stable situation. It is generally considered that ESs of 0.3 , 0.5, and 0.8 or greater represent small, moderate and large effects , respectively. In this study, ESs for cataract surgery were all greater than 1 for the QOL scales and close to 3 or greater for most of the VF scales. (presented in table 4).

Table 4. Vision Function and Quality of Life Scale Scores Preoperatively and 3 and 12 Months Postoperatively*

	Score, Mean (SD)			
		Postoperatively		
Category	Preoperatively	3 mo	12 mo	Est
Vision function				
General	9.8 (15)	66.3 (20)	66.7 (28)	3.7
Visual perception	20.4 (17)	83.6 (18)	83.9 (22)	3.6
Peripheral vision	19.3 (21)	77.9 (24)	80.7 (24)	2.8
Sensory adaptation	21.5 (18)	79.4 (16)	76.8 (21)	2.9
Depth perception	29.5 (31)	89.1 (20)	86.3 (23)	1.8
Total	20.5 (17)	80.5 (17)	79.8 (20)	3.5
Quality of life				
Self-care	53.2 (27)	92.9 (13)	92.7 (17)	1.4
Mobility	32.9 (24)	86.0 (19)	85.4 (23)	2.2
Social	45.1 (33)	87.2 (22)	85.9 (27)	1.2
Mental	58.0 (30)	86.3 (21)	87.6 (25)	1.0
Total	48.0 (23)	88.9 (15)	88.5 (20)	1.7

*Scores are given for 83 patients with data at all time points. All changes at 3 and 12 months are significantly different from baseline at $P < .001$ or greater.

The effect size (ES) is calculated as the difference between the baseline and 12-month scores/SD at baseline, according to Kazis et al.

source: Fletcher et al. (1997), Measurements of vision function and quality of life in patients with cataracts in Sothern India.

These ESs are compatible with the profound effects of cataract surgery and are evidence of the high responsiveness of both questionnaires. The large ESs also give reassurance that the questionnaires will be responsive to differences in improved VF and QOL between different surgical options if such differences do exist. These between-treatment ESs will be of a much smaller order. The development of the instrument described in this study will enable the comparative effects of surgical treatments on the everyday well-being of patients to be evaluated and, hence, provide a comprehensive and meaningful picture of treatment benefits.

2.18 Visual functioning and quality of life outcomes among cataract operated and unoperated blind populations in Nepal

Pokharel , Selvaraj, Ellwein (1991) evaluated visual acuity and vision related quality of life outcomes in cataract surgery in a population based survey in two geographic zones (Lumbini and Bheri zones) of Western Nepel.

The VF/QOL questionnaires used in this study originated in a large scale clinical trial of the comparative safety and efficacy of ICCE and ECCE in Madurai, India.(Fletcher, et al, 1997) ***The VF score does not include the general vision question.***

VF/OQL INTERVIEWING

All people with presenting visual acuity of < 6/60 in either eye were referred for VF/QOL interviews. All cataract surgery suspects were also interviewed, regardless of visual acuity levels. Additionally, a one in 20 sample of individuals with normal or near normal vision (6/18 in both eyes) was administered the VF/QOL questionnaires. (Wording in the QOL questionnaire is not appropriate for individuals not experiencing a vision problem, and so it was not administered to the full normal sample.)

The researcher found that on a 0-100 scale, mean VF and QOL scores were 87.2 and 93.9 respectively in normally sighted unoperated individuals, dropping to 15.6 and 29.5 for those severely blind (<3/60). Among the cataract operated, mean VF and QOL scores were 47.5 and 55.4, respectively. VF and QOL scores correlated with vision status at statistically significant levels ($P < 0.0001$)

Responses in both VF and QOL questionnaires had high internal consistency. For the total VF scale, the Coronbach alpha was 0.97 ($P < 0.0001$), with item total correlations ranging from 0.66 to 0.88. For the total QOL scale, the Cronbach alpha was also 0.97 ($P < 0.0001$), with item total correlation ranging from 0.78 to 0.90. The association between mean scores and vision status is very strong for each VF and QOL subscale (Kruskal-Wallis $P < 0.0001$).

In linear regression analysis, 60.8% of the observed variability in total VF scores can be explained by vision status alone. Adding socio-demographic variables in a multiple regression model explains 66.5% of score variance. In addition to vision status, age, and zone are statistically significant (Wald test, $P < 0.0001$); sex ($P = 0.130$), literacy ($P = 0.793$), and urban/rural area ($P = 0.706$) are not. Regression analysis of total QOL scores yields similar results: vision status alone explains 42.3% of the observed score variability. With multiple regression, 50.5% of the variability is explained, along with vision status, by age ($P < 0.0001$), zone ($P < 0.0001$), and sex ($P = 0.011$) at statistically significant levels; literacy ($P = 0.408$) and area ($P = 0.356$) are not significant. VF and QOL scores decrease with older age, residence in Bheri zone, and female sex.

The researcher concluded that VF and QOL outcomes parallel visual acuity outcomes. VF and QOL scores were significantly associated with visual acuity in both unoperated and operated cases (evidence as to the validity of the questionnaires).And suggested that vision and its impact on activities of daily living apparently goes far beyond what is measurable in the clinic with the Snellen chart.

2.19 Visual Acuity and Quality of Life in Patients with Cataract in Doumen County, China

He, et, al. (1999) evaluated the effectiveness of cataract surgery in achieving sight restoration and vision-related quality-of-life (QOL) in patients from rural southern China. They used the Early Treatment Diabetic Retinopathy Study tumbling E chart (Precision Vision, Villa Park, IL) in 5288 of the 5342 participants examined. Presenting visual acuity measurement (with usual correction) was followed by measurement with pinhole in all with presenting acuity less than 0.63.

Main outcome measures : decimal visual acuity , VF and QOL questionnaire scores

The VF/QOL questionnaires used in this survey originated in a large-scale clinical trial of cataract surgery at the Aravind Eye Hospital in India. These Chinese versions were used here. The questionnaires were also administered successfully in a recent survey in Nepal.

The VF questionnaire consists of four subscale: visual perception (four question dealing with activity limitation, near vision, intermediate vision, and distance vision); peripheral vision (one question); sensory adaptation (six questions dealing with light/dark adaptation, visual search, color discrimination, and glare disability); and depth perception (one question). ***The VF score does not include the general vision question.***

The 12 questions in the QOL instrument deal with self-care (bathing, eating, dressing, toiletting), mobility (walking to neighbors, walking to shops, doing household chores), social interaction (attending social functions, meeting friends), mental well-being (burden on other, dejection, loss of confidence). Using a four-point scale, each question asks about the extent to which the individual is currently experiencing a difficulty, from ‘’not at all’’ to

‘’a lot.’’ The QOL questionnaire addresses difficulties attributable specifically to vision problems. Subscale scores were linearly transformed so that a score of zero reflected a maximum difficulty level and 100 reflected the absence of any difficulty.

They found that on a 0 to 100 scale, mean VF and QOL scores for the cataract operated population were 41.6 and 54.5, respectively. Mean scores ranged from 84.4 and 93.4, respectively, for the unoperated persons with normal vision, to 14.6 and 31.2, respectively, for those with visual acuity less than 0.05 in both eyes. The VF and QOL scores were closely correlated with presenting visual acuity in both cataract operated and unoperated populations (r = 0.49-0.64). Scores among the cataract operated population were not influenced by age, gender, or education level. Among the unoperated population, lack of education was associated with lower VF and QOL scores (P = 0.017 and P = 0.005, respectively), and older age was associated with lower QOL scores (P < 0.001).

Vision Function and Quality-of Life Outcomes

The VF and QOL interviews were successfully completed in 99 (90.8%) of the 109 cataract operated individuals and in 535 (85.5%) of 626 unoperated individuals with presenting visual acuity less than 0.10 in at least 1 eyes. One hundred nineteen subjects with normal/near-normal vision were also interviewed.

For the total VF scale, the internal consistency of responses to the 12 questions as measured by the Crombach alpha statistic was 0.958. Deletion of any question resulted in a lowering of the alpha statistic, indicating that each question produced responses consistent with the total scale. The item-total score correlations ranged from 0.682 to 0.845.

The internal consistency of responses in the QOL questionnaire was equally strong (Crombach alpha = 0.953). The question dealing with being a burden to others because of a vision problem was borderline in term of consistency with the total QOL scale , item-total

correlation of 0.446. (The Crombach alpha increased marginally to 0.958 with is deletion.) The item-total correlations for the other questions ranged form 0.715 to 0.856.

Table 1 presents interview information from the cataract operated subjects. Mean VF/QOL scores decreased consistently across all subscales with reduction in vision status. The strong correlation between VF/QOL subscale scores and visual acuity is evidenced by Spearman correlation coefficients ranging from 0.362 to 0.475.

Table 1. Visual Function (VF) and Quality of Life (QOL) Mean Scores and Standard Deviations by Presenting Visual Acuity Status for Cataract Operated Individuals

	Presenting Vision Category						
	Normal	*Vision Impairment*	*Unilateral Blindness*	*Moderate Blindness*	*Severe Blindness*	*All*	
No. of cases	8	14	45	15	17	99	
Median age (yrs)	63	75	74	76	74	74	Spearman
% male	37.5	50.0	46.7	40.0	23.5	41.4	Correlation
% illiterate	12.5	57.1	35.6	80.0	70.6	49.5	Coefficient
VF scales							
Vision perception	75.00 ± 15.43	43.45 ± 27.57	46.48 ± 28.28	28.33 ± 25.74	16.18 ± 24.02	40.40 ± 30.10	0.471
Peripheral vision	83.33 ± 17.82	45.24 ± 30.96	39.26 ± 38.46	28.89 ± 33.01	13.73 ± 23.74	37.71 ± 36.78	0.412
Sensory adaptation	70.83 ± 16.06	42.86 ± 22.37	39.82 ± 28.37	25.56 ± 24.69	14.71 ± 20.53	36.28 ± 28.45	0.475
Depth perception	91.67 ± 15.43	59.52 ± 35.03	54.82 ± 33.45	46.67 ± 17.03	23.53 ± 36.83	51.85 ± 37.56	0.400
Total VF	80.21 ± 13.08	47.77 ± 24.29	45.09 ± 27.50	32.36 ± 25.01	17.03 ± 21.06	41.56 ± 29.02	0.494
QOL scales							
Self care	91.6 ± 11.79	63.10 ± 26.09	67.96 ± 27.92	50.00 ± 33.18	37.26 ± 34.88	61.20 ± 31.97	0.390
Mobility	87.50 ± 15.07	58.73 ± 30.33	55.31 ± 31.56	31.11 ± 26.96	29.41 ± 37.05	50.28 ± 34.35	0.448
Social	83.33 ± 13.90	59.52 ± 40.15	42.59 ± 38.20	32.22 ± 31.79	17.65 ± 29.15	42.59 ± 38.48	0.438
Mental	88.89 ± 11.88	77.78 ± 27.56	64.44 ± 31.48	48.15 ± 23.63	53.60 ± 33.85	63.97 ± 30.95	0.362
Total QOL	88.37 ± 9.64	64.78 ± 27.04	57.58 ± 27.74	40.37 ± 24.08	34.48 ± 26.34	54.51 ± 29.30	0.489

The relationship between visual acuity and VF is further demonstrated in a univariat regression analysis, in which 26.8% of the variance in the VF total score was explained by visual acuity status (treated as an ordinal variable; $P < 0.001$). In a multivariate model amount of VF score variance explained by vision status did not increase, suggesting that the VF responses were in dependent of age, gender, and education level. (Although other socioeconomic expectation, may have influenced responses, this information was no collected.)

Similar results held for the QOL responses. Visual acuity status explained 21.6% of the variance in QOL total scores. Age, gender, and education had no influence in a multivariate model.

The VF/QOL scores for the 654 unoperated individuals are listed in Table 2. The correlation of VF/QOL subscale scores with visual acuity status was even stronger than that with the cataract operate; Spearman correlation coefficients were consistently higher. In univariate analyses, 40.5% of the variance in VF total scores was explained by visual acuity status, and 33.2% of the QOL total score variance was explained, Adding age, gender, and education in a multivariate model increased the explained variance by a small mount to 41.7% and 36.4%, respectively. Significantly lower VF and QOL total scores were obtained from those with no education compared to those with more than 5 years of schooling (P = 0.017 and P = 0.005, respectively). Compared to those 50 to 59 years of age, the 60 to 69 and 70 + year age groups scored lower on the VF total scale (P = 0.138 and P = 0.075, respectively) and on the QOL total scale (P = 0.023 and P < 0.001, respectively). There was no association with gender on either scale.

Table 2. Visual Function (VF) and Quality of Life (QOL) Mean Scores and Standard Deviations by Presenting Visual Acuity Status for Unoperated Individuals

	Presenting Vision Category					
	Normal	*Unilateral Blindness*	*Moderate Blindness*	*Severe Blindness*	*All*	
No. of cases	119	386	58	91	654	
Median age (yrs)	61	71	74	76	70	
% male	51.3	38.3	34.5	35.2	39.9	Spearman Correlation Coefficient
% illiterate	28.6	50.0	60.3	65.9	49.2	
VF scales						
Vision perception	84.45 ± 17.42	48.51 ± 29.37	28.45 ± 26.22	14.01 ± 33.73	48.47 ± 33.73	0.618
Peripheral vision	85.71 ± 23.60	49.83 ± 34.25	33.03 ± 33.54	14.65 ± 26.86	49.80 ± 37.79	0.559
Sensory adaption	73.32 ± 20.52	42.36 ± 28.09	21.55 ± 22.68	10.07 ± 20.28	41.65 ± 31.60	0.601
Depth perception	94.12 ± 12.76	66.32 ± 33.63	46.55 ± 37.43	19.78 ± 30.62	63.15 ± 37.62	0.564
Total VF	84.40 ± 15.70	51.75 ± 27.45	31.89 ± 25.17	14.63 ± 21.91	50.77 ± 32.10	0.636
QOL scales						
Self care	94.68 ± 11.82	73.21 ± 27.76	59.91 ± 31.93	33.70 ± 33.56	70.44 ± 32.14	0.532
Mobility	92.81 ± 12.99	64.85 ± 30.89	43.49 ± 33.25	26.62 ± 34.22	62.73 ± 35.12	0.555
Social	92.86 ± 14.97	61.96 ± 36.04	38.79 ± 38.54	18.13 ± 30.49	59.43 ± 39.33	0.554
Mental	93.37 ± 15.47	71.53 ± 15.45	59.00 ± 32.66	46.27 ± 28.70	70.88 ± 30.73	0.467
Total QOL	93.43 ± 9.64	67.89 ± 27.42	50.30 ± 29.88	31.18 ± 27.63	65.87 ± 31.37	0.587

In general, the unoperated subscale mean scores were higher than those of the cataract operated with similar visual acuity status, except for the severe blindness category, in which the cataract operated scored slightly better.

The correlation between visual acuity measured in a clinical setting and patient-reported VF and vision-related QOL was clear. The performance of the VF/QOL questionnaires and the correlation between scores and vision status are consistent with the original experience in India and with those in both Shunyi County and Nepal, where the same instruments were used.

Although the correlation between visual acuity and patient self-reporting of VF was unambiguous, it was far from absolute . Substantial variation in VF/QOL scores within visual acuity categories existed. Among the unoperated patients, lower scores were associated with the absence of education and older age; gender was not a significant factor. Among the cataract-operated patients, none of these patient characteristics were significant. (Perhaps in a larger study, they would have been.) Socioeconomic factors undoubtedly contribute to the variability in scores. Differences in environmental settings, such as the family support structure, along with attitude and adaptation are potentially important sources of variation. Whatever the circumstance, it is apparent that the limited ‘’clinical’’ setting in which visual acuity is measured is not a full reflection of VF in the real world; it is not a surrogate for direct assessment of VF/QOL.

2.20 Life expectancy at birth and at age 60 classified by region and gender

Region	Life expectancy at birth		Life expectancy at age 60	
	Male	female	Male	female
The whole kingdom	69.97	74.99	20.29	23.89
Bangkok	75.57	79.71	25.41	27.99
The Central Part (excluding Bangkok)	72.15	75.72	20.50	23.26
The North	69.05	75.85	22.01	26.45
The Northeast	68.43	73.71	18.00	22.17
The south	68.11	73.45	20.83	24.59

Source : National statistical office, 1995-1996

2.21 Average Number of years of Life Remaining at Beginning of Age Interval (The whole kingdom)

Age	Male	Female
Under 1 year	69.97	74.99
1-4	71.08	76.05
5-9	67.52	72.39
10-14	62.87	67.08
15-19	58.17	62.90
20-24	53.69	58.37
25-29	49.30	53.91
30-34	44.97	49.45
35-39	40.67	45.00
40-44	36.35	40.53
45-49	32.08	36.12
50-54	27.91	31.71
55-59	23.67	27.61
60-64	20.29	23.69
65-69	17.14	20.20
70-74	14.18	16.89
75-79	11.87	14.60
80 and over	10.90	13.60

Source : National statistical office, 1995-1996

2.23 Ethical consideration

For studies in humans (or involving human biological materials) evidence must be provided that the proposed research has been approved by the local, institutional or equivalent ethics committee and/or the national ethics committee.

A form must be provided with the proposal to indicate that the research subject has decided to take part in the study of her/his own free will.

Selection of subjects should comply with principle of justice. At the level of the individual, justice in selecting subjects requires that researchers exhibit fairness : potentially beneficial research should be offered to all subjects, and risky research must not be confined to persons judged to be “undesirable” by either the researchers themselves or by the society. Social justice requires that neither the benefits or the burdens of research fall disproportionately on a single social, economic, racial, or ethnic group. (world health organization [WHO], 200)

CHAPTER 3

METHODOLOGY

3.1 Study design

This study was a cohort study in which the information of "before and after" surgery was needed. Consequently , the retrospective study was impossible. The study included, by score gained, the vision function (VF) and the quality of life (QOL) before and after the Phacoemulsification with the 3 different brand names of polymethyl methacrylate intraoclar lenses .The data was collected by questionnaires during 1 October 2001 to 22 March 2002 at Lampang Hospital, Thailand.

3.2 Study population

Study population were 150 cataract patients of Lampang Hospital. Who were selected by the opthalmologists with the inclusive criteria (Inclusive/Exclusive Criteria in **3.5** of this chapter), all of whom were interviewed with the questionnaires on VF and QOL before and after the Phacomulsification with the intraocular lens implantation.

3.3 Operational definition

Intra-operative complication = The complication which occurs during the surgery

Post-operative complication = The complication which occurs after the surgery

Visual status data entered in this analysis.

Distance visual acuity	VA	Decimal	LogMAR
1/800 (Light perception)	1	0.00125	2.9
1/400 (Hand motion)	2	0.0025	2.6
1/200 (Counting finger)	3	0.005	2.3
3/200	4	0.015	1.82
4/200	4	0.02	1.7
20/800	5	0.025	1.6
20/400	6	0.05	1.3
20/200	7	0.1	1.0
20/100	8	0.2	0.7
20/70	9	0.28571	0.54
20/50	10	0.4	0.4
20/40	11	0.5	0.3
20/30	12	0.66667	0.18
20/25	13	0.8	0.1
20/20	14	1	0

Note : Counting finger, hand motion, light perception (Flecher et al, 1997).

3.4 Conceptual Framework

The conceptual framework was proposed to describe the ways of acquiring the information and its analysis so as to compare the scores of VF and QOL derived from the same Phacomulsification but the different brand names of intraocular lenses (different prices)

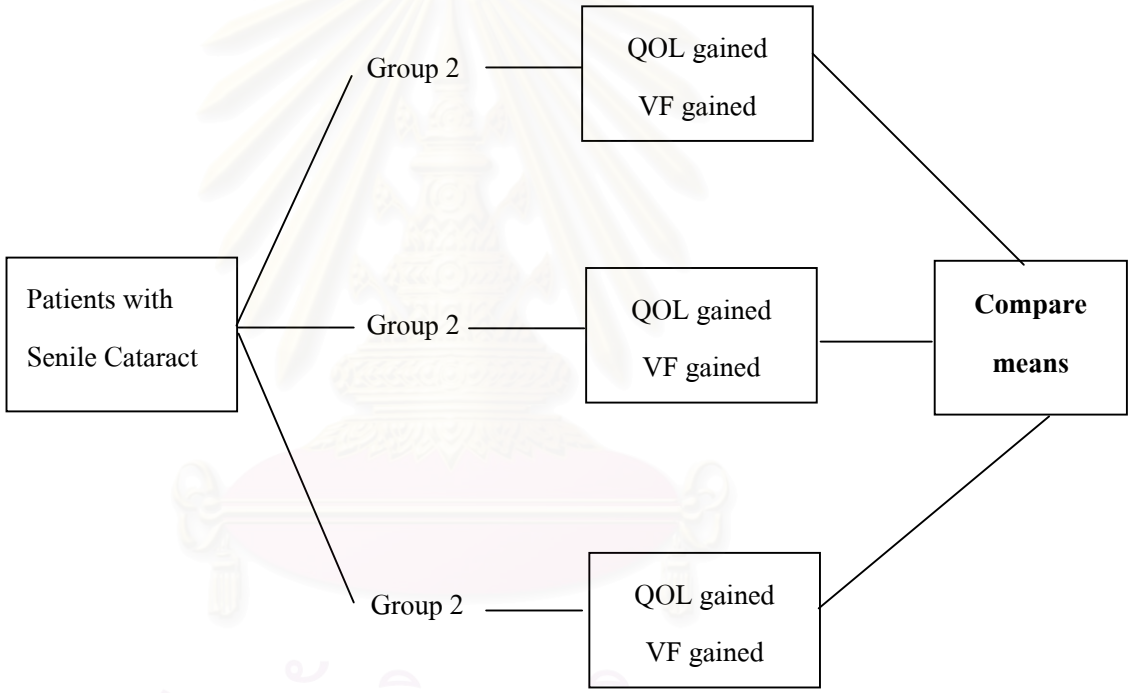

Figure 3.1 Conceptual Framework

3.5 Criteria for the selection of subjects

In order to get the cataract patients of equalized character in clinical status and to avoid the influence of confounding factors, the inclusion/exclusion criteria must have been defined in all of the 3 groups of cataract patients.

Inclusion criteria

Patients with immature or mature senile cataract in at least 1 eye

Exclusion criteria

Senile cataract patients who had such

1) Ocular conditions as :

1.1 Anterior segment eye diseases :

- Refractive error
- Uveitis
- Zonule dialysis
- Advance pterygium
- Strabismus
- Central corneal scar
- Previous ocular surgery

1.2 Posterior segment eye diseases :

- Optic atrophy
- Diabetic retinopathy
- Glaucoma
- Chrorioretinal scar
- Retinal vascular disease

- Chrorioretinitis
- Retinal detachment

1.3 Systemic-associated eye diseases :

- Hypertensive retinopathy

1.4 Genetic-associated eye diseases :

- Retinitis pigmentosa
- Age-related macular degeneration

2) Medical condition as :

- Diabetes mallitus [except for FBS <= 180 mg% (even still controlled by drugs)]
- Hypertention [except for BP <= 160/80 mmHg (even still controlled by drugs)]
- Heart Disease
- Tuberculosis
- Rheumatoid artritis
- Stroke
- Mental condition

3.6 The sample size

Calculation of sample size using Standard Deviation from the study of 16 pilot cases

The formular for n with continuous data (Cochran,1962)

$$n = \frac{\left(\frac{ts}{d}\right)^2}{1 + \frac{1}{N}\left(\frac{ts}{d}\right)^2}$$

t = 1.96 d = 0.05 for SG, VAS, TTO d = 5 for VF, QOL

N= 7,895 (Prevalence of cataract patients in Lampang Province)

	Standard Deviation	Sample size
SG	.30	135.92
VAS	.06	5.53
TTO	.18	49.48
VF	16.26	40.42
QOL	22.60	77.71

(This study would select more of at least 10% of subjects for substitution of the loss-follow- up patients.)

Total 150 cataract patients will be divided into 3 groups :

Lens group 1 would be used in 90 patients

Lens group 2 would be used in 30 patients

Lens group 3 would be used in 30 patients

(This proportion is the previous using of PMMA IOLs brands in January to March 2001 at Lampang Hospital)

Sampling Techniques

After the cataract patients were selected by the established criteria, sampling technique is to be used to select the first 150 patients who were registered for surgery.

3.7 Intervention and treatment allocation

Phacoemulsification with intraocular lens implantation were performed by post-graduate opthalmologists who have at least 5 years' experience in cataract surgery who were assumed to have the same skills.

The patients was stratified to 8 categories by 2 characteristics (2x4). In order to get the cataract patients of equalized character in clinical status and to avoid the influence of confounding factors, some more criteria, other than the inclusion/exclusion criteria mentioned before, must had been defined in all of the 3 groups of cataract patients as follows :

1) Age : Age <= 65 years , and Age > 65 years
2) Visual acuity of better seeing eye

   VA: better than 20/100

   VA: 20/100 to 3/200

   VA: Fc (Finger count) to Hm (Hand motion)

   VA: Pj (Light projection) to Pl (Light perception)

In each category, the intraocular lenses were arranged following the proportion of using PMMA IOLs of different brand names during January to March, 2001 at Lampang Hospital; which are:

At every 5 PMMA IOLs : IOLsA will be used in 3 cases,
IOLsB will be used in 1 case,
And IOLsC will be used in 1 case

3.8 Data collection

1) Preparing the questionnaires for 15 pretests
2) Preparing the final questionnaires for the target group patients: all of them was interviewed to get information about their quality of life (QOL) and vision function (VF) at the time of:

- Pre(immediately)- surgery,
- 2 days after surgery and
- 2 weeks after surgery

By using the following steps:

1) Identifying the health state and describing the elements of health state by using EuroQol classification system
2) Combining the elements of each health state into a single number reflecting the value assigned to that particular health state by interviewing and using the following methods:
   2.1) Standard gamble (only before surgery) , which was applied by supposing that the would-be-surgical eye would be gambled while the other eye was supposed to be absolutely blind (stable factor)
   2.2) Visual analogue scale (Pre and post surgery)
   2.3) Time trade off (Pre and post surgery)
3) Interviewing by VF questionnaire, first developed by Fletcher et al. (Pre and post surgery)
4) Interviewing by QOL questionnaire, first developed Fletcher et al. (Pre and post surgery)

The results of these methods will be tested for construct validity by correlation and regression analysis.

3.9 Data analysis

In this analysis, the valid tools were necessary before going through the step of comparing means of the 3 brands of PMMA IOLs. To find out the validity of the tools, according to Froberg et al(1989), could be conducted by

1.examining the degree to which the results of the relationship between the preferences and other variables were empirically supported

2.examineg the degree to which the results of different scaling methods converge

Test of relationship will be conducted by the method of “partial correlation”.

Following are the steps of the analysis in this thesis :

- Test for construct validity of the indicators by partial correlation and regression analysis
- Calculating the quality of life and vision function scores of each patient (before and after surgery)
- Calculating the mean and standard deviation of QOL and VF scores gained of each PMMA IOLs group.
- Using T-test to calculate (test hypothesis) the following data
  - Comparing VF and QOL gained among the 3 PMMA IOLs Brands
- Calculating the relative risk of complication among the 3 PMMA IOLs Brands that will lead to another aspect for decision making (Using the prospective study in 2 weeks' period after surgery)

CHAPTER 4

RESULT AND DISCUSSION

This chapter provides the results ,as well as their discussions, which follow the objectives and conceptual framework of the study. The study results are divided into 2 parts: The first part deals with descriptive data and the second with analytical data.

4.1 Descriptive Data

Which are divided into 2 parts

4.1.1 Patients characteristics.

4.1.2 Descriptive quantitative data of visual acuity

4.1.1 Patients Characteristics

In this study, 37 cataract patients at Lampang Hospital were interviewed from October 2001 to 22 March 2002 by the designed questionnaires. The results is as follows :

4.1.1.1Sociodemographic characteristics i.e. age , education , family income , visual loss time , literacy , sex , residence area , marital status and occupation

Age characteristic : The mean age was 69.11
Standard deviation was 6.70
Minimum age was 56.
Maximum.age.was.82 .

This was consistent with the report of Singkalwanich et al (1999), which stated that senile cataract were found in the patient of age 52-85. The old age might be one of the problems in interviewing of the complicated SG, VAS, TTO: which might be too difficult of the patients to understand.

Educational level : The mean educational year was 2.5 years

The standard deviation was 1.6 years.

The Minimum educational year was 0 year.

The Maximum educational year was 4 years.

The low level of educational year might be of of the problems in interviewing of the complicated SG, VAS, TTO; which might be too difficult for the patients to understand.

Family income per year : The mean family income was 12,094 THB/year.

The standard deviation was 11,333 THB/year.

The minimum family income was 0 THB/year.

The maximum family income was 60,000 THB/year.

It showed that the cataract patients in Lampang Province came from the poor family who had the mean income only 12,094 THB/year or only 1,000 THB/month.

- **Visual loss time :** The visual loss time is defined as the time during which the patients could feel that they lost their vision capability before they access the clinical service.

The mean visual loss time was 13.38 moths.

The standard deviation was 12.04 months.

The minimum was 1 month.

The maximum was 48 month.

Some patients had too long visual loss time due to the delayed access to the clinical service. It might be partly because of the lack of ophthalmologists, and the lack of intraocular lenses. If these problems can be solved, the visual loss time might be decreased.

- **Literacy :** From 36 observations, there were 27 patients (75%) who were literate and 9 patients(25%) who were illiterate. Some had the chance to learn but can't read. While the others had no chance to learn in school but can read. However, the illiteracy was not the obstacle in VAS test. If they could see and could read the number on scale, the VAS test

can be done. Except that if their better-seeing eye was less than 20/200, they could not read for sure, and the VAS test can't be done accordingly.

- **Sex :** From 37 observations, there were 15 (40.5%) males and 22 (59.5%) females.

- **Residence Area :** From 33 observations, there were 31 (93.9%) patients who lived in rural areas and 2 of them (6.1%) lived in urban areas. This indicated that the majority of the patientswere in the rural areas.

- **Marital Status :** From 36 observations, there were 29 (80.6%) married people, 6 (16.7%) widowed and 1 (2.7%) divorced.

- **Occupation before visual loss :** From 37 observations, the majority were farmers which were 26 (70.3%). The rest were 7 Housewives (18.9%), 1 merchant (2.7%) , 2 unemployed and others was 1 (2.7%).

4.1.1.2 Some clinical pattern.

From 37 observations; 21 were operated on the right eye.

16 were operated on the left eye.

Stage of cataract of right eye, form 36 observations (1 case was invalid)

Immature cataract in 27 eyes (75%).

Mature cataract in 9 eyes (25%).

Stage of cataract of left eye, from 35 observations (2 cases were invalid)

Immature cataract in 25 eyes (71.4%)

Mature cataract in 10 eyes (28.6%).

In this thesis, it was noticeably found that all of the patients had the same stage of cataract in both eyes.

As shown above, the frequency and percentage of cataract stage of both eyes were unequal. It was due to the invalid cases.

4.1.2 Descriptive Quantitative data visual acuity

This part presented the visual of the better-seeing eye at "before" and "2 weeks after surgery" and scores gained from "before" to "2 weeks after surgery" in terms of VA, decimal and logmar.

If considering the mean, it showed that the mean of visual acuity after surgery tended to be better. That was :

- In VA, increasing +3.34,
- In decimal, increasing +.2931,
- And in logmar, increasing -.6280 (The minus sign was normally better, in logmar measurement)

Generally before surgery, the would-be-operated eye was never better than the other. But after surgery, the operated eye mostly turned to be better. However, if considering at the minimum of VA_{13} and $decimal_{13}$(see the table 4.1 on the next page), it was equal to "0" (zero) and the maximum of $logmar_{13}$ was also equal to "0" (zero). It was because in some cases (2 cases), the visual acuity after surgery of the operated eye was equal to the one before surgery, due to posterior capsular rupture in one case, and due to macular hole in another case. And there was 1 case that the visual acuity after surgery was even worse than before surgery due to the bleeding in anterior chamber of the eye (hyphema). It consequently turned out that the better eye was the unoperated eye; in other words, the unoperated eye was the better eye after surgery. And the score gained of visual acuity of better seeing eye was accordingly equal to '0" (zero). Because it was the same eye.

Table 4.1 Visual status of cataract patients at Lampang Hospital

	N	Minimum	Maximum	Mean	Std. Deviation
VA of better eye before surgery	37	3	10	6.54	1.82
Decimal of better eye before surgery	37	.01	.40	.1151	.1017
Logmar of better eye before surgery	37	.40	2.30	1.1396	.4827
VA of better eye 2 wks after surgery	35	7	14	9.97	1.76
decimal of better eye 2 wks after surgery	35	.10	1.00	.4129	.2127
logmar of better eye 2 wks after surgery	35	.00	1.00	.4434	2.2399
VA 13	35	0	9	3.34	2.85
decimal 13	35	.00	.90	.2931	.2439
logmar 13	35	-2.12	.00	-.6280	.6154

4.2 Analytical data

This part was focusing on the "mean comparing" of the vision function and the quality of life scores gained in the cataract patients under Phacoemulsification with the 3 Brands of PMMA IOLs which were :

Brand 1 : IOLs A, from USA., THB 2,000 (USD44.97) / lens (Price in the year 2001)

Brand 2 : IOLs B, from Nepal, THB 600 (USD13.49) / lens (Price in the year 2001)

Brand 3 : IOLs C, from USA, THB 900 (USD20.24) / lens (Price in the year 2001)

Considering which one had the better mean score gained of VF and QOL.

The 4 tools which were selected to be used in this process were VAS, TTO, VF and QOL. As for SG, it was impossible for the process as it was too difficult for the patients to understand the questionnaire tests after surgery.

Before considering the result, it was necessary to examine how much each tool was reliable by studying the reliability and validity of each individual tool.

According to Froberg et al (1988), the reliability was a measure (of a tool) which was relatively free of measurement error, producing consistent result with respect to the scaling of health state. The reliability could be assessed in 3 ways which were intra-rater reliability, test retest reliability and inter-rater reliability.

And as for the validity matter, according to Froberg et al (1988), a scaling method is valid if it accurately measures what it was intended to measure. Validity is generally thought to be 3 types which are : content, criterion and construct. The most popular is construct. And these are so many approaches. But only two of them were hereby demonstrated :

1. To examine the degree to which the results of relationship between preferences and other variables were empirically supported.

2. To examine the degree to which the results of different scaling methods converge

The reliability study in this thesis was not available due to the limitation of time. However, the information of the reliability of VAS and TTO, of Froberg et al, (1988), is on page 40-42 of this thesis. And also the information of the reliability of VF and QOL, of Fletcher et al(1997), exists on page 54. The result of that of Froberg et al and that of Fletcher et al showed that the reliability was rather high.

What was studied in this thesis was the construct validity of the tool which were:

4.2.1 Validity of the tools (Indicators)

So as to find out the validity of the tools, according to Froberg et al (1989), it could be conducted with these 2 ways :

1) To examine the degree to which the results of the relationship between the preferences and other variables were empirically supported.

In this method, visual acuity was to be used as “other variables” because the visual acuity was the most important variable which was currently used in the evaluation of “before” and “after” surgery (follow-up). “Decimal visual acuity” which existed in the research of Ober et al (2000) was brought to be used. Relationship test was conducted by the method of “partial correlation”. The result was as follows:

The relationship between vision and indicators

$Decimal_1$	correlate	SG	P = 0.957	r = -.009	n = 37 wrong sign
	correlate	VAS_1	P = 0.413	r = .150	n = 32
	correlate	TTO_1	P = .697	r = .066	n = 37
	correlate	VF_1	P = .08	r = 0.2953	n = 34
	correlate	QOL_1	P = .286	r = .1943	n = 30
$Decimal_3$	correlate	VAS_3	P = .634	r = .1206	n = 16
	correlate	TTO_3	P = .947	r = .012	n = 35
	correlate	VF_3	P = 0.688	r = .0793	n = 26
	correlate	QOL_3	P = .145	r = .2553	n = 32
$Decimal_{13}$	correlate	VAS_{13}	P = .044	r = .5251	n = 13
	correlate	TTO_{13}	P = .706	r = -.066	n = 36 wrong sign
	correlate	VF_{13}	P = .709	r = .0697	n = 30
	correlate	QOL_{13}	P = .013	r = .4266	n = 31

From the result of the correlation, it indicated that if considering "P" (Probability of significance) ;

Before surgery to 2 weeks after surgery : the scores gained of Dec_{13} was significantly related to QOL_{13} and VAS_{13}.

2) To examine the degree to which the results of different scaling methods converge.

In this method Partial correlation was hereby conducted to test in pair the relationship of the 4 tools which were selected to be used in this process. All of them were VAS, TTO, VF and QOL. The results which were significantly correlated were as follows :

VAS_1	correlate	QOL_1	P=.049	r=.3753	n= 26
TTO_3	correlate	QOL_3	P=.018	r=.3962	n= 33
VF_1	correlate	QOL_1	P=.000	r=.6257	n= 29
VF_3	correlate	QOL_3	P=.002	r=.5568	n= 26
VF_{13}	correlate	QOL_{13}	P=.000	r=.6166	n= 29

From the 2 ways mentioned above, it was concluded that QOL was the best validate tool. VF and VAS were in the middle rank. And the worst was TTO. SG was not available as it was skipped in the post-surgery questionnaire test. By the way, the relationship shown above could be done in another way which was the regression analysis.

4.2.2 The regression analysis

The regression analysis was brought to be studied in this thesis as another way for the purpose of examining the relationship between tools and visual acuity and to see if there was the validity of the tools. Moreover, it was to check whether there were some more significant variables which had the relationship with the tools so as to be the useful information for the following analysis including the mean comparing.

In this part, multiple regression was used by the following processes :

1. Dependent : choosing indicators one by one
2. Independent :
   2.1 Choosing age, time loss, sex, education, literacy, the brand names of PMMA IOLs, family income and the doctors who performed the surgery

Note : The brand name and the said doctors were included in regression only after surgery.

2.2 Combining with the same period of visual status (Decimal)

3. Running Backward at first; if there was an appropriate equation, it would be run again by the Enter method.

Some interesting equations are shown here.

$$QOL_{13} = 32.907 - 26.179\ IOLsC + 52.136\ Decimal_{13} - 23.151\ illitercy$$

$$(14.492) \qquad (19.476) \qquad (11.236)$$

. $$t = \quad -1.806 \qquad 2.677 \qquad -2.060$$

$$\overline{R}^2 = .338 \qquad n=34$$

This equation meant that 33.8% of the variance in the total QOL_{13} scale score were explained by the model. $Decimal_{13}$ was significantly related to the total QOL_{13} scale. In case $Decimal_{13}$ increased 1 score, QOL_{13} would increase 52.14 scores. In this case, QOL_{13} had relationship with $Decimal_{13}$ (visual status). It supported the idea that QOL was the valid tool, which was previously proved. Literacy was significantly related to the total QOL_{13} scale. In case of illiterate patients, QOL_{13} will be decreased 23.15 scores compared to the literate patients.

In case IOLsC was used in the operation, QOL_{13} was reported 26.18 scores poorer than the other brands of PMMA IOLs.

VF_{13} = 63.802 – 24.166 IOLsB – 16.05 Doctor – 25.355 illiteracy

(6.889) (6.383) (7.61)

. t = -3.508 -2.514 -3.332

$\overline{R}^2$ = .452 n = 35

This equation meant that 45.2 % of the variance in the VF_{13} scale score were explained by the model. The use or the no-use of IOLsB was significantly related to the total VF_{13} scale. In case IOLsB was used in the operation, VF_{13} was reported 24.17 scores poorer than the other brands of PMMA IOLs. The factor of doctors was significantly related to the total VF_{13} scale: one doctor who performed the operation resulted in more 16.05 scores of VF_{13} than another doctor. Literacy was also significantly related to the total VF_{13} scale. The illiteracy had 25.36 scores less than the literacy.

VAS_{13} = .553 - .151 IOLsC - .00649 Age - .00000716 faminc + .163 $Decimal_{13}$

(.045) (.003) (.000) (.078)

t = -3.368 -2.593 -2.954 2.077

+ .0858 illiteracy

(.046)

t = 1.874

$\overline{R}^2$ = .510 n = 21

This equation meant that 51% of the variance in the VAS_{13} scale score were explained by the model. The use or the no-use of IOLsC was significantly related to the total VAS_{13} scale. In case IOLsC was used in the operation, VAS_{13} was reported .151 score poorer than the other brands of PMMA IOLs. The factor of age was significantly related to the total VAS_{13} scale. VAS_{13} would increase .006 score at every 1 additional year age. The

family income was also significantly related to the total VAS_{13}: VAS_{13} would decrease .07 score at every increasing THB 10,000/year.

In case $Decimal_{13}$ increased 1 score, VAS_{13} would increase .16 score. The illiteracy had 0.086 score more than the literacy.

Some part of the regression analysis result was in accordance with the previously set objective of the thesis which was to find out whether the different brands of PMMA IOLs effected the scale scores. From the equation which had QOL_{13} and VAS_{13} as dependent variables, the operation with IOLsC had less scores than with IOLsA and IOLsB. And from the equation which had and VF_{13} as dependent variables, the operation with IOLsB had less scores than with IOLsA and IOLsC. In conclusion, the result from the regression analysis indicated that IOLsA was always the best whether measured with QOL_{13} ,VAS_{13} or VF_{13}

4.2.3 Comparing means

In this part, following was comparing means of the scores gained from "before" to "2 weeks after surgery" of ***vision function and the quality of life*** among the 3 brands of PMMA IOLs, which were the major objective of this thesis. As there was unequal variance in some test population, the independent T-test was selected to use to compare in pair, without using "ANOVA"

Comparing means for VAS_{13} among the 3 brands of PMMA IOLs

IOLsA VS IOLsB : When IOLsA compared to IOLsB, the significance (2-tailed) was .520 This meant that the VAS_{13} scores of both IOLsA and IOLsB were not significantly different.

IOLsA VS IOLsC : When IOLsA compared to IOLsC, the significance (2-tailed) was .165.This meant that the VAS_{13} scores of both IOLsA and IOLsC were not significantly different.

IOLsB VS IOLsC : When IOLsB compared to IOLsC, the significance (2-tailed) was .348.This meant that the VAS_{13} scores of both IOLsB and IOLsC were not significantly different.

Comparing means for TTO_{13} among the 3 brands of PMMA IOLs

IOLsA VS IOLsB : When IOLsA compared to IOLsB, the significance (2-tailed) was .277 This meant that the TTO_{13} scores of both IOLsA and IOLsB were not significantly different.

IOLsA VS IOLsC : When IOLsA compared to IOLsC, the significance (2-tailed) was .526 This meant that the TTO_{13} scores of both IOLsA and IOLsC were not significantly different.

IOLsB VS IOLsC : When IOLsB compared to IOLsC, the significance (2-tailed) was .876 This meant that the TTO_{13} scores of both IOLsB and IOLsC were not significantly different.

Comparing means for VF_{13} among the 3 brands of PMMA IOLs

IOLsA VS IOLsB : When IOLsA compared to IOLsB, the significance (2-tailed) was .002 and t-statistics was positive.This meant that the VF_{13} scores of IOLsA was significantly more than IOLsB.

IOLsA VS IOLsC : When IOLsA compared to IOLsC, the significance (2-tailed) was .089 and t-statistics was positive. This meant that the VF_{13} scores of IOLsA was significantly more than IOLsC.

IOLsB VS IOLsC : When IOLsB compared to IOLsC, the significance (2-tailed) was .448 This meant that the VF_{13} scores of both IOLsB and IOLsC were not significantly different.

From the regression analysis of VF_{13}, it is found that

VF_{13} = 63.802 – 24.166 IOLsB – 16.05 Doctor – 25.355 illiteracy

(6.889) (6.383) (7.61)

. t = -3.508 -2.514 -3.332

$\overline{R}^2$ = .452 n = 35

From the above equation, it demonstrated that the factor of doctors which was very important and was a nominal variable, had influence on VF_{13}. To avoid the confounding factors from the doctor variable, the means comparing were run again focusing on doctors (doctor M and doctor N).

Comparing means for VF_{13} in terms of Doctor M among the 3 brands of PMMA IOLs

IOLsA VS IOLsB : When IOLsA compared to IOLsB, the significance (2-tailed) was .012 and t-statistics was positive. This meant that the VF_{13} scores of IOLsA was significantly more than IOLsB.

IOLsA VS IOLsC : When IOLsA compared to IOLsC, the significance (2-tailed) was .092 and t-statistics was positive. This meant that the VF_{13} scores of IOLsA was significantly more than IOLsC.

IOLsB VS IOLsC : When IOLsB compared to IOLsC, the significance (2-tailed) was .597 This meant that the VF_{13} scores of both IOLsB and IOLsC were not different.

Comparing means for VF_{13} in terms of Doctor N among the 3 brands of PMMA IOLs

IOLsA VS IOLsB : When IOLsA compared to IOLsB, the significance (2-tailed) was .021 and t-statistics was positive. This meant that the VF_{13} scores of IOLsA was significantly more than IOLsB

*** IOLsA VS IOLsC and IOLsB VS IOLsC** could not be evaluated due to the too small sample size.

Comparing means for QOL_{13} among the 3 brands of PMMA IOLs

IOLsA VS IOLsB : When IOLsA compared to IOLsB, the significance (2-tailed) was .667 This meant that the QOL_{13} scores of IOLsA and IOLsB were not different.

IOLsA VS IOLsC : When IOLsA compared to IOLsC, the significance (2-tailed) was .355 This meant that the QOL_{13} scores of IOLsA and IOLsC were not different.

IOLsB VS IOLsC : When IOLsB compared to IOLsC, the significance(2-tailed) was .433 This meant that the QOL_{13} scores of both IOLsB and IOLsC were not different.

The result of all the comparing of the means shown above can be simplified as follows:

	IOLsA : IOLsB	IOLsA : IOLsC	IOLsB : IOLsC
VAS_{13}	=	=	=
TTO_{13}	=	=	=
VF_{13}	>	>	=
VF_{13} (& Doctor M)	>	>	=
VF_{13} (& Doctor N)	>	*	*
QOL_{13}	=	=	=

*Can't be compared due to the too small sample size

From the above information, even though the doctors were divided into 2 groups: Doctor M and Doctor N, IOLsA remained the highest scores. In conclusion, IOLsA remained the highest scores in VF_{13}. Accordingly, VF_{13}. in comparing means ,could

presently be considered as the best tool which could tell the difference of the score means for the 3 brands of PMMA IOLs.

However, if we look over the mean regardless of the standard deviation, it could be seen that in every test (tool), it gradually showed that the mean of IOLsA was higher than the others, even in $Decimal_{13}$ as shown in the table 4.2.

Table 4.2 Mean and Standard deviation of VAS_{13}, TTO_{13}, VF_{13}, QOL_{13}, $Decimal_{13}$ among the 3 brands of PMMA IOLs

Tool	Brand	N	Mean	Standard deviation
VAS13	IOLsA	9	8.889E-02	.1054
	IOLsB	8	5.625E-02	9.797E-02
	IOLsC	4	.0000	8.165E-02
TTO13	IOLsA	20	.1302	.2606
	IOLsB	11	3.364E-02	.1654
	IOLsC	5	4.9E-02	.2077
VF13	IOLsA	20	53.3350	17.3597
	IOLsB	11	25.4245	29.3889
	IOLsC	5	37.0320	22.3982
QOL13	IOLsA	20	44.5845	25.4500
	IOLsB	11	40.2164	29.0407
	IOLsC	5	18.4860	55.0875
Deciamal13	IOLsA	19	.3203	.2686
	IOLsB	11	.2543	.2295
	IOLsC	5	.2751	.2028

4.2.4 Relative risk

Calculating the relative risk of complication among the 3 PMMA IOLs brands by the prospective study in 2 weeks' period after surgery.

Among totally 37 patients ;

IOLsA were used in 20 cases, IOLsB in 12 cases and, IOLsC in 5 cases.

There are 7 kinds of complication from 7 patients as follows :

Case no.	Complication	Time of occurrence	IOLs brands
7	Tear posterior capsule	Intraoperative	IOLsA
28	Hyphema	Intraoperative	IOLsA
1	Mild increase IOP*	2 days after surgery	IOLsA
32	Uveitis	2 days after surgery	IOLsB
36	Mild wound edema	2 days after surgery	IOLsB
16	IOL displacement	2 weeks after surgery	IOLsB
27	Pigment&cellular deposition	2 weeks after surgery	IOLsB
32	Pigment&cellular deposition	2 weeks after surgery	IOLsB

*IOP = Intraocular pressure

The number of the complication cases at the moment was too small to calculate in 2X2 table of relative risk which cause the 3rd objective of the study unaccomplished. More information from the rest of the project is necessary for the most accurate result in terms of sensitivity analysis. But the theory of calculation of relative risk can be shown here.

		Look ahead for disease: Yes	Look ahead for disease: No		risk	relative risk
exposure	Yes	a	b	(a+b)	a/(a+b)	$\frac{a(c+d)}{c(a+b)}$
	No	c	d	(c+d)	c/(c+d)	
		(a+c)	(b+d)			

Figure 4.1 Relative risk

CHAPTER 5

CONCLUSION, POLICY IMPLICATIONS AND RECOMMENDATIONS

This chapter consists of the conclusion, the policy implications, the limitations, the further studies and the recommendations of the study.

5.1 Conclusion

The study for this thesis was the starting point of the study of the effectiveness of the treatment by the Phacoemulsification with the intraocular lenses (of different prices) implantation, which basically had the same characteristics : 6 – millimeter diameter, modified C-loop with 1 piece of haptic under the same treatment method which was the mentioned Phacoemulsification. This particular method was one of the most preferable among the opthalmologists for the cataract surgery because of the low-rate complication. It was implemented at Lampang Hospital, Ministry of Public Health, Thailand.

The objective of the study was to compare the vision function (VF) and the quality of life (QOL) by the scores gained after the surgery by using the 3 brands of PMMA IOLs mentioned in the previous chapters, and to find out the risk factors of the complication from the surgery.

Cataract patients were examined and selected by the opthalmologists based on the Inclusive/Exclusive criteria. Those particular selected subjects would be interviewed with the VF and QOL questionnaires, first developed by Fletcher et al. In addition to VF and QOL, the other 3 measurements were SG, VAS and TTO. Then comparing mean of VF and

QOL scores gained among the 3 brands of PMMA IOLs was done. Another thing to be done was the calculation of the risk factors of the complication from the surgery.

There were totally 37 cataract patients for the project which was implemented during October 2001 and March 2002 : 15 males and 22 females. In this amount, the average age was 70 years of age with low educational level and low income. The majority was married. Most of them were farmers who lived in the rural areas. 75% of them were literate. The visual loss time was average 13 months which indicated that there were still a lot of lack-of-treatment cataract patients. Among the 37 operated eyes, they were 21 right eyes and 16 left eyes. As for the stage of cataract : 75% of the 36 right eyes were immature cataract and the rest 25% were mature cataract. 71.4% of the 35 left eyes were immature cataract and the rest 28.6% were mature cataract.

The mean of visual acuity gained from before to 2 weeks after surgery is +3.34 in VA, + .2931 in decimal and -.6280 in logmar.

There were 2 cases of which, before and after surgery, VA of both periods were compared equal. And there was only 1 case that VA after surgery was even worse than before surgery.

As for ***the validity of the tool***, it provided the reliability of the measurements which hereby were the correlation between the tool and the visual acuity concerned, and the correlation between each pair of tools. The best tool was QOL. The middle ranks were VF and VAS. And the worst was TTO. That's why QOL, VF and VAS were accordingly mainly focused.

Some part of the result from the regression analysis was consistent with the set objective of this thesis and answered to the research question: which intervention among the 3 brands of PMMA IOLs provided more quality of life and vision function. That was; IOLs C, when compared with IOLsA and IOLsB, had the lower scores when measured with QOL_{13},VAS_{13}. And IOLsB, when compared with IOLsA and IOLsC , had the lower scores

when measured with VF_{13}. Generally speaking, IOLsA always remained in the top rank, whether measured with QOL_{13},VAS_{13} or VF_{13}.

As for comparing mean, the result showed that IOLsA had the highest score mean of VF_{13} . And if we looked over the mean regardless of the standard deviation, it could be seen that in every test (tool), it gradually showed that the mean of IOLsA was higher than the others, even $decimal_{13}$. It was rather certain that IOLsA had the highest scores. However, if the sample size were larger, it would be more certain.

As for the calculating of complication, the number of the complication cases at the moment was too small to calculate the 2x2 table of the relative risk, which consequently could not accomplish the 3rd objective of this thesis. More information from the rest of the project was necessary for the most accurate result.

5.2 Policy implications

To provide the policy implications of the effective use of PMMA IOLs in cataract surgery from a macro-perspective, all information in this study will be proposed to the authorities of the Thai Eye Institute and also to the authorities of the national level. Based on this study, two policies might need to be adapted.

5.2.1 Choosing of PMMA IOLs

5.2.2 Using QOL and VF as a tool to evaluate the patients or as a measure in clinical research

5.2.1 Choosing of PMMA IOLs

There was some degree of significant difference among the 3 PMMA IOLs brands, in terms of vision function gained from “Before surgery” to “2 weeks after surgery”. And

IOLsA was likely to be Number one, which had the best result. However, it was not able to be finally assumed due to the time limitation and the small sample size. Actually, the time of research should be expanded so as to have more cases, and to achieve the goal in accordance with the protocol which is 2, 6 , or 12 months after surgery, which we possibly can do only with 2 or 6 months after surgery. As, according to Fletcher et al,1997, the result of QOL and VF at 3 and 12 months after surgery are not different.

IOLs A may be the best in quality but the most expensive. Further study should be done to quantify its cost-effectiveness (efficiency), not only the effectiveness as currently assessed. Because if it turns out that IOLsA has better sign in both effectiveness and cost-effectiveness, it should be undoubtedly the best choice.

The government has to bear in mind that the majority of the cataract patients are poor. Therefore the free-of-charge program has to be inevitably promoted. The ones who can afford including the civil servants who can have the compensation for the treatment, are the minority group of the population. And with the budget constraint, the government has to pay careful attention to the problem solving.

Moreover, in the policy implication, both of the ***efficiency*** and the ***equity*** must be simultaneously considered. That is; if the government chooses the cheaper brand which may have more efficiency : lower expenses for the free-of-charge program provided for the population, it might create the inequity in the society. As the poor have no chance to use the high quality lens with lower efficiency. It is in accordance with the ***theory of Efficiency and Equity*** which might be traded off. The government has to find ample information to think it over for the thorough problem solving.

5.2.2 Using QOL and VF as a tool to evaluate the patients or a measure in clinical research

According to this research, it is found that VF and QOL are not too difficult. Consequently the interviewer may not be the health personnel. From the correlation test with the visual acuity, and the correlation test between each pair of tools, VF and QOL are the valid tools. Therefore, it should be useful to have this kind of tool in the follow-up of the treatment outcome. The community hospitals and the sub-district health offices should share the important role in this task, especially the latter part of the follow-up such as 6 months after surgery. The eye-operated patients who live in the remote areas (which are the majority subjects, according to this research) consequently have no need to come into the province hospital so often. Moreover there might be some score criteria for the necessity of the referral system.

Moreover, QOL and VF can be used as indicators in any research of clinical cataract in any hospitals including the university hospitals.

5.3 Limitation

This study was conducted under the time constraint and under the numerous criteria (which were necessary however). Therefore during 5 months there were only 37 cataract patients at Lampang Hospital who were selected for the project which caused some difficulty in finding out some part of information due to the too small sample size. So in some particular part, compiling more cases for re-analyzing are necessary for the clearer information. Moreover, that the relative risk of complication could not be calculated caused the 3rd objective of this study unaccomplished.

Due to the time limitation as mentioned above, this thesis could study only the effectiveness. A further study should be done in the part of the cost-effectiveness (efficiency), not only the effectiveness as currently assessed. In addition, due to the senior and low-educated patients, it tended to cause bias to the answer for the tools, especially SG and TTO. That's why the tools had to be developed from time to time and careful interview was specifically needed. Moreover, in case the patients whose better-seeing eye was less than 20/200, they could not read for sure. So the VAS test hereby could not be done. And this was the reason why the sample size decreased in VAS test.

5.4 Further studies

This study focused only on the effectiveness. However, the cost-effectiveness study is also needed for the decision making of administrative decision-makers and the opthalmologists. Therefore it is needed to study further on the cost of cataract surgery, the cost of complication treatment and the probability of the complication which will be calculated to find out the cost-effectiveness of cataract surgery.

5.5 Recommendations

- The study results showed that the intraocular lenses of different brand names or different prices had an unequal effectiveness. Therefore the results should be disseminated to the opthalmologists and the administrators for the purpose of the database in choosing of intraocular lenses.

- In health policy making, the issue of quality of IOLs should be taken into account. In this study it was found that higher quality of IOLs resulted in higher

VF and higher quality of life. So the quality of IOLs is associated with the VF. Therefore the issue of quality of IOLs should be considered in the health policy.

- There should be more researches of cataract or even any other eye diseases in Thailand in such different matters as clinical knowledge to respond to the problems in the diagnosis and the treatment, or as the matter of health economics or alternatively both. As for the matter of health economics itself, the cost-effectiveness analysis such as the cost-utility analysis of some diseases should be studied to find out which economic-affected diseases have more efficiency so as to help in managing the constrained budget. The comparison of the cost-utility between the cataract surgery and the artificial heart valve transplantation can be an example of this statement. The information in the research can be the database concerning the efficiency (cost-effectiveness) for the government in the budget arrangement to make the most of money.
- The health personnel in the community level like sub-district health officers and the personnel in the community hospitals should be trained to use QOL tool and VF tool. Those particular tools can be used in arranging the priority of the severity of cataract in patients for the referral to the opthalmologists or for the follow-up and evaluation, other than using the visual acuity which was previously the only instrument. The existing treatment including the referral and the treatment follow-up system may be more efficient with the additional QOL and VF. The opthalmologists may study the QOL and VF and set the number which indicates the critical level that the referral is needed. With this way, the patients will acquire more efficient treatment while saving time and cost of travelling and it also reduces the opthalmologists' work load and allows them to do just the necessary things for the patients.

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APPENDICES

APPENDIX I

THE GENERAL QUESTIONNAIRE

Questionnaire

General data (date / /)

Name _____ Age _____ years

Hospital number _____ Admission number _____

Residence ☐ Urban ☐ Rural

Sex ☐ Male ☐ Female

Marital ☐ Married ☐ Single ☐ Widow ☐ Divorce ☐ Separated

Number of people permanently living in the same house as you in the last year

Family size _____ persons

Number of child _____ Number of survived child now _____

Education : How many years did you study?

Education _____ years

Occupation

☐ Agriculyures ☐ Merchants ☐ Employee
☐ Civil servant ☐ Unemployee ☐ House wife
☐ Retired ☐ Other (specified _____)

What is your estimated annual income in the last year?

Annual income _____ Bath

What is your estimated annual household income in the last year?

Annual income _____ Bath

How many visits to health care providers, for example, a hospital, a clinic, a doctor, a health center and a drug store in the last year?

Health care _____ Times

APPENDIX II

DOCTOR RECORD

OF

CATARACT PATIENT

Doctor record of cataract patient

(date / /)

Name _____ Age _____ years

Hospital number _____ Admission number _____

BP _____ PR _____ BT _____ RR _____

Visual acuity : **right eye**_____ **left eye**_____

Stage of senile cataract

- ☐ 1. Incipient cataract
- ☐ 2. Immature cataract
- ☐ 3. Mature cataract
- ☐ 4. Hyper mature cataract

Any other disease _____

_____

Any other symptoms (such as pain from arthritis)_____

_____

Date of operation ____ /____ /____

Operation time (minutes) _____

Type of lens used (code _____)

Any intraoperative complications _____

_____

APPENDIX III

THE QUALIY ASSUARANCE

Food and Drug Administration
2098 Gaither Road
Rockville, Maryland 20850

Certificate No. 5898-7-2000

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

NAME OF PRODUCTS	MANUFACTURER LOCATION
See Attached List (1 Page)	Bausch & Lomb Surgical, Inc. 8342 Jeronimo Road Irvine, CA 92618

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Gene Sullenger
Branch Chief
Information Processing and
Office Automation Branch
Office of Compliance
Center for Devices and
Radiological Health

ตรวจสอบแล้ว
3 ม.ค. 2543

THIS CERTIFICATE EXPIRES 24 MONTHS FROM THE DATE NOTARIZED.

COUNTY OF MONTGOMERY
STATE OF MARYLAND

Subscribed and sworn to before me this 17 day of August month 2000 year.

Donna K. Hibbard

DONNA K. HIBBARD
NOTARY PUBLIC STATE OF MARYLAND
My Commission Expires December 4, 2000

Eng./Nep. Translation
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Nepal Ophthalmic Society

Kathmandu, Nepal

P.O. Box 8750, Kathmandu, Nepal. Phone – 422694, Fax : 977-1-420142 e-mail: bkplcos@healthnet.org.np

Ref. No.

6.9.1999 A.D.

(2056/5/21 B.S.)

No. 13/2542 30 SEP 1999
Certified genuine signature of Mr. Arjun Kant Mainali, Section Officer of the Ministry of Foreign Affairs of Nepal
(Miss Sushmadevi Wagleswasdi)
Third Secretary
Royal Thai Embassy, Kathmandu.

No. 14/2542 30 SEP 1999
Certified true copy
(Miss Sushmadevi Wagleswasdi)
Third Secretary
Royal Thai Embassy, Kathmandu.

Certificate of Free Sale

It is hereby certified that the Fred Hollows Intraocular Lens Laboratory, Tilganga Eye Centre, Kathmandu, Nepal manaufactures the product FH 106 posterior chamber intraocular lenses and is legally distributing in Nepal in accordance with the statutory requirement. The lenses are ISO 9002 / EN 46002 and 'CE' mark certified. The lenses are quite popular among the Nepalese ophthalmic surgeons.

Ministry of Foreign Affairs
His Majesty's Government of Nepal
Kathmandu

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President

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In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below

Name of Product(s)	Name of Manufacturer Distributor, Address
See Attached List (One Page)	Ophthalmic Innovations International, Inc. 4290 East Brickell Street Ontario, CA 91761

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Leila Craddock
Export Team Leader
Information Processing and
Office Automation Branch
Office of Compliance
Center for Devices and
Radiological Health

12 ก.ค. 2544

This certificate expires 24 months from the date notarized.

COUNTY OF MONTGOMERY
STATE OF MARYLAND

Subscribed and sworn to before me this 24 day of October month 2000 year.

Donna K. Hibbard

DONNA K. HIBBARD
NOTARY PUBLIC STATE OF MARYLAND
My Commission Expires December 4, 2000

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Publications : (Year of publication in-groups)

1. The Factor associated to the birth weight of the newborns delivered at Sainoi Hospital in Fiscal Year 1998-2000 (2001)