14 The MacDQOL Individualized Measure of the Impact of Macular Disease on Quality of Life

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Abstract: The MacDQOL is an individualized measure of the impact of ❯ macular disease (MD) on quality of life. It was designed with reference to people who had MD, using focus groups, and to the literature. An early draft was pilot tested with a postal study in which participants (N = 65) were recruited from the membership of the UK Macular Disease Society. This study showed significant differences in MacDQOL scores between people who were not registered and those who were registered blind (p < 0.001) or partially sighted (p < 0.001) and the findings offered early evidence of ❯ construct validity.

There followed a ❯ longitudinal study (N = 156) to enable further validation of the MacDQOL. Participants were recruited from an ophthalmic specialist's patient list. ❯ Principal components analysis revealed a single scale with excellent internal consistency reliability (Cronbach's alpha = 0.946). ❯ Test-retest reliability was excellent with MacDQOL scores at time 1 and time 2 highly correlated (r = 0.946) and no differences in scores between time 1 and time 2 (p = 0.85). Construct validity was demonstrated by the MacDQOL's sensitivity to several measures of vision (near and distance ❯ visual acuity, contrast sensitivity, reading speed, color recognition). There was some correlational evidence of responsiveness to change in vision over time.

Good response rates and completion rates indicated that the MacDQOL is acceptable to participants and does not impose too great a burden.

The MacDQOL has been used in clinical trials and a number of other studies. Evidence to date indicates that MD has a negative impact on the quality of life of people with the condition and that the negative impact increases with increasing severity of MD. The MacDQOL promises to be a valuable tool in the investigation of changes in patients' quality of life in clinical trials of medical treatments and rehabilitative interventions.

List of Abbreviations: *ADDQOL,* audit of diabetes dependent quality of life; *AWI,* average weighted impact; *FS,* ❯ functional status; *HS,* health status; *LVQOL,* low vision quality of life measure; *MacDQOL,* macular disease dependent quality of life measure; *MD,* macular disease; *MDS,* Macular Disease Society; *NEI-VFQ25,* National Eye Institute vision function questionnaire – 25 item; *QOL,* quality of life; *RetDQOL,* diabetic ❯ retinopathy dependent quality of life measure; *SEIQOL,* schedule for the evaluation of individual quality of life; *VA,* visual acuity

1 Introduction: Macular Degeneration

Age-related macular degeneration (MD) is a chronic, progressive eye disorder that mainly affects people over the age of 50. Incidence increases with age. It is the leading cause of blindness in the Western world in people over 60 yrs (WHO, 2004) and it is the third most common cause of blindness globally after cataract and glaucoma (WHO, 2004). MD causes 8.7% of the global estimate of 161 million cases of visual impairment (Resnikoff et al., 2004). Recently it was estimated that, in the UK, with a population of 59 million (National Statistics Online, 2004), approximately 417,000 people have some degree of MD, of whom 214,000 have sufficient visual impairment for registration as partially sighted or blind (Owen et al., 2003). It has been estimated that there are 1.75 million people with some degree of MD in the USA and this is likely to increase to almost three million by 2020 due to the aging population (Friedman et al., 2004).

MD damages the central part of the retina, the macula, which is responsible for fine, detailed vision needed for tasks such as reading, driving, watching TV and recognizing faces. Peripheral vision is usually retained but impairment can be sufficient to warrant registration as

blind. MD impairs proficiency in carrying out many activities in daily living and can compromise the ability to live independently (for illustrations of the effect of MD on vision please see other chapter by Mitchell and Bradley in this book).

There are two types of MD. The less serious "dry" or "non exudative" MD accounts for 85–90% of cases of MD. It develops slowly, is usually bilateral and in most cases does not lead to the most serious vision loss. It is characterized by the presence of fatty deposits behind the retina which cause the retina to thin and dry out. Currently there is no medical or surgical treatment for dry MD. Wet or neovascular MD (also known as exudative MD) usually develops quickly and frequently leads to serious visual impairment. Wet MD is caused by the growth of new blood vessels (a process known as choroidal neovascularization) behind the retina. These new blood vessels are weak and have a propensity to leak, damaging the retinal cells and leading to scar tissue. Although it represents only 10–15% of cases of MD, wet MD accounts for over 90% of serious vision loss due to MD (Chisholm, 1998). Treatments are available for some categories of wet MD. The treatments can halt the progress of the condition for an indeterminate period rather than cure it although the most recent treatment developments do offer the hope of an improvement in vision for a proportion of patients (Kaiser and Do, 2007).

2 Measuring Quality of Life

The importance of measuring quality of life (QOL) in health care is increasingly recognized but frequently the instruments used would more correctly be referred to as ❯ measures of health status (HS) and functional status (FS)(Gill and Feinstein, 1994). While such measures are useful in investigating the impact of medical conditions and their treatment they are not measures of QOL. HS measures investigate the quality of health rather than QOL (Bradley, 2001) and a measure of vision function assesses the impact of vision impairment on functioning, not its impact on QOL. Individuals regard some aspects of HS or FS as more important than others and some as not important at all. The importance that is attributed to these aspects differs from one individual to another and a measure of HS or FS that gives equal importance to all aspects measured does not properly represent the impact of those different aspects on an individual's QOL. Joyce commented that "it is not the observed functioning of the individual that is of primary concern but that individual's perception of and reactions to functioning" (Joyce, 1994, p. 46). The distinction between HS, FS and QOL is also often overlooked in the ophthalmology literature. Since the impact of MD and other vision impairment may have an effect on length of life only indirectly (possibly through accidents or suicide), its impact is primarily on QOL and it is important that the distinction is made and that an appropriate measure is used in the assessment of QOL.

Early measures of QOL tended to consist of items derived from researchers or health professionals but not the patients themselves. The Schedule for the Evaluation of Individual Quality of Life (SEIQOL) (McGee et al., 1991) differs fundamentally from such instruments because it allows respondents to name the five ❯ domains of life that they perceive as most important to their own QOL and to rate the relative importance of each one to their overall QOL. The importance ratings are used to weight the domain ratings and the weighted ratings are summed to give a single QOL score. The Patient Generated Index (Ruta et al., 1999) uses a similar approach but it is condition-specific in that it invites respondents to name five areas of life that are most affected by their medical condition and to rate how badly affec-

ted they are in each area. Participants then indicate the areas in which they would most value an improvement by giving points to each area. The individual area ratings are weighted by the points given and the areas' weighted scores are summed to produce a single index designed to measure the impact of the medical condition in areas of their life most important to them. Again the relevance of domains for the respondent is paramount. ❯ Weighting an assessment by an importance value allows respondents to indicate more accurately the impact of any situation (e.g. a chronic health state) on their QOL by the use of multiple criteria.

The philosophy underpinning the SEIQOL was adopted by Bradley and her colleagues in the development of the Audit of Diabetes Dependent Quality of Life (ADDQOL) (Bradley et al., 1999, Bradley and Speight, 2002; Wee et al., 2006), a diabetes-specific measure of the impact of diabetes on QOL. Interviews with people who had diabetes, feedback from clinicians including dieticians, and the research literature were used in determining domains of life that were impacted by diabetes and important for QOL. For each item respondents rate the impact of diabetes on that domain of life and the importance of the domain for QOL. Impact and importance ratings are multiplied to give weighted impact scores for each domain. Some items have a preliminary question that acts as a "not applicable" option. The ADDQOL includes two overview items, the first measuring present QOL and the second investigating diabetes-specific QOL. A substantial body of evidence attests to the value of the ADDQOL e.g. (Bradley et al., 1999; Kinmonth et al., 1998; Woodcock et al., 2001; DAFNE Study Group, 2002; Speight et al., 2007;) and similar measures have been developed for use in diabetic retinopathy, RetDQOL (Woodcock et al., 2004; Brose et al., 2007), renal failure, RDQOL (Bradley, 1997), growth hormone deficiency, HDQOL (McMillan et al., 2006), hypothyroidism, ThyDQOL (McMillan et al., 2007), age-related hormone decline in men, A-RHDQOL, (McMillan et al., 2003), diabetes in teenagers, ADDQOL-Teen (McMillan et al., 2004) and children, ADDQOL Junior and ADDQOL Junior+ (Wilson et al., 1998) and the ADDQOL Senior for frail elderly people with diabetes in care homes (Speight et al., 2003). The design of the MacDQOL individualized measure of the impact of macular disease on quality of life was guided by the philosophy underpinning the SEIQOL and the ADDQOL and related instruments.

3   Design of the MacDQOL

Items for the initial draft of the MacDQOL were derived in consultation with a person who had MD and with reference to a survey of 1420 members of the UK Macular Disease Society (MDS) (Mitchell et al., 2002) and to the research literature.

The MacDQOL was designed for completion by visually impaired people. Text is presented in Arial font 16 bold and is justified to the left. This helps respondents to navigate down the page. The use of capital letters is avoided except where dictated by grammar as lower case letters are easier to identify for people with MD. Response options are presented vertically and dotted lines guide the reader to response boxes as shown in the example item in ❯ Figure 14-1.

The first draft of the MacDQOL was tested at meetings of two local groups of the MDS (N = 6 and N = 11). There were four parts to each meeting:

■ **Figure 14-1**
Format of the MacDQOL domain-specific items (with scoring indicated, not shown in actual questionnaire). Part (a) investigates impact of MD on an aspect of life (e.g. friendships and social life). Part (b) investigates the importance of the aspect of life to quality of life

If I did not have MD, my friendships and social life would be:

- very much better......................... -3
- much better.................................. -2
- a little better................................. -1
- the same....................................... 0
a - worse... 1

My friendships and social life are:

- very important............................. 3
- important...................................... 2
- a little important.......................... 1
b - not at all important...................... 0

1) Participants were told:
   Imagine you wake up tomorrow and discover that, by some magic, you no longer have macular disease and your central vision has been restored. In what important ways would that affect your quality of life?
   Participants wrote down ways in which their QOL would change. Help was given to people who had difficulty writing.
2) Participants completed the draft MacDQOL, with assistance where necessary.
3) Participants discussed the MacDQOL and their ideas in small groups while the researchers reviewed lists generated in (1) and questionnaires completed in (2).
4) A general discussion of the MacDQOL and QOL followed in which irrelevant and missing items were identified and discussed and wording of some new items devised.

As a result of the two meetings, some changes were made to the measure.

The MacDQOL questionnaire begins with two overview items measuring: (a) Present QOL (*In general, my present quality of life is:* scored from +3 [*excellent*], through 0 [*neither good nor bad*] to −3 [*extremely bad*] on a 7-point scale); (b) MD-specific QOL (*If I did not have MD, my quality of life would be:* scored from −3 [*very much better*] through 0 [*the same*] to +1 [*worse*] on a 5-point scale). There follow 23 domain-specific items. Each item has two questions to investigate a) the impact of MD on a particular aspect of life and b) the importance of that aspect of life to the individual's QOL (see ❯ *Figure 14-1*).

Some domains have a preliminary question which acts as a "not applicable" option. For example the family life item is preceded by the question "Do you have family/relatives?"

For each domain-specific item, the impact score (from −3 to +1) is multiplied by the importance score (from 0 to 3) to give a weighted impact score of between −9 (maximum negative impact) and +3 (maximum positive impact). An ❯ average weighted impact score (AWI) is obtained by summing the weighted impact scores of all items except *work* and dividing by the number of applicable items for each individual. *Work* is applicable to very few

people in this predominantly retired population but important for those to whom it is applicable. *Work* item scores are, therefore, analyzed separately. In a final item respondents are invited to state whether MD affected his/her life in any ways not already covered by the questionnaire, with a space to elaborate for people who reply "yes." Domains included in the MacDQOL (UK-English version) are listed in ❱ *Table 14-1*.

◘ Table 14-1

MacDQOL items and response options

MacDQOL overview items		
1	In general, my present quality of life is	Excellent – extremely bad
2	If I did not have MD, my quality of life would be	Very much better - worse
Domain-specific items		
	If I did not have MD	Response options
1	I could handle my household tasks	Very much better – worse
2	I could handle my personal affairs (letters, bills, etc)	Very much better – worse
3	My experience of shopping would be	Very much better – worse
4*	My working life and work-related opportunities would be	Very much better – worse
5*	My closest personal relationship would be	Very much better – worse
6*	My family life would be	Very much better – worse
7	My friendships and social life would be	Very much better – worse
8	My physical appearance (including clothes and grooming) would be	Very much better – worse
9	Physically, I could do	Very much more – less
10	I could get out and about (e.g. on foot, or by car, bus or train)	Very much better – worse
11*	My holidays would be	Very much better – worse
12	I could enjoy my leisure activities and interests (e.g. reading, TV, radio, hobbies)	Very much more-less
13	My self-confidence would be	Very much better – worse
14	My motivation to achieve things would be	Very much better – worse
15	The way people in general react to me would be	Very much better – worse
16	My feelings about the future (e.g. worries, hopes) would be	Very much better – worse
17	My financial situation would be	Very much better – worse
18*	I could do things independently	Very much better - worse
19	I could do things for others as I wish	Very much better – worse
20	I would have mishaps or would lose things	Very much less – more
21	I could enjoy meals	Very much more – less
22	The time it takes me to do things would be	Very much less – more
23	I could enjoy nature	Very much more – less

Each item starts with "If I did not have MD," followed by the main part of the question (e.g. I could handle my household tasks). The respondent chooses a response option from e.g. very much better; much better; a little better; the same; worse (scored −3, −2, −1, 0, 1 respectively). In the second part of the item the respondent is asked how important that aspect of life is to his/her quality of life. Response options are: very important, important, somewhat important, not at all important (scored 3, 2, 1, 0 respectively)

*These items begin with a yes/no question e.g., item 6 "Do you have family/relatives?" If the respondent answers "no," the item is not applicable and it is not completed

4   Design and Development Studies

Two studies were carried out to investigate the properties of the MacDQOL and to refine it as necessary.

4.1   Postal Pilot Study

Following the initial design work, the second draft of the MacDQOL was tested in a ❯ postal pilot study (Mitchell and Bradley, 2004). The questionnaire was sent to 65 randomly selected members of the MDS who had indicated in previous research (Mitchell et al., 2002) a willingness to participate in future work. Forty-seven people responded. Further changes followed this study and a small number of people (N = 5) completed a third draft during a trial of an electronic data collection system. Data from the postal pilot and the electronic data collection trial were combined with those obtained from the design phase focus groups to give a total of 69 respondents (52 women, 17 men [sex unspecified for one person], mean age 76.6, SD 12.2). Fifty-two people had MD in both eyes and 11 had only one eye affected (no data for 6 people). Twenty-eight people were registered blind, 18 were partially-sighted and 16 were not registered (no data for 7 people). The data were used to investigate face, content and construct validity.

4.2   Nottingham Validation Study

A longitudinal study was carried out to investigate the ❯ psychometric properties of the MacDQOL (Mitchell et al., 2005). Participants with MD were recruited from a Nottingham consultant's patient list (99 women, 57 men, mean age 78.96 years, 150 people [96.2%] had MD in both eyes, 6 people [3.8%] had it in one eye only). Participants took part in a telephone interview during which they completed the MacDQOL. Within 14 days of the interview they underwent a vision assessment. The vision assessment included measurement of monocular and binocular distance visual acuity (VA), near VA, contrast sensitivity and comfortable VA. Comfortable VA was computed from the time taken to read script of different sizes of print. Time taken to read each line was recorded. When the time to read a line increased substantially, this showed that it was no longer "comfortable" to read that size print and smaller print. Presence of distortion or ❯ scotoma in the central 10 degrees of vision was also investigated for monocular and binocular vision. Color vision and recovery from glare were assessed for binocular vision only. The MacDQOL interview and vision assessment were repeated one year later (N = 135). Baseline data were used to investigate scale structure, internal consistency reliability and construct validity. Baseline and follow-up data were used to investigate test-retest reliability and responsiveness (Mitchell et al., 2008).

5   Psychometric Development

5.1   Factor Structure

Baseline data from the Nottingham study were used to investigate factor structure. Principal components analysis yielded a 4-factor structure but six items double loaded and the factors were not conceptually distinct. In a forced 1-factor solution all items except *work* and *finances*

loaded well (>0.4). *Work* was only applicable to three people but those for whom it was applicable reported a high negative impact. The item was removed from the scale but retained in the questionnaire to be scored separately. *Finances* had the lowest weighted impact score of all the remaining 22 items. However negative impact was reported by 35 (23%) participants and only nine (5.8%) thought it was not at all important. Finances was retained because it is likely to be of particular relevance to people (whether in the UK or elsewhere) who have to pay for treatment. In the forced 1-factor solution *finances* loaded at 0.356 and 49% of the variance was explained (Mitchell et al., 2005).

In an international study to investigate the factor structure and properties of the MacDQOL, Berdeaux et al. (Berdeaux et al., 2006) combined MacDQOL data from an international clinical trial and a cross-sectional survey. In principal components analysis four factors were elicited, all with Cronbach alpha > 0.8: (1) essential tasks, (2) family/social life, (3) activities and capabilities, (4) embarrassment. The item *finances* did not load well on to any of the factors and detracted slightly from the alpha in the subscale *embarrassment.* Further research is needed to establish whether stable MacDQOL subscales can be elicited in future samples. Subscales, including those demonstrated by Berdeaux et al. (2006) would be valuable in evaluating rehabilitation needs, where they may indicate the need for practical low vision rehabilitation and/or psychological intervention.

5.2   Internal Consistency Reliability

Several items in the MacDQOL have a "not applicable" (N/A) option and these result in significant amounts of missing data in those items. For the purposes of internal consistency reliability analysis, those missing data were recoded as zero to maximize the number of cases included in the analysis. Under those conditions (with an overall N of 151 completed questionnaires, 94 of which had missing data recoded as zero) Cronbach's alpha coefficient of internal consistency reliability was 0.944 which is highly satisfactory. When the analysis was repeated with N/A items recorded as missing, Cronbach's alpha was 0.946 (N = 62). In both cases, only *finances* detracted marginally from the reliability, by 0.012 in each case. The pattern of results was similar for both methods of dealing with N/A items (Mitchell et al., 2005).

5.3   Test-retest Reliability

MacDQOL data were collected on two occasions, one year apart (Mitchell et al., 2008). Among participants whose visual acuity had changed by <0.2 logMAR during that period (N = 87), AWI scores were highly correlated (r = 0.946). There were no differences in scores between time 1 and time 2 (t = 0.19, df 86, p = 0.85). The findings indicate excellent test-retest reliability for the MacDQOL.

5.4   Face and Content Validity

The design methodology, in particular the contributions of people with MD during the early design stages ensured the ❯ face validity of the measure (Mitchell and Bradley, 2004). Following the Nottingham study in which the MacDQOL was completed on two occasions

(Mitchell et al., 2005), no new domains were identified that were not already included in the MacDQOL (as evidenced by responses to the final, open question).

In the Nottingham study, at baseline the full range of scoring options for impact was used in four domains and all options except +1 (indicating a positive impact of MD on QOL) were used in all remaining items except *work*, which was an applicable domain for only three people. The full range of importance scores were used in all domains except work and close personal relationship where there were no scores of zero (which would indicate that the domain was not at all important for QOL).

The findings suggest that the measure has good ❯ content validity. The wide individual variation in scores of impact and of importance for the items in the measure confirms that an individualized measure is needed.

❯ *Figure 14-2* shows the weighted impact scores of the 23 items in the MacDQOL (Nottingham study follow-up data). Work shows the highest negative impact, followed by independence, leisure and personal affairs.

▣ Figure 14-2

Weighted impact scores of MacDQOL items. Weighted impact score = impact of MD on aspect of life X importance of aspect of life to quality of life
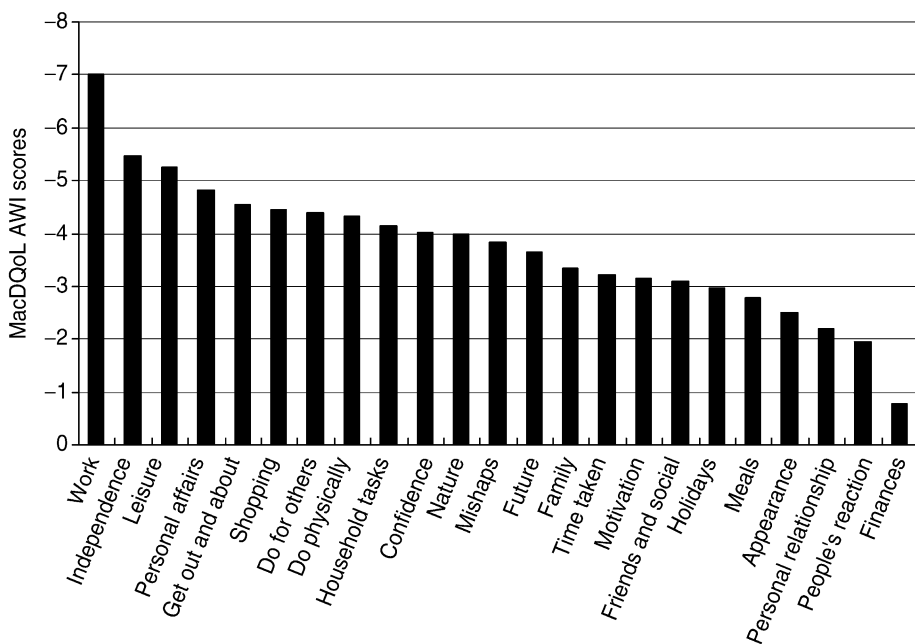
5.5   Concurrent Validity

There is no information on concurrent validity because there is no other appropriate measure of the impact of MD on QOL that can be used to assess concurrent validity. A number of measures are claimed to be measures of QOL for visually impaired people but they would

more appropriately be termed measures of vision function e.g. NEI-VFQ 25 (Mangione et al., 2001), LVQOL (Wolffsohn and Cochrane, 2000).

5.6   Construct Validity

In the postal pilot study (Mitchell and Bradley, 2004), construct validity was investigated by comparing the scores of the MacDQOL overview items and the AWI scores of people who were registered blind, registered partially-sighted and not registered. There were significant differences in the AWI scores between the not registered and both the blind and the partially-sighted groups (❯ *Table 14-2*) but not between the blind and the partially-sighted groups. The two overview items were found to be less sensitive than the AWI score (❯ *Table 14-2*). They did,

■ Table 14-2

Results of Kruskal-Wallis tests comparing QOL scores of people registered blind, partially-sighted and not registered and post hoc comparisons: mean differences in average weighted impact scores, MD-specific QOL overview item scores and generic present QOL overview item scores

Kruskal-Wallis test		Mann Whitney post hoc comparisons			
QOL measure	Chi-square, N, df & p-value	Vision Category	Comparison categories	Mean difference	Mann Whitney value
Present QOL overview item	chi^2 = 7.81, N = 61, df = 2, p < 0.05	not registered	blind	1.14	70.0**
			p/s	0.42	157
		Blind	p/s	−0.72	176.0
MD-specific overview item	chi^2 = 9.36, N = 61, df = 2, p < 0.01	not registered	blind	0.81	70.0**
			p/s	0.66	123.5*
		Blind	p/s	−0.15	221.5
Average weighted impact score	chi^2 = 14.03, N = 62, df = 2, p < 0.001	not registered	blind	2.66	52.0***
			p/s	2.34	86.0***
		Blind	p/s	−0.32	226.5

Average weighted impact score: lower score = greater negative impact of MD on QOL. The MacDQOL scores distinguished between not registered and blind and between not registered and partially sighted but not between blind and partially sighted participants

*p < 0.05, **p < 0.01, ***p < 0.001, N = number of cases; df = degrees of freedom; p/s = registered partially-sighted. Table reproduced with kind permission of Springer Science and Business Media.

however, indicate the same differences that were shown using the AWI score, with the exception of the comparison of not registered and partially-sighted groups using the generic present QOL overview item. In this instance the difference was non-significant, whereas the MD-specific overview item scores and the AWI scores showed significant differences between the two groups. As expected, the AWI was correlated more highly with the MD-specific overview item (r = 0.688, p < 0.01) than with the present QOL overview item (r = 0.541, p < 0.01) though both associations were significant.

In the Nottingham study (Mitchell et al., 2005) construct validity was investigated by correlation of MacDQOL scores with a number of measures of vision (❯ *Table 14-3*). Where appropriate, measures of vision in the better eye, worse eye and with binocular vision were compared with the MacDQOL. It is usual for stronger correlations to be found with the better eye and binocular vision, as vision function depends more highly on the better eye than the worse eye.

◘ Table 14-3

Correlations (Spearman's r) between MacDQOL outcome variables and vision measures

		Present QOL	p-value	MD-specific QOL	p-value	AWI	p-value
Distance VA	better eye	−0.301	<0.001*	−0.310	<0.001*	−0.431	<0.001*
	worse eye	−0.229	0.004	−0.258	0.001*	−0.350	<0.001*
	binocular	−0.292	<0.001*	−0.311	<0.001*	−0.419	<0.001*
Near VA	better eye	−0.327	<0.001*	−0.192	0.017	−0.326	<0.001*
	worse eye	−0.140	>0.05	−0.214	0.008	−0.226	0.001*
	binocular	−0.220	0.006	−0.157	0.05	−0.326	<0.001*
Contrast	better eye	0.200	0.012	0.300	0.001*	0.392	<0.001*
Sensitivity	worse eye	−0.064	>0.05	0.305	<0.001*	0.266	0.001*
	binocular	0.246	0.002	0.322	<0.001*	0.423	<0.001*
Color vision	binocular	−0.204	0.011	−0.291	<0.001*	0.417	<0.001*
Comfortable VA	binocular	−0.207	0.012	−0.121	>0.05	−0.283	<0.001*
Recovery from glare	binocular	−0.069	>0.05	−0.010	>0.05	0.022	>0.05

Present QOL overview item: higher score = better QOL. MD-specific QOL overview item: lower score = greater negative impact of MD on QOL. AWI (average weighted impact score): lower score = greater negative impact of MD on QOL. Poorer MacDQOL scores were associated with poorer scores of most clinical measures of vision. *VA*= visual acuity

*Correlations were still significant after correcting for the possibility of chance associations due to multiple correlational analyses (Bonferroni correction)

To control for the possibility of family wise error with 36 correlations, a Bonferroni correction was applied ($p < 0.00138$ accepted as significant). Thirty of the 36 correlations indicated associations of poorer QOL with worse vision, with p-values of <0.05. Twenty-one of these associations were still significant after correcting for family wise error. In most cases, the AWI score correlated with vision measures more strongly than the two overview items and correlations between MacDQOL variables and vision measures were generally stronger with better-eye and binocular scores than with worse-eye scores, as expected. For near and distance

VA, the strongest correlations were with better-eye scores. Associations between contrast sensitivity and MacDQOL variables were all significant except between contrast sensitivity in each eye separately and present QOL if the Bonferroni correction is applied. Comfortable VA and color recognition were not associated with present QOL if Bonferroni is applied and comfortable VA was not associated with the MD-specific QOL overview item with or without Bonferroni. None of the three MacDQOL variables was associated with recovery from glare even without applying Bonferroni's correction (❯ *Table 14-3*), neither were individual items, such as *holidays* or *get out and about*.

Findings from both the postal pilot study and the Nottingham study indicate that the MacDQOL has good construct validity, differentiating between levels of visual ability using a number of measures of vision as well as registration status.

Test-retest and construct validity have been clearly illustrated in the postal pilot study and the Nottingham study.

5.7   Responsiveness

When investigating the impact of treatment or rehabilitative interventions on QOL an important quality in an outcome measure is its potential to detect change over time (responsiveness). The responsiveness of the MacDQOL was investigated in the Nottingham study (Mitchell et al., 2008). Of 135 people who completed baseline and follow-up investigations, 35 experienced a deterioration in their distance VA of 0.2 logMAR (minimum clinically important change (Bailey et al., 1991)) or more during the year. Correlational analysis indicated that poorer QOL at follow-up, measured by the MacDQOL present QOL overview item, was associated with deterioration in both the better eye and binocular distance VA ($r = 0.29$, $p = 0.001$; $r = 0.21$, $p = 0.016$ respectively, N = 135). There was a positive correlation between deterioration in the MacDQOL AWI score and deterioration in both binocular near VA and reading speed ($r = 0.20$, $p = 0.019$; $r = 0.18$, $p = 0.041$ respectively, N = 135). These early indications of the responsiveness of the MacDQOL are encouraging and this is reinforced by the test-retest reliability which de Boer and colleagues (2004) assert is a prerequisite in a responsive measure.

In the Berdeaux et al. (2007) study, the range of scores across different visual acuities was greater in the MacDQOL than in the NEI-VFQ25, a well validated measure of vision function (Mangione et al., 2001). This suggests that the MacDQOL may be more responsive to change than the NEI-VFQ25.

Further evidence of the MacDQOL's sensitivity to change will be sought in forthcoming studies. The measure is now being adopted in a number of studies and this increase in use can be expected to increase health professionals' confidence in the MacDQOL.

5.8   Missing Data

The MacDQOL AWI can be computed despite some missing data. Missing data for up to half the items can be tolerated without Cronbach's alpha falling below 0.8. The AWI can be calculated from the items for which responses have been given providing at least 11 items have complete responses (Mitchell et al., 2005).

6   Weighting

The impact of weighting was investigated using data from the postal pilot study. Investigation of the impact scores for each domain indicated that the greatest negative impact was reported for *work*, followed by *personal affairs* and *getting out and about*. When the impact scores were multiplied by importance scores to give weighted impact scores the rank order of domains changed for 12 out of the 22 domains. Scrutiny of the raw data revealed that impact and importance scores were often the same other than when either score was zero. Correlations between impact and importance scores ranged between -0.195 (*personal affairs*) to -0.865 (*future*). When all cases with zero scores for either impact or importance were removed the correlation between the impact score and the importance score was very high in all domains ($r \geq 0.744$) except *work* ($r = 0.320$). It was considered that a simpler use of the data, which might yield equivalent results, would be to score as zero all impact scores with a corresponding importance rating of zero and then analyze the impact scores rather than the product of importance and impact scores. This procedure was carried out for all domains. Using this method the rank order of domains remained the same as unweighted impact scores except that the positions were reversed in two pairs of domains (*shopping* and *leisure*; *future* and *friends and social life*). The findings suggested that weighting does refine the measure, particularly when the full range of importance ratings is used, as was the case in 14 of the 22 domains. The fact that, in the postal pilot study, only three item means remained in the same rank order of impact once importance ratings had been incorporated shows that incorporating importance scores has a noticeable effect on QOL domain scores even at the level of group means and individual scores are even more markedly affected by weighting with importance scores. Such refinement is a characteristic of multi-criteria decision making (Nobre et al., 1999) and is particularly valuable when the full range of importance ratings is used. The inclusion of "not applicable" options for some domains further enhances the individualized nature and acceptability of the measure.

7   Equivalence of Completion Methods

Although the MacDQOL is designed for completion by visually impaired people, 20–25% of people with MD are unable to read at all, even with low vision aids (data from UK Macular Disease Society). They would, therefore, be unable to complete the MacDQOL without help and, in a research study, assistance would need to be provided or the sample would be biased, with only the less visually impaired people completing the questionnaire.

Self-completion, telephone interview and face-to-face interview are commonly used methods of questionnaire implementation. Since self-completion of questionnaires received by post is the cheapest administration method it would be advantageous if this method produced equivalent results to more expensive interviewer-based methods. More than one implementation method could then be used in the same study. Some vision-related questionnaires have been shown to yield different scores from self-completion and interview (Wolffsohn et al., 2000; Frost et al., 2001) but others show no differences (Mangione et al., 1992). A study was carried out to investigate the equivalence of MacDQOL scores obtained by self-completion and telephone interview (Mitchell et al., 2004). Participants (N = 127, 100 women, 27 men, mean age = 78.22) were recruited at MDS local group meetings. They were randomized to experimental subgroups (self-completion [paper] at time 1 then

telephone interview at time 2, one month later, or *vice versa*) or control group (self-comple-tion twice). At time 1, there were no differences in MacDQOL AWI scores between the three groups, (p > 0.05). At time 2 there were differences in AWI scores between groups (F (2, 124) = 3.39, p = 0.037). Mean AWI scores of the telephone/paper subgroup showed increased negative impact of MD on QOL at follow-up than did those of the paper/telephone subgroup (p = 0.016) and control group (p = 0.036). There was an interaction between time and completion method (F (1,62) = 21.37, p < 0.001) showing that self-completion elicited scores indicating greater negative impact of MD on QOL at time 2 compared with interview elicited scores at time 1 (▶ *Figure 14-3*).

◻ **Figure 14-3**

Mixed model ANOVA: comparison of paper and telephone interview AWI scores at time 1 and time 2 (experimental subgroups only). *AWI* average weighted impact score (sum of all applicable weighted impact scores divided by number of applicable items). Paper/telephone: questionnaire completed using pen and paper at time 1 and by telephone interview at time 2.
Telephone/paper: questionnaire completed by telephone interview at time 1 and using pen and paper at time 2
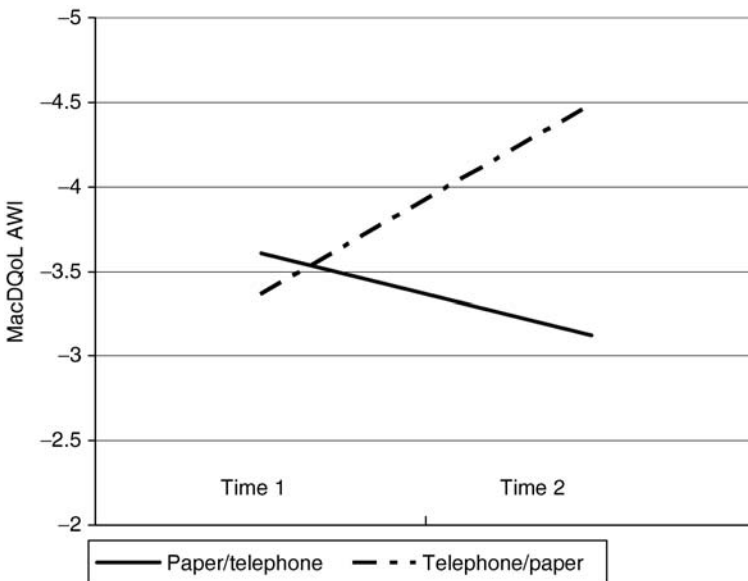
It may be that the interview experience was pleasant, causing respondents to view their situation more favorably, or that there was some social desirability bias in responding (Oppenheim, 1968). Alternatively, telephone interviewees may have wanted to be seen to be coping well with their condition (Wolffsohn et al., 2000). It is likely that self-completion is a difficult and slow task for visually impaired people, particularly those with more severe impairment. Responses may thus be negatively biased because of the effort of responding by this method (Wolffsohn et al., 2000). The authors concluded that completion methods should

ideally not be mixed in one study. If participants self-completed at time 1 and had a telephone interview at time 2 because their vision had deteriorated, completion method bias could lead to under-reporting of negative impact of MD on QOL at time 2 and possibly mask a real difference in QOL due to severity of MD.

8   Acceptability and Respondent Burden

The MacDQOL takes 10 to 20 minutes to self-complete, depending on reading speed, and 15–20 minutes to complete by interview. Studies using the MacDQOL have all had good response rates and few missing data (99.8% completion rate for participants in the baseline phase of the Nottingham study), suggesting that respondents do not experience significant difficulty in completing the measure. In the longitudinal study only two participants declined to take part at follow-up without giving a reason such as poor health or spouse's poor health. Participants' willingness to complete the measure a second time and very low levels of missing data in any studies attest to the measure's acceptability.

9   Studies Using the MacDQOL

The MacDQOL has been used in a clinical trial of *anecortave,* a treatment for wet MD (Covert et al., 2007) and it is to be used in a forthcoming UK National trial (the IVAN trial) comparing two treatments and two treatment regimens for wet MD. The measure is being used to evaluate programmes to train people with MD in eccentric viewing and steady eye skills. The increase in use can be expected to increase health professionals' confidence in the MacDQOL.

10   Availability in Multiple Languages

The MacDQOL is currently available in 17 languages. These language versions have been translated and rigorously linguistically validated by Mapi Research Institute in collaboration with the Royal Holloway team using gold standard procedures.

11   Conclusion

The MacDQOL is an individualized measure of the impact of MD on QOL that has good face and content validity. It has excellent internal consistency and test-retest reliability. There is good evidence of construct validity and encouraging indications of responsiveness. Findings from studies using the MacDQOL show that macular degeneration has a considerable negative impact on the QOL of people who have the condition and that the impact increases with increasing severity of MD.

The MacDQOL, as with the ADDQOL and other related QOL instruments designed by the Royal Holloway team, will remain under scrutiny and will be further refined if it is felt to be necessary.

12   Use of the MacDQOL

For access to and license to use the MacDQOL contact the copyright holder, Professor Clare Bradley. Email:c.bradley@rhul.ac.uk.

Summary Points

- The MacDQOL is an individualized measure of the impact of macular disease (MD) on quality of life (QOL). MD is a chronic, progressive eye condition that mainly affects people over the age of 50. MD causes loss of central vision.
- During the design of the measure the researchers talked to people with MD to elicit their views on the ways in which MD impacted on QOL to ensure that all potentially important and impacted aspects of life were investigated by the measure.
- The MacDQOL has been psychometrically validated and studies have shown that it has good psychometric properties and is a reliable and valid measure that can confidently be used in clinical trials and other research where investigators wish to measure the impact of MD on QOL.
- The MacDQOL can detect differences in reported QOL due to differing severity of MD and there is evidence that it is sensitive to changes in vision over time. These qualities are important in evaluating medical or rehabilitative interventions.
- When vision remains stable over time, MacDQOL scores remain unchanged, so it can reliably be used in longitudinal studies.
- There is some evidence that using different completion methods (pen and paper and telephone interview) may yield different results, with less negative impact of MD on QOL reported during telephone interviews. It would be best for only one administration method to be used in any study.
- The MacDQOL is currently linguistically validated in 17 languages.

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