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Supporting Evidence
iotaSOFT® Insertion System

Supportive Literature for Robotic-Assisted Insertion

Many variables associated with cochlear implants, such as patient demographics, hearing loss etiology, surgical techniques and speech rehabilitation, have been attributed to impact patient outcomes. Until recently, reduction in speed and force through manual insertion, one variable potentially influencing outcomes, was limited by the human ability to deliver a slow, consistent insertion.

With the recent clearance of iotaSOFT Insertion System, iotaMotion demonstrated that a robotic-assisted insertion system can both control and reduce speed, and resulting force, beyond human capability. The references below outline specific published data with robotic-assisted insertions.

Key Article Insights:	Citations:
Results confirmed previous data that suggest CI electrode insertion can cause pressure transients with intensities similar to those elicited by high-level sounds. Results suggest that the use of a micro-mechanical insertion control system may mitigate trauma from pressure events, both by reducing the amplitude and the number of pressure spikes resulting from CI electrode insertion.	Banakis Hartl RM, Kaufmann C, Hansen MR, Tollin DJ. Intracochlear Pressure Transients During Cochlear Implant Electrode Insertion: Effect of Micro-mechanical Control on Limiting Pressure Trauma. Otol Neurotol. 2019;40(6):736-744.
Electrode array insertions performed by a robotics-assisted system showed significantly lower insertion forces and variability. Manual electrode array insertions had a significantly higher overall trauma score of 3.1 compared with .9 for robotics-assisted insertions. The robotic-assisted insertion system reduced trauma events associated with CI electrode insertions in cadaveric cochlea compared with manual insertions. Surgical devices which help to precisely and more consistently insert electrodes may improve CI outcomes and hearing preservation.	Kaufmann CR, Henslee AM, Claussen A, Hansen MR. Evaluation of Insertion Forces and Cochlea Trauma Following Robotics-Assisted Cochlear Implant Electrode Array Insertion. Otol Neurotol. 2020;41(5):631-638.

Clinical Relevance of Speed

Multiple studies, summarized below, have demonstrated the correlation between speed, pressure, force and corresponding trauma to the cochlea during insertion of a cochlear implant electrode. For context, the iotaSOFT® Insertion System controls the speed between 0.1 mm/s and 1 mm/s, ultimately providing the surgeon control over the insertion forces within the cochlea.

Key Article Insights:	Citations:
Progressive increase in insertion speed resulted in significant, proportional increase in average insertion forces. High insertion speeds cause significant increase of the forces. Cochlear implant surgeons should use low and stable speeds during the insertion.	Kontorinis G, Lenarz T, Stover T, Paasche G. Impact of insertion speed of cochlear implant electrodes on the insertion forces. Otol Neurotol. 2011 32:565-570
Insertion speed had a significant impact on various insertion characteristics, as well as hearing preservation and vestibular function. Slow electrode speed appears to facilitate full electrode insertion, reduce occurrence of insertion resistance, as well as promote preservation of residual hearing and vestibular function after cochlear implantation.	Rajan GP1, Kontorini G, Kuthubutheen J. The effects of insertion speed on inner ear function during cochlear implantation: a comparison study. Audiol Neurootol. 2013;18(1):17-22
A direct correlation between speed and pressure was observed. Mean maximum values of intracochlear fluid pressure varied between .41mm Hg and 1.27 mm. These results showed the fluid pressure changes due to insertional speeds of CI electrodes.	Todt I, Mittmann P, Ernst A. Intracochlear fluid pressure changes related to the insertional speed of a CI electrode. Biomed Res Int. 2014;2014:507241.
Pressures in scala vestibuli and tympani were measured in cadaver temporal bones with fiber-optic pressure sensors inserted into the cochlear near the oval and round windows. Pressures in scala tympani tended to be larger in magnitude than pressures in scala vestibuli. Electrode insertion produced a range of pressure transients in the cochlea that could alone or train of spikes with equivalent peak sound pressure levels in excess of 170dB. Results suggest that electrode design, insertion mechanism and surgical technique affect the magnitude and rate of intracochlear pressure. Pressure transients could cause damage to the basilar membrane and/or hair cells	Greene NT, Mattingly JK, Banakis Hartl RM, Tollin DJ, Cass SP. Intracochlear Pressure Transients During Cochlear Implant Electrode Insertion. Otol Neurotol. 2016;37(10):1541-1548.

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hearing, advanced.

ADVANCING CI SURGERY

BEYOND HUMAN CAPABILITY.

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The iotaSOFT Insertion System is intended to aid the surgeon in placement of cochlear implant electrode arrays into a radiographically normal cochlea by controlling the speed of implant insertion. The iotaSOFT Insertion System is intended for use in cochlear implant patients ages 12 years and older during cochlear implant procedures using either a round window or cochleostomy approach.

3-00027-00