ANNUAL REPORT 2019

Surgical Hearing Implant Program

Otolaryngology – Head & Neck Surgery

SHIP Annual Report
Health Sciences Centre
Shared Health Services
Manitoba Health, Seniors and Active Living

COCHLEAR IMPLANT PROCEDURE – FEATURING NEW ROTATIONAL MAGNET ELECTRODE

2019 Annual Report

Surgical Hearing Implant Program

Shared health Soins communs Manitoba

University of Manitoba

REPORT HIGHLIGHTS

Message from the Director

by Dr. Jordan Hochman – SHIP Medical Director

2019 has been an active and productive year for the Surgical Hearing Implant Program (SHIP).

The Universal Newborn Hearing Program has helped SHIP continue to lower the age of pediatric implantation. Dr. Darren Leitao and SHIP coordinator Justyn Pisa have designed a system that ensures infants receive immediate diagnostic and imaging studies once identified with hearing loss at birth. This has results in an average age of implantation of 11.8 months, which will positively affect the ease and speed of language acquisition in these children.

Through vendor negotiations and strict budget management, adult sequential bilateral cochlear implantation has become a standard of care for our Centre. We are proud to offer this service to Manitobans with profound hearing loss.

Jordan Hochman MD
Medical Director
December 2019

Our research in surgical simulation and the ethics of implantation continues to evolve. The work has been recognized with a large Federal grant as well as publications and presentations in North America and Europe.

Our cochlear implant research has generated two peer-reviewed ethics articles, both of which seek to determine the correct balance patient benefit and advancements in technology with wait time management under a single-payer health care system. We are proud that our implant centre is viewed at the forefront of these national issues.

I would like to express my gratitude to our team members at HSC as well as at our offsite location, the Central Speech & Hearing Clinic for a very productive and collaborative year. I look forward to new accomplishments and challenges in 2020 and beyond!

Cochlear Implant Summary

A detailed description of cochlear implant surgical production for 2019, including information on program finances, changes in wait times and the current adult waiting list.

Page 3

Bone Anchored Implant Summary

A detailed description of bone anchored implant surgical production for 2019, including information on program finances, changes in wait times and the current adult waiting list.

Page 4

Program Personnel

- Jordan Hochman MD – Director and Adult Cochlear Implant Surgeon
- Darren Leitao MD – Pediatric Cochlear Implant Surgeon
- Les Garber MD – Bone Anchored Implant Surgeon.
- Justyn Pisa AuD – Program Coordinator
- Pam Campbell – Executive Director, Central Speech & Hearing Clinic
- Kristy Mackie MSc – Audiologist
- Daniela Stangherlin AuD – Audiologist
- Jacob Sulkers MSc – Audiologist
- Kelly Boyd – Office Manager

JUSTYN PISA – PROGRAM COORDINATOR

Justyn Pisa is an implant audiologist and has been the coordinator of SHIP since the program was initiated in 2011.

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Coordinator Program Summary

by Justyn Pisa AuD, Program Coordinator

The following report will outline the current status of the Surgical Hearing Implant Program (SHIP) of the Department of Otolaryngology – Head & Neck Surgery at Health Sciences Centre (HSC) as of December 31, 2019.

2019 represented a productive year for SHIP amidst the changing landscape of health care delivery in Manitoba. Despite staffing changes and funding adjustments, SHIP increased productivity quotas for both cochlear implant and bone anchored implants. This resulted in decreased adult wait times to within national norms for both implant programs.

2019 also marked a milestone for SHIP in reaching our **300th implant** for the Province. While we are proud of this achievement, significant challenges remain in order to balance patient demand within a fixed budget.

For example, several cochlear implant (CI) manufacturers released new technology in 2019 that enables implant recipients to receive MRI up to 3.0 Tesla without removal of the internal magnet. This is a great benefit to the patient, but comes with an increased per unit cost which translates to fewer implant procedures per year.

To address this issue, SHIP performed a retrospective analysis of its implant recipients to gauge potential for MRI needs in the future. This information was used to design a decision-making algorithm for SHIP's implant cohort to effectively manage patient need under a single-payer health care system.

This work was recently published in a peer-reviewed journal to highlight how our implant centre tackles complex issues for emergent health care in Manitoba.

CI Sound Processor Upgrades

In 2019, a total of **14** pediatric patients were granted **23** cochlear implant sound processor upgrades through the provincial cochlear implant replacement program. This program provides 80% of the cost towards processor upgrades for pediatric recipients every 5 years. Since 2013, the program has processed **58** applications for a total of **62** sound processors.

Newborn Hearing Screening

Since 2016, the WRHA's universal newborn hearing screening program has identified a total of **18** potential candidates for cochlear implantation with an average of just over **6** infants per year. To date, **11** of these infants have been implanted bilaterally under 12 months of age, representing a significant decrease in the average age of implantation for pre-lingually deafened recipients. We look forward to following the progress of this cohort.

Research in Ethics

2019 saw the publication of another research paper on ethical issues around cochlear implantation within a public health system. This recent article described balancing patient need with financial restraint when incorporating new technology into a publicly funded implant program. We are proud to be leading Canadian implant centres in this research area!

2020 Contract Negotiations

Over the past 8 years, SHIP has maintained a consistent patient flow with a static device budget. This is largely due to previous negotiations with vendors to ensure the cost of medical devices remains as low as possible. In 2020, SHIP will re-enter negotiations for a new contract which will seek to continue this tradition while ensuring our patients receive state of the art technology that is comparable to other implant centres.

Cochlear Implant Summary

by Justyn Pisa AuD, Program Coordinator

The Cochlear Implant (CI) Program completed **41** surgeries in 2019. These included **35** unilateral procedures and **6** bilateral procedures on **31** adult patients and **10** pediatric patients. Since the start of the program, SHIP has implanted a total of **318** cochlear implants on **287** individual patients.

Wait Times

There are currently **9** patients awaiting trial for audiological candidacy assessment and **33** patients awaiting cochlear implant surgery.

The cochlear implant program continues to generate an average of approximately 3 (**3.08**) new surgical candidates per month.

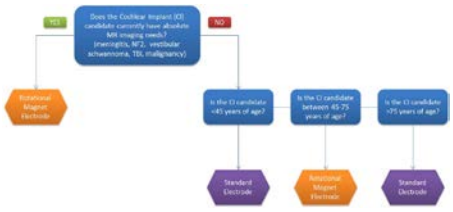
The current surgical wait time was approximately **8.86** months for cochlear implant surgery in 2019. This represented an average decrease of **5.7** months from the previous year, largely due to a few expedited cases. The average wait time is expected to return to approximately 12.5 months by the end of the 2020 fiscal year, putting SHIP on par with the national implant centre norms.

Rotational Magnet Technology

Over the past year, 3 of the 4 global manufacturers released new electrode arrays that feature a magnet within the housing of the receiver-stimulator that rotates 3-dimensionally. This technological advancement is important as it allows cochlear implant recipients to undergo MRI scans at both 1.5 and 3.0 Tesla without requiring a head wrap procedure or surgery for magnet removal.

However, this technology comes with added cost per unit, which impacts the total number of procedures each year and can significantly increase adult wait times for surgery.

To examine this issue, SHIP performed a retrospective analysis on 257 cochlear implant recipients to assess overall need for serial imaging. This analysis included a comparison of MRI rates within the general population. All of this information was used to create a decision-making algorithm for utilizing this new technology only on patients with the greatest potential for post-operative imaging.



This process allows SHIP to balance the provision of cutting edge health care with the need for budget restraint in a fiscally challenging environment. This work was compiled into a research article and subsequently published in the Journal of Otolaryngology – Head & Neck Surgery.

2020 RFP Negotiations

One of the tools SHIP has for maintaining a consistent level of care, despite increasing patient demand and an expanding patient base; is our ability to negotiate lower pricing for medical equipment. We will begin negotiations for a new vendor contract in 2020 and will look to continue current costing estimates while incorporating new technology into our device portfolio.

Future Outlook

Aside from pricing, SHIP also plans to focus on funding for new diagnostic and fitting equipment as well as research assistance to assist in quality assurance measures.

47

2019 CI Production

The surgical hearing implant program utilized 47 cochlear implant products on 41 individual patients in the 2019 calendar year. This represents a 38% (9 units) increase in surgical output from 2018.

10.8 mos

2019 Average Adult Wait Time

The average adult wait time in 2019 was 8.86 months (+/- 4.6 months). This represents an average decrease in wait times by 7.7 months from 2018 which is relatively in-line with national norms across Canadian implant centres.

32

Current Adult Waiting List

The current adult wait list comprises 32 patients. SHIP cleared an average of 3.08 new cochlear implant candidates per month in 2019, with a projected wait list of 42 patients by the start of the next fiscal year in 2020.

Bone Anchored Implant Summary

by Justyn Pisa AuD, Program Coordinator

The Bone Anchored Implant (BAI) Program completed **5** surgeries in 2019. These 5 unilateral procedures were all adult cases. Since the start of the program, SHIP has implanted a total of **113** bone anchored implants on **112** individual patients.

Wait Times

There are currently **7** patients awaiting trial for audiological candidacy assessment and **8** patients awaiting bone anchored implant surgery.

The bone anchored implant program generated an average of **1.2** new surgical candidates per month, a decrease from previous years due to limitations placed on candidacy criteria.

The current surgical wait time is **11.1** months for bone anchored implant surgery, representing an average decrease of **2.0** months from the previous year. Considering BAI production over the past two years, the overall wait times for adult patients is largely due to available operating room time for the surgeon and has not been limited by the SHIP device budget.

Increased Costs

The number of revision surgeries required each year continues to grow as our patient population expands and new treatment options become available. The availability of abutment extensions has altered typical treatment for chronic wound management issues with the bone anchored implant.

The longer abutments are seen by both the surgical team and patients as a preferable treatment option to tissue reduction for chronic skin growth and infection around the abutment. As a result, surgical costs have increased to accommodate the need for abutment replacement in these cases. Despite the fact that these cases comprise less than 10% of all bone anchored implant recipients, it does represent a considerable impact on the SHIP annual budget.

Funding

Despite the number of revision surgeries to treat chronic skin infections in 2019, SHIP is still within its device budget allocation for BAI procedures. However, as we continue to support more patients each year, the costs of maintaining the internal and external equipment are projected to grow.

Reduced Surgical Count

Over the past two years, the BAI program has not met its device quota of 14 implant procedures per fiscal year. There are a number of contributing factors involved in this recent decline which suggest this drop in surgical output may only be temporary.

The BAI program currently has 12 pediatric patients wearing a sound processor on soft headband who are awaiting outer ear reconstruction from Plastic Surgery before considering implantation. Further, there are several patients also waiting for "active transcutaneous" technology which will eliminate the need for a visible abutment that protrudes through the skin. We believe this technology will radically improve surgical options for a very specific patient population and are looking forward to the release of these products in the near term.

Collaborative Research

SHIP remains partnered with the University of Alberta and the University of Western Ontario on a BAI project designed to verify prescriptive fitting targets for both adult and pediatric patient populations. This is a nation-wide study that will have long lasting impacts on the bone anchored implant field going forward.

5

2019 BAI Production

The surgical hearing implant program utilized 11 bone anchored implant products on 11 individual patients in the 2018 calendar year. This production is consistent with previous years since the program's inception.

11.1 mos

2019 Average Adult Wait Time

The average adult wait time in 2018 was 11.1 months (+/- 9.6 months). This represents a decrease in the average wait time by 2 months compared to 2018 and represents a positive change in wait times since the program's inception.

8

Current Adult Waiting List

The current adult wait list comprises 8 patients. SHIP cleared an average of 1.2 new bone anchored implant candidates per month in 2019 with a projected wait list of 15 patients by the start of the next fiscal year in 2020.

Patient Spotlight: *Adult Bilateral CI Recipients*

by Justyn Pisa AuD, Program Coordinator

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Adult Bilateral Candidates

Demand for bilateral implantation in adults continues to grow from our community of current recipients. SHIP has allocated funding for 2 sequential bilateral cases each year in order to address this patient driven effort. Subjective reports from recipients are extremely positive as they regain the use of both ears for better speech understanding, localization and hearing in noise.

To date, SHIP has implanted 12 adult recipients with bilateral cochlear implants. 3 of those cases were simultaneous (implanted within the same procedure) and 9 were sequential (the second device was implanted at a later date). All three simultaneous implantations were expedited cases with associated comorbidities (traumatic brain injury, bacterial meningitis infection, and Neurofibromatosis Type II).

The bilateral implant recipients are generally younger adults who demonstrated significant benefit from their first implant, yet advocated for a second based on communication needs in adverse listening environments. SHIP has begun to closely monitor performance in this group.

New Research Potential

While relatively small, this new patient cohort represents an opportunity to accurately measure the benefit provided from a second implant in adult populations. Provided these patients meet candidacy requirements for implantation in their second year, SHIP policy dictates that patients receive bilateral implantation to improve their ability to communicate at work, with family, and in social environments.

Preliminary results have been promising, with our initial bilateral implant recipients achieving an average speech perception score of **93.8%** (SD = +/- 3.1%), versus the average unilateral score of **68. 4%** (SD = +/- 24.8%).

Being fit with and adjusting to technology is a long and sometimes arduous process for patients. Additional time to accumulate aggregate data is needed before SHIP can accurately measure the benefit of two cochlear implants versus one; however preliminary results remain very encouraging. Our current plan is for a 24-month study of 10 individual patients with eventual peer-reviewed publications on this and many other cochlear implant related topics. Stay tuned!

How have cochlear implants changed the lives of our patients?

Click the video to find out!

Clinician's Corner: *Group Information Sessions*

by Daniela Stangherlin AuD, Implant Audiologist

Cochlear Implant Centre Update

2019 has been another successful year for our implant program. Central Speech and Hearing Clinic is our implant program's outpatient (re)habilitation centre for both children and adults.

Here at CSHC, we have continued to offer our adult candidates an opportunity to attend a group information session.

The group information session is a shared medical appointment where (on average) approximately 3 to 8 patients who are potential audiological candidates for receiving a cochlear implant (CI) attend. These sessions generate an average of just over 3 new CI candidates per month.

A New Experience

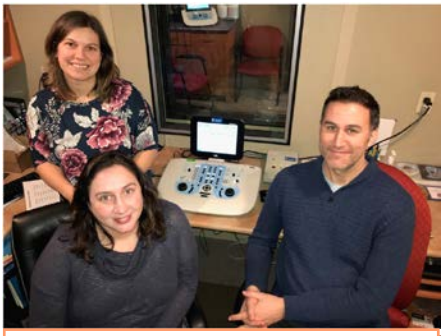
For many of our adult patients, the group information session is the start of their implant journey and first contact with the implant team.

Implant audiologists Kristy, Jacob and Daniela host a Wednesday afternoon group information session every 6 weeks; these sessions usually last a couple of hours. All new implant candidates are asked to attend with a partner.

Daniela (left) with patient Sally, who has been using her cochlear implant for 9 months.

Involving the CI Community

The group information sessions begin with a formal presentation by the audiologists who utilize a soundfield amplification system and provide typed captioning for comprehension.



Our audiology implant team has been providing specialized care to all of our recipients since 2010: Kristy Mackie (back left), Daniela Stangherlin (front left), and Jacob Sulkers.

An existing implant user then speaks about his or her cochlear implant experience before opening the floor to questions. Patients are also asked to complete some paperwork which includes contact information, a case history form and two quality of life questionnaires.

Patient Response

The response from patients has been overwhelmingly positive with regard to our group sessions. In fact, we took the opportunity to present data we collected in the early stages of development in the form of a poster presentation at the international ACI CI conference in 2016 held in Toronto.

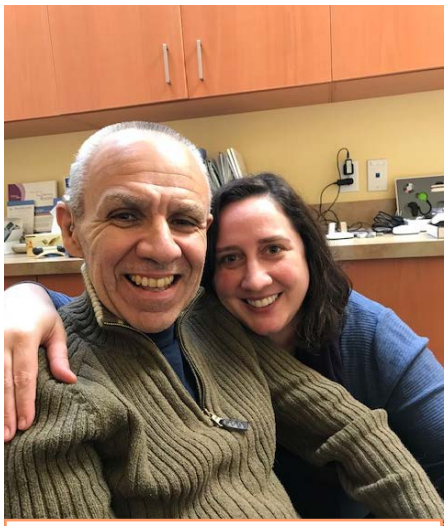
We have also found our group sessions to be beneficial to the clinicians in terms of burnout and effective time management and overall patient experience.

Future Outlook

The group information sessions for adult CI candidates began in December 2014 and we have had 5 years of successful execution. We plan to continue our group information sessions into the future.

Patients report the most beneficial part of the sessions is the opportunity to meet a cochlear implant user in person. We attempt to recruit a varied pool of CI users that will speak honestly about their learning experience and their hearing experience with implants.

We have come to realize that the group information sessions enable us to spend fewer hours counseling individual patients and are an excellent source of improved patient care. However, the greatest benefit these information sessions have generated is that they have enabled both our potential implant candidates and our implant recipients to meet and form long lasting bonds. We are proud to help foster and be a part of this budding community.



Daniela with newly implanted patient Cyril, celebrating the one-month mark of his hearing rehabilitation journey.

SHIP Research Production

by Justyn Pisa AuD

Podium/Poster Presentations

Hochman J., Unger B., Kraut J., Hombach-Klonish S. Gesture-Controlled Three Dimensional Anatomy: A Novel Teaching Tool in Head and Neck Surgery. American Academy of Otolaryngology Annual Meeting. Washington DC. September 2012.

Kraut J, Hochman JB, and Unger B. 2013. Temporal bone surgical simulation employing a multicore architecture. Proceedings of 2013 26th Annual IEEE Canadian Conference on Electrical and Computer Engineering (CCECE – Regina, SK) pp. 1–6.

Wong D, Hochman J, Unger B, Kraut J. Face and Content Validation of a Rapid Prototyped Temporal Bone Model. Presented at the 2013 Annual Canadian Society of Otolaryngology - Head & Neck Surgery Meeting, June 2-4. Banff, AB.

Wong D, Hochman J, Unger B, Kraut J. Soft Tissue Modeling in Temporal Bone Simulation. Presented at the 2013 Annual Canadian Society of Otolaryngology - Head & Neck Surgery Meeting, June 2-4. Banff, AB.

Wong D, Hochman J, Unger B, Kraut J. Controlled Interactive Three Dimensional Anatomy: A Novel Teaching Tool in Head and Neck Surgery. Presented at the 2013 Annual Canadian Society of Otolaryngology - Head & Neck Surgery Meeting, June 2-4. Banff, AB.

Le T., Leitao D., Hochman J. Hair Barrette Induced Cochlear Implant Receiver Stimulator Site Infection with Extrusion. Canadian Society of Otolaryngology, Banff Ab, June 2013.

Kraut J., Unger B., Hochman J. Temporal Bone Surgical Simulation Employing A Multicore Architecture. Canadian Conference on Electrical and Computer Engineering, Regina SK, June 2013.

Unger B, Kraut J, Hochman JB. A Novel Rapid Prototyped Temporal Bone Model for Surgical Dissection. American Academy of Otolaryngology Annual Meeting. Vancouver BC. Sept. 2013.

Unger B., Kraut J., Hochman J. Comparison of Isomorphic 3D Printed and Virtual Haptic Temporal Bone Simulation in Education. Simulation Summit, RCPSC, Vancouver BC, Nov. 2013.

Wong D., Kraut J., Unger B., Hochman JB. Comparison of Isomorphic 3D printed and Virtual Haptic Temporal Bone Simulation. Canadian Society of Otolaryngology (CSO), Ottawa ON, May 2014.

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Hochman J, Rampersad V, Sepehri N, Kraut J, Pisa J, Unger B. Import of Haptic Manipulandum & Device Fidelity on Expert User Perception in Virtual Temporal Bone Surgery. Presented at 2015 Annual Combined Otolaryngology Spring Meetings (COSM) April 22-25; Boston, MA.

Hochman J,. Kraut J., Pisa J., Rhodes C., Unger B. Comparison of Anatomically Matched 3D Printed and Virtual Haptic Temporal Bone Simulation. Combined Otolaryngology Spring Meeting COSM, May 2014, Las Vegas, NV.

Hochman J, Tordon B, Unger B, Pisa J. Importance of Stereoscopy in Haptic Simulation for Temporal Bone Surgical Training. Presented at the 2015 Annual Canadian Society of Otolaryngology - Head & Neck Surgery Meeting, June 6-9. Winnipeg, MB.

Hochman J, Rampersad V, Sepehri N, Unger B, Pisa J. Import of Haptic Manipulandum and Device Fidelity on Expert User Perception in Virtual Temporal Bone Surgery. Presented at the 2015 Annual Canadian Society of Otolaryngology - Head & Neck Surgery Meeting, June 6-9. Winnipeg, MB.

Moore P., Hochman J., Blakley B. Vestibular Hypofunction as an Indicator of Lateral Skullbase Pathology. Canadian Society of Otolaryngology (CSO), Winnipeg Canada, June 2015.

Pisa J, Sulkers J, Butler J, West M, Hochman J. Impact of Stereotactic Radiosurgery on Cochlear Implant Performance in Patients with Neurofibromatosis Type II. Presented at the 2016 Annual American Cochlear Implant Alliance Conference. May 11-14, Toronto, ON.

Hochman J, Unger B, Pisa J, Fliker A. Mixed Reality Simulation. Presented at 2017 Annual AAO – HNSF Meeting & OTO Experience. September. Chicago, IL.

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Unger, B. Tordon, B., Pisa J., Hochman J. Importance of Stereoscopy in Haptic Training of Novice Temporal Bone Surgery. Medicine Meets Virtual Reality. Los Angeles CA, April 2016.

Kazmerick K, Pisa J, Gentile L, Unger B, Hochman J. Comparison of Drill Technique; Cadaveric and Printed Temporal Bone. Presented at 2017 Annual Combined Otolaryngology Spring Meetings (COSM) April 26-30; San Diego, CA.

Gousseau M, Unger B, Pisa J, Mowat S, Westerberg B, Hochman J. Validation of Novel Temporal Bone Dissection Scale. Presented at 2017 Annual Combined Otolaryngology Spring Meetings (COSM) April 26-30; San Diego, CA.

Sulkers J., Mackie K., Stangherlin D., Pisa J., Hochman J. Cochlear Implant Benefit by Age: Comparing Speech Perception Outcomes in Adults Implanted Prior to and After Seventy. ACI International Cochlear Implant Conference, Toronto ON, May 2016.

Hochman J., Pisa J., Rampersad V., Unger B., Sepheri N. The Effect of Haptic Force Resolution in Virtual Temporal Bone Surgery. American Academy of Otolaryngology Annual Meeting. San Diego. Sept. 2016.

Kazmerick K, Pisa J, Gentile L, Unger B, Hochman J. Printed Bone Hand Motion Analysis. Presented at 2017 Annual National Medical Students Research Forum. April. Galveston, TX.

Dolatabdi A.D., Hochman J., Mousavi Z., Unger B. Automated Assessment of Temporal Bone Surgical Simulation Employing an Improved Model of Bone-Drilling Force Feed Back. EuroHaptics. Pisa Italy. May 2018.

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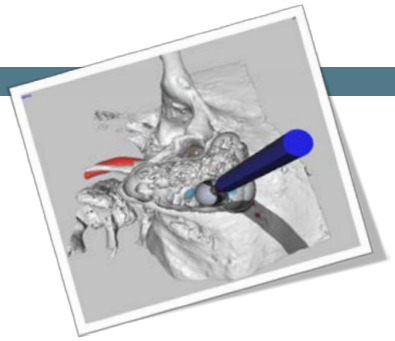
Gigiotti D., Blakley B., Moore P., Hochman J. MRI is not Indicated in the Management of Isolated Vestibular Weakness. Canadian Society of Otolaryngology Meeting, Quebec City Quebec. June 2018.

Wong V., Pisa J., Unger B., Hochman J. Appraisal of a Printed Bone Substitute. American Academy of Otolaryngology Annual Meeting. Atlanta. Sept. 2018.

Pisa J. Hearing Health Care: An Investment in the Future. Presented for the Faculty of Medicine, University of Manitoba. Winnipeg, Manitoba. October, 2018.

SHIP Research Production

by Justyn Pisa AuD



Singh S, Pisa J, Unger B, Hochman J. Distinct Temporal Bone Dissection Scales Demonstrate Equivalence in Distinguishing Trainee Performance. Presented at 2019 Annual Combined Otolaryngology Spring Meetings (COSM) May 1-5; Austin, TX.

Wong, V, Pisa J, Hochman J. Construct Validation of a Printed Bone Substitute in Otologic Education. Presented at 2019 Annual Combined Otolaryngology Spring Meetings (COSM) May 1-5; Austin, TX..

Pisa J. Bone Conduction Hearing Devices – Practice and Pitfalls from a Canadian Implant Centre. Presented at 2019 Annual Conference for the Canadian Academy of Audiology (CAA). October 26-30; Halifax NS.

Davari, A. Automated Assessment of Trainee Temporal Bone Surgical Skill Employing Simulated Surgery. Presented for Thesis Defense, Faculty of Medicine, University of Manitoba. November 2019; Winnipeg, MB.

Andrews C, Hochman J, Pisa J. Rationing Rotational Magnet Cochlear Implant Technology in a Single Payer Healthcare System. Presented at the Combined Sections Meetings, Triological Society. January 2020; Coronado, CA.

Singh S, Pisa J, Unger B, Blakley B, Leitao D, Jones J, Hochman J. Comparison of Summative Temporal Bone Dissection Scales Demonstrate Equivalence. Presented at AAO-HNSF 2019 Annual Meeting & OTO Experience, September 15-18; New Orleans, LA.

Peer-Reviewed Publications

Forzley B, Chen J, Nedzelski J, Lin V, Shipp D, Godlovitch G, Hebert P, Hochman J. Considerations of Candidacy for Bilateral Cochlear Single Payer Universal Health Care System. Laryngoscope. 2013 Dec;123(12):3137-40.

Kraut J., Unger B., Hochman J. Temporal Bone Surgical Simulation Employing A Multicore Architecture. Electrical and Computer Engineering, 2013 26th Annual IEEE Conference. 10.1109/CCECE.2013.6567771, Page1-6.

Unger B., Kraut J., Hochman JB. Method and System For Rapid Prototyping Of Complex Structures. United States Patent and Trademark Office Publication No.US-2014-0031967-A1, Publication Date:01/30/2014.

Unger BJ, Kraut J, Rhodes C, Hochman J. Design and Validation of 3D Printed Complex Bone Models with Internal Anatomic Fidelity for Surgical Training and Rehearsal. Stud Health Technol Inform. 2014;196:439-45.

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