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Nipple-areolar Complex Reconstruction following Postmastectomy Breast Reconstruction: A Comparative Utility Assessment Study

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Background: Nipple-areola complex (NAC) reconstruction occurs toward the final stage of breast reconstruction; however, not all women follow through with these procedures. The goal of this study was to determine the impact of the health state burden of living with a reconstructed breast before NAC reconstruction.
Methods: A sample of the population and medical students at McGill University were recruited to establish the utility scores [visual analog scale (VAS), time trade-off (TTO), and standard gamble (SG)] of living with an NAC deformity. Utility scores for monocular and binocular blindness were determined for validation and comparison. Linear regression and Student's *t* test were used for statistical analysis, and significance was set at $P < 0.05$.
Results: There were 103 prospective volunteers included. Utility scores (VAS, TTO, and SG) for NAC deformity were 0.84±0.18, 0.92±0.11, and 0.92±0.11, respectively. Age, gender, and ethnicity were not statistically significant independent predictors of utility scores. Income thresholds of <$10,000 and >$10,000 revealed a statistically significant difference for VAS ($P = 0.049$) and SG ($P = 0.015$). Linear regression analysis showed that medical education was directly proportional to the SG and TTO scores ($P < 0.05$).
Conclusions: The absence of NAC in a reconstructed breast can be objectively assessed using utility scores (VAS, 0.84±0.18; TTO, 0.92±0.11; SG, 0.92±0.11). In comparison to prior reported conditions, the quality of life in patients choosing to undergo NAC reconstruction is similar to that of persons living with a nasal deformity or an aging neck requiring rejuvenation. *(Plast Reconstr Surg Glob Open 2015;3:e380; doi: 10.1097/GOX.0000000000000133; Published online 20 April 2015.)*

The goal of breast reconstruction following mastectomy is ultimately the creation of a breast that is aesthetically pleasing and closely resembles its natural configuration. Breast reconstruction is generally performed in multiple stages and may include many revisions to address issues with shape and symmetry.[1–3] As such, there is no clear indication as to when the reconstructive process is complete.[1] It is considered by some to be when patients are satisfied with the appearance of their breast or when no more procedures are required.[1]

Nipple reconstruction is a fundamental part of the reconstructive process as patients associate this step with the endpoint of the reconstructive process.[2,4] Moreover, it provides improved aesthetic

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outcomes and self-esteem.[5,6] Despite the multitude of techniques described to preserve nipple shape and projection over time, none have been able to attain consistent results.[2,7–15] The most commonly used flaps are associated with loss of nipple projection in up to 70% of cases over the course of the first 3 years postoperatively.[12] Matching the color of the areola to the contralateral breast can be problematic. Intradermal tattooing has a tendency to fade over time, reduce nipple projection, and is often difficult when matching pigment color in unilateral cases.[2,16]

In spite of these limitations, many women will choose to undergo nipple reconstruction to restore body image.[2] There is currently a void in the literature in objective assessments of the health state of living with a breast reconstruction before nipple-areola complex (NAC) reconstruction. Moreover, studies in the literature have reported conflicting outcomes.[2,16–20] Some have demonstrated increased satisfaction rates following NAC reconstruction,[2,16,17,19] whereas others have observed either dissatisfaction with reconstruction, particularly in younger patients, or greater satisfaction with breast mound reconstruction only.[18,20]

Utility scores are standardized tools offering a validated means of measuring the health state preference of a disease state or health condition. They range from 0 (death) to 1 (perfect health).[21] Utility scores have been used previously to quantify the risk-benefit ratio for a range of conditions and assist in surgical decision making.[21–32] Furthermore, they may aid in the design of quantitative comparisons in economic decision analysis for resource allocation in treatment and research pertaining to individual health states.[33,34] The goal of this study was to determine the health burden of living without NAC reconstruction through an objective utility assessment.

METHODS

Participant Recruitment

Prospective participants from the general population were recruited through online classifieds to the internet-based utility assessment Web site. The classified ads ran for 1 year. These ads were posted on http://www.kijiji.ca and http://www.craigslist.org. Medical students at McGill University (Montreal, Quebec) were sent online participation requests. Participation in this study was completely voluntary.

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All those participants taking part in the study were asked to complete a health state questionnaire, an anonymous demographic questionnaire, and a utility assessment. An incentive for participation in this study was a raffle entry with a chance to win prize money. To ensure the validity of our study and to avoid variations in societal values, participants recruited for this study were from the general population in Canada. Furthermore, having respondents exclusively from Canada, the concept of gain is minimized. Despite variations in the healthcare system, using these unbiased data could contribute to a better understanding of what conditions warrant medical coverage given that social norms and values are otherwise comparable between Canada and the United States. Demographic information including age, gender, level of education, level of income, and race were obtained from each volunteer participating in this study through the online survey. An internet-based survey was used primarily to reach as wide of a participant population as possible. In addition, it has numerous advantages[35,36]:

1. The data gathered can be easily imported into data analysis programs.
2. Data are available in real time and numerical format.
3. It is cost effective.
4. The time needed for implementation is shorter.
5. It is relatively straightforward to send out reminders and follow-up on nonrespondents.

Moreover, Chang et al[36] reported that the use of an internet-based questionnaire for utility assessment enabled them to enroll a large number of study participants with a reliable ability to understand the study, resulting in a high rate of usable responses.

Inclusion and Exclusion Criteria

To assess the comprehension capacity of volunteers in this study, participants were asked to appropriately rank binocular blindness (having lower utility score or a health state closer to death) and monocular blindness. Those that ranked binocular blindness as having a higher utility (closer to perfect health) than monocular blindness were excluded from the study. To prevent multiple entries from a single participant, it was mandated that a valid e-mail address be included at the end of the survey. A 5-point Likert scale was used to assess the simplicity of the online survey and ease of its understanding. Volunteers were only accepted if they were above 18 years old.

Utility Outcome Analysis

Three validated health state preference instruments were used for the measurement of utility

scores. These include visual analog scale (VAS), time trade-off (TTO), and standard gamble (SG).[36–38] Data gathered for analysis have been done using internet-based surveys obtained from either the general population based on the presentation of a proposed health problem or a group of patients experiencing a given health problem.[21,36] The use of all 3 tools helps to minimize the possible shortcomings of any single measure, increase reliability, and decrease bias.

In the survey, participants were shown a photograph of a patient who underwent breast reconstruction without right NAC reconstruction. In the VAS, participants were asked to "visualize" themselves in the described health state and provide a score ranging from 0 (death) to 100 (perfect health) using a slide bar scale. VAS was calculated as utility health state = score ÷ 100.

In TTO, participants were asked to select between 1 of 2 options: either "trade-off" a set number of years to live in perfect health or live a certain number of years in the described health state (breast reconstruction without NAC reconstruction). TTO was calculated as utility = (number of years specified in the described health state – number of years traded off at the indifference point) ÷ number of years specified in the described health state. Participants were also asked to rate their own health state using TTO and EuroQol.[39,40]

In SG, participants were given 2 options from which they were asked to select one: either gamble with a certain degree of success (perfect health) or failure (death) or remain in the given health state (breast reconstruction without NAC reconstruction). Success and failure were then varied in the form of percentages until the participant became unconcerned about whether to take a gamble or stay in the given health state. SG was calculated as utility health state= (1.00 – risk of death at the point of indifference) ÷ 100.

Ethics Approval

Approval for this study was obtained in accordance with the Declaration of Helsinki ethical guidelines for human subjects by the Research Ethics Board at McGill University. The patient whose photograph was used in this study signed a consent form permitting its use for research purposes and publication (Fig. 1). Before their participation in this study, an electronic consent form was signed by all volunteers.

Statistical Analysis

Statistical analysis was performed using SPSS for Windows, PASW Statistics 18, Release 18.0.0 (SPSS, Chicago, Ill.). Independent and paired *t* tests were done to compare continuous variables and obtain mean utility scores. Chi-square test or Fisher's exact test was done to compare categorical variables. Using age, sex, race, and education as independent predictors, a linear regression model was used to assess each of the utility outcome measures (SG, TTO, and VAS). A value of $P < 0.05$ was deemed statistically significant.

Fig. 1. Image of the patient without reconstructed NAC following breast reconstruction shown to prospective participants.

RESULTS

Basic Participant Demographics

In total, 118 prospective volunteers were enrolled in our study over a period of 6 months; 87.3% ($n = 103$) of participants were included for utility assessment, whereas the remaining volunteers ($n = 15$) were excluded from our survey because they rated binocular blindness as being higher than monocular blindness. The average age of participants in this study was 24.7±8.2 years; there were more females than males ($n = 81$ versus $n = 22$), and the predominant race included was white (62.1%). Our prospective subjects found the study easy to comprehend. Participant demographics are summarized in Table 1.

Utility Outcome Scores

All 3 measures (VAS, TTO, and SG) for breast reconstruction without NAC reconstruction (0.84±0.18, 0.92±0.11, and 0.92±0.11, respectively) differed significantly ($P < 0.001$) from those of binocular blindness (0.32±0.19, 0.64±0.27, and 0.66±0.25, respectively) and monocular blindness (0.60±0.20, 0.84±0.17, and 0.85±0.18, respectively) (VAS, $P < 0.0001$; TTO, $P < 0.0001$; and SG, $P < 0.0001$; respectively) (Table 2). The TTO and SG

Table 1. Study Participant Demographics

Characteristics	*N* (%)
Age	24.7±8.2
Gender	
Male	22 (21.4)
Female	81 (78.6)
Race	
Whites	64 (62.1)
Nonwhites	39 (37.9)
Hispanic	4 (3.9)
Asians	5 (4.9)
African Americans	4 (3.9)
Prefer not to answer	14 (13.6)
Others	12 (11.7)
Education	
Medical education	6 (5.8)
Nonmedical education	97 (94.2)
High school	7 (6.8)
Some college	45 (43.7)
College graduate	17 (16.5)
Prefer not to answer	13 (12.6)
Income	
<$10,000	36 (35.0)
>$10,000	67 (65.4)
$10,000–$25,000	9 (8.7)
$25,000–$50,000	6 (5.8)
$50,000–$100,000	6 (5.8)
Prefer not to answer	46 (44.7)

utility scores for NAC deformity (both 0.92±0.11) correspond to a willingness to sacrifice 2.8 years of life and to go through a procedure with an 8% chance of death to obtain perfect health.

A comparison of the utility scores between medical students and a sample of the general population did not show statistically significant difference (VAS, $P = 0.086$; TTO, $P = 0.166$; and SG, $P = 0.093$) (Table 3). Similarly, utility measures for whites versus nonwhites were not significant (VAS, $P = 0.739$; TTO, $P = 0.596$; and SG, $P = 0.989$) (Table 3). With regard to gender, utility assessments for female participants were not appreciably different from those of their male counterparts (VAS, $P = 0.422$; TTO, $P = 0.152$; and SG, $P = 0.616$) (Table 3). Finally, utility outcomes for income <$10,000 and >$10,000 revealed a statistically significance difference for VAS ($P = 0.049$) and SG ($P = 0.015$) but not for TTO ($P = 0.456$) (Table 3). Interestingly, participants with a higher income were willing to risk and gamble more to attain an NAC reconstruction.

Statistical Analysis

Linear regression analyses revealed that medical education (including members of the general population with a medical background), in particular, had an effect on utility scores. Medical education was directly proportional to the SG and TTO scores ($P < 0.05$). For every increase in the level of medical education of the volunteers, there was an increase of 0.048 and 0.014 in the SG and TTO scores, respectively. Nonmedical education, age, sex, and race did not serve as statistically significant predictors of the utility scores investigated in this study.

DISCUSSION

NAC reconstruction represents a final step in completing the breast reconstruction process.[1,16] The result may be more aesthetically pleasing, and it may also have significant psychological benefit.[41] In the current healthcare environment, improving quality of life and patient satisfaction are important measures of the standard of care.[42] Momoh et al[2] reported in their assessment of 695 breast reconstruction patients that those patients who chose to undergo nipple reconstruction had significantly higher general and aesthetic satisfaction scores. Goh et al[16] found that 96% of women considered NAC reconstruction and tattooing important; furthermore, 93% stated that they would undergo the procedure again. Losken et al[1] found that timing of NAC reconstruction impacts patient satisfaction; a longer time interval between the initial breast procedure and NAC reconstruction decreases satisfaction. In addition, they observed that women who underwent adjuvant therapy and those with complications were more likely to take longer to complete the process and therefore were more likely to be dissatisfied.

Although patient satisfaction and enhanced quality of life are key outcomes for breast and NAC reconstruction, to date, there is no objective measure assessing the impact of living with breast reconstruction without NAC reconstruction, or NAC deformity, and the utility of undergoing NAC reconstruction. We therefore investigated the utility outcomes of NAC deformity using well-described models (VAS, TTO, and SG).[22,34,38] In this study, the health state preference of living with an NAC deformity (VAS, 0.84±0.18; TTO, 0.92±0.11; and

Table 2. Utility Scores of Nipple-areola Complex Deformity, Monocular Blindness, and Binocular Blindness

Utility Score	Monocular	Binocular	NAC Deformity	Self	*P**
VAS (mean ± SD)	0.60±0.20	0.32±0.19	0.84±0.18		<0.0001
TTO (mean ± SD)	0.84±0.17	0.64±0.27	0.92±0.11	0.91±0.15†	<0.0001
SG (mean ± SD)	0.85±0.18	0.66±0.25	0.92±0.11		<0.0001

**t* test.
†$P = 0.513$ for self TTO versus NAC deformity.

Table 3. Utility Scores of Nipple-areola Complex Deformity following Regression Analysis

Utility Score	Medical Student	General Population	*P**
VAS (mean ± SD)	0.90±0.06	0.84±0.18	0.086
TTO (mean ± SD)	0.95±0.04	0.92±0.11	0.166
SG (mean ± SD)	0.96±0.04	0.92±0.11	0.093
	Whites	Nonwhites	
VAS (mean ± SD)	0.85±0.17	0.84±0.20	0.739
TTO (mean ± SD)	0.92±0.10	0.93±0.11	0.596
SG (mean ± SD)	0.92±0.10	0.92±0.13	0.989
	Male	Female	
VAS (mean ± SD)	0.87±0.10	0.84±0.19	0.422
TTO (mean ± SD)	0.87±0.17	0.93±0.08	0.152
SG (mean ± SD)	0.91±0.13	0.93±0.11	0.616
	<$10,000	>$10,000	
VAS (mean ± SD)	0.88±0.09	0.82±0.21	0.049
TTO (mean ± SD)	0.93±0.09	0.91±0.12	0.456
SG (mean ± SD)	0.96±0.06	0.91±0.13	0.015

*t test.

SG, 0.92±0.11) was found to be similar to that of other previously reported aesthetically compromised conditions, including aesthetic nasal deformity after primary rhinoplasty requiring revision (VAS, 0.80±0.13; TTO, 0.90±0.12; and SG, 0.91±0.13), aging neck needing rejuvenation (VAS, 0.89±0.07; TTO, 0.94±0.08; and SG, 0.95±0.10), and massive weigh loss necessitating a body contouring procedure (VAS, 0.79±0.13; TTO, 0.89±0.12; and SG, 0.89±0.15), but higher than respective utility scores for facial disfigurement requiring facial transplantation (VAS, 0.46±0.02; TTO, 0.68±0.03; and SG, 0.66±0.03) and unilateral mastectomy (VAS, 0.75±0.17; TTO, 0.87±0.15; and SG, 0.86±0.18) (Table 4).[28,30–32,43] These findings suggest that if faced with the choice of having to undergo NAC reconstruction, the participants in our study would be as willing to take a theoretical risk on that procedure as they would for revision rhinoplasty, a neck rejuvenation procedure, or body contouring surgery. Moreover, they would be willing to sacrifice less to address NAC deformity than they would facial disfigurement necessitating facial transplantation or unilateral mastectomy warranting breast reconstruction based on the fact that the respective values for VAS, TTO, and SG for these disease states were lower than those for NAC deformity.[38,44] In other words, the higher the utility score, the less the willingness to risk morbidity/mortality and the lower the number of years a participant would be willing to sacrifice to attain "perfect health." The study volunteers would undergo NAC reconstruction with a hypothetical 8% chance of mortality and would be prepared to sacrifice 2.8 years of their life to attain the desired aesthetic outcome.

There was no significant difference in utility outcomes between the sample populations, among ethnic groups, and amid males and females. Although the issue of whether or not to undergo NAC reconstruction following mastectomy may be a more pertinent concern for women, the purpose of this study was to collect data on population preferences as a whole rather than just that of women. This method was intended to make the study more comprehensive; in this way, males may also recognize the relevance of procedures to reconstruct the nipple-areolar complex. Our findings can perhaps be explained by similarities in the perception of living with NAC deformity. Alternatively, it can be attributed to the minimal morbidity associated with NAC reconstruction even in high-risk patients. This is in agreement with a study by Jensen et al[45] who demonstrated viability of the NAC in patients who were at increased risk of developing nipple necrosis following mastectomy. Furthermore, our data suggest that patients are willing to give up less in terms of chance of mortality and life years to undergo NAC reconstruction to enhance their appearance, which supports the suggestion by Jabor et al[18] that NAC reconstruction is more satisfying to plastic surgeons' perception of beauty rather than the patient's perception of beauty.

Analysis of mean utility scores for income was significant with VAS and SG, suggesting that patients are willing to sacrifice income and time to have the procedure done and attain the desired health state (reconstructed NAC). Interestingly, this is in spite of the current economic setting and the general notion that delayed procedures contribute to increased expense.[46] This result may be useful in analysis of cost-effectiveness and can aid us in comparing the value of NAC deformity with other disease states. Furthermore, volunteers with a higher annual income were willing to take higher risks and gamble more percent

Table 4. Comparison of Utility Scores for NAC Deformity to Other Plastic Surgical Conditions

Plastic Surgical Conditions	Visual Analog Scale	Time Trade-off	Standard Gamble
NAC deformity	0.84±0.18	0.92±0.11	0.92±0.11
Aesthetic nasal deformity after primary rhinoplasty requiring revision[28]	0.80±0.13	0.90±0.12	0.91±0.13
Aging neck needing rejuvenation[31]	0.89±0.07	0.94±0.08	0.95±0.10
Massive weight loss necessitation a body contouring procedure[30]	0.79±0.13	0.89±0.12	0.89±0.15
Facial disfigurement requiring facial transplantation[32]	0.46±0.02	0.68±0.03	0.66±0.03
Unilateral mastectomy[43]	0.75±0.17	0.87±0.15	0.86±0.18

chance of death to attain an NAC and ranked the absence of an NAC to being closer to death than their lower-income counterparts. This can suggest that there is more importance or value on one's body image in the former subgroup. People with higher incomes appear to give more value to the completeness of all stages of breast reconstruction, including NAC reconstruction, when compared with volunteers with a lower annual income.

Medical education played an important role in the outcome of utility scores in the surveyed population. It was found to be directly proportional to the SG and TTO utility scores. That is to say, there was a significant increase in both these measures as the level of education, explicitly medical education, increased. From this, we can ascertain that individuals in our study population that received some form of medical education were more willing to risk years of life and theoretical percent chance of mortality to undergo NAC reconstruction to potentially complete breast reconstruction. This finding can perhaps be associated with the fact that this subgroup of participants is privy to the risks and benefits associated with this procedure.

One of the limitations of our study is the extent to which our sample population is representative of an entire society. To limit inherent bias, information ascertained for this study was not specifically derived from women undergoing breast reconstruction or NAC reconstruction. Future studies may compare utility scores in these groups of patients both before and after NAC reconstruction. Furthermore, it should be noted that by surveying practicing plastic surgeons for NAC reconstruction, responses may be biased; inherent bias may place further value on NAC reconstruction, which may in turn be relevant for financial coverage for this procedure resulting in conflict of interest. Only 6 participants had some medical education, which lacks adequate statistical power. Recruitment of additional participants with medical education, who have strong comprehension of the risks associated with surgical procedures, would provide greater insight into the effect of education on perceived utility of NAC reconstruction. Moreover, no data were ascertained on the occupation of participants who were members of the general population, which would have enhanced the quality of our analyses. Future studies focused on determining the health burden of living without NAC reconstruction through an objective utility assessment will include a larger participant population to establish adequate statistical power.

Other limitations include the fact that NAC absence is not considered a disease state, and although it has been recommended by panels on cost-effectiveness in health and medicine that utility outcomes be performed on a sample from the general public, a questionnaire aimed at the general public might not adequately be able to capture the influence of the described health state on those affected.[47] In addition, there was no standard definition used for NAC reconstruction. Had participants understood the available options for NAC reconstruction (in the operating room under general anesthesia along with a skin graft versus in the clinic followed by tattooing or tattooing alone), it may have impacted the final utility outcomes. This could potentially have been avoided by recruiting only patients who had undergone NAC reconstruction in both those who experienced complications and those who did not. Also, many of the responders chose not to report their annual income, which may have affected the final outcome. Unfortunately, the data obtained do not enable us to analyze what the participants would be willing to pay monetarily for NAC but is a factor that should be considered in other potential utility outcome studies. Finally, cost-effectiveness may also be limited by bias. However, these issues may be overcome by our large sample size ($n = 103$) and subgroup analysis excluding patients who could not comprehend the nature of the study.

CONCLUSIONS

NAC reconstruction following reconstructive breast surgery in breast cancer patients can now be objectified using utility scores (VAS, 0.84 ± 0.18; TTO, 0.92 ± 0.11; and SG, 0.92 ± 0.11). In comparison to prior reported conditions, the quality of life in patients choosing to undergo NAC reconstruction is similar to those living with a nasal deformity or an aging neck requiring rejuvenation. The outcomes of this study may be useful in analyzing cost-effectiveness and establishing a comparison of the value of NAC deformity with other plastic surgical conditions.

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