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The Value of Retinal Implants

Wrobel W.-G.
Retina Implant AG, Reutlingen, Germany

wrobel@retina-implant.de

Abstract

Recent progress in retinal implant clinical studies is compared with the utility values of retinal therapies. Visual results allowing finger counting and letter reading correspond to improvements of utility values by +0,27. Residual lifetimes of RP patients lead to a utility of 4,7 quality adjusted life years and a break even point for cost effectiveness at 140 TSD EUR. Retinal implants could be a cost-effective therapy for retinitis pigmentosa and related retinal degeneration diseases.

1 Introduction

The eye is generally considered the most useful and therefore the most important sense organ. It is therefore included in the attempt to compare the severity of individual medical conditions and even to attribute an economic and financial value to these very conditions [1,2]. This allows the attribution of a "benefit" to the appropriate therapies enabling the calculation of a cost-benefit ratio. The initial idea of this was to reach rationally founded decisions regarding therapy. Such approaches can obviously also be adopted for the most efficient use of limited social resources. And finally, they serve as a justification for market pricing for new therapies.

It is relatively easy to determine the cost of therapies. The assessment of the benefit, however, is much more difficult. The loss of earnings, as practiced by insurance companies, can be used as a base. But it is not sufficient. The subjective quality of life of the patient needs to be considered too.

This has led to the coining of new terms such as QALY (quality adjusted life years). A year free of complaints receives the value 1. Each physical limitation or pain leads to a subtraction from this value. The value of one year of one's life without any health issues is then, somehow arbitrarily, equaled to an economic factor (for example the average yearly income).

There are, however, different approaches as to how these health limitations are assessed and how vastly different medical conditions compare on a standardized scale. There is consensus that the subjective evaluation of healthy subjects should be used for this. This is achieved through surveys and is called „value-based medicine“ [2-8].

The frequently used „standard gamble“ method is objectionable since it may lead to false high utility values. Many authors therefore prefer the „time trade-off“ method [1].

The subject is first asked what he expects his own remaining life expectancy to be. He then has to assume that he now develops a certain disease. He is now asked how many (remaining) years of his life he is willing to sacrifice for therapy guaranteeing him unrestricted quality of life, but reducing his lifespan. The utility value is then calculated as follows:

Utility value = (remaining years of life – sacrificed years) / remaining years of life

The utility value is between 1 (= the disease in question does not lead to any subjective limitation of the quality of life) and 0 (= death in the near future). This rather simple method produces solid, reliable and valid data.

BROWN et.al. [3-7] determined utility values for ophthalmologic conditions in a number of publications. So far these studies could not be applied to retinal implants since there were not enough reports available about quantifiable visual results and since these results could not be compared on the scales available so far.

2 Results with Retinal Implants

ZRENNER et.al. [8] describe the visual results with a subretinal, active chip. For the first time ever, these studies enabled determination of the visual acuity with conventional methods in a few implant patients.

According to the study protocol the patients did not have any functional vision anymore before being enrolled in the study. Most of them did not have any light perception either. After the implantation some patients were able to recognize objects such as a finger, the hand of a clock or the like and distinguish objects of everyday life (knife, fork, spoon, etc.). They correctly recognized letters and read words. For the first time ever the visual acuity in pa-

tients with retinal implants could be determined with the Landolt C (FrACT-Test [9]): the decimal visual acuity achieved was 0.021.
A comparison of these results with utility values from previous publications (summarized in [2]) produces the following summary (Table 1).

Visual acuity	Utility value	Best visual results
	[2]	[8]
0.05	0.54	0.021 achieved
Counting fingers	0.52	corresponds to 0.01
		0.021 achieved
Hand motions	0.35	achieved
Beam of light	0.35	achieved
Nulla lux	0.26	before implantation

Table 1 Comparison of recent retinal implant visual results with value-based utility data

The visual acuity was determined with the FrACT test. Already LANGE [9] demonstrated that counting fingers corresponds to a visual acuity of 0.01 in the FrACT test; a value exceeded by ZRENNER [8].
A simplified conclusion is that in some patients the implantation was able to increase the utility value from 0.26 ("nulla lux") to about 0.53 (i.e. visual acuity of 0.05 was not achieved, but counting fingers was exceeded). It was therefore possible to improve the utility value by +0.27.

3 Utility during duration of life

The improvement of the utility value by +0.27 applies as long as the implant works and the patient is able to use it. There is little information available about the long-term stability.
As for epiretinal implants, Humayun's group reports that the visual impressions or rather the implant was stable over the course of several years [10].
Zrenner's group was only able to report results of a limited period of time since the study protocol required explantation after 4 weeks and later after 4 months. In one case, however, a patient refused the explantation; he has been wearing a chip since the fall of 2005, without any complaints. Clinical trials conducted over the course of years are still required for valid long-term results.
Meaningful estimates are therefore only possible with regard to the remaining life expectancy of implant patients. So far these implants have been used nearly exclusively for RP patients.
There are numerous studies about the number of patients with RP. The general assumption is that the disease affects one person out of every 4000. A summary based on different sources [11] is shown in Table 2.

Blind or severely vision impaired patients because of RP

(in thousands)	**2005**	**2007**	**2010**
USA	91	96	103
Canada	6	7	7
France	12	13	13
Germany	16	17	19
Italy	12	12	13
Spain	8	8	9
UK	12	13	14
Japan	26	27	29
Total	**183**	**193**	**207**

Annually new blind patients because of RP

(in thousands)	**2005**	**2007**	**2010**
USA	4,1	4,3	4,6
Canada	0,4	0,5	0,5
France	0,8	0,9	1
Germany	1,2	1,2	1,3
Italy	0,8	0,9	0,9
Spain	0,6	0,6	0,6
UK	0,8	0,9	1
Japan	1,8	1,9	2
Total	**10,5**	**11,2**	**11,9**

Table 2 Blind or severely impaired retinitis pigmentosa patients

A comparison of the number of RP patients who are blind or experience a severe visual impairment with the number of newly diagnosed cases reveals an average remaining life expectancy of about 17.4 years. The use of an implant could therefore lead to a utility of 0.27 x 17.4 = 4.7 QALY (quality adjusted life years).
The financial evaluation is the subject of numerous discussions. The value of one QALY is generally equaled to the statistical average income or the gross national income (per capita). In Germany both values in 2008 were about EUR 30 thousand [12,13]. This would produce an overall utility of about EUR 140 thousand.

4 Cost effectiveness

The cost-benefit ratio is determined by comparing the cost of therapy with the effect for the patient.
The presumed costs of the implant vary between EUR 20 thousand [14] and about EUR 50 thousand [15]. Furthermore there are the costs of the implantation, probably comparable with the expenses of a complex, surgical procedure of the retina (about EUR 5-10 thousand). The cost for the instruction of the patient regarding the use of the implant is still unknown. We estimate it to be EUR 5 thousand. The operating costs (batteries and the like) are probably negligible.
The utility is therefore contrasted by possible overall costs of EUR 30 – 65 thousand. There are different evaluations of an acceptable cost-benefit ratio. According to the

WHO the cost effectiveness is high if the costs per QALY remain below the amount of the per capita gross domestic product. Based on the definition above, this would be the case if the costs of the therapy remained below EUR 140 thousand.
Other points of view (especially in the USA) are based on the “dialysis standard”: Cost effectiveness is attained if the expenses per QALY do not exceed the yearly expenses for a patient requiring dialysis. This leads to a limit of $ 100 thousand/QALY – the case here is clearly below this limit.
The NICE in Great Britain acts on the assumption that all procedures with a cost of < EUR 50 thousand are put to a simplified test and considers them to be efficient until proven otherwise.
In Germany the cost-benefit ratio is often determined before reaching decisions regarding payments. The deciding panel, however, points out that decisions are not strictly based on financial criteria.

5 Summary

For the first time a well-founded cost-benefit analysis based on the value for the patient can be conducted due to new results for retinal implants. Retinal implants can improve the quality of life of RP patients by up to 4.7 QALY. Even with a total cost of EUR 50 to 140 thousand they are still considered cost-effective.
We would like to point out that this utility evaluation is exclusively based on the point of view of healthy subjects. It is a well-known fact that people already affected by a disease may reach other conclusions.
GIZYCKI et.al. [16], for example, determined when surveying patients with retinal degeneration, that the interest in a retinal implant and the willingness to have one implanted was especially high in patients that were diagnosed with retinal degeneration, but had not completely lost their vision yet. This willingness was significantly lower in patients that had already lost their vision completely.
We can therefore assume that in the future the people who expect to go blind soon will be the ones to make the basic decision for an implant. This confirms our initial assumptions.

6 Literature

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