INTRODUCTION

When summarizing the performance achieved by users of a cochlear prosthesis, results are typically reported as means and standard deviations of speech recognition scores (also Brimacombe and Beiter, unpublished observations, 1992). These statistics constitute a valid description of the data only when scores are distributed normally, i.e., as a bell-shaped curve. On the basis of theoretical considerations, however, a bimodal distribution might be expected. Patients with poor auditory nerve survival or atrophic central auditory systems would be expected to have uniformly poor results, while patients with intact auditory nervous systems should, in general, achieve excellent results with a well-designed and -fitted cochlear prosthesis. The Clarion cochlear prosthesis provides both the Multi-Strategy speech processor and the University of California–San Francisco (UCSF) radial bipolar electrode, a combination that provides capabilities to fit the stimulation strategy to the auditory nervous system of each individual patient. We have examined the distributions of speech recognition scores in order to understand the relative importance of biological versus technological limits in the benefits derived from cochlear prostheses.

STUDY DESIGN

We analyzed the 6-month postoperative scores of all of the first 64 patients implanted with the Clarion in the investigational device study approved by the US Food and Drug Administration. Speech perception tests included the open-set CID Sentences (100% maximum, 0% chance), the open-set NU-6 monosyllabic words (100% maximum, 0% chance), and the open-set Overlearned Sentences administered over the telephone (100% maximum, 0% chance). The patients ranged in age from 20 to 81 years (mean, 53) and had been profoundly deaf from various causes for 2% to 81% of their lives. At their initial and subsequent fittings, the patients were tested with a range of compressed analog (CA) and continuous interleaved sampled pulses (CIS) strategies and sent home with the strategy that produced the best speech recognition; 86% were using the monopolar CIS strategy at the 6-month test interval reported here. Preoperative data considered in this report include age at onset of hearing loss, duration of partial and complete hearing loss as a percentage of life span, cause of deafness, and indications of other neurologic deficits. Postoperative parametric data include the thresholds for biphasic square waves (77 microseconds per phase, cathode-first, 833 pulses per second) and the dynamic range from threshold to most comfortable loudness level of individual monopolar channels.

RESULTS

All three tests of speech recognition showed clear deviations from normal distributions, most strikingly for the CID and telephone test results, which were clearly bimodal (Fig 1). On the basis of the CID results, which are probably most indicative of everyday function, we divided our patients into three performance categories: poor (CID score 0% to 30%), moderate (CID score 31% to 70%), and excellent (CID score 71% to 100%). The bimodal distribution of the NU-6 results, a more difficult test, is more readily discerned when these scores are also grouped into performance categories as follows: poor (0% to 10%), moderate (11% to 30%), and excellent (31% to 100%). The NU-6 data shown in Fig 1 are then distributed with 47% (30 patients) in the excellent category and 30% (19 patients) in the poor category, with only 23% (15 patients) in the midrange. In fact, there was a high degree of correlation between the CID test and both the NU-6 (r = .94) and the telephone test (r = .93).

The correlations between CID test scores and most parametric test results were fairly low. Figure 2 shows the weak but significant relationship between CID scores and maximal dynamic range. Note that low dynamic range (<6 dB) is a good indicator of poor function, but high dynamic range is only a necessary, not a sufficient, condition for good function.

To understand the possible causes for the small cluster of poor perceptual results, we conducted a post hoc, blind review...
of patient data to identify possible preoperative predictors of poor performance. In particular, we found that duration of profound deafness as a percentage of life span had a high channel parameters to identify indicators of unusual cochlear of patient data to identify possible preoperative predictors of association with poor results for durations greater than 60% (N = 5, from Fig 2), one with all thresholds above 300 µA, and one with a shallow electrode insertion. We also identified three other patients with subjective factors, including two who had severe but not profound hearing loss throughout early childhood, and one whose first language was Spanish (in which her performance was reported to be much better than for the hood, and one whose first language was Spanish (in which her first language was Spanish (in which her performance was reported to be much better than for the English tests administered). These results are summarized in Fig 3 and suggest that the majority of poor results may be attributable to biological factors. However, we could identify no causative factors for the remaining minority of subjects who had poor results (N = 6; 9% of total population), or for all of those with only moderate results (N = 11; 17%).

**DISCUSSION**

To place these results in historical perspective, it is important to remember that until recently, significantly nonzero scores on “difficult” open-set, sound-only measures were considered remarkable. On sentence materials, results over 30% were indicative of good performers, and results over 50% were equated with “star” performers. As device designs and fitting procedures improved and as more patients gained experience with their prostheses, mean test scores gradually improved, but the distributions remained broad in the middle regions, somewhat like the normal distributions associated with attributes such as intelligence. One interpretation of this trend is that the sensations produced by those cochlear prostheses were very unlike natural speech sounds, and that subjects learned to interpret those sounds, to a greater or lesser degree, using higher cognitive skills. A parallel might be drawn to lipreading, a similarly difficult cognitive skill for which subjects also exhibit long learning curves and broad distributions of ultimate performance.8

The bimodal distribution of test scores achieved with the Clarion plus the learning curve data presented elsewhere (Loeb and Kessler, this suppl, section 14) suggest that Clarion may generate relatively natural temporospatial patterns of auditory nerve activity in patients whose auditory nervous systems provide sufficient signal capacity. These patterns appear to evoke percepts of speech sounds that are correctly interpreted by those patients in the excellent category. It remains to be determined whether the minority of unexplained poor-to-moderate results can be decreased by further improvements in electrode design and/or speech-encoding strategy.

These bimodal score distributions for the Clarion demonstrate that traditional reporting of medians or means and standard deviations may be highly misleading in terms of the likely outcome for an individual patient. For the CID score distributions reported here, the median was 78.5%, with a mean of 60% ± 38% SD; in fact, only four of the subjects (6%) had scores in the entire range from 60% to 80%. The implications for the selection of patients and devices become much clearer when score distributions are reported for the entire population of implanted patients, not just selected subsets (eg, Skinner et al8). To compare groups of patients implanted with different devices, statistics appropriate for non-normal distributions (ie, statistics that do not describe central tendencies) should be used.23 For example, the χ² test can be applied to the numbers of patients falling into performance categories such as poor, moderate, and excellent as defined here.

**REFERENCES**