Cross-sectional International Multicenter Study on Quality of Life and Reasons for Abandonment of Upper Limb Prostheses

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Background: This multicenter study aimed to examine the reasons for prosthesis rejection and assess the quality of life (QOL) among patients with upper limb deficiency.

Methods: Three rehabilitation centers in Japan and 1 academic medical center in the United States participated. Patients between the age of 12 and 75 years with unilateral or bilateral upper limb absence from the level of wrist to shoulder disarticulation were included. Two questionnaires were used, an original questionnaire on prosthesis use and the EQ-5D, which were completed by both the participant and a live-in proxy.

Results: Of the 367 patients with upper limb loss invited, 174 patients participated in this study. Eighty percent of the study population were male patients. The most common amputation level was transradial. Trauma was the most common cause of limb loss. The prosthesis rejection rate was 9% (n = 16). The most common reason for abandonment was a lack of prosthesis functionality. Ten of 16 prosthesis nonusers (63%) and 59 prosthesis users (38%) were unemployed or students. The mean EQ-5D utility score was significantly higher in prosthesis users than in nonusers (0.762 versus 0.628, \( P < 0.01 \)). Live-in proxies significantly overestimated QOL in male patients (0.77 versus 0.807, \( P=0.01 \)).

Conclusions: The current prosthesis rejection rate is low. QOL was significantly higher in prosthesis users than in nonusers. More prosthesis users were employed compared with nonusers. Care should be taken not to overestimate the QOL of male patients with upper limb loss as their proxies often did. (Plast Reconstr Surg Glob Open 2019;7:e2205; doi: 10.1097/GOX.0000000000002205; Published online 24 May 2019.)

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INTRODUCTION
Currently, 541,000 American and 82,300 Japanese individuals are estimated to be living with upper limb loss. The use and abandonment of upper limb prostheses have been researched previously, but small sample sizes and highly specific cohorts limited the effectiveness of these studies. Furthermore, standardized patient-reported outcome measures have seldom been used. Researchers are continually designing and building more functional and innovative prosthetic devices, and recent advances have assisted many patients in returning to the activities they were involved in before their injury. However, although progress is tangible, it is possible that these developments have not affected prosthesis abandonment rates.

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The likelihood of prosthesis abandonment depends on a variety of factors including the patient’s age, sex, origin and level of limb absence, and type of prosthesis. Among prostheses users, rejection rates are higher for pediatric patients than for adults. A systematic review of 25 years of literature found that the mean pediatric rejection rates were 45% and 35% for body-powered and electric prostheses, respectively, whereas the mean adult rejection rates were significantly lower (26% and 23%, respectively). Predictably, the comfort and function of prostheses were important factors in their use or abandonment. A cross-sectional study with data from multiple rehabilitation and academic centers is necessary to estimate the true rates of prosthesis use and rejection and determine the most common reasons for abandonment.

When treating patients, quality of life (QOL) is often evaluated with a patient-reported outcome measure (PROM). Considering that upper limb prostheses may help people function in daily life and also improve their appearance, patients who use upper limb prostheses may have higher QOL scores than those who do not.

At times, QOL measurement may rely, in part, on proxy information obtained from patients’ significant others or healthcare providers. Although patient and proxy ratings often agree, there is evidence that this may not be true for patients with upper limb deficiencies. Children with unilateral, congenital, below-elbow deficiencies reported higher function and QOL than their parents perceived. This may point to a societal misconception about amputees and their QOL. Moreover, in palliative care, the agreement between QOL assessments by patients and physicians was poor, providing further indication of misconceptions in some medical fields about a patient’s QOL and abilities. Data on the discrepancies in QOL assessments would be useful to better understand the possible societal misconceptions about patients living with upper limb deficiencies.

The purpose of this study was to examine prosthesis use and abandonment among patients with upper limb deficiencies in the United States and Japan. We determined the most common reasons for abandonment and compared prosthesis users and nonusers according to a variety of demographic and clinical characteristics. We hypothesized that prosthesis users would have higher QOL than nonusers and that patients who used myoelectric prostheses were more likely to be employed. We also compared EQ-5D scores between patients and their live-in proxies to determine their level of agreement regarding QOL, hypothesizing that patient-reported QOL would be superior to proxy-reported values even among adults.

MATERIALS AND METHODS

Study Design

Three rehabilitation centers in Japan and 1 academic medical center in the United States participated in this cross-sectional survey-based international multicenter study. All 4 institutions provide intensive rehabilitation courses for patients with upper limb loss. Institutional review board approval was granted by each center before initiation of the study, and the patients gave their written informed consent to participate. We screened current and past patients from each center and invited those who met the inclusion criteria to participate via either electronic mail or written mail.

Inclusion and Exclusion Criteria

Surveys were distributed to patients who had been treated for an upper limb deficiency at the participating centers. Individuals included in the study cohort were patients with unilateral or bilateral upper limb absence from the level of wrist disarticulation to the level of shoulder disarticulation who were 12–75 years of age. Patients were eligible to participate regardless of (1) origin of limb absence, (2) laterality of limb absence, (3) status of prosthesis use, and (4) type of prosthesis used. We excluded patients who could not complete questionnaires in either English or Japanese or who had any current musculoskeletal injuries.

Questionnaires

Two questionnaires were used. Participants first completed an original questionnaire on their past and present prosthesis use by answering both closed- and open-ended questions (Appendix 1). This 4-part survey was developed in consultation with several prominent hand surgery and rehabilitation researchers and clinicians in the United States and Japan. The standard translation, back-translation method was used. In brief, the questionnaire was written in English and, then, translated into Japanese by a native Japanese speaker. Another native Japanese-speaking researcher translated it back to English. Finally, an English-speaking researcher confirmed that the translated questionnaire had the same meaning as the original. This survey took about 10 minutes to complete and also collected demographic information. Participants then completed the 5-level EQ-5D (EQ-5D-5L), comprising the following 5 dimensions: (1) mobility, (2) self-care, (3) usual activity, (4) pain/discomfort, and (5) anxiety/depression. It is the most commonly used QOL instrument worldwide and includes a “crosswalk” to convert QOL into utility values. The EQ-5D-5L is available in both American English and Japanese and has been validated for use by participants 12 years and older. This survey is expected to take less than 5 minutes for the average adult to complete.

In addition to the version completed by the patient, a proxy was asked to complete the EQ-5D-5L on the participant’s behalf. The proxy was a family member or close friend who lives with the participant and interacts with the participant on a daily basis. The EQ-5D has also been validated for proxy use. We compared EQ-5D data between patients and their proxies to understand discrepancies in the perception of patients’ QOL.

Data Analysis

We compared the response rate between the United States and Japan. We also examined the use and abandonment of prostheses among patients with upper limb loss and compared prosthesis users and nonusers according
to age, sex, dominant or nondominant hand involvement, level of upper limb loss, health status, cohabitation status, and employment status. $\chi^2$ and $t$ tests were used for nominal and interval data, respectively. A post hoc power analysis was performed using the G*Power software for comparisons between prosthetic users and nonusers. Tukey–Kramer tests were used to compare EQ-5D utility scores between each level of upper limb deficiency.

We also compared patient- and proxy-reported EQ-5D utility scores. The mean difference between the patient and proxy responses was calculated, and $t$ tests were used to evaluate the results. To determine the effect of age, we calculated the Pearson’s correlation coefficient between the EQ-5D utility score and patient age. To determine the effect of sex, we compared the mean difference between male patients and their proxies with that of female patients and their proxies using a $t$ test.

**RESULTS**

**Patient Demographics**

We invited 367 current or former patients, and 174 patients agreed to participate. The total response rate was 47%. The number of participants from each institution along with their age, sex, and the levels and causes of amputation are shown in Table 1. The response rate in the United States was significantly lower than that in Japan (19% versus 61%, $P < 0.01$). There was no significant difference with respect to sex between responders and nonresponders ($P = 0.4$), but the mean age of nonresponders was significantly younger than that of responders (47 versus 51 years, $P = 0.01$).

More males than females responded at each center. The mean age at the time of survey was 51 years. The mean age at amputation excluding respondents with congenital limb deficiency was 40 years. Nine patients (5%) had a bilateral upper limb deficiency. The majority of limb loss was caused by trauma (83%), with transradial amputation the most common level (53%). Good-to-excellent health status was reported by 92% of patients; the other 8% reported fair-to-poor health. The most common symptom experienced at the stump was tingling (51%), followed by phantom pain (45%) (Fig. 1).

One hundred fifty-eight patients (91%) were actively using their prosthesis, whereas 16 patients (9%) were nonusers. A total of 95 patients (55%) worked full time or part time, whereas 74 patients (42%) were either unemployed, receiving disability payment, or retired. The remaining 3% were students. Myoelectric prosthesis users were the most prevalent (n = 75), followed by 50 body-powered prosthesis users and 33 cosmetic hand users (Fig. 2). The average number of days per week and hours per day that users wore their prosthesis is shown in Figures 3 and 4. The activities for which patients reported using their prosthesis are shown in Figure 5. Patient satisfaction with their prosthesis is shown in Figure 6.

**Reasons for Prosthesis Abandonment**

Sixteen patients (9%) did not use their prosthesis. Reasons for prosthesis abandonment are listed in Table 2. The prosthetic rejection rate in the United States was higher than that in Japan (18% versus 8%, $P = 0.1$). One nonuser had bilateral congenital deficiency from the transradial level. Ten nonusers had rejected a body-powered prosthesis.

### Table 1. Participant Demographics

| Institution | UM | Chubu | NRCD | Hyogo* |
|-------------|----|-------|------|--------|
| Invited patients | 117 | 91 | 28 | 131 |
| Responders (response proportion) | 22 (19%) | 51 (56%) | 21 (75%) | 80 (61%) |
| Male | 14 | 45 | 18 | 62 |
| Female | 8 | 6 | 3 | 18 |
| Mean age (range) (years) | 49 (24–68) | 57 (12–75) | 44 (21–68) | 51 (1–75) |
| 12–19 | 0 | 2 | 0 | 3 |
| 20–59 | 20 | 23 | 16 | 46 |
| 60–75 | 2 | 26 | 5 | 31 |
| Mean age at amputation (range) (excluding congenital limb loss) (years) | 38 (16–60) | 38 (17–69) | 42 (22–63) | 41 (4–71) |
| Laterality of amputation | | | | |
| Bilateral | 2 | 2 | 2 | 3 |
| Right | 7 | 37 | 10 | 44 |
| Left | 13 | 12 | 9 | 32 |
| Level of amputation | | | | |
| Shoulder | 1 | 1 | 1 | 7 |
| Transhumeral | 3 | 12 | 6 | 19 |
| Elbow | 5 | 3 | 0 | 4 |
| Transradial | 15 | 27 | 10 | 39 |
| Wrist | 0 | 10 | 6 | 14 |
| Congenital | 7 | 2 | 3 | 4 |
| Acquired | 15 | 49 | 18 | 76 |
| Trauma | 12 | 46† | 16 | 71 |
| Disease | 3 | 0 | 2 | 5 |
| Mean health status | 2.64 | 2.51 | 2.55 | 2.53 |

Health status key: 1, excellent; 2, very good; 3, good; 4, fair; 5, poor.
†Data were unavailable for 3 cases.
sis: 6 had tried a cosmetic prosthesis and 4 had trained with a myoelectric prosthesis. The most common (81%) reason for abandonment was limited functionality.

**Comparison Between Prosthesis Users and Nonusers**

The mean ages of prosthetic users and nonusers were 51 and 47 years, respectively. The prosthetic rejection rate of congenital amputees was significantly higher than that of acquired amputees ($P < 0.05$). Although there was no significant difference between patients with below or above the elbow amputation in terms of prosthetic abandonment, the percentage of patients with above elbow amputation was greater among nonusers than users (53% versus 32%) and the percentage of patients with transradial amputation was lower among nonusers than users (35% versus 51%). There were no significant differences between prosthesis users and nonusers with regard to age, sex, dominant or nondominant hand involvement, cohabitation status, level of amputation, or health status.

The mean EQ-5D utility score of prosthesis users was significantly higher than that of nonusers (0.762 versus 0.628, $P<0.01$). Sixty-four prosthesis users (41%) and 10 nonusers (63%) were retired or unemployed, receiving disability payment, whereas 90 prosthesis users (57%) and 5 nonusers (31%) were working full time or part time. Excluding students, prosthesis users tended to be employed more often than nonusers ($P = 0.06$) (Table 3).

**Employment Status by Prosthetic Type**

Employment status differed according to the type of primary prosthesis used. The rates of full- or part-time em-
Employment were highest among users of myoelectric (65%), followed by cosmetic (51%) and body-powered (48%) prostheses. The rate of patients who were retired or unemployed, receiving disability payment, was the lowest among users of myoelectric (32%), followed by cosmetic (42%) and body-powered (52%) prostheses.

**EQ-5D Utility Score by Prosthetic Type, Level of Limb Loss, and Age**

Cosmetic users had the highest EQ-5D score (0.797), followed by myoelectric (0.754) and body-powered (0.748) users (Table 4). The EQ-5D score did not significantly differ according to the level of upper limb deficiency (Fig. 7). Age was not correlated with the EQ-5D score reported by patients ($r = 0.007, P = 0.94$).

**Comparison of EQ-5D Utility Score Between Patients and Live-in Proxies**

Proxies reported higher EQ-5D utility scores than patients. Although the EQ-5D utility score reported by female patients and their proxies did not significantly differ, male patients reported significantly lower EQ-5D utility scores than their proxies (0.77 versus 0.807, $P = 0.01$) (Table 5). Proxies overestimated the QOL of male patients and tended to underestimate the QOL of female patients.

**DISCUSSION**

The prosthesis rejection rate in this study was 9%, which is lower than those previously reported. Biddiss and Chau summarized 25 years of publications and found that the mean rejection rates of adult prostheses were 26% for body-powered prosthesis and 23% for myoelectric prosthesis. The most common reason for abandonment in this study was lack of functionality of the prosthesis. Prosthesis users reported better QOL than nonusers, as indicated by the EQ-5D utility score, and tended to work full time or part time at higher rates than nonusers.

We hypothesized that myoelectric prosthesis users were more likely to be employed full time and indeed they demonstrated the highest rate of patients working full time or part time and the lowest rate of those receiving disability payments. Although the myoelectric prosthesis is the most expensive type, it helps improve patients’ productivity in society. Many patients reported their desire for a more functional prosthesis including myoelectric one but cost was a serious issue according to what they wrote in the free-response section of the questionnaire, because a current myoelectric prosthesis is about 10 times more expensive than a cosmetic hand.

In our study, a prosthetic was utilized every day by 70% of users, with 67% wearing relying on it for more than 8 h/d. Patients used their prosthesis for activities throughout the day including their jobs.

Based on data from this study, myoelectric prostheses need to be better available and sufficiently practical for regular use. Among the latest developments in prosthetic technology, sockets for both traditional and osseointegration-based systems have been equipped with multiple surface electromyography sensors. Furthermore, integrated approaches combining advanced microsurgical tech-
Table 2. Summary of Prosthesis Nonusers

| Sex | Age (years) | Level | Institution | Reason for Amputation | Types of Prostheses Tried | Reason for Abandonment |
|-----|-------------|-------|-------------|------------------------|---------------------------|------------------------|
| F   | 55          | Both transradial | UM | Congenital | Body powered | Functionality, skin issues |
| F   | 66          | Elbow | UM | Congenital | Body powered | Functionality, discomfort |
| F   | 24          | Transradial | UM | Disease | Missing data | Missing data |
| M   | 43          | Transhumeral | Chubu | Trauma | Body powered | Problems with fit |
| M   | 72          | Elbow | Chubu | Trauma | Cosmetic, body powered | Sweating in the socket |
| M   | 72          | Transhumeral | Chubu | Trauma | Cosmetic | Functionality |
| M   | 31          | Transradial | NRCD | Trauma | Cosmetic, body powered, myoelectric | Weight of prosthesis |
| F   | 14          | Wrist | Hyogo | Trauma | Cosmetic | Othersome |
| M   | 20          | Transhumeral | Hyogo | Trauma | Body powered | Useless |
| M   | 71          | Transhumeral | Hyogo | Trauma | N/A | Functionality |
| M   | 71          | Transhumeral | Hyogo | Trauma | Body powered | Useless |
| M   | 45          | Shoulder | Hyogo | Trauma | Body powered | Functionality, useless |
| M   | 30          | Wrist | Hyogo | Trauma | Myoelectric | Obesity |
| F   | 42          | Transradial | Hyogo | Trauma | Cosmetic | Appearance |
| M   | 27          | Transradial | Hyogo | Trauma | Cosmetic, body powered, myoelectric | Weight of prosthesis |

Chubu: Chubu Rosai Hospital; F, female; Hyogo, Hyogo Rehabilitation Center Central Hospital; M, male; NRCD, National Rehabilitation Center for Persons with Disabilities; UM: University of Michigan.

Table 3. Patient Characteristics of Prosthesis Users and Nonusers

|                          | User       | Nonuser     | P      | Effect Size | Power |
|--------------------------|------------|-------------|--------|-------------|-------|
| Mean age (years)         | 51 ± 15    | 47 ± 21     | 0.27   | 0.22        | 0.59  |
| Sex                      |            |             |        |             |       |
| Male                     | 128        | 11          |        |             |       |
| Female                   | 30         | 5           | 0.2    | 0.31        | 0.99  |
| Dominance of amputated limb* | 78    | 9           |        |             |       |
| Dominant side            |            |             |        |             |       |
| Nondominant side         | 55         | 3           | 0.27   | 0.33        | 0.99  |
| Reason for amputation    |            |             |        |             |       |
| Congenital               | 12         | 4           |        |             |       |
| Acquired                 | 146        | 12          | <0.05  | 0.66        | 1     |
| Cohabitation status†     |            |             |        |             |       |
| Lives alone              | 12         | 1           | 0.87   | 0.05        | 0.89  |
| Lives with other(s)      | 131        | 13          |        |             |       |
| Level of amputation‡      |            |             |        |             |       |
| Shoulder, n (%)          | 9 (5%)     | 1 (6%)      |        |             |       |
| Transhumeral, n (%)      | 95 (21%)   | 5 (29%)     |        |             |       |
| Elbow, n (%)             | 9 (5%)     | 3 (18%)     |        |             |       |
| Transradial, n (%)       | 85 (51%)   | 6 (35%)     |        |             |       |
| Wrist, n (%)             | 28 (17%)   | 2 (12%)     |        |             |       |
| Above elbow              | 58         | 9           |        |             |       |
| Below elbow              | 113        | 8           | 0.08   | 0.45        | 0.99  |
| Employment status§       |            |             |        |             |       |
| Not working, n (%)       | 64 (41%)   | 10 (63%)    |        |             |       |
| Employed, n (%)          | 90 (57%)   | 5 (31%)     | 0.06   | 0.5         | 0.99  |
| Mean health status       | 2.5 ± 0.8  | 2.8 ± 0.7   | 0.18   | 0.4         | 0.73  |
| EQ-5D utility            | 0.762 ± 0.14 | 0.625 ± 0.24 | <0.01 | 0.74        | 0.60  |

Health status key: 1, excellent; 2, very good; 3, good; 4, fair; 5, poor.
*Twenty-five users and 4 nonusers did not indicate their handedness.
†Fifteen prosthesis users and 2 nonusers did not provide their cohabitation status.
‡Eight bilateral deficiencies among prosthesis users and 1 among nonusers.
§Patients who were students were excluded from this analysis.

Table 4. Employment Status and EQ-5D Utility Score Stratified by Primary Prosthesis Type

|                          | Cosmetic | Body Powered | Myoelectric | Nonuser |
|--------------------------|----------|--------------|-------------|---------|
| Mean age (SD) (years)    | 52 ± 17  | 56 ± 14      | 50 ± 14     | 47 ± 21 |
| Total no. patients       | 33       | 50           | 75          | 16      |
| Full-time, n (%)         | 15 (45)  | 20 (40)      | 39 (52)     | 4 (25)  |
| Part-time, n (%)         | 2 (6)    | 4 (8)        | 10 (13)     | 1 (6)   |
| Unemployed, n (%)        | 2 (6)    | 4 (8)        | 3 (4)       | 1 (6)   |
| Retired, n (%)           | 0 (0)    | 1 (2)        | 4 (5)       | 2 (13)  |
| Receiving disability     | 12 (36)  | 21 (42)      | 17 (23)     | 7 (44)  |
| The mean EQ-5D utility score (SD) | 0.797 ± 0.17 | 0.748 ± 0.13 | 0.754 ± 0.12 | 0.628 ± 0.24* |

*P < 0.05,
niques with novel hardware promise the best approximation of restored hand function. Yet, the development of better functioning, more comfortable, and less expensive prosthetic systems remains the current imperative.

Not all prosthesis nonusers had experienced a myoelectric prosthesis. Although 10 prosthesis rejecters had used a body-powered prosthesis, only 4 had tried a myoelectric prosthesis. Although age, sex, handedness, and cohabitation status did not significantly differ between users and nonusers, the cause of their amputation was significantly different. Congenital amputees have significantly higher rejection rates than acquired amputees. Biddiss and Chau reported that the level of limb absence is a primary predisposing factor in prosthesis acceptance. In this study, the percentage of patients with above elbow amputation was greater among nonusers than users (53% versus 32%). Thus, reason for the level of limb loss remains critical to predicting device abandonment.

The mean EQ-5D utility score of prosthesis users was significantly higher than that of nonusers. Surprisingly, among prosthesis users, those who used a cosmetic prosthesis had the highest EQ-5D score, followed by users of myoelectric and body-powered prostheses, despite the functional limitations of passive prostheses. This study revealed the central role that cosmetic and body-powered prostheses continue to have for prosthetic users. We should consider this fact even amidst advances in myoelectric prosthetic technology coupled with dedicated rehabilitation and training programs that promote their use.

We hypothesized that patient-reported QOL would be better than proxy-reported values. Contrary to our expectations, the reported EQ-5D utility score of live-in proxies was slightly higher than that of patients. However, live-in proxies demonstrated different trends in their responses according to the sex of the patient. Although the difference was not significant, female patients reported better EQ-5D utility scores than their live-in proxies. Conversely, male patients reported significantly lower EQ-5D utility scores compared with their proxies. These findings indicate misconceptions about the QOL of patients with upper limb deficiencies, with proxies tending to overestimate QOL in males and underestimate QOL in females. These misconceptions should be considered when interpreting proxy-reported QOL, and steps should be taken to correct them through improved education to caregivers.

This study has several limitations. First, the response rate was low especially in the US population. The response rate might influence the calculated prosthetic rejection rate; however, a low response rate does not necessarily indicate nonresponse bias. In an analogous postal questionnaire survey on respiratory health, differences between responders and nonresponders were small. If we perform a telephone interview with nonresponders, the mode of interview differs from original questionnaires. This risks introducing survey bias. The proportion of people who respond is not always an indicator of the likelihood of nonresponse bias, because it does not logically follow in all instances. We could not compare patients across countries of residence except for response and rejection rates because the numbers are quite different. Instead, we reported detailed data from each institution. Although few patients had congenital upper limb deficiencies, this heterogeneous cohort is reflective of the frequency observed in society. Despite these limitations, the shortcomings of prostheses reported by patients with upper limb loss in this study will be valuable for future prosthesis development.

In conclusion, the prosthetic rejection rate was low in these highly sophisticated centers. Individuals who use a myoelectric prosthesis are more likely to be employed than both users of other prosthesis types and nonusers. QOL was significantly higher among prosthesis users than nonusers. It is beneficial for society to provide intensive rehabilitation to patients with upper limb loss and minimize prosthetic rejection because prosthetic users have greater productivity and fewer barriers in conducting daily life. Furthermore, particular attention should be given to avoiding the overestimation of QOL in male patients with upper limb deficiency.

### Table 5. Comparison of EQ-5D Utility Score Between Patient and Live-in Proxy

|                      | Patient (Mean ± SD) | Live-in Proxy (Mean ± SD) | P    |
|----------------------|---------------------|--------------------------|------|
| Mean utility score in total | 0.771 (± 0.15)      | 0.792 (± 0.16)           | 0.39 |
| Mean utility score of female patient | 0.765 (± 0.19)      | 0.753 (± 0.19)           | 0.62 |
| Mean utility score of male patient | 0.77 (± 0.13)       | 0.807 (± 0.14)           | 0.01 |

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