

Implantation with the Cochlear Nucleus® CI532 Implant, Early Experience Study

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Section 10.1 of this study protocol stated that demographic and outcomes data would be tabulated individually along with group summary descriptive statistics. Speech perception scores were presented for each study evaluation, pre- and postoperatively, in order to evaluate postoperative progress over time.

The primary study endpoints were difference between the mean preoperative speech perception scores and postoperative scores for the activated, CI532 cochlear implant subjects who completed speech perception testing. Mean scores as measured by AzBio sentences in quiet and noise were compared. The null hypothesis tested was that there is no difference for the subjects between their pre- vs. postoperative speech performance

Individual scores obtained at 3 months will be compared with those obtained, on the same measures preoperatively, based on the binomial model where appropriate (see Thornton and Raffin, 1978; Boothroyd and Nittrouer, 1988).