

Measuring quality of life in oculoplastic patients

Edward Ridyard¹, Clare Inkster²

¹University of Manchester, Oxford Road, Manchester, Greater Manchester, M13 9PL, UK

²The Eye Unit, Royal Bolton Hospital, Minerva Road, Farnworth, BL4 0JR, UK

Correspondence to: Edward Ridyard. 9 The Meadows, Rainhill, Prescot, Merseyside, L35 0PQ, UK. edward-ridyard@doctors.org.uk

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Abstract

• **AIM:** To investigate if there is any published evidence of impaired quality of life in conditions which are corrected by oculoplastic surgery and whether there is proven benefit in the quality of life such procedures.

• **METHODS:** We searched a number of databases to determine the level of evidence available for common conditions amenable to oculoplastic surgery. Search terms concentrated on quality of life measures rather than anatomical correction of deformities.

• **RESULTS:** The level of evidence available for different conditions was very variable. Certain conditions had extensive research documenting reduction in quality of life, with some evidence for improvement after surgery. Some other common conditions had little or no evidence supporting of reduction in quality of life to support the need for surgery.

• **CONCLUSION:** The evidence is sparse for quality of life improvement after some of our most commonly performed procedures. Many of these procedures are now being identified by primary care trusts (PCTs) as of "low clinical value", and are no longer being routinely commissioned in certain parts of the UK. There is a need to address this lack of evidence to determine whether oculoplastic surgery should continue to be commissioned by PCTs.

• **KEYWORDS:** quality of life; patient-reported outcomes; oculoplastics; low value clinical treatments

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INTRODUCTION

Since the 1970's there has been an exponential rise in quality of life research. The increase may partly be explained by the increase in the quality and availability of healthcare, with an increase in life expectancy. Quality of life can be used to evaluate effective management of disease. Quality of life has also been suggested as a tool for assessing treatment outcomes, alongside morbidity and mortality^[1]. Furthermore quality of life is used by policymakers when allocating health resources and has become an important component of research in any healthcare area^[2]. Moons *et al*^[3] defined quality of life as "global, yet unidimensional, subjective assessment of one's satisfaction with life".

In April 2011 the UK audit commission produced a report entitled: "reducing spending on low value clinical treatments". Low value clinical treatments (LVCTs) are treatments which are clinically ineffective or not cost effective. The report proposed that LVCTs should be collated by each primary care trust (PCT) and subsequently decommissioned. As part of the quality, innovation, productivity and prevention (QIPP) initiative each PCT has to produce its own list of LVCTs. They should provide evidence to say why a particular treatment is clinically ineffective or not cost effective. QIPP is part of the larger Department of Health strategy aimed at increasing the quality and quantity of national health service (NHS) health care provision by 2014/15 whilst at the same time making savings of £20 billion (\$30.17 billion). The Audit Commission estimated that if the widespread decommissioning of LVCTs in each PCT takes place it could result in an annual saving of between £179-441 million (\$270-665.20 million).

Although no national guidelines exist outlining what constitutes a LVCT, the Croydon PCT's list is accepted as the gold standard and is where most PCTs start when compiling their own list of LVCTs. Croydon PCT's list contains 34 LVCTs one of which is "aesthetic ophthalmology". The list is further broken down into five categories with "aesthetic ophthalmology" appearing under the heading "potentially cosmetic procedures". If a certain treatment is placed on the list of LVCTs then evidence must be provided to justify its appearance^[4]. Quality of life indices evaluating both physical and psychosocial aspects of a patient's condition are the best measure of the efficacy of such treatments, and an improvement in quality of life post-intervention can demonstrate their clinical benefit. The aim of this study is to determine if there is evidence for a reduction in quality of life

in oculoplastic conditions and whether there is improvement after surgery. This should enable an informed decision to be made in commissioning surgery for oculoplastic disease.

METHODS

Search Strateg A structured search of PubMed, OvidSP (1946-June 2012), the cochrane database (the cochrane library from the cochrane collection) and NHS evidence was performed. To make the search more thorough a manual search of the abstracts from past meetings of the following societies was also performed: American Academy of Ophthalmology, 2000-2012 (AAO), Association for Research in Vision and Ophthalmology (ARVO), 2002-2012, British Oculoplastic Surgical Society (BOPSS) 2005-2012, American Society of Ophthalmic and Plastic Reconstructive Surgery (ASOPRS) and European Society of Ophthalmic and Plastic Reconstructive Surgery (ESOPRS). The following conditions were selected for the search:

1) Thyroid eye disease (TED)/thyroid ophthalmopathy/Grave's orbitopathy; 2) Ptosis; 3) Nasolacrimal duct obstruction (NLDO); 4) Entropion; 5) Ectropion; 6) Dermatochalasis.

Along with the names of the conditions mentioned above, the following individual search terms were used as keywords within the databases using the standard Boolean system linking (Boolean operator AND): "quality of life", "psychology/psychological", "psychosocial", "patient-reported outcomes", "emotions". The references of each paper included following critical appraisal were also investigated for relevant content. Two researchers who were not blind to the decision of the other screened the abstract for relevance and shortlisted suitable papers for critical appraisal so that the final list of papers and abstracts for each condition could be compiled.

Inclusion Criteria and Critical Appraisal The primary focus of the research had to be quality of life for each of the conditions to be considered suitable. The main outcome measure was quality of life with a validated method of measuring it such as the Glasgow benefit inventory (GBI), medical outcomes survey short form-36 (SF-36) or a condition-specific quality of life index. If a paper or abstract detailed a new quality of life index for a specific condition it again must be the primary focus of the research and provide evidence of validity. Other inclusion criteria included were English language, original work and full-text availability of the papers included.

Exclusion Criteria Papers on anatomical deformity or anatomical correction of deformity without any validated quality of life evidence were not included. Papers indexed in PubMed without an abstract were not included.

RESULTS

The search showed there was a large amount of variation in evidence between the conditions. Broadly there were two groups: 1) three conditions (TED, NLDO, ptosis) with a

reasonably large amount of quality of life research and 2) three conditions (entropion, ectropion and dermatochalasis) which had a noticeably smaller amount of research.

Thyroid Eye Disease TED had the most amount of evidence available with 31 papers having a primary focus of quality of life (18 of which came from the database search and the remaining 13 from the references of the initial 18) and 2 abstracts from the different meetings^[5-37]. There were two quality of life indices that were specific to TED: the Graves' Orbitopathy-Quality of Life (GO-QOL), Thyroid Eye Disease-Quality of Life (TED-QOL) indexes.

The GO-QOL was developed by a Dutch group and is a 16-item questionnaire which has two subscales: one for visual function and one for the psychosocial implications of the disease^[6-10]. During its development patients were interviewed and asked to rate which aspects of the condition bothered them most: these were included in the questionnaire. The GO-QOL was used in 11 of the studies to assess quality of life.

The TED-QOL is a three-item questionnaire which encompasses 1) visual function, 2) physical appearance and 3) overall quality of life. Validity was comparable to the GO-QOL questionnaire^[32]. The TED-QOL was used in two papers and was assessed in one abstract for its ability to measure quality of life.

Ptosis There were two papers and two abstracts following critical appraisal, the primary focus of which was quality of life^[38-41]. The main constituent of the physical symptoms was visual function determined by upper eyelid position and functional status in due to the limitation of ptosis (Table 1). The articles which satisfied the inclusion criteria, a summary of the quality of life scales, and the main outcome measures used in the studies can be found in chronological order for each condition excluding TED in Table 1.

Nasolacrimal Duct Obstruction There were six papers and two abstracts detailing quality of life in NLDO^[42-49]. Of these one paper reviewed quality of life in congenital NLDO and the remainder focussed on adult NLDO. Similarly to TED there were two NLDO-specific quality of life indices: 1) the Nasolacrimal Duct Obstruction Quality of Life index (NLDO-QOL) scale and 2) the Nasolacrimal Duct Obstruction Symptom Score (NLDO-SS)^[43]. The NLDO-HRQOL scale was detailed in one paper and involved parents rating their child's quality of life when affected by congenital NLDO^[43]. This had two subscales 1) physical symptoms and 2) psychosocial factors such as appearance. The results demonstrated worse scores on both scales for parents with children who had NLDO compared to the control group. Furthermore the scores on both subscales improved following treatment for the condition.

The NLDO-SS was used in 2 papers for adults suffering from NLDO^[46,47]. The NLDO-SS focusses mainly on the nasal and

Table 1 Summary of each of the papers/abstracts which satisfied the inclusion criteria in chronological order for each condition with reference, main outcome measures and index used

Reference	Main outcome measures	Index used
Ptosis		
Papers		
Battu <i>et al</i> ^[38]	Vision-related activity and symptoms	27-item questionnaire developed for study
Federici <i>et al</i> ^[39]	Visual function; general quality of life	Adapted from: Comprehension assessment+referral evaluation interview schedule; duke-UNC health profile; sickness impact profile
Abstracts		
Brach <i>et al</i> ^[40]	Visual function; general quality of life	NEI-NFQ-25; EQ-5D
Harrad <i>et al</i> ^[41]	Psychological implications; Social implications	Derriford appearance scale; Fear of negative evaluation scale; CARVAL (measure of subjective importance of appearance); HADS
Nasolacrimal duct obstruction		
Papers		
Bakri <i>et al</i> ^[42]	Change in health status	GBI and 5 further questions designed to rate ocular symptoms
Holmes <i>et al</i> ^[43]	Physical symptoms; health-related quality of life	NLDO-health-related quality of life (NLDO-HRQOL) questionnaire
Ho <i>et al</i> ^[44]	Change in health status	GBI
Spielmann <i>et al</i> ^[45]	Change in health status	GBI
Smirnov ^[46]	Ocular and nasal symptoms	NLDO-symptom score (NLDO-SS)
Smirnov <i>et al</i> ^[47]	Ocular and nasal symptoms	NLDO-SS
Abstracts		
Cheung <i>et al</i> ^[48]	Sight; reading; driving; sport; mood; work; embarrassment	Questionnaire designed specifically for study
Yeniad <i>et al</i> ^[49]	Ocular symptoms	Questionnaire designed specifically for the study
Entropion		
Abstracts		
Shams <i>et al</i> ^[50]	Change in health status	GBI
Blepharoplasty		
Papers		
Kosowski <i>et al</i> ^[51]	Appearance; functional outcome; social acceptance	Blepharoplasty Outcomes Evaluation (BOE)
Bullock <i>et al</i> ^[52]	Subjects asked to rate: intelligence; threat; friendliness; health; trustworthiness; mental illness; financial success; attractiveness; alcoholism; happiness	Subjects shown photographs of patients with dermatochalasis

ocular symptoms but has a final score for patients' "general condition" which includes their quality of life as a result of the condition (Table 1).

Entropion One abstract extracted from a meeting (ARVO) which involved telephone consultations with patients postoperatively using the GBI to measure quality of life^[50] (Tables 1, 2). Table 2 shows the number of abstracts for each condition following a search of the abstracts from the previous meetings: AAO, ARVO, BOPSS, ASOPRS, ESOPRS. There were no published papers for quality of life on entropion in any of the databases searched.

Ectropion There were no abstracts or published papers from any of the databases or past meetings detailing quality of life in ectropion.

Dermatochalasis There were no abstracts from meetings, however there were two papers aiming to assess quality of life in dermatochalasis. One paper detailed the Blepharoplasty Outcome Evaluation (BOE). This assessed

Table 2 It shows the number of papers for each condition following critical appraisal for primary focus of quality of life content and inclusion of the relevant papers from the references of the articles found on the original search

Condition	No. of abstracts on original search	No. of abstracts following critical appraisal
Thyroid eye disease	2	2
Entropion	1	1
Ectropion	0	0
NLDO	3	2
Ptosis	4	2
Dermatochalasis	0	0

postoperative improvement in quality of life (Table 1). The BOE is a six-item questionnaire with 3 subscales: 1) appearance, 2) function and 3) social acceptance^[51].

The main generic scales used were the SF-36 and the shortened SF-12^[5,11,12,16,18,25,27,28,36] (used in 9 of the 41 papers), the GBI^[42,44,45,50] (used in 4 of the 41 papers and) and the Hospital Anxiety and Depression Scale (HADS)^[16,41] (used in

2 of the 41 papers). There were 5 condition-specific outcome measures: 2 for TED (thyroid eye disease-quality of life index, TED-QOL^[32,37] and the Graves' orbitopathy quality of life index, GO-QOL^[6-10]); 2 for NLDO (Nasolacrimal Duct Obstruction Health-Related Quality of Life index, NLDO-HRQOL^[43] and the Nasolacrimal Duct Obstruction-Symptom Score, NLDO-SS^[48,49]) and 1 for dermatochalasis^[51] (Blepharoplasty Outcome Evaluation, BOE).

DISCUSSION

Quality of Life vs Quality of Life Post-Interventi This study shows the evidence base for quality of life impairment in several oculoplastic conditions is variable. Improvement in quality of life as a result of intervention is the ideal, rather than simple evidence for reduction in quality of life due to the condition. Interestingly, however, if we narrow our inclusion criteria down further to include only papers or abstracts which demonstrate an increase in quality of life post-intervention we get even fewer studies: 4 TED papers^[9,10,14,33], 4 ptosis papers^[38-41], 6 NLDO papers and 2 NLDO abstracts^[42-49], one entropion abstract^[50], and 2 dermatochalasis papers^[51,52].

Although some conditions have a significant amount of evidence supporting intervention, such procedures are still appearing on PCTs' lists of LVCTs. With the evidence base even smaller for post-intervention improvement in quality of life studies there is an urgent need to address this in order to accurately compile the list of LVCTs. In its recent report the Audit Commission stated that the case for any intervention must be based on the "latest clinical evidence". More research is needed to reflect those interventions which produce the most benefit^[4].

Condition-Specific Quality of Life Indices Although the NLDO-SS was proven to show correlation with the GBI, there is no published data on its validity and reliability. The NLDO-HRQOL scale was developed for parents to rate objectively their children's quality of life pre and postoperatively. Kosowski *et al*^[51] published a list of desired criteria for a post-intervention quality of life assessment tool. This condition-specific index has evidence to prove consistency and reliability. Although evidence exists for consistency and reliability there was no evidence for the NLDO-HRQOL satisfying the remaining components of the list. Similarly TED-QOL and BOE have proven reliability and consistency but do not have any published data on the remaining components of the list^[37,51]. Kosowski *et al*^[51] in their review stated that there was not enough published data about the BOE to evaluate it as an assessment tool. To our knowledge the GO-QOL is the only index in the study which is truly valid as it provides evidence for every part of Kosowski's list.

However in contrast to condition-specific indices generic health status instruments such as the SF-36, the GBI and the

Sickness Impact Profile assess the health-related aspect of quality of life and therefore cannot be used to measure overall quality of life^[3]. The studies in which these health status instruments are used they accurately measure the condition-related dimension of the patients' quality of life, but unless they include additional tools which assess the non-health related aspects of a patient's life they cannot accurately measure a patient's overall quality of life. In the future as well as providing more evidence for post-operative change in quality of life it is important that the tools used to measure quality of life are validated.

In addition to its condition-specific indices, TED has the The Amsterdam Declaration which was produced by a group of international experts to implement measures to increase its early diagnosis and management^[53]. However it was not included in the study as it does not measure quality of life.

How Much Evidence is Enough? Overall the amount of evidence available for quality of life in oculoplastic conditions is relatively small. When a similar search was done for "cataract" and "quality of life" the number of search results were 542 papers (23rd June, 2012). This is much greater than TED which had 83 results prior to critical appraisal, and the most results out of any of the conditions in this study. However, cataract surgery also appears on Croydon's list of LVCTs (The Audit Commission, 2011) even though the evidence base for postoperative improvement in quality of life is well known and well documented.

Following Croydon PCT's example North Yorkshire and Hull PCT have produced their own guidelines on interventions for common oculoplastic conditions^[54]. Surgical treatment for entropion and NLDO is not routinely commissioned. Before surgery is approved for a specific patient, approval must be sought from the PCT's Individual Funding Request Panel. The paperwork required is a 3-page form regarding the intervention needed and the specific clinical evidence for it. This must be filled up by the primary care provider. Furthermore North Yorkshire and Hull PCT only commission surgery for "ptosis/dermatochalasis" when a patient demonstrates a reduction in visual field by 20°. No justification is given for this cut-off point before surgery is considered and further quality of life research would be required before it could be accurately stated whether a patient would benefit from surgery before (or indeed after) this reduction in visual field has occurred.

In the Audit Commission's recent report it detailed that some PCTs felt that a UK national body such as National Institute for Health and Care Excellence (NICE) would be better placed to set national guidelines on LVCTs^[4]. In addition to research coming from within the specialty the Right Care strand of QIPP is also developing its own evidence base for the efficacy of common interventions for different conditions. The World Health Organisation defines health as "a state of

complete physical, mental and social well-being and not merely the absence of disease or infirmity." Quality of life research is essential therefore to determine the health benefits of any surgical intervention. The amount of evidence available for the decrease in quality of life due to oculoplastic conditions, and an increase in quality of life following intervention is variable and in some cases non-existent. In compiling lists of LVCTs commissioners require specific evidence and addressing this deficit will ensure that quality of life is taken into account. The right care strand of QIPP is developing its own evidence base but the specialty itself is well placed to provide high quality evidence to illustrate the efficacy or otherwise of these interventions.

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