Quality of life in patients with facial prosthesis

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON36001

Source
ToetsingOnline

Brief title
Quality of life in patients with facial prosthesis

Condition

- Other condition
- Adjustment disorders (incl subtypes)

Synonym
nvt

Health condition

defect in het gelaat

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: facial prosthesis, quality of life

Outcome measures

Primary outcome

For comparison and statistical analysis the patient group will be subdivided into those with an ear prosthesis, nose prosthesis, eye prosthesis and composite prosthesis. Furthermore, the group will be subdivided into those using an adhesive, magnets or a click system.

Statistical analyses will be preformed with the Statistical Package for Social Sciences (SPSS). The quality of life subscales (general, anxiety, depression, satisfaction, head and neck specific) of this patient group will be compared to those of the general population with comparable demographic features (sex, age, socio-economic status, postal code). A regression analyses will be used to determine if these socio-demographic and clinical variables are significant with the quality of life results. The influence of age, time passed since the surgery **, sex, etc will be correlated with these QOL measures. The body image scale will be correlated with QOL as well as the different types of prostheses and defects.

** The coping strategy after facial reconstruction is important for the

satisfaction (12). It is likely to think that patients with a facial prosthesis cope in a similar way. It takes time to coping with facial disfigurement (21). In this analysis will be distinguished if patient are reconstructed with a prosthesis; recently (1-2 years ago), moderate (3-5 years ago) or in the last (>5 years ago).

Data collected by means of the in-depth interviews will be analyzed by means of a process of coding (26). To facilitate and standardize this process the software program NVivo will be used, and to obtain a structured description of patients* lived through experience, codes will be further analyzed according to the (empirical) phenomenological method (27-29). The interviewer(s) will analyze the data together with Prof. G. Widdershoven and Dr. J Slatman. The specific aim of the qualitative data analysis is to identify (various) *patterns* of embodied self-experiences in people with facial prostheses, i.e. the ways in which people experience their prosthesis as related or belonging to their own body. It is predicted that the degree to which the prosthesis is experienced as part of one*s body is constitutive for the degree to which a patient is able to cope with it.

The investigators preserve the confidentiality of subjects taking part in this trial. Names of participating patients will not be passed to persons not directly participating on the study. The information obtained during the

conduct of this study is confidential.

Secondary outcome

nvt

Study description

Background summary

Head and neck cancer has an enormous impact on the quality of life of patients (1). Radiation and chemotherapy in combination with surgery is the treatment generally used for malignant tumours of the head and neck region (2). The adverse effects of these treatments may result, besides dysfunction, in a significant facial disfigurement. This can cause self image difficulties for the patient, possibly evolving into psychosocial dysfunction (3). Therefore aesthetic repairs of head and neck lesions may be just as important to the patient as the treatment itself. In some patients, reconstructive surgery is possible to reconstruct facial defects. However, although multiple procedures are often needed, the results of surgical reconstruction of extensive facial defects are often disappointing (4). As a result most aural-, nasal- and ocular defects are reconstructed by a prosthesis. Prostheses provide better results than reconstructive surgery when restoring large facial defects (5). Using silicone and plastic resin, an inconspicuous restoration of the facial defect can be achieved in many patients. In the past, the facial prostheses were supported by a surgically constructed skin tunnel or attached to spectacles (4). These methods had many drawbacks, e.g. difficulties with the positioning and retaining the prosthesis. Nowadays the facial prostheses are attached by special glue or extra oral implants with realistic results (6). The cosmetic result is an important outcome measure of the procedure and even more important is the patient*s satisfaction with the results (7).

Limited research has been conducted assessing the consequences in quality of life of patients with facial prostheses. Irish et al. (8) determined the quality of life after prosthetic rehabilitation for maxilla and palatal defects. They concluded that the prosthesis improves the obturator function that leads to a better quality of life. In general prosthesis for aural, nasal and ocular reconstruction do hardly improve the functional loss. The article of Chang et al. (9) evaluated the patient*s satisfaction with adhesive-retained prostheses versus implant-retained facial prostheses studying patients with an auricular, nasal or orbital prosthesis. They concluded that the implant-retained facial prosthesis offers significant advantages over the adhesive-retained prosthesis. According to this article this is due to the ease of use and secure retention of the prosthesis during the day. Though Younis et

al. (10) who examines the Branemark-type, bone-anchored, ear prosthesis shows that patients fitted with this type of implant are pleased with the aesthetic appearance but experience skin and implant related problems affecting their satisfaction. Besides Dos Santos et al. (11) describes that the satisfaction of auricular prosthesis depends on the colour stability of the resin and silicone.

Compared to the studies investigating psychosocial consequences in patients with a facial prosthesis, more research has been done evaluating the contention on aesthetic surgery and the impact and anticipation after surgery of head and neck cancer (7, 12). Mary Jo Dropkin is a prominent researcher in this field. She evaluated the various aspects of the quality of life and body image after head and neck cancer surgery. In her early articles she constructed a quantitative scale to measure the perception of severity of visible disfigurement and explored the coping with this disfigurement and dysfunction after head and neck cancer surgery (13, 14). In 1999 her study indicates a correlation between body image reintegration and the subsequent quality of life in these patients (15).

To evaluate the general well-being of an individual or a group, the term *Quality of Life* is generally used. Definitions of this term are as numerous and diverse as the methods of assessing it (16). The various quality of life questionnaires and additional specific questionnaires show that there are also many different ways to investigate the quality of life in head and neck patients (1, 17, 18). Since the evaluation of one*s bodily appearance and function are commonly considered as crucial for the way one evaluates one*s quality of life, body image-, body satisfaction-, or disfigurement / dysfunction scales are frequently added to the quality of life questionnaires (3, 19-21). To answer the question which composition to use for our group Ching et al. (7) assessed in a review of literature how to measure the outcomes of aesthetic surgery. They have concluded that the Body Image and Quality of Life measure are most valuable determining aesthetic surgery outcomes.

In a small pilot study we assessed the feasibility of giving these questionnaires to 5 patients who visited the anaplastologists. Questionnaires were filled in by all of them within one hour. After filling in the questionnaire the patients answered 10 feedback questions to evaluate our questionnaire.

In our hospital a group of 135 patients consult the anaplastologists for construction and maintenance of their facial (aural-, nasal- or ocular-) prosthesis. Most of these patients have to cope with their facial deformity and find ways to accept their handicaps. Initially almost all of these patients have psychological problems after the ablative head and neck surgery (1,3). As time passes, these problems will (partly) subside. However, it is well known that some patients cope better with their handicaps than other patients. Decision making on treatment should be done in dialogue with the patient and although the alternative are generally limited, it would be helpful for both

the clinician and the patient if realistic predictions can be made on both the mutilation as well as the expected coping problems.

Study objective

The purpose of our study is to describe the quality of life of patients who had facial surgery and who are using a facial prosthesis (for at least 1-10 years), with a specific emphasis on bodily experiences (concerning both function and appearance). This current study wants to provide further insight into the social-, psychical- and physical- situation and the possible limitations of these patients with a facial prosthesis. With this knowledge we hope to notice the possible problems in this patients group and anticipate if necessary. By using in-depth interviews in 10-15 purposively selected patients (different prostheses, age, sex etc.) we will identify specific problems and possible solutions for these patients. Furthermore we hope to find clues on whether we can predict the satisfaction, coping and QOL.

Study design

This study will be carried out as a cross sectional study. In this hospital 135 patients consult the anaplastologists on a frequent (> once a year) basis for maintenance of their facial prosthesis. These 135 eligible patients will be asked to participate in the study and sign the informed consent form.

The participating patients will be divided in a study group (inclusion criteria) and a rest group (non-cancer patients, reconstruction occurred >10 years ago). The patients in rest group (approximately 40 patients) also visit the anaplastologist on a frequent base. The study patients will answer the complete questionnaire. This complete questionnaire includes a Quality of Life-, facial prosthesis-, Body Image- and Survival of Cancer questionnaire. From this group approximately 10 to 15 patients will be selected and will be invited for an in-depth interview. The rest group will be asked to fill in the QOL-, Body Image and facial prosthesis questionnaire.

Study burden and risks

nvt

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Primary diagnosis of head- and neck cancer, including melanoma, treated with ablative surgery .
* At least one year tumour free
* Reconstructed with a facial prosthesis of the ear, orbita or nose.
* Reconstruction occurred between 1 and 10 years ago.
* Age between 18 and 85 years.
* Frequent (at least once a year) consultation of the anaplastologists.;* Patients with other facial defects caused by surgery or trauma. (These patients will not be included in the study group, though they will be asked to fill in the QOL-, Body Image and facial prosthesis questionnaire.)

Exclusion criteria

*Patients who are incompetent in answering questionnaires due to mental disorders or limiting co-morbidity.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-04-2011
Enrollment:	135
Type:	Actual

Ethics review

Approved WMO

Date:	28-01-2011
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL35486.031.11