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The round window approach for MED-EL VSB in difficult-to-treat middle ear problems

V. Colletti, M. Carner, L. Colletti, L. Sacchetto, Verona; Italy

The present criteria for the Vibrant Med-El Soundbridge (VMSB) device limits its application to patients with sensorineural hearing loss (SNHL) and normal middle ear function. We have extended the indications of the VMSB to include patients with ossicular chain defects and implanted the floating mass transducer (FMT) onto the round window (RW) membrane. The very good preliminary results of this new approach observed in five patients (Colletti et al, 2005) prompted us to extend the experience to another seven patients for a total of 12 patients, all with severe mixed hearing loss. Their age spanned 1 - 74 years. Ten patients had been unsuccessfully operated on ossiculoplasty several times for ossicular chain defects, related to chronic otitis media in nine patients and external and middle ear malformations in one subject; 1 patient with SNHL had the VMSB crimped on the incus without hearing gain, and one 1-year-old child suffering from Goldenhar syndrome had external and middle ear malformations. A classic transmastoid approach with posterior tympanotomy was used in eleven patients, and a transcanal approach was utilized in one patient. In all patients a reshaping of the round window area for fitting the transducer was performed. The FMT was placed onto the round window membrane and covered with temporalis fascia and fibrin glue. The receiver/stimulator was placed at the level of the squama temporalis. No intra- or postoperative complications were observed and all patients were discharged 1-3 days after surgery. Short term test results from adult patients indicate dramatic improvements in pure tone threshold and speech understanding with outcomes very similar to stapes surgery. In adults the sum of the mean PTA (0,5-4 kHz) was 76.67 (SD=+/-4.7) pre-operatively and 20.69 (SD=+/-6.8) dBHL, 12 months post-operatively ($p<0.01$). The sum of mean percentage of bi-syllabic words was 6.5 (SD=+/-3.4) before surgery and 89.4 (SD=+/-8.1), 12 months post-operation ($p<0.01$). No short term complications have been observed so far. Pre- and post-op. ABR testing indicated remarkable improvements in threshold in the 1-year-old child. No complications have been observed so far. The experience gained by this preliminary study shows that the VMSB with the FMT placed on the RW has new indications that can be summarized as follows : 1- bilateral conductive mixed hearing loss " resistent " to multiple middle ear reconstructive procedures, 2- external and middle ear malformations, 3- patients with sensorineural hearing loss obtaining limited benefit from MEI. Colletti V. et al .: Round window stimulation with the floating mass transducer: a new approach for surgical failures of mixed hearing losses. Proceedings of the XVIII IFOS World Congress – Rome 25-30 June, 2005 MEMRO 2006