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**Role of Appearance-Pain in breast surgery:
Impact on patient's appearance perception of autologous and
implant based breast reconstruction following mastectomy
and analysis of possible predictive factors of satisfaction**

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The Role of Appearance: Definition of Appearance Pain (App-Pain) and systematic review of patient-reported outcome measures used in literature

Introduction

Body image is a multifaceted psychological experience of embodiment that encompasses evaluative thoughts, beliefs, feelings, and behaviors related to one's own physical appearance. Health Related Quality of Life is broadly defined as an individual's perception of the effects of an illness and/or treatment on the physical, psychological and social aspects of their life. The theme of suffering as "global suffering" can be understood as an emerging, multi-causal reality produced by anxiety, somatic pain, fear, and depression. Understanding this systemic concept of suffering is useful for clinicians to appropriately intervene in their relationship with the patient. Additionally, it is necessary that each patient understands the other components of his or her diagnosis that may be connected to their specific state of health. This is why the concept of global suffering should be assessed with other experiences of suffering and identified from both a quantitative and qualitative point of view. The appearance has an important role in the Health Related Quality of Life and it must be analyzed in our clinical practice. As it stands, "Appearance-Pain" is a construct for which no nosographic classification yet exists, and, consequently, does not have validated evaluation tools. This term, not present in literature, may be defined as the suffering resulting from the perception of one's own appearance. To define the elements of self-evaluation (estimation, safety, and sense of integration), we will use the emerging correlations found in the formulation of a theory of suffering that arises from one's appearance, placing it outside of Anderson's logic, for which correlations are sufficient without working through interpretative theories, and so on. Influence the level and type of suffering related to appearance Disorders related to appearance are diagnosed in the medical field through nosographic classifications, (eg. Disorders of Somatic Symptoms and Related Disorders, Nutrition Disorders and Nutrition, or Joseph Parnas Group Analysis on the Disorders of Self Experience). None of these nosographic classifications provide a broad assessment of appearance



and any related disturbances. In literature there is not a review about patient-reported outcomes measures to evaluate appearance. So, the objectives of the current study are: 1) To perform a systematic review of the existing scientific literature on appearance and any subsequently related disorders, 2) research in literature the correlation between the role of appearance and patient's disease.

Materials and methods

A systematic review protocol was developed a priori in accordance with the Preferred Reporting for Items for Systematic Reviews and Meta-Analyses-Protocols (PRISMA-P) guidance. The search strategy was constructed in line with PRISMA guidelines, the Cochrane handbook, and guidance from Terwee et al. A multistep search of the PubMed, MEDLINE, Embase, Premedline, Ebase, CINAHL, PsychINFO and Cochrane databases was performed to identify studies on patient satisfaction, quality of life, and body image (table 1). Key words or MeSH terms were used where available (table 2). The search strategy was trialed and modified in collaboration with an experienced librarian, with an example of the final search strategy. Both abstracts and complete articles were reviewed. References were also searched to identify any previously missed studies. Each potential study was examined by 2 independent reviewers for adherence to inclusion/exclusion criteria. Exclusion criteria included: i) reports not written in English; ii) reports on nonhuman subjects iii) reports that did not assess patient satisfaction or analyze patient appearance or did not use questionnaires and iv) reports that analyze outcomes following surgery (e.g. breast surgery, facial surgery, sex reassignment surgery) using specific patient reported outcome measures. Discrepancies were discussed between the two reviewers. The search strategy was re-run prior to submission in February 2018 to identify any new articles. Data required for the following analyses were extracted from each paper and collated in Word and Excel for Mac (V14.5.7).

Results



Our search generated a total of 347 articles. 320 of these articles were identified using the search terms shown in Table 2. 27 additional articles were identified by reviewing the references of the first 320 articles. Results are presented as tables and a narrative synthesis. We summarized the questionnaires used in all included studies and categorized them as generic, surgery specific, or ad hoc and identified whether they contained validated or not yet validated measures.

Figure 1 summarizes our search results; 301 studies were excluded based on the content of the abstracts and an additional 28 studies were excluded based on the content of the complete article. We performed a systematic review of the 18 remaining studies, which had sufficient data and met all inclusion criteria. All studies identified from the literature review were assessed to determine the utilization of validated patient satisfaction questionnaires. The questionnaires were analyzed by reviewers to assess adherence to the rules of the US Food and Drug Administration (U.S. FDA) and the Scientific Advisory Committee (SAC) of the Medical Outcomes Trust (MOT). We identified 27 individual questionnaires, including the Appearance Schemas Inventory, the Derriford Appearance Scale, the Body Dysmorphic Disorder Examination, the Body Dysmorphic Disorder Questionnaire, the Yale Brown Obsessive Compulsive Scale Modified for Body Dysmorphic Disorder, the Dysmorphic Concern Questionnaire, the Beck Depression Inventory, the Body Dysmorphic Symptoms Scale, the Body Image Concern Scale, the Rosenberg scale, the Body Image Scale, the Body-Cathexis and Self-Cathexis Scale, the Body Dissatisfaction and Appearance Magazine Exposure, the Appearance Conversations with Friends, the Peer Appearance Criticism, the European Organization for Research and Treatment of Cancer (EORTC) Breast Cancer-Specific Quality of Life Questionnaire (QLQ-BR23), the Functional Assessment of Cancer Therapy – Breast, the Tridimensional Personality Questionnaire, the Body Uneasiness Test, the Barratt Impulsiveness Scale, the Freiburg Questionnaire on Aesthetic Dermatology and Cosmetic Surgery, the Body-Self Relations Questionnaire, the Short Form-36 Health Survey Questionnaire, the Acceptance of Cosmetic Surgery Scale, the Body Appreciation Scale, the Sociocultural Attitudes Toward Appearance Questionnaire, and the Photographic Figure Rating Scale for body image



assessment. Ad hoc instruments or instruments not described by a complete manuscript were excluded. Table 3 summarizes our assessments of the development and validation characteristics of the 27 validated measures used in the studies. Evaluation of the content of each measure is presented in Table 4. DAS59 was deemed to have adequate levels of methodological and psychometric evidence. Any studies clarify the role of appearance and more specific its relation with patient's disease.

Discussion

Body image is a multifaceted psychological experience of embodiment that encompasses thoughts, beliefs, feelings, and behaviors related to one's own physical appearance. Two schools of thought prevail in the broader discussion of body image. On one side, research focuses more on issues related to beauty in plastic surgery, suggesting that surgeons should have a clear, objective, and sharable aesthetic concept of cosmetic medicine. On the other side, the assessment of quality of life before and after surgery cannot be based on personal considerations of the attending physician, but must be expressed through objective studies. Patients require clear communication in their pre-surgical consultations to ensure that the surgeon clearly understands the patient's expectations. Usually, the patient perspective is measured using self-report instruments, which are becoming increasingly relevant in modern clinical outcome research.

Plastic surgeons must have a clear, objective, and sharable aesthetic concept on which to build a new vision of cosmetic medicine that is systematically connected with other medical branches. This concept must allow surgeons to actively cooperate in the planning, definition, and solution of the clinical problem. To date, five important reviews of Patient-reported outcome measures (PRO) have been reported, applying to cosmetic facial surgery and/or nonsurgical facial rejuvenation, breast surgery, rhinoplasty, gynecomastia correction, and sex reassignment surgery. We are unaware of any studies examining the role of appearance in our society, in general, or the role of appearance in patients with a specific disease. Our research consisted of the systematic review of patient-reported



outcome measures in medical literature that may be used by doctors to analyze satisfaction in body perception and appearance. As previously discussed, a complete instrument should be composed of functional, psychosocial, and cosmetic survey questions and be well validated following the rules of the U.S. FDA and the SAD of the MOT. Tables 2 and 3 contain an analysis of all of the instruments used in articles that reported on body and appearance perception. We also analyzed the role of appearance in literature because a lot of studies focused on appearance. Chua AS et al used the Appearance Schemas Inventory-Revised on 356 breast cancer patients undergoing mastectomy and breast reconstruction. Cogliandro A et al. utilized 400 adult patients with a history of previous plastic surgeries and 400 adult patients without any history of plastic surgeries to validate an Italian version of the DAS59. The first Italian translation of this questionnaire was conducted according to the DAS59 protocol that was designed by the original authors of the questionnaire. Felix GA et al. utilized the Body Dysmorphic Disorder Examination questionnaire to conclude that Rhinoplasty may be indicated in the treatment of female patients with mild to moderate Body Dysmorphic Disorder. He W et al. gave the Body Image Concern Scale to 328 male and 365 female Chinese university students to validate the measure and to establish gender preponderance. Herruer JM et al. (53) applied the Derriford Appearance Scale and Rhinoplasty Outcome Evaluation, which is a surgical specific questionnaire and is not included in our review, to demonstrate a significant improvement in quality of life achieved by rhinoplasty. Although males are equally satisfied as females, they tend to benefit less from the surgery in daily life. The Rosenberg Self-Esteem Scale was used to establish the outcome of rhytidectomy as perceived by the patient and to further understand the association of self-esteem and the results of aesthetic facial rejuvenation. Joseph AW screened patients for Body Dysmorphic Disorder (BDD) using the Body Dysmorphic Disorder Questionnaire, corroborated by a surgeon evaluation following each encounter, rating the likelihood that a participating patient had BDD. Validated instruments were used to assess satisfaction with facial appearance, including the FACE-Q, Blepharoplasty Outcomes Evaluation, Facelift Outcomes Evaluation, Rhinoplasty Outcomes Evaluation, and Skin Rejuvenation Outcomes Evaluation. They



concluded that BDD is a relatively common condition across facial plastic and oculoplastic surgery practice settings, and patients who screen positive on the Body Dysmorphic Disorder Questionnaire tend to have lower satisfaction with their facial appearance at baseline. Kelsall JE used a body image scale on women who had either undergone Oncoplastic breast conserving surgery or who may otherwise require a mastectomy and desire immediate reconstruction. van den Elzen ME used the Body Cathexis Scale on 59 adults who had completed treatment for their severe facial cleft and recommend screening patients for non-acceptance, with consideration for psychological treatment before surgery is performed. Nerini A utilized a questionnaire containing the Appearance Conversations With Friends Scale, the Perception of Teasing Scale for Friends, the Peer Attribution Scale, the Pressure and Internalization-General subscales of the Sociocultural Attitudes Towards Appearance Questionnaire-3, the Feedback on Physical Appearance Scale, the Physical Appearance Comparison Scale, and the Consider subscale of the Acceptance of Cosmetic Surgery Scale on 429 Italian women, from which they concluded that cosmetic surgeons should consider adopting a psychological approach to their interactions and assessment of patients. Onesti MG used the EOCRT QLQ C-30 and QLQ BR-23 questionnaires on 52 patients who underwent one-stage muscle-sparing breast reconstructions with acellular dermal matrix and received an implant. Similarly, Pavan C, used the Mini International Neuropsychiatric Interview, the Beck Depression Inventory II, the Yale-Brown Obsessive Compulsive Scale modified for Body Dysmorphic Disorder, the Tridimensional Personality Questionnaire, the Body Uneasiness Test, the Barratt Impulsiveness Scale 11, and the Binge Eating Scale on 36 post-bariatric patients seeking plastic surgery and 21 clinically matched controls who were not seeking shape remodeling surgery. Reavey PL reviewed studies utilizing the Freiburg Questionnaire on Aesthetic Dermatology and Cosmetic Surgery, the Derriford Appearance Scale, and three breast reduction measures (the Breast Reduction Assessed Severity Scale Questionnaire, the Breast Related Symptoms questionnaire, and the BREAST-Q reduction module) which were the only validated questionnaire used in postbariatric surgery available at that time (2011). As this review is currently outdated, another review to



investigate the best patient reports of outcome in this type of surgery is suggested. Saariniemi KM used the Eating Disorder Inventory, Raitasalo's modification of the Beck Depression Inventory, and the 15D general quality-of-life questionnaire to demonstrate that cosmetic breast augmentation results in a significant improvement in women's body satisfaction and self-esteem. Song P used the Multidimensional Body-Self Relations Questionnaire and the Short Form 36 on 175 patients prior to undergoing bariatric surgery. Swami V used the Acceptance of Cosmetic Surgery Scale on 311 Brazilian adults to develop a Portuguese translation. van de Grift TC used the Multidimensional Body-Self Relations Questionnaire, the Appearance Schemas Inventory, the Body Image Quality of Life Inventory, the Rosenberg Self-Esteem Scale, the Situational Inventory of Body Image Dysphoria, and the Body Image Scale for Transsexuals to conclude that body satisfaction and feelings of "passing" in social situations are both associated with a higher quality of life and self-esteem. Wang Q used the Multidimensional Body- Self Relations Questionnaire, appearance scales, and the Rosenberg Self-Esteem Scale to observe a high prevalence rate (14.2 %) of body dysmorphic disorder in aesthetic procedure seekers. They concluded that patients suffering from BDD were more likely to be dissatisfied with the results of the aesthetic medical procedures compared to those without BDD. All of these questionnaires are limited by their content range and psychometric properties. Only the DAS59 covered most of the content and psychometric properties, as shown in Tables 3 and 4. This questionnaire has several domains that examine both psychosocial and physical conditions and examines the role of appearance relative to these constructs. To date, we are unaware of any research that examines the role of appearance in patients with medically diagnosed disease and self-perception of body image.

This review also studied how the concept of appearance is complex with regards to a system in which the components interact in multidimensional ways and follow the general, local, and circular rules, with a non-linear logic. This is why, in our opinion, so far aspects of appearance have been calculated through a lawful and useful reduction operation which now requires the consequent action of re-composition through at least 5 axes which however, in any case, require the following



two premises. Premise 1 is the concept of appearance as "perceived by me" and of how "I am perceived by others" with feedback on synthetic perception (appearance) strengthening (I think I am positively perceived and therefore I perceive myself even more positively, independently from who is perceiving me), contrasting (I think I'm perceived negatively and therefore I perceive myself more negatively, without variations, or better than before, in relation to my concept of who is perceiving me) or, being absent (I perceive to not to have been perceived and this can produce a strengthening, diminutive, or no relevance feedback). Premise 2 suggests that appearance becomes a dynamic reality that varies according to at least the following five indicators, which will be those used in the work of re-composition. These five indicators are 1) appearance changes in my time and in the time of the observer; 2) the whole in which I expose myself (eg. I evaluate the appearance in the family, at school or on television); 3) the characteristics of the observer (eg. s/he is a friend of mine, s/he is my friend, s/he is the person I love, s/he is a doctor; 4) co-morbidity and / or pathologies (eg. I am anorexic, I am psychotic, I am in a post-traumatic situation); 5) concurrent factors (eg. I have success / failure in the rest of my life, I am alone or I have a rich relational life, I am in a state of war or peace). The nosographic concept of Appearance-Pain, which is not present in literature, that we propose consists of the re-composed systemic view of experimental indicators of suffering, linked to one of these dimensions of one's appearance. The importance of this potentially new nosographic entity is the possibility of inserting the logic of precision medicine or personalized medicine into cosmetic medicine, combining, according to a logic of complexity, the psychological, objective, and relational dimension of the perception of perceived beauty. Using this rationale, we completely leave Newtonian logic, where the observer was ruled out, to voiding falling into an aesthetic subjectivism that would deny the possibility of reaching a clinical indication based on scientific evidence for cosmetic surgery. All this has a considerable importance for building a best practice which, from the point of view of applied ethics, is the doctor's first duty.

Conclusions



Appearance is a part of a complex system whose components interact in multidimensional ways and follow general, local and circular rules with non-linear logic. App-Pain consists of the re-composed systematic view of the experimental indicators of suffering, linked to one of the dimensions of appearance. The use of reliable, valid, and responsive patient questionnaires is essential to provide information about appearance and body image in each patient. This is the first systematic review about appearance and the DAS59 results currently the only validated, complete patient reported outcome measure which could be of use to evaluate appearance in our clinical practice.

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Table 4. Content Analysis

Figure

Figure 1: flow diagram search strategy



Tesi di dottorato in Scienze biomediche integrate e bioetica, di Mauro Barone, discussa presso l'Università Campus Bio-Medico di Roma in data 16/06/2021. La disseminazione e la riproduzione di questo documento sono consentite per scopi di didattica e ricerca, a condizione che ne venga citata la fonte.

Table 1: PICOS criteria

Parameters	Inclusion criteria	Exclusion criteria
Patient, population or problem	i) Patient candidate to cosmetic or reconstructive surgery ii) Databases research (Medline, EMBASE, Premedline, Ebase, CINAHL, PsycINFO).	Patient with psychiatric disorder, with abuse of alcohol or drug
Intervention, prognostic factor, or exposure	Analysis of the role of appearance in patient	
Comparison or intervention (if appropriate)	The use of PROMs in patient's evaluation	
Outcome you would like to measure or achieve	i) Variation of quality of life ii) Evaluation of the role of appearance in medicine and surgery	
Study design	i) Articles published up to february 2018 ii) Studies in the English language iii) All articles focused on the patient's Satisfaction, body image, body' perception, appearance perception	i) All reports not written in English ii) Reports on nonhuman subjects iii) Reports that did not assess patient satisfaction after surgery iv) Reports that did not analyze outcomes following surgery v) Case reports, expert opinions, reviews, letters to editor, comments, conference reports



Table 2. Search Terms

Search group	Search terms
PROM	Treatment outcome, personal satisfaction, outcome assessment, quality of life, quality-of-life, questionnaire, outcome, satisfaction, instrument, survey-, assessment-, appearance, pain, body image, Dysmorphic Disorder
Surgical procedures	Rhinoplasty, Rhinoseptoplasty, Septorhinoplasty, Septoplasty, facial lift, Postbariatric surgery, bariatric surgery, brachioplasty, thighlift, mastopexy, abdominoplasty, body contouring, gynecomastia correction, reduction mammoplasty, dermolipectomy, buttocklift, cosmetic medicine
Elective procedures	Aesthetic, cosmetic, elective

PROM: Patient reported outcome measure

Table 3. Development and Validation Criteria

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	
<i>Item generation</i>	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Patient interviews	+				+					+									+									
Literature			+						+											+			+	+	+	+	+	
Expert opinion	+				+				+										+									
Develop conceptual model	+	+	+			+	+	+	+		+	+	+	+	+	+	+		+	+			+	+	+	+		
<i>Item reduction</i>	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Expert opinion					+		+																					
Item redundancy	+						+																					
Endorsement frequencies	+																											
Missing data																												
Factor analysis	+					+		+		+									+									
Test of scaling assumptions																												
<i>Psychometric analysis</i>	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Acceptability	+	+					+																					
Internal consistency reliability	+	+		+			+				+	+							+	+		+	+				+	
Item total correlations	+						+					+							+								+	
Inter-rater reliability	+			+			+		+		+	+							+							+	+	
Test-retest reliability	+			+			+				+								+		+	+						
<i>Validity</i>	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Within scale	+								+				+	+	+				+	+					+	+	+	
Comparison with other measures	+								+										+									
Hypothesis testing	+						+	+	+		+	+								+						+	+	+
Responsiveness	+		+				+	+			+															+	+	+

1. Derriford Appearance Scale
2. Beck Depression Inventory
3. Tridimensional Personality Questionnaire
4. Body Uneasiness Test
5. Freiburg Questionnaire on Aesthetic Dermatology and Cosmetic Surgery
6. Body-Self Relations Questionnaire
7. Short Form-36 Health Survey Questionnaire
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14. Body Dissatisfaction and Appearance Magazine Exposure
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16. Peer Appearance Criticism
17. Body Dysmorphic Symptoms Scale
18. Dysmorphic Concern Questionnaire
19. Body Dysmorphic Disorder Examination
20. Barratt Impulsiveness Scale
21. Photographic Figure Rating Scale for body image assessment
22. Sociocultural Attitudes Toward Appearance Questionnaire
23. Body Dysmorphic Disorder Questionnaire
24. Yale Brown Obsessive Compulsive Scale Modified for Body Dysmorphic Disorder
25. Rosenberg scale
26. European Organization for Research and Treatment of Cancer (EORTC) Breast Cancer-Specific Quality of Life Questionnaire (QLQ-BR23)
27. Functional Assessment of Cancer Therapy – Breast



Table 4. Content Analysis

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
<i>Self-perception of body appearance</i>	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\
Satisfaction with appearance	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Noticeable change in appearance	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Noticeable improvements in "feature"	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Family and friends' satisfaction with appearance	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Reliance on concealment of appearance	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Looking to undergo additional procedures to improve appearance	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
<i>Self-concept</i>	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\
Self-esteem/confidence	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Feeling/looking "normal"	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Feeling attractive	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Ability to look at self	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Negative feelings about self	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Concern regarding others' negative perception of self	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Shame/stigma/embarrassment	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
<i>Psychological functions</i>	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\	\
Optimism	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Social/professional interactions	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Concern/excessive worry	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Avoidance of uncomfortable situations	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Sexual comfortable	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
acceptability as a sexual partner	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Ability to enjoy life	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Appearance in photographs	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

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Impact on patient's appearance perception of autologous and implant based breast reconstruction following mastectomy using BREAST-Q

Introduction

The breasts represent the fulcrum of female sexuality and are one of the central and most important points for all women. It has been well known for decades that mastectomy after the whole breast involves not only a physical demolition, but also results in psychological discomfort in a woman's social, relational, and sexual life. Over the decades, reconstructive surgery techniques have been increasingly refined in order to allow patients to have a high quality of life. The reconstructive technique must be chosen based on the characteristics of the patient, the therapies already performed or to be performed, and the tissue to be reconstructed. However, we can evaluate in the long term and with the same initial condition and therapy, what is the percentage of the body of women who have undergone mastectomy and who have been reconstructed with microsurgical flaps and breast implants. Patient-reported outcomes following breast reconstruction are one of the most important success parameters. In this systematic review and meta-analysis, we aimed to compare the two methods using the recognized BREAST-Q questionnaire. In the literature, there are already comparative and prospective studies concerning this topic, all of which conclude that microsurgical reconstructions lead to the best long-term results, with fewer secondary procedures and with a better quality of life. Many studies have been performed with generic evaluation scales, with ad hoc questionnaires, and others with specific questionnaires. BREAST-Q is currently the most complete questionnaire and is indicated as the best tool for post-operative evaluation of breast interventions. Few studies have used BREAST-Q. In Italy, there is no study that compares the two long-term reconstructive techniques using the BREAST-Q. For this reason, the purpose of this study is to determine if there is a better quality of life with one of the two techniques and if the results are in line with those already present in the literature. The hypothesis from which we started is to demonstrate that cancer patients who undergo a deep inferior epigastric perforator flap (DIEP)



breast reconstruction surgery are more satisfied and have a higher level of quality of life compared to those subjected to an intervention of reconstruction with prosthesis.

Materials and methods

An institutional review board approved this study, which was performed to evaluate PROs in post-mastectomy breast reconstruction and which were assessed as a component of routine clinical care.

All patients undergoing reconstruction from January 2010 to July 2018 were eligible for inclusion.

This is a retrospective cohort study carried out using the patients of two plastic surgery departments who have undergone 193 (monolateral and bilateral) implant based reconstructions at the Plastic and Reconstructive Surgery Unit, Campus Bio-Medico University of Rome, Chair Prof. Paolo Persichetti and 133 (monolateral and bilateral) DIEP flap breast reconstructions at Department of Plastic Surgery, Faculty of Medicine and Psychology, Sapienza University of Rome, Sant'Andrea Hospital, Chair Prof. Fabio Santanelli di Pompeo. We administered the questionnaire electronically almost one year after surgery. Patients were divided into two groups: implant based and autologous breast reconstruction with DIEP flaps.

Inclusion criteria consisted of patients who underwent to breast reconstruction for cancer, had a follow-up of at least two years, were fluent in the Italian language, and signed the study consent. Patients having undergone prophylactic mastectomy due to genetic indication from deleterious BRCA1/2 or CDH1 mutations were also included in the study. Patients were excluded if they underwent delayed procedures, had a follow-up of less than two years, had post-operative complications that compromised reconstruction, and were legally incompetent, as well as women who did not sign the consent form to participate to this study. The BREAST-Q PROM was administered preoperatively and postoperatively almost two years from the last surgical procedure. Patient responses were recorded on-site, either electronically or physically. Demographic data, treatment method, and postoperative outcomes were recorded secondarily. Variables recorded for each patient included age, body mass index (BMI), history of smoking, preoperative/postoperative



breast irradiation, neoadjuvant/adjuvant chemotherapy, diabetes, hypertension, and timing. Baseline demographics and preoperative patient characteristics were analyzed using a Students t-test (continuous variables) or Chi-square/Fisher's exact test (categorical variables). Mean standard deviation (SD) BREAST-Q scores were reported for the overall cohort and by modality for the postoperative period. The linear regression model was applied to all BREAST-Q score with all predictor factors.

BREAST-Q

BREAST-Q, published in 2009, is a rigorously developed and validated breast surgery-specific PRO-instrument. It has been used to evaluate over 22,000 women who had different types of breast surgery. Development of the BREAST-Q conceptual framework and scale set involved a literature review, 48 patient interviews, and 46 cognitive patient interviews, along with an expert opinion panel comprising plastic surgeons and other healthcare professionals. The scales were then tested on a sample of 2715 patients, with a response rate of 72%. The BREAST-Q reconstruction module has the following scales: satisfaction with breasts, outcome satisfaction, psychosocial wellbeing, sexual wellbeing, physical wellbeing, and chest and upper body satisfaction. In the BREAST-Q development sample (n=1950), each scale fulfilled the Rasch and traditional psychometric criteria (including person separation index, 0.79 to 0.95; Cronbach's alpha, 0.83 to 0.95; and test-retest reproducibility, 0.73 to 0.94).

Ethics Approval

This study was approved by the Ethics Committee of our institutes, Faculty of Medicine and Psychology, Sapienza University of Rome (Sant'Andrea Hospital) and Campus Bio-Medico University of Rome. Each subject provided written informed consent before participating in the study.



Conflict of interest: none

Results

Of the 1125 patients involved, only 325 met the inclusion criteria and were enrolled in this study; specifically, 133 (41%) DIEP and 192 (59%) prosthetic reconstructions. The characteristics of the population studied (age, BMI, years since reconstruction, type of mastectomy, chemotherapy, radiotherapy, hormone therapy, comorbidities including diabetes, hypertension, and smoking) are shown in Table 1. Amongst those who underwent DIEP flap, 49 had a modified radical mastectomy, 11 had a radical mastectomy, 29 had a skin sparing mastectomy, 27 had a nipple mastectomy, and 7 patients had another type of mastectomy. For implant based reconstruction, 30 patients underwent a modified radical mastectomy, 30 had a radical mastectomy, 30 had a skin sparing mastectomy, 50 underwent a nipple sparing mastectomy, 18 had a skin reducing mastectomy, and 34 patients had another type of mastectomy. There were 82.5% patients that underwent unilateral and 17.5% who underwent bilateral mastectomy and reconstruction. Pre-reconstructive therapies included radiotherapy in 48.3%, chemotherapy in 37.5%, and hormone therapy in 37.5%. Table 2 shows the results of all of the modules of BREAST-Q between the two groups with a statistical significance for the DIEP group (all scales with a P value < 0.001). In Figure 1, we summarized the average values of the BMI, age of patients, and follow up of the two groups. For the age: First, there are no significant differences for the mean and variance of the 2 distributions (Levene's test is just > 0.05, 0.053 to be precise). The boxplot shows that the heterologous distribution has greater variability, the height of the boxplot is more marked (18 vs 13 years), as is the median (delta = 1.5). For follow up: The tests do not reveal a significant difference between the means, while the variance is significant. At a glance, it is easy to see that the DIEP distribution is more variable than the implant based (although the average and median are fairly aligned). DIEP patients had a lower BMI. The tests show that there are differences on average and the DIEP distribution is more variable. In Figure 2, we summarized the results of the principal



scales of BREST-Q module: satisfaction with breast, psychosocial well-being, satisfaction with outcome, and sexual well-being in which the autologous group was always more satisfied. In Figure 3, we represent the quality of life and satisfaction of the two groups in base of the type of reconstruction with a higher satisfaction and quality of life for DIEP. From Table 3 to Table 7, we reported results of all linear regression models with higher values for the DIEP group independently from predictors.

Discussion

In the literature, there is a systematic review and meta-analysis comparing BREAST-Q data between autologous and implant-based breast reconstructions. This systematic review and meta-analysis was performed to compare patient reported outcomes of implant based and autologous breast reconstruction. We found that autologous reconstruction yields a higher satisfaction with overall outcomes and breast. These findings can aid clinicians when discussing breast reconstruction options with patients. Only 9 studies published in literature are reported in this review and none for the Italian population. A comparative study on breast reconstruction with prosthesis or autologous should ideally be conducted in every country due to cultural issues and to have data from all countries regarding this type of surgery. Cultural influences are important and play a central role in the perception of the body. Furthermore, the use of BREAST-Q with all its modules needs to have as much feedback as possible for the cultural adaptation of the translation. Alshammari from Saudi Arabia concluded the paper saying that, amongst the 61 patients studied, there was no significant difference in satisfaction between the autologous breast reconstruction and implant based reconstruction group; however, this study was limited by a small sample with a short follow up period, but it remains a study from the Arabic population. Dean, with a population from Australia, concluded their paper by saying that breast reconstruction is highly effective in improving the well-being of women undergoing mastectomy and that BREAST-Q is well suited for



clinical effectiveness research and is easily incorporated into routine patient care. The same conclusion was made in the study by Lagendijk from the Netherlands, who found that the scores of BREAST-Q serve as a reference value for different types of surgery in the study population and enable prospective use of patient-reported outcome in shared decision-making. Liu, who studied a cohort of 119 patients from China, concluded that the majority of patients in their study were most satisfied with the microsurgical abdominal flap breast reconstruction using BREAST-Q. McCarthy conducted a study on 308 patients from the United States and concluded that immediate autogenous tissue reconstruction experience results in significantly less chest and upper body morbidity than in those who undergo either mastectomy with implant-based reconstruction or mastectomy alone. Moberg from Norway concluded that women who underwent autologous-tissue breast reconstruction were more satisfied with the overall outcome than those who underwent implant-based breast reconstruction. Pirro from the Czech Republic found that 65 patients who underwent autologous tissue reconstruction had better satisfaction and outcomes with the reconstructed breast, while both techniques appear to equally improve psychosocial well-being, sexual well-being, and chest satisfaction. Moreover, the group of Santosa from USA concluded that patients who underwent autologous reconstruction were more satisfied with their breasts and had greater psychosocial well-being and sexual well-being than those who underwent implant reconstruction. Weichman from Germany affirmed in the conclusions that in their sample, the microsurgical breast reconstruction is efficacious in patients with a body mass index less than 22 kg/m and, when compared with prosthetic reconstruction, results in higher satisfaction with breasts. Another study which is not included in the first review that we cited because the authors did not use the BREAST-Q but analyzed the Assessment of Outcomes and Healthcare Resource Utilization After Immediate Breast Reconstruction Comparing Implant- and Autologous-based Breast Reconstruction, found that complications and secondary breast procedures, including unplanned revisions, after breast reconstruction were common and varied by reconstructive modality, and the frequency of these secondary procedures adds substantial healthcare charges to the care of the breast reconstruction



patient. Hu, et al. (USA) compares 110 expander/implant and 109 transverse rectus abdominis myocutaneous reconstructions and they concluded that in the long term, TRAM patients had significantly greater aesthetic satisfaction compared to those that had an expander/implant performed. One of the most important published studies about this topic is by Nelson, et al. (USA) that consisted of a cohort of 3268 patients, including 336 who underwent autologous breast reconstruction and 2932 that had implant-based breast reconstruction. This study presented the largest prospective examination of patient reported outcomes in post-mastectomy reconstruction to date. Patients who opted for an autologous breast reconstruction had significantly higher satisfaction with their breast and quality of life at each assessed time point, but IBR patients had stable long-term satisfaction and quality of life postoperatively. All of these studies are important because they highlight two important points: 1) breast reconstruction is an integral part of the treatment after mastectomy and represents the surgical part that improves the quality of life of patients and 2) the choice of the technique is important and must be based on precise criteria and according to patient characteristics; moreover, reconstruction with the autologous technique remains the most satisfactory in the long term. There is no one better technique than another, but we can certainly say that autologous techniques are better perceived by patients. It would be excellent to discuss the bioethical concepts of a breast prosthetic device and its role in breast reconstruction to understand the real perception that one has of this device that is not originally part of the body. Our study is the first to be carried out on an Italian population and it contributes to increasing the case history regarding the comparison between autologous techniques and the use of prostheses and their impact on the patient's quality of life. There have not been any other studies conducted in our country concerning this topic. Therefore, our contribution is fundamental to communicate that autologous techniques are also perceived as the most satisfactory in the long term in our population.

Conclusions



This is the first study performed on the Italian population that compares autologous surgical techniques with the implantation of breast implants. In this population, DIEP is considered the technique that leads to the highest satisfaction in all BREAST-Q scores. Each country should conduct a study on this topic because the perception of one's body could be influenced by cultural factors and it would be interesting to analyze the case history of each country that deals with this type of surgery.

Tables:

Table 1: population data

Table 2: Results of all of the modules of BREAST-Q between the two groups

Table 3: linear regression model: satisfaction with breasts

Table 4: linear regression model: satisfaction with outcome

Table 5: linear regression model: psychosocial wellbeing

Table 6: linear regression model: sexual wellbeing

Table 7: linear regression model: physical wellbeing chest

Figures:

Figure 1: the average values of the BMI, age of patients, and follow up of the two groups

Figure 2: results of the principal scales of BREAST-Q module

Figure 3: quality of life and satisfaction of the two groups in base of the type of reconstruction

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Table 1: population data

Characteristic	Procedure Type		P Value
	Autologous Reconstruction (DIEP) (n = 133)*	Implant Based Reconstruction (n = 192)*	
Age, mean (SD)	51.3 (9.5)	51.9 (10.7)	.622
Years After Surgery, mean (SD)	4.7 (2.7)	4.8 (1.2)	.632
BMI**, mean (SD)	25.2 (4.0)	26.2 (2.9)	.017
Laterality of reconstruction, number (%)			
Unilateral	110 (82.7)	158 (82.3)	.923
Bilateral	23 (17.3)	34 (17.7)	
Mastectomy Type, number (%)			
Modified radical	49 (36.8)	30 (15.6)	<.001
Radical	11 (8.3)	30 (15.6)	
Skin Sparing	29 (21.8)	30 (15.6)	
Nipple Sparing	37 (27.8)	50 (26.0)	
Other	7 (5.3)	52 (27.1)	
Radiotherapy, number (%)			
Yes, adjuvant	50 (37.6)	76 (39.6)	.698
Yes, neoadjuvant	11 (8.3)	20 (10.4)	
No	72 (54.1)	96 (50.0)	
Chemotherapy, number (%)			
Yes, adjuvant	8 (6.0)	25 (13.0)	.035
Yes, neoadjuvant	32 (24.1)	57 (29.7)	
No	93 (69.9)	110 (57.3)	
Hormone Therapy, number (%)			
Yes	46 (34.6)	76 (39.6)	.360
No	87 (65.4)	116 (60.4)	
Diabetes, number (%)			
Yes	4 (3.0)	8 (4.2)	.586
No	129 (97.0)	184 (95.8)	
Hypertension, number (%)			
Yes	33 (24.8)	56 (29.2)	.387
No	100 (75.2)	136 (70.8)	
Smoking Status, number (%)			
Never Smoker	62 (46.6)	96 (50.0)	.724
Previous Smoker	34 (25.6)	42 (21.9)	
Current Smoker	37 (27.8)	54 (28.1)	

* the cell values may not total to the overall cohort size owing to missing data
** Calculated as weight in kilograms divided by height in meters squared.

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Table 2: Results of all of the modules of BREAST-Q between the two groups

BREAST-Q	Procedure Type		P Value
	Autologous Reconstruction (DIEP) (n = 133)*	Implant Based Reconstruction (n = 192)*	
Satisfaction with Breast, mean (SD)	62.7 (16.2)	52.9 (12.1)	<.001
Satisfaction with Outcome, mean (SD)	77.7 (18.8)	66.5 (17.2)	<.001
PsycoSocial Well-being, mean (SD)	67.1 (20.4)	57.7 (11.9)	<.001
Sexual Well-being, mean (SD)	52.6 (23.5)	42.4 (10.3)	<.001
Physical Well-being: Chest, mean (SD)	73.3 (16.6)	65.2 (9.5)	<.001

* the cell values may not total to the overall cohort size owing to missing data



Table 3: linear regression model: satisfaction with breasts

LINEAR REGRESSION MODEL
Satisfaction with Breast

Variable	B	Standard Error	t	P Value
<i>Procedure Type (ref=IBR)</i>				
DIEP	11,169	1,781	6,270	,000
<i>Mastectomy Type (ref=Modified Radical)</i>				
Radical	4,446	2,893	1,537	ns
Skin Sparing	,658	2,478	,265	ns
Nipple Sparing	4,978	2,268	2,194	,029
Other	5,958	3,334	1,787	ns
<i>Laterality (ref=Bilateral)</i>				
Unilateral	4,157	2,866	1,450	ns
Years After Surgery	-,644	,436	-,1477	ns
<i>Radiotherapy (ref=None)</i>				
Adjuvant	-,2444	1,722	-,1,420	ns
Neoadjuvant	2,166	2,759	,785	ns
<i>Chemotherapy (ref=None)</i>				
Adjuvant	2,617	2,731	,958	ns
Neoadjuvant	-,933	1,831	-,509	ns
<i>Hormonotherapy (ref=No)</i>				
Yes	1,274	1,639	,777	ns
Age At Interview	-,029	,077	-,379	ns
BMI	-,202	,248	-,814	ns
<i>Smoking (ref=Nonsmoker)</i>				
Previous Smoker	-,703	2,001	-,351	ns
Current Smoker	-,1,523	1,879	-,810	ns
<i>Diabetes (ref=No)</i>				
Yes	-,3,651	4,196	-,870	ns
<i>Hypertension (ref=No)</i>				
Yes	-,1,539	1,779	-,865	ns



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Table 4: linear regression model: satisfaction with outcome

LINEAR REGRESSION MODEL
Satisfaction with Outcome

Variable	B	Standard Error	t	P Value
<i>Procedure Type (ref=IBR)</i>				
DIEP	11,536	2,304	5,008	,000
<i>Mastectomy Type (ref=Modified Radical)</i>				
Radical	4,424	3,729	1,186	ns
Skin Sparing	1,264	3,198	,395	ns
Nipple Sparing	6,365	2,939	2,166	,031
Other	0,289	4,306	0,067	ns
<i>Laterality (ref=Bilateral)</i>				
Unilateral	-1,229	3,688	-0,333	ns
Years After Surgery	-,746	,562	-1,328	ns
<i>Radiotherapy (ref=None)</i>				
Adjuvant	-2,524	2,219	-1,138	ns
Neoadjuvant	-0,421	3,553	-,119	ns
<i>Chemotherapy (ref=None)</i>				
Adjuvant	4,072	3,513	1,159	ns
Neoadjuvant	1,665	2,362	,705	ns
<i>Hormonotherapy (ref=No)</i>				
Yes	2,569	2,115	1,215	ns
Age At Interview	,186	,100	1,861	ns
BMI	-,268	,332	-,809	ns
<i>Smoking (ref=Nonsmoker)</i>				
Previous Smoker	2,125	2,578	,824	ns
Current Smoker	0,617	2,423	,255	ns
<i>Diabetes (ref=No)</i>				
Yes	-0,070	5,397	-,013	ns
<i>Hypertension (ref=No)</i>				
Yes	-0,129	2,301	-,056	ns



Table 5: linear regression model: psychosocial wellbeing

LINEAR REGRESSION MODEL
PsychoSocial Wellbeing

Variable	B	Standard Error	t	P Value
<i>Procedure Type (ref=IBR)</i>				
DIEP	11,082	1,967	5,633	,000
<i>Mastectomy Type (ref=Modified Radical)</i>				
Radical	6,921	3,203	2,161	,032
Skin Sparing	-2,468	2,722	-,907	ns
Nipple Sparing	7,301	2,492	2,929	,004
Other	1,879	3,664	0,513	ns
<i>Laterality (ref=Bilateral)</i>				
Unilateral	-0,093	3,150	-0,029	ns
Years After Surgery	-1,669	,480	-3,480	,001
<i>Radiotherapy (ref=None)</i>				
Adjuvant	2,513	1,892	1,328	ns
Neoadjuvant	3,260	3,071	1,061	ns
<i>Chemotherapy (ref=None)</i>				
Adjuvant	4,462	3,000	1,487	ns
Neoadjuvant	-854	2,013	-,424	ns
<i>Hormonotherapy (ref=No)</i>				
Yes	1,013	1,802	,562	ns
Age At Interview	,232	,085	2,727	,007
BMI	-,228	,272	-,837	ns
<i>Smoking (ref=Nonsmoker)</i>				
Previous Smoker	1,581	2,201	,718	ns
Current Smoker	-2,566	2,068	-1,241	ns
<i>Diabetes (ref=No)</i>				
Yes	5,185	4,611	1,125	ns
<i>Hypertension (ref=No)</i>				
Yes	1,292	1,963	,658	ns



Table 6: linear regression model: sexual wellbeing

LINEAR REGRESSION MODEL
Sexual Wellbeing

Variable	B	Standard Error	t	P Value
<i>Procedure Type (ref=IBR)</i>				
DIEP	11,036	2,189	5,042	,000
<i>Mastectomy Type (ref=Modified Radical)</i>				
Radical	-0,641	3,494	-0,183	ns
Skin Sparing	-2,319	3,031	-.765	ns
Nipple Sparing	1,681	2,761	0,609	ns
Other	1,533	4,116	0,372	ns
<i>Laterality (ref=Bilateral)</i>				
Unilateral	5,444	3,513	1,550	ns
Years After Surgery	-.873	,528	-1,651	ns
<i>Radiotherapy (ref=None)</i>				
Adjuvant	-0,563	2,085	-0,270	ns
Neoadjuvant	4,287	3,276	1,309	ns
<i>Chemotherapy (ref=None)</i>				
Adjuvant	3,047	3,351	,909	ns
Neoadjuvant	-1,917	2,221	-.863	ns
<i>Hormonotherapy (ref=No)</i>				
Yes	-1,019	1,982	-.514	ns
<i>Age At Interview</i>				
BMI	-.030	,095	-.315	ns
<i>Smoking (ref=Nonsmoker)</i>				
Previous Smoker	-.273	,316	-.862	ns
Current Smoker	2,870	2,441	1,175	ns
<i>Diabetes (ref=No)</i>				
Yes	0,087	2,265	,038	ns
<i>Hypertension (ref=No)</i>				
Yes	0,323	4,981	,065	ns
Yes	0,983	2,170	,453	ns

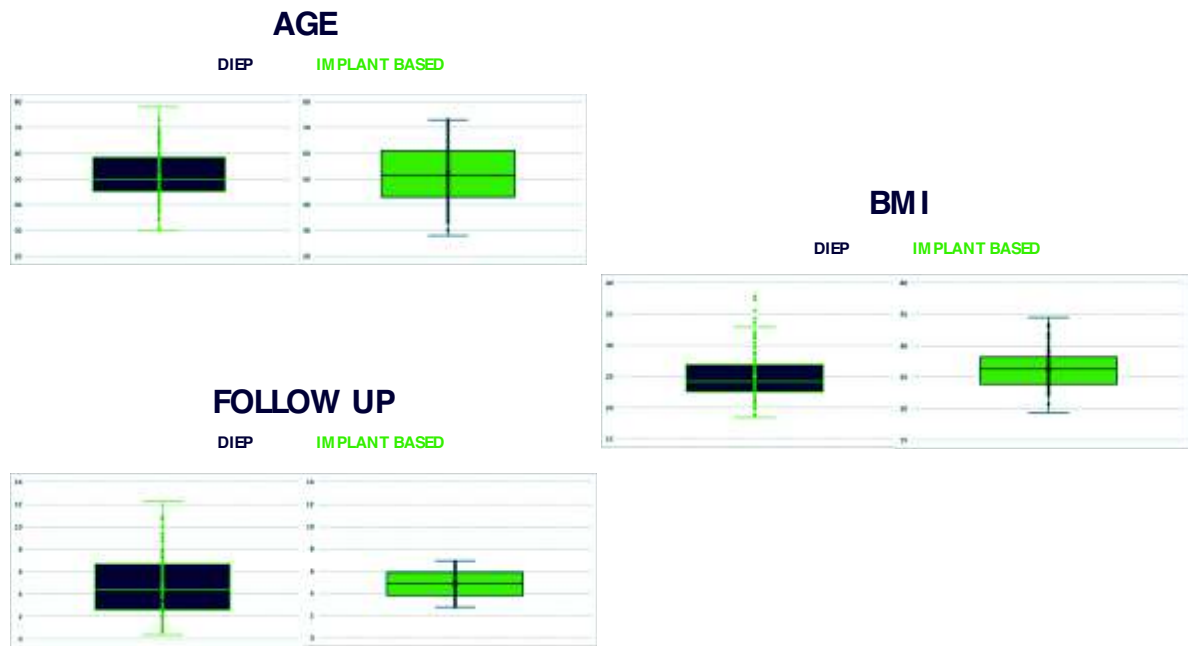


Table 7: linear regression model: physical wellbeing chest

LINEAR REGRESSION MODEL
Physical Wellbeing Chest

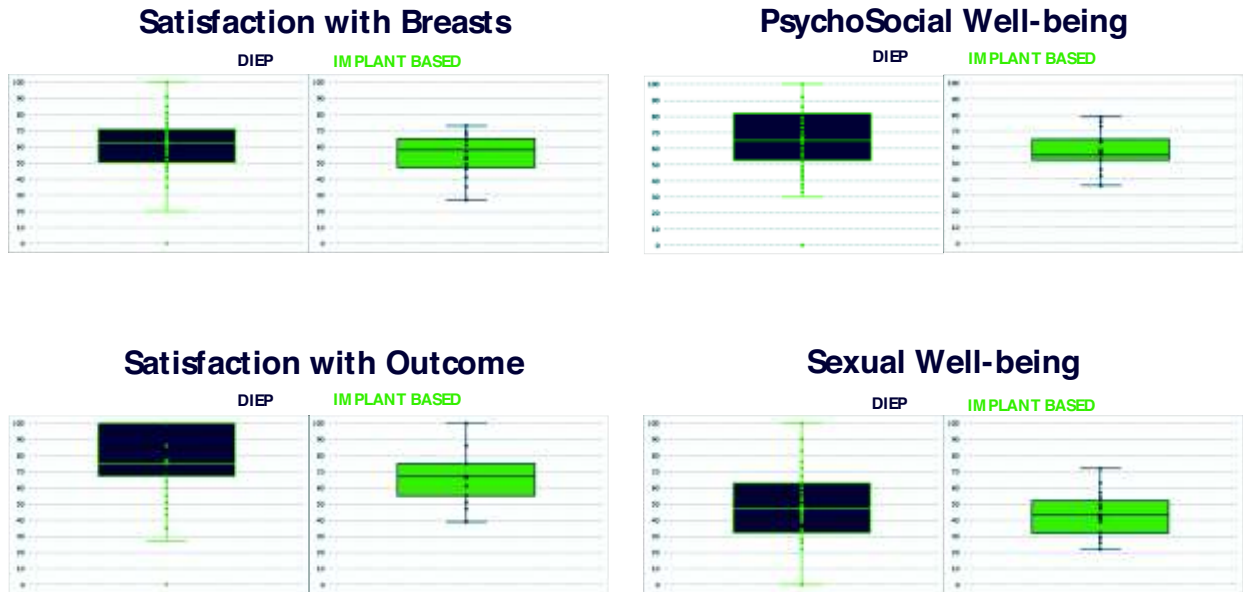
Variable	B	Standard Error	t	P Value
<i>Procedure Type (ref=IBR)</i>				
DIEP	10,164	1,652	6,154	,000
<i>Mastectomy Type (ref=Modified Radical)</i>				
Radical	4,687	2,673	1,754	ns
Skin Sparing	-,610	2,288	-,267	ns
Nipple Sparing	4,454	2,106	2,115	,035
Other	7,255	3,079	2,356	,019
<i>Laterality (ref=Bilateral)</i>				
Unilateral	5,394	2,647	2,038	,042
Years After Surgery	-,762	,402	-,1894	ns
<i>Radiotherapy (ref=None)</i>				
Adjuvant	1,300	1,591	0,817	ns
Neoadjuvant	3,645	2,550	1,429	ns
<i>Chemotherapy (ref=None)</i>				
Adjuvant	3,308	2,522	1,312	ns
Neoadjuvant	-,412	1,693	-,834	ns
<i>Hormonotherapy (ref=No)</i>				
Yes	1,675	1,518	1,104	ns
Age At Interview	,023	,072	,316	ns
BMI	,051	,231	,221	ns
<i>Smoking (ref=Nonsmoker)</i>				
Previous Smoker	-,421	1,851	-,227	ns
Current Smoker	-,2731	1,738	-,1571	ns
<i>Diabetes (ref=No)</i>				
Yes	-,1067	3,875	-,275	ns
<i>Hypertension (ref=No)</i>				
Yes	0,573	1,652	,347	ns

Figure 1



Mauro Barone

Figure 2



Mauro Barone

Figure 3



Predictive factors of satisfaction following breast reconstruction: do they influence patients?

Introduction

When one thinks of breast cancer the first thing that comes to mind is the disease and the demolition surgery. In truth, reconstructive surgery is an integral part of oncological surgery and is now considered a path for the patient to undertake. A patient living now will never experience the shock of being demolished, but she will always see herself with a breast, whether it is with an expander or a prosthesis, or an autologous flap. It would be natural to think that during this path that the patient undertakes, there are factors that can influence the perception of the body and also influence the satisfaction of patients after reconstructive surgery. It is natural to hypothesize that a patient undergoing radiotherapy or chemotherapy may be less satisfied or in any case that she may see her own body negatively compared to those who do not perform these therapies. Furthermore, according to the concept of appearance-pain, the disease in one way or another influences the perception of one's body, and adding delimiting therapies could worsen this perception. Another hypothesis could be the type of mastectomy and the possible preservation of the nipple. In addition, the passing years can also change the perception of one's body for better or for worse. Could all these factors affect a patient's quality of life or post-operative satisfaction? The purpose of this study is to analyze, on a sample of patients who have undergone both autologous and prosthetic mastectomy and reconstruction, that all or only some of these factors can influence the perception of the body. The usefulness of these results is to consider predictive factors that may influence patients in order to prepare them for the type of path and perception they will have once undertaken.

Materials and methods



An institutional review board approved this study that was performed to evaluate PROs in post-mastectomy breast reconstruction, which were assessed as a component of routine clinical care. All patients undergoing reconstruction from January 2010 to July 2018 were eligible for inclusion.

This is a retrospective cohort study carried out using the patients of two plastic surgery departments who have undergone 193 (monolateral and bilateral) implant based reconstructions at the Plastic and Reconstructive Surgery Unit, Campus Bio-Medico University of Rome, Chair Prof. Paolo Persichetti and 133 (monolateral and bilateral) DIEP flap breast reconstructions at Department of Plastic Surgery, Faculty of Medicine and Psychology, Sapienza University of Rome, Sant'Andrea Hospital, Chair Prof. Fabio Santanelli di Pompeo. Predictive factors that were analyzed for all patients enrolled in this study included chemotherapy, radiotherapy, hormonotherapy, body mass index (BMI), age, type of mastectomy, and evaluation of satisfaction with shorter and longer follow up. Inclusion criteria were: patients who underwent breast reconstruction for cancer, patients with a follow-up of at least 2 years, a good understanding of the Italian language, and signed consent. Patients having undergone prophylactic mastectomy due to genetic indication from deleterious BRCA1/2 or CDH1 mutations were also included in the study. We excluded patients who underwent delayed procedures, had a follow-up less than 2 years, patients with post-operative complications that compromised reconstruction, women who were legally incompetent, and women who did not sign the study consent form. The BREAST-Q PROM was administered preoperatively and postoperatively almost 2 years from the last surgical procedure. Patient responses were recorded on-site, either electronically or physically. Demographic data, treatment method, and post-operative outcomes were recorded secondarily. Variables recorded for each patient included age, body mass index (BMI), history of smoking, pre-operative/post-operative breast irradiation, neoadjuvant/adjuvant chemotherapy, diabetes, hypertension, and timing. Baseline demographics and preoperative patient characteristics were analyzed using a Students t-test (continuous variables) or Chi-square/Fisher's exact test (categorical variables). Mean standard deviation (SD) BREAST-Q



scores were reported for the overall cohort and by modality for the post-operative period. The linear regression model was applied to all BREAST-Q scores with all predictor factors.

BREAST-Q

BREAST-Q, published in 2009, is a rigorously developed, validated, breast surgery-specific PRO-instrument that has been used to research over 22,000 women who have had different types of breast surgery. Development of the BREAST-Q conceptual framework and scale set involved a literature review, 48 patient interviews, and 46 cognitive patient interviews, along with an expert opinion panel comprising plastic surgeons and other healthcare professionals. The scales were then tested on a sample of 2715 patients, with a response rate of 72%. The BREAST-Q reconstruction module has the following scales: satisfaction with breasts, outcome satisfaction, psychosocial wellbeing, sexual wellbeing, and physical wellbeing, chest and upper body satisfaction . In the BREAST-Q development sample (n=1950), each scale fulfilled Rasch and traditional psychometric criteria (including person separation index, 0.79 to 0.95; Cronbach's alpha, 0.83 to 0.95; and test-retest reproducibility, 0.73 to 0.94).

Ethics Approval

This study was approved by the Ethics Committee of our institutes: Faculty of Medicine and Psychology, Sapienza University of Rome (Sant'Andrea Hospital) and Campus Bio-Medico University of Rome. Each subject provided written informed consent before participating in the study.

Conflict of interest: none

Results



Of the 1125 patients involved, only 325 met the inclusion criteria and were enrolled in this study; specifically, 133 (41%) DIEP and 192 (59%) prosthetic reconstructions. The characteristics of the population studied (age, BMI, years since reconstruction, type of mastectomy, chemotherapy, radiotherapy, hormone therapy, comorbidities including diabetes, hypertension, and smoking) are shown in Table 1. Amongst those who underwent DIEP flap, 49 had a modified radical mastectomy, 11 had a radical mastectomy, 29 had a skin sparing mastectomy, 27 had a nipple mastectomy, and 7 patients had another type of mastectomy. For implant based reconstruction, 30 patients underwent a modified radical mastectomy, 30 had a radical mastectomy, 30 had a skin sparing mastectomy, 50 underwent a nipple sparing mastectomy, 18 had a skin reducing mastectomy, and 34 patients had another type of mastectomy. Pre-reconstructive therapies included radiotherapy in 48.3%, chemotherapy in 37.5%, and hormone therapy in 37.5%. In Figure 1, we represented the Q-SCORE to evaluate the difference of satisfaction between DIEP reconstruction and implant based reconstruction considering the type of mastectomy (RAD MDF: radical modified mastectomy, RAD: radical mastectomy, skin sparing mastectomy, and nipple sparing mastectomy). The DIEP flap reconstruction group with a pregress nipple sparing mastectomy showed the most satisfying results. In Figure 2, we edited the Q-SCORE of all samples considering the follow up after the reconstruction procedure and we concluded that with a longer follow up, there is less satisfaction than a shorter follow up, which could be considered as an assessment of the outcome. In Figure 3, we considered the influence of radiotherapy on patients and found no significant difference between those that did and did not receive radiotherapy. The same consideration was given to patients who received chemotherapy (Figure 4) and hormone therapy (Figure 5). We analyzed possible predictive factor as characteristics of patients; we found that age (Figure 6) and BMI (Figure 7) had no influence on patient satisfaction.

Discussion



In the literature, few studies address this topic and analyze several predictive factors that can affect the satisfaction and perception of the bodies of patients undergoing mastectomy and reconstruction. The ultimate goal of reconstructive surgery is to never make patients feel demolished after the mastectomy and above all to increase the quality of life. Reconstructive surgery is an integral part of the life-saving process of breast cancer patients. But what should plastic surgeons expect from reconstruction? How are patients affected by surgical choices? Can oncological therapies impact the patient's perception of appearance? These are questions that our research group tried to answer with this study and to clarify some aspects that are the basis of our clinical practice. Santosa from U.S. performed a multicenter prospective study about the effect of patient age on outcomes in breast reconstruction. The authors concluded that age does not affect complication rates significantly. Despite previous concerns among some surgeons about the potential risks of post-mastectomy reconstruction in older women. In addition, older patients appear to enjoy many of the same quality of life benefits of reconstruction as younger women do. For older patients considering breast reconstruction and for surgeons performing these procedures, the study findings confirm that reconstruction is a viable option, with risks and benefits comparable with those reported in younger women. This is a very interesting paper that shows that age is not a predictive factor in breast reconstruction outcomes. Cereijo-Garea from Spain, in his paper about predictive factors of satisfaction and quality of life after immediate breast reconstruction using the BREAST-Q, provides clinical and epidemiological information on the profile of patients who underwent immediate reconstruction following a mastectomy due to cancer. It makes it possible to identify the variables that modify quality of life and satisfaction with breast cancer reconstruction and care received. It also suggests the need for multi-disciplinary involvement in the care of and monitoring of women with immediate breast reconstruction. They concluded that the type of treatment and lymphedema modify the patient's quality of life. Nicotine dependence is associated with lower satisfaction with breast reconstruction and the outcome. Matthews from UK presented their study about predictors of satisfaction and quality of life following post-mastectomy breast reconstruction. Their findings



demonstrated the need for healthcare providers to consider the psychosocial wellbeing of patients both pre- and postoperatively; DIEP flap patients reported greater satisfaction with breast appearance and outcome satisfaction. The limitations of our study include omission of pre-surgical data and the cross-sectional study design, which does not distinguish the direction of the relationships or account for the changing nature of the outcomes over time and satisfaction may fluctuate during long-term survivorship. Additionally, some clinical characteristics could not be ascertained including other treatment types, number of reconstructive surgeries, and any reconstructive complications. These factors are not included in our study. Future studies should be prospective, longitudinal, and consist of a qualitative design to provide a comprehensive understanding of the trajectory of satisfaction and quality of life following breast reconstruction. However, our study is the first to underline the importance of factors that may influence patient's quality of life. Also, it is applicable to the Italian population, therefore with a limited cultural adaptation to our country. It may be that studying a population of another country may produce different results due to a different culture and different concepts of corporeality. Surprisingly, some factors that we initially considered important did not influence the quality of life of our patients, and their perception of appearance was not impacted by therapies, age, or BMI. The only factor that statistically significantly affects values is the surgical choice with regard to the type of mastectomy performed and the type of reconstruction chosen.

Conclusion

This study is the first that groups a large number of patients and analyzes predictive factors of long-term satisfaction of patients undergoing breast reconstruction. Other studies are needed to corroborate these data and can evaluate, with different cultural adaptations, this same topic. This can be regarded as a pilot study to raise the awareness of everyone's clinical practice to predict the attitude that patients have after surgery and to prepare them in the best possible way. In our study, none of the predictive factors influenced post-operative satisfaction except the type of mastectomy



and the type of reconstruction performed. Patients undergoing nipple sparing mastectomy and DIEP flap reconstruction were the most satisfied, regardless of age, BMI, or type of cancer therapies performed.

Tables:

Table 1: population data

Figures:

Figure 1: Q-SCORE to evaluate the difference of satisfaction between DIEP reconstruction and implant based reconstruction considering the type of mastectomy (RAD MDF: radical modified mastectomy, RAD: radical mastectomy, skin sparing mastectomy, and nipple sparing mastectomy).

Figure 2: Q-SCORE of all samples considering the follow up after the reconstruction procedure

Figure 3: the influence of radiotherapy on patients

Figure 4: the influence of chemotherapy on patients

Figure 5: the influence of hormone therapy on patients

Figure 6: age and patients satisfaction

Figure 7: BMI and patients satisfaction

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Table 1: population data

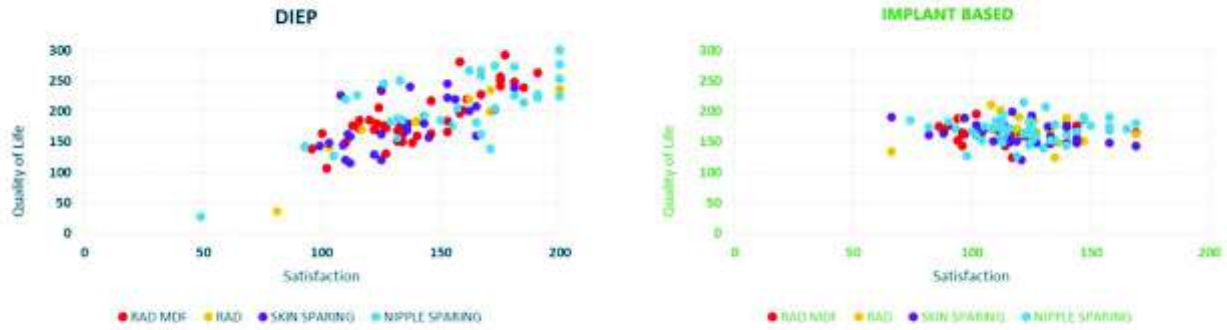
Characteristic	Procedure Type		P Value
	Autologous Reconstruction (DIEP) (n = 133)*	Implant Based Reconstruction (n = 192)*	
Age, mean (SD)	51.3 (9.5)	51.9 (10.7)	.622
Years After Surgery, mean (SD)	4.7 (2.7)	4.8 (1.2)	.632
BMI**, mean (SD)	25.2 (4.0)	26.2 (2.9)	.017
Laterality of reconstruction, number (%)			
Unilateral	110 (82.7)	158 (82.3)	.923
Bilateral	23 (17.3)	34 (17.7)	
Mastectomy Type, numer (%)			
Modified radical	49 (36.8)	30 (15.6)	<.001
Radical	11 (8.3)	30 (15.6)	
Skin Sparing	29 (21.8)	30 (15.6)	
Nipple Sparing	37 (27.8)	50 (26.0)	
Other	7 (5.3)	52 (27.1)	
Radiotherapy, number (%)			
Yes, adjuvant	50 (37.6)	76 (39.6)	.698
Yes, neoadjuvant	11 (8.3)	20 (10.4)	
No	72 (54.1)	96 (50.0)	
Chemotherapy, number (%)			
Yes, adjuvant	8 (6.0)	25 (13.0)	.035
Yes, neoadjuvant	32 (24.1)	57 (29.7)	
No	93 (69.9)	110 (57.3)	
Hormone Therapy, number (%)			
Yes	46 (34.6)	76 (39.6)	.360
No	87 (65.4)	116 (60.4)	
Diabetes, number (%)			
Yes	4 (3.0)	8 (4.2)	.586
No	129 (97.0)	184 (95.8)	
Hypertension, number (%)			
Yes	33 (24.8)	56 (29.2)	.387
No	100 (75.2)	136 (70.8)	
Smoking Status, number (%)			
Never Smoker	62 (46.6)	96 (50.0)	.724
Previous Smoker	34 (25.6)	42 (21.9)	
Current Smoker	37 (27.8)	54 (28.1)	

* the cell values may not total to the overall cohort size owing to missing data
** Calculated as weight in kilograms divided by height in meters squared.



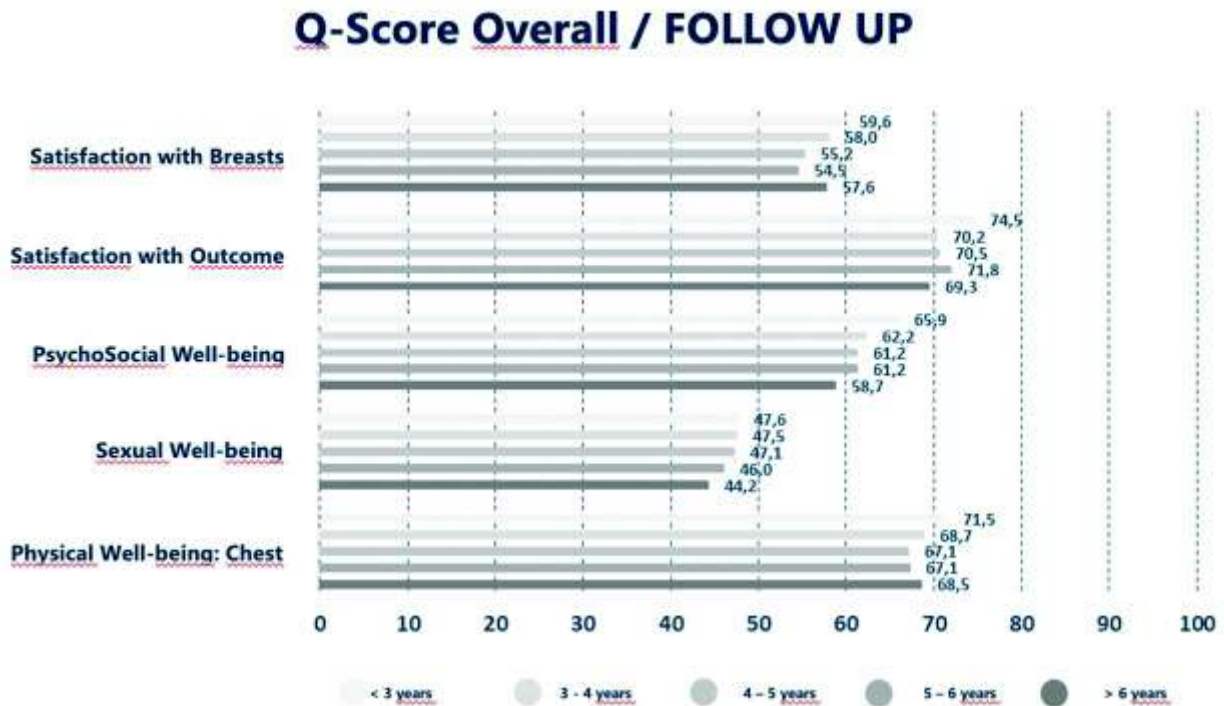
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Figure 1



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Figure 2



Tesi di dottorato in Scienze biomediche integrate e bioetica, di Mauro Barone, discussa presso l'Università Campus Bio-Medico di Roma in data 16/06/2021. La disseminazione e la riproduzione di questo documento sono consentite per scopi di didattica e ricerca, a condizione che ne venga citata la fonte.

Figure 3

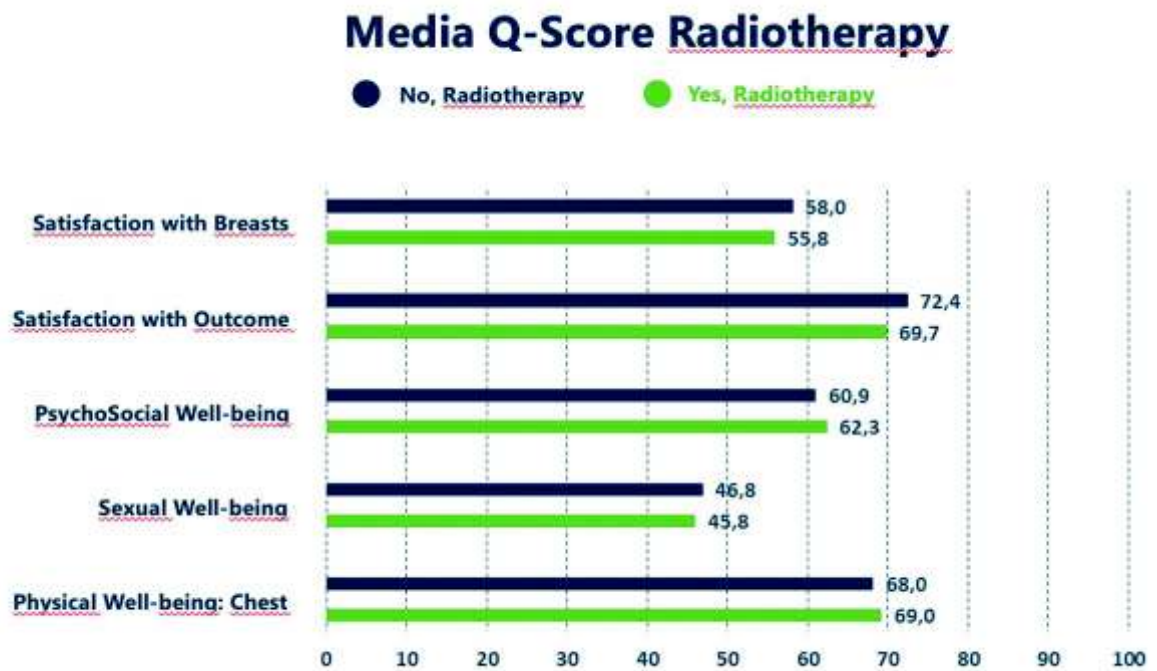


Figure 4

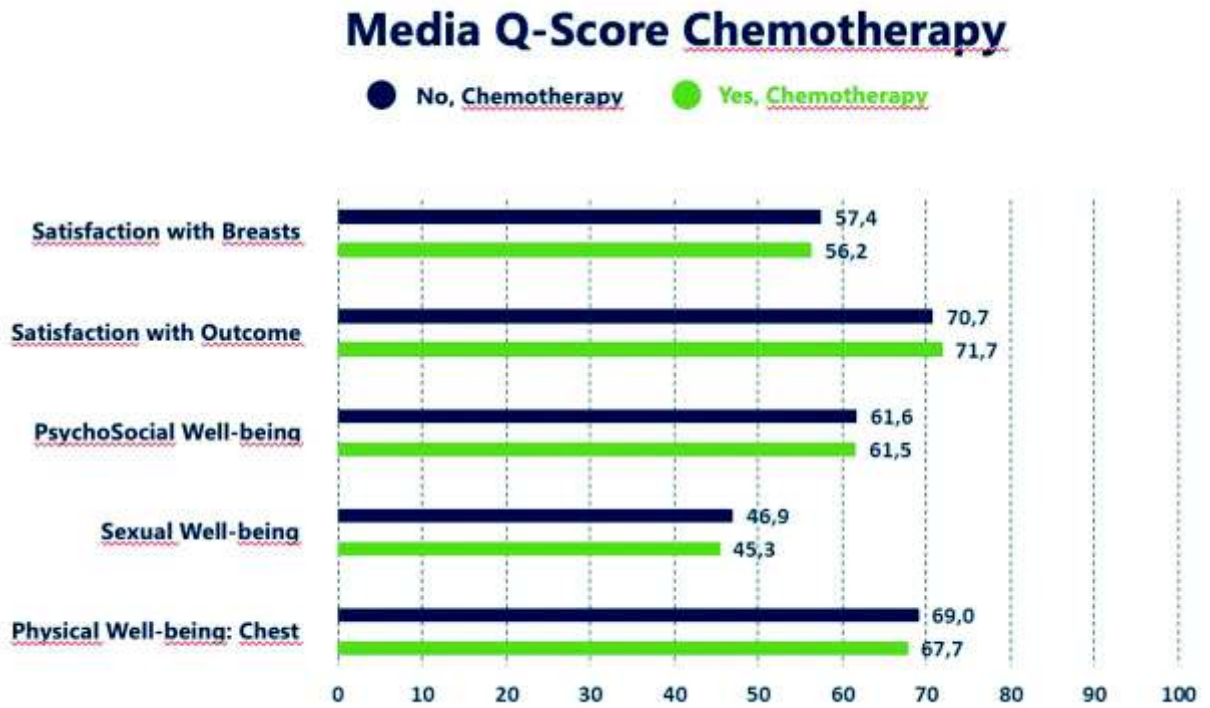


Figure 5

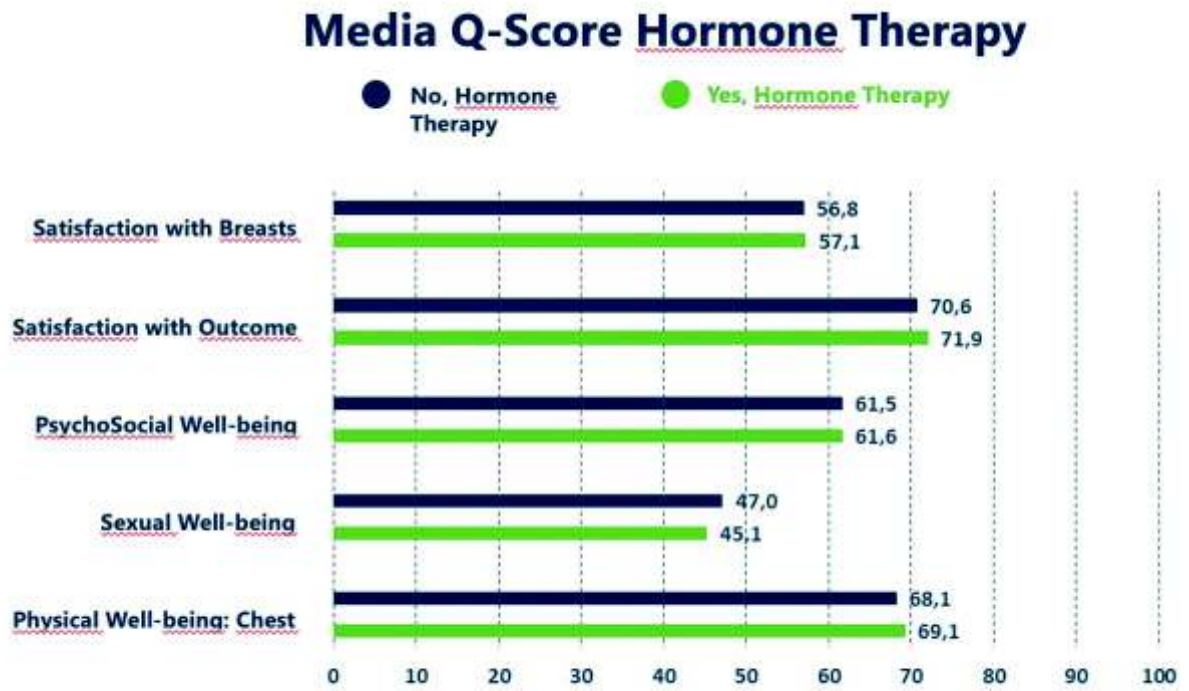


Figure 6

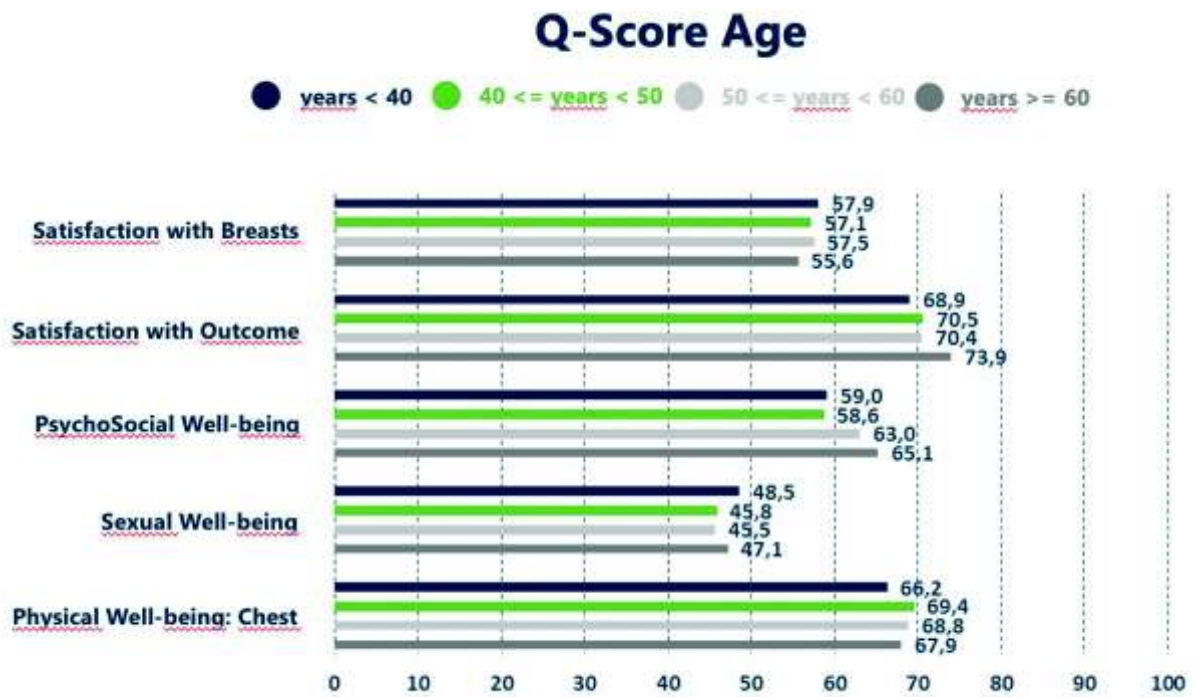


Figure 7

