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Patient factors associated with novel EAR-Q appearance, psychosocial, and social scales: A cross-sectional study and regression analysis

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Abstract *Introduction:* The EAR-Q is a rigorously validated patient-reported outcome measure, which evaluates ear appearance and health-related quality of life (HRQL) in patients with congenital or acquired ear conditions. The aim of this study was to conduct an exploratory analysis to examine the factors associated with EAR-Q appearance and HRQL scale scores.
Methods: In this study, 862 participants, aged 8–29 years, with congenital or acquired ear conditions, completed the EAR-Q as part of an international field-test study. Patients responded to demographic and clinical questions as well as the EAR-Q. Univariable and multivariable linear regression analyses were used to determine factors that were significant predictors for the scores on the EAR-Q Appearance, Psychological, and Social scales.
Results: Most participants were men (57.4%), awaiting treatment (55.0%), and had a microtia diagnosis (70.4%), with a mean age of 13 ($\pm$4) years. Worse ear appearance scores ($p < 0.02$) were associated with male gender, microtia, no history of treatment, ear surgery within 6 months, unilateral involvement, and greater self-reported ear asymmetry. Decreased psychological scores ($p < 0.01$) were associated with increasing participant age, no treatment

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history, recent ear surgery, and dissatisfaction with ears matching or overall dissatisfaction. Lower social scores ($p \leq 0.04$) were associated with no treatment history, those awaiting surgery, ear surgery within the last 6 months, bilateral involvement, and self-reported ears matching or overall appearance.

Conclusion: This analysis identified patient factors that may influence ear appearance and HRQL scale scores. These findings provide evidence of patient factors that should be adjusted for when undertaking future observational research designs using the EAR-Q in this patient population.

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Microtia and prominent ears are two of the most common congenital ear conditions, affecting 3–5[1] and 500[2] in 10,000 live births, respectively. It is well documented that individuals with a visible facial difference may report low self-confidence, negative body image, and difficulties with social interaction.[3,4] Furthermore, existing studies have identified an association between facial differences and diminished overall health-related quality of life (HRQL).[5] Given these findings, congenital or acquired ear conditions may have psychological and aesthetic consequences to patients.

Within plastic surgery, it is important to capture the outcomes that are meaningful to patients to improve their quality of care. To date, systematic reviews of patient-reported outcome measures (PROMs) for conditions associated with facial differences identified only one ear-specific PROM, known as the Congenital Aural Atresia Questionnaire, which measures outcomes specific to hearing function and psychosocial concerns.[6,7] Furthermore, only five ear-specific PROMs exist in the literature for ear reconstruction[8–12]; however, the samples used to develop these scales were limited to individuals with microtia diagnosis or selected from single country populations.

Given the paucity of valid and generalizable PROMs for ear conditions and its associated reconstruction, our research team developed a PROM which measures the outcomes that matter to patients with congenital or acquired ear conditions: the EAR-Q.[13,14] This PROM was designed for children and young adults, aged 8–29 years, with congenital or acquired ear conditions, and underwent an international field-test to establish its reliability and validity.[14]

The ***primary objective*** of this study was to perform an exploratory analysis using data collected from the international field-test of the EAR-Q to evaluate which patient demographic and clinical variables were associated with scores for the EAR-Q Appearance, Psychological, and Social scales.

Patients and methods

Sample and recruitment

Research ethics board approval was obtained from the Hamilton Integrated Research Ethics Board (#14-763) at the McMaster University and participating sites. Participants in the international field-test were recruited between May 2016 and December 2019 from 21 collaborating centers in Australia, Brazil, Canada, China, Ireland, Spain, the United Kingdom, and the United States as part of a larger field-test validation study.[15,16] Participants were aged 8–29 years with any congenital or acquired ear condition, at any stage of treatment or follow-up, and completed one or more of the EAR-Q scales.

EAR-Q scales

The EAR-Q is composed of six independently functioning scales or checklists that measures outcomes specific to three overarching domains: 1) Appearance (1 scale); 2) Health-Related Quality of Life (HRQL; 4 scales); and 3) Adverse Effects (1 scale) (https://qportfolio.org/ear-q/).[13] The Appearance scale includes 10-items that ask the patients how their ears look from their perspective. The HRQL scales evaluate psychological, social, and school function as well as appearance-related distress. Lastly, the Adverse Effects checklist asks patients to rate the severity of adverse effects associated with an ear intervention (e.g., pain and diminished sensation). The Ear Appearance and HRQL scales are subsequently converted from an ordinal score into a continuous scale, from 0 to 100, where *higher* scores correspond to *improved* appearance and HRQL outcomes. For this study, only outcomes specific to the EAR-Q Appearance, Psychological, and Social scales were analyzed. These scales were selected as they were most frequently completed as part of a larger field-test validation study.[15,16]

Data analysis

Descriptive statistics were used to evaluate participant demographic and clinical characteristics. A simple linear regression analysis was used to evaluate the existence of a linear relationship between each predictor variable and EAR-Q Appearance, Psychological, and Social scales. Patient demographics and clinical variables used for this analysis were selected by the study authors based on their hypothesized impact on EAR-Q scale scores. The variable "How much do you like how your ears look overall?" was not used to evaluate the EAR-Q Appearance scale as it was felt to directly evaluate the "appearance" construct.

Statistical significance was determined using the Wald test (for continuous variables) or partial F-test (for

categorical variables). Pre-determined variables were selected based on their hypothesized negative association with HRQL[17-20] and run in a univariate linear regression model. Those that demonstrated a statistically significant linear relationship from these analyses were then entered into a multivariable linear regression model, using a backward stepwise selection based on the stopping rule of 0.10. Standardized coefficients (ß*) were used to compare the relative importance of predictor variables. The total variability explained through this model was summarized using the coefficient of determination (R^2). An a priori variance inflation factor (VIF) > 5 was used to denote definite multicollinearity.

Given a sample size rule of thumb of 10–20 participants per predictor,[21] the sample size (n = 862) was deemed to be sufficient. To ensure the normality and homoscedasticity assumptions for linear regression were met, residuals were examined using visual inspection and P-P plots. Listwise deletion (i.e., complete case analysis) was performed to address missing data within the univariable and multivariable models. Statistical significance was considered at $p \leq 0.05$. All analyses were performed using SPSS® version 26.0 (IBM Corporation, Armonk NY, USA for Windows®).[22]

Results

Demographic and clinical characteristics

The study included n = 862 participants who completed the Appearance scale and at least one other HRQL scale. Within this sample, most participants were men (n = 495, 57.4%), located in China (n = 361, 41.9%), awaiting treatment (n = 474, 55.0%), and had microtia diagnosis (n = 607, 70.4%). The mean age of participants was 13 (±4) years, with most respondents having unilateral ear diagnoses (n = 618, 71.7%). Participant demographics are summarized in Table 1. Respondents had a mean (±SD) score of 45.0 (±29.0), 69.0 (±20.0), and 72.0 (±19.0) for the Appearance scale, Psychological, and Social scales, respectively (Table 2).

EAR-Q appearance scale

Following a univariable linear regression analysis (Table 3), improved ear appearance (i.e., higher scores) was significantly associated with the female gender (ß 5.39, 95% CI, 1.53 to 9.24 $p < 0.01$), a non-microtia diagnosis ($p < 0.01$), having received treatment for this condition ($p < 0.01$), greater than 6 months duration since surgery (ß −17.1, 95% CI, −22.3 to −11.9, $p < 0.01$), a bilateral ear diagnosis (ß 6.11, 95% CI 1.51 to 10.70, $p < 0.01$), and greater self-reported ears matching ($p < 0.01$).

When statistically significant variables from the univariate analysis were included in a multivariable linear regression model, the type of ear condition ($p = 0.02$), treatment status ($p < 0.01$), and greater self-reported ears matching ($p < 0.01$) remained statistically significant (Table 4). Using standardized coefficients (ß*), patient self-reported ears matching (ß* = −0.78) was determined to be the most important predictor variable for EAR-Q Appearance Score. Overall, the multivariable model explained 56.3% of the variability in Appearance scale scores (R^2 =0 .563, F (10, 791) = 101.75, $p < 0.01$).

Table 1 Demographic and clinical information for participants.

Participant characteristics	N = 862	N%
Age (years)		
8–10	231	26.8%
11–13	291	33.8%
14–17	207	24.0%
18–29	133	15.4%
Country		
Australia	8	0.9%
Canada	219	25.4%
China	361	41.9%
Ireland	14	1.6%
Spain	28	3.2%
United States of America	35	4.1%
United Kingdom	175	20.3%
Brazil	20	2.3%
Gender		
Male	494	57.4%
Female	367	42.6%
Ear condition		
Microtia	607	70.4%
Prominent	145	16.8%
Other	110	12.8%
Treatment status		
Did not undergo treatment	474	55.0%
Underwent treatment	287	33.3%
Underwent treatment but required further intervention	101	11.7%
Ear surgery in the last 6 months?		
Yes	131	15.3%
No	726	84.7%
How much do you like how your ears look overall?		
Very much	189	22.2%
Quite a bit	192	22.6%
A little bit	239	28.1%
Not at all	230	27.1%
How well do your ears match each other (look the same)?		
Very much	180	21.0%
Quite a bit	165	19.3%
A little bit	211	24.6%
Not at all	301	35.1%
Sides affected		
Unilateral	618	76.1%
Bilateral	194	23.9

Table 2 Distribution of EAR-Q scale scores.

EAR-Q Scale	N	Mean (SD)	Minimum	Maximum
Appearance scale	862	45 (±29)	0	100
Psychological scale	846	69 (±20)	0	100
Social scale	841	72 (±19)	3	100

Table 3 Simple linear regression of EAR-Q appearance scale on participant variables.

Variable	ß	p-value	(95% CI)
Age, years	−0.33	0.16	−0.78 to 0.13
Gender (ref = male)	5.39	**< 0.01****	1.53 to 9.24
Ear condition (ref = microtia)		**< 0.01****	
Prominent ear	7.38		2.24 to 12.52
Other	12.45		6.69 to 18.22
Treatment status (ref = no treatment, treatment planned)		**< 0.01****	
Prior treatment, additional needed	14.09		8.54 to 19.65
Prior treatment, no additional	27.31		23.51 to 31.10
Ear surgery in the last 6 months (ref = no)	−17.10	**< 0.01****	−22.32 to −11.89
How well do your ears match each other (look the same)? (ref = very much)		**< 0.01****	
Quite a bit	−19.09		−23.41 to −14.78
A little bit	−33.62		−37.68 to −29.56
Not at all	−53.50		−57.27 to −49.73
Unilateral versus bilateral ear affected (ref = unilateral)	6.11	**< 0.01****	1.51 to 10.70

EAR-Q psychological scale

Following univariable regression (Tables 5 and 6), improved Psychological scales scores (i.e., higher scores) were associated with younger participant age (ß − 0.76, 95% CI, −1.08 to −0.44, $p < 0.01$), history of prior treatment ($p < 0.01$), greater than 6 months after surgery (ß − 5.70, 95% CI, −9.48 to −1.93, $p < 0.01$), greater self-reported ear appearance overall ($p < 0.01$), and greater self-reported ears matching ($p < 0.01$).

Moreover, when these statistically significant variables were included in a multivariable linear regression model, only participant age ($p < 0.01$), greater self-reported ear appearance overall ($p < 0.01$), and greater self-reported ears matching ($p < 0.01$) remained statistically significant after adjusting for all other variables in the model. Using the standardized coefficient (ß*), patient self-reported ear appearance overall (ß* = 0.49) was determined to be the most important predictor variable for EAR-Q Psychological scale score. Overall, the multivariable model explained 25.7% of the variability in the Psychological scale scores ($R^2 = 0.257$, $F(10, 817) = 28.3$, $p < 0.01$).

EAR-Q social scale

Following a univariable linear regression analysis (Table 7), improved social scale scores (i.e., higher scores) were associated with prior treatment for congenital or acquired ear conditions ($p < 0.01$), greater than 6 months duration since surgery (ß −3.59, 95% CI, −7.13 to −0.05, $p = 0.04$), an unilateral ear diagnosis (ß −3.27, 95% CI, −6.34 to −0.19, $p = 0.04$), greater self-reported ear appearance overall ($p < 0.01$), and greater self-reported ears matching ($p < 0.01$).

When these variables were included in a multivariable model (Table 8), only ear laterality ($p < 0.01$), greater self-reported ear appearance overall ($p < 0.01$), and greater self-reported ears matching ($p < 0.01$) remained statistically significant after adjusting for all other variables in the

Table 4 Multivariable linear regression of EAR-Q appearance scale on participant variables.

Variable	ß	Standardized ß*	p-value	(95% CI)	VIF
Gender (ref = male)	0.24	0.01	0.87	−2.50 to 2.97	1.05
Ear Condition (ref = microtia)			**0.02****		
Prominent ear	0.42	0.01		−4.77 to 5.61	2.19
Other	5.95	0.07		1.50 to 7.71	1.24
Treatment Status (ref = no treatment, treatment planned)			**< 0.01****		
				2.82 to 12.45	1.43
Prior treatment, additional needed	7.64	0.09		12.44 to 19.43	1.58
Prior treatment, and no additional treatment	15.94	0.27			
Ear Surgery in the last 6 months (ref = no)	−1.51	−0.02	0.48	−5.64 to 2.63	1.35
How well do your ears match each other (look the same)? (ref = very much)			**< 0.01****		
Quite a bit	−18.49	−0.26		−22.73 to −14.24	1.62
A little bit	−31.58	−0.48		−35.59 to −27.57	1.77
Not at all	−46.70	−0.78		−50.79 to −42.61	2.20
Unilateral versus bilateral ear affected (ref = unilateral)	−1.72	0.01	0.44	−6.11 to 2.66	2.02

Table 5 Simple linear regression of EAR-Q psychological scale on participant variables.

Variable	β	p-value	(95% CI)
Age, years	−0.76	**< 0.01****	−1.08 to −0.44
Gender (ref = male)	−0.09	0.95	−2.87 to 2.68
Ear Condition (ref = microtia)		0.63	
Prominent ear	1.47		−2.24 to 5.17
Other	1.48		−2.67 to 5.63
Treatment Status (ref = no treatment, treatment planned)		**< 0.01****	
Prior treatment, additional needed	2.17		−2.20 to 6.55
Prior treatment, no additional treatment	7.92		4.96 to 10.88
Ear Surgery in the last 6 months (ref = no)	−5.70	**< 0.01****	−9.48 to −1.93
How much do you like how your ears look overall? (ref = very much)		**< 0.01****	
Quite a bit	−12.35		−15.97 to −8.74
A little bit	−19.28		−22.72 to −15.84
Not at all	−26.59		−30.07 to −23.12
How well do your ears match each other (look the same)? (ref = very much)		**< 0.01****	
Quite a bit	−11.22		−15.22 to −7.22
A little bit	−17.30		−21.07 to −13.53
Not at all	−20.01		−23.51 to −16.50
Unilateral versus bilateral ear affected (ref = unilateral)	−0.09	0.96	−3.37 to 3.19

Table 6 Multivariable linear regression of EAR-Q Psychological scale on participant variables.

Variable	β	Standardized β*	p-value	(95% CI)	VIF
Age, years	−0.56	−0.12	**< 0.01****	−0.85 to −0.28	1.05
Treatment status (ref = no treatment, treatment planned)			0.46		
Prior treatment, additional needed	−2.76	−0.04		−7.11 to 1.60	1.61
Prior treatment, no additional treatment	−0.99	−0.02		−4.19 to 2.21	1.38
Ear surgery in the last 6 months (ref = no)	−1.39	−0.04	0.47	−5.17 to 2.38	1.32
How much do you like how your ears look overall? (ref = very much)			**< 0.01****		
Quite a bit	−8.78	−0.18		−12.76 to −4.81	1.97
				−18.84 to −10.44	2.54
A little bit	−14.64	−0.22		−26.86 to −17.70	2.91
Not at all	−22.28	−0.49			
How well do your ears match each other (look the same)? (ref = very much)			**< 0.01****		
Quite a bit	−5.06	−0.10		−9.18 to −0.94	1.89
A little bit	−8.22	−0.18		−12.40 to −4.03	2.33
Not at all	−6.39	−0.15		−1.63 to −2.15	2.90

model. Using the standardized coefficient (β*), self-reported ear appearance overall (β* = 0.30) was determined to be the most important predictor variable for EAR-Q Social scale score. Overall, the multivariable model explained 12.1% of the variability in Social scale scores ($R^2 = 0.121$, $F(10, 777) = 10.7$, $p < 0.01$).

Discussion

This is the first exploratory analysis to evaluate the impact of clinical and demographic factors on EAR-Q appearance and HRQL scales using a large sample of 862 pediatric and young adult patients with various congenital or acquired ear conditions. Specifically, we identified that participants who completed the initial treatment with greater than 6-month follow-up after surgery had greater self-reported ear appearance overall and self-reported ears matching, scored higher on the EAR-Q Appearance, Psychological, and Social scales.

Notably, female participants and those with a non-microtia diagnosis demonstrated greater self-reported ear appearance overall as measured using the EAR-Q appearance scale. However, only ear condition remained statistically significant after adjusting for other statistically significant variables within a multivariable model. Moreover, increasing participant age was associated with a decrease in Psychological scale scores, with each additional 1-year increase in age corresponding to an average of 0.76 point reduction.

These results largely conform to those in the existing literature with HRQOL improving with ear surgery. Specifically, an observational study evaluating the quality of

Table 7 Simple linear regression of EAR-Q social scale on participant variables.

Variable	ß	p-value	(95% CI)
Age, years	−0.24	0.12	−0.54 to 0.06
Gender (ref = male)	1.39	0.29	−1.20 to 3.99
Ear Condition (ref = microtia)		0.35	
Prominent ear	−2.24		−5.72 to 1.25
Other	−1.81		−5.69 to 2.06
Treatment Status (ref = no treatment, treatment planned)		**< 0.01****	
Prior treatment, additional needed	3.99		2.84 to 8.41
Prior treatment, no additional	5.62		−0.13 to 8.10
Ear Surgery in the last 6 months (ref = no)	−3.59	**0.04****	−7.13 to −0.05
How much do you like how your ears look overall? (ref = very much)		**< 0.01****	
Quite a bit	−6.31		−9.94 to −2.68
A little bit	−12.61		−16.06 to −9.16
Not at all	−16.78		−20.25 to −13.30
How well do your ears match each other (look the same)? (ref = very much)		**< 0.01****	
Quite a bit	−6.39		−10.31 to −2.47
A little bit	−9.55		−13.26 to −5.83
Not at all	−12.99		−16.43 to −9.55
Unilateral versus bilateral ear affected (ref = unilateral)	−3.27	**0.04****	−6.34 to −0.19

Table 8 Multivariable linear regression of EAR-Q social scale on participant variables.

Variable	ß	Standardized ß*	p-value	(95% CI)	VIF
Treatment status (ref = no treatment, treatment planned)			0.84		
Prior treatment, additional needed	0.27	0.01		−4.30 to 4.85	1.42
Prior treatment, no additional	−0.52	−0.13		−3.95 to 2.90	1.68
Ear Surgery in the last 6 months (ref = no)	−0.42	−0.01	0.85	−3.83 to 3.17	1.08
How much do you like how your ears look overall? (ref = very much)			**< 0.01****		
				−8.62 to −0.28	1.92
Quite a bit	−4.52	−0.10		−13.98 to −5.35	2.44
A little bit	−9.81	−0.23		−17.49 to −8.24	2.71
Not at all	−13.08	−0.30			
How well do your ears match each other (look the same)? (ref = very much)			**< 0.01****		
Quite a bit	−3.34	−0.07		−7.67 to 1.00	1.88
A little bit	−5.18	−0.12		−9.62 to −0.70	2.41
Not at all	−5.92	−0.15		−10.48 to −1.24	3.12
Unilateral versus bilateral ear affected (ref = unilateral)	−4.37	−0.10	**< 0.01****	−7.40 to −1.31	1.08

life outcomes in prominent ear patients by Carvalho et al.[19] found that otoplasty was associated with a statistically significant increase in aesthetic and HRQL outcomes. In addition, a retrospective cohort study by Horlock et al.[20] demonstrated that 91% of children had a significant psychosocial benefit following ear reconstruction.[20] However, there are several hypotheses as to why variables may be associated with poorer outcomes. Li et al.[3] found that male gender and increasing age were associated with greater psychosocial difficulties in a sample of 170 microtia patients. Our study also identified that Psychological scale scores decreased with age; however, no gender difference was identified in EAR-Q psychological or social outcomes. Although not explicitly identified, it may be possible that men had decreased scores as they often have shorter hair and their ears are more visible and age may be a contributing factor as the psychological toll over time may lead to the development of mental health problems.[5] Further research may be needed to better understand the impact of gender on EAR-Q psychological and social scale scores. Finally, our study identified that patients with bilateral ear differences had lower social scores relative to unilateral conditions. This finding is supported by the work of Fan et al.[21] who concluded that a sample of pediatric patients with bilateral microtia were more likely to report loneliness when compared to patients with a unilateral diagnosis,[21] and is likely more noticeable as this ear condition has more anatomical differences than the average ear. However, the findings of lower social scores in bilateral ears does contradict the findings of lower appearance scores associated with unilateral involvement.

There are several limitations to this analysis. First, as data were self-reported by the participants, patient demographic and clinical information could not be independently verified. Second, given that this study involved a convenience sample of pediatric and young adult patients

who self-selected to participate in the international field-test study, the results of this study may be subject to selection bias.[22] Third, as most participants were from high income countries, the results may not be generalizable to patients in low middle income countries. Finally, as there is no minimal clinically important difference established for the EAR-Q Appearance, Psychological, and Social scales, we were unable to interpret whether these variables lead to a clinically meaningful difference in outcomes. Therefore, statistical significance may not equate to clinical importance.

It has become increasingly important to quantify surgical procedures. Several other authors have examined the use of HRQOL tools to determine the psychological, social, and emotional wellbeing of children prior to and following ear surgery.[5,17-19] However, these studies did not investigate all domains or were generalizable to multiple ear conditions or surgical procedures. We anticipate that the EAR-Q will be used in clinical practice and research. It may be a helpful tool to guide preoperative and post-operative discussions with patients regarding their expectations and goals. Further, the EAR-Q will also be useful for researchers to help better understand the patient perspective of important outcomes pre and post ear surgery.

Conclusions

This exploratory regression analysis identified patient factors that may influence EAR-Q Appearance, Psychological, and Social scale scores. This study provides evidence of clinical and demographic factors that should be adjusted for when undertaking future observational research designs using the EAR-Q in pediatric and young adult patients with congenital or acquired ear conditions. The results support the notion that clinicians and researchers should have detailed discussions with their patients prior to surgery and discuss how the potential baseline factors may impact their expectations or HRQL post-operatively. This is particularly important for patients who are in pre-treatment, had recent surgery, and are older, to address potential concerns with ear related appearance and HRQL concerns. Future prospective research is necessary to confirm these associations in diverse populations, establish if there is a longitudinal relationship, determine anchor-based minimal clinical important differences for the EAR-Q scales and assess the EAR-Q scales with various treatment options.

Ethics

This study conforms to the World Medical Association Declaration of Helsinki (June 1964) and received ethics approval from Hamilton Integrated Research Ethics Board (#14-763) at the McMaster University.

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Conflict of Interest

The EAR-Q is owned by McMaster University and the Hospital for Sick Children. Drs. Anne Klassen and Karen Wong Riff co-developed the EAR-Q and receive a share of any license revenues associated with for-profit use of these scales as royalties based on their institutions' inventor sharing policy. The remaining authors have no conflicts of interest to report.

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