Peer Review File

Article information: https://dx.doi.org/10.21037/ajo-23-12

Reviewer A

The authors present an interesting paper on the outcomes of TB fracture in a large series of patients. The results presented are useful reminders to surgeons about the poorer outcomes excepted in otic capsule involving fractures.

Major Issues

Comment 1: The authors state that there were two patients implanted for single sided deafness and in their conclusion, state that the results in these patients do not justify surgery. Can the authors please clarify this.

Reply 1:

In retrospect, this recommendation is too strong given our limited data set. There were only two patients implanted for single sided deafness in our study, with one patient with an otic capsule sparing fracture performing well (CVC word score 65% and CVC phoneme score 84% at 12 months), while the other patient with an otic capsule violating fracture failed to attend any follow up.

Previous systematic reviews have also failed to give a recommendation, citing a "paucity of data." (Cowan et al.)

As such, we have changed our recommendation regarding single sided deafness, suggesting that it be may be contraindicated in the presence of an otic capsule violating fracture given the poorer audiological outcomes in otic capsule violating fractures in general demonstrated in our study. Changes in the text:

Sentence regarding implantation for single sided deafness removed. Replaced with new paragraph: (lines 311-312):

"Implantation in the setting of single sided deafness should be considered cautiously, and may be contraindicated in the presence of an otic capsule violating fracture given the poorer audiological outcomes. Only two patients with single sided deafness were implanted in our study, with one patient with an otic capsule sparing fracture performing well (CVC word score 65% and CVC phoneme score 84% at 12 months), while one patient with an otic capsule violating fracture failed to attend any follow up."

Comment 2: Line 166 and 171 - Could the authors please clarify this paragraph. Do they mean that the majority of patients who had TB fractures did better than the large control group?

Reply 2: In retrospect this may be a confusing paragraph, and better represented in the referenced figures. It also doesn't separate the otic capsule sparing and otic capsule violating groups in comparing the outcome scores to the control group means. The next paragraph describing the statistical comparison between groups provides better insight into the outcomes of the groups. While the otic capsule sparing fractures did perform better (mean 78.8% vs 63.7%) this was not a statistically significant difference.

Changes in the text: Have removed the mid portion of this paragraph comparing the outcomes to the mean scores. Instead have summarized the control group outcomes.

CVC word and phoneme scores are represented in Figures 4 and 5 respectively, compared to the mean score from the control group. The control group mean CVC word scores were 36% at 3 months and 44% at 12 months. The control group mean CVC phoneme scores were 58% at 3 months, 65% at 12 months. The mean post implantation CVC word score for patients with temporal bone fractures was 34% (range 0%-88%), while the mean CVC phoneme score was 53.54% (range 0%-95%), at last follow up.

Comment 3: Line 234 - why does the CT scan overlook ossification? Isn't this the best modality to look for this or are the author's meaning fibrosis is overlooked?

Reply 3: Siedman's article (reference number 15 of the article, also provided below) describes that ossification, present intraoperatively, was not identified in 22% of HRCT performed pre-operatively.

In 5 of 18 cases in their experience, the round window membrane was found to be ossified with a patent cochlear lumen. In 7 of 18 cases, ossification was found to extend for up to 2mm into the cochlear lumen. In 6 cases, 3-9mm of the basal turn was occluded. In all of these cases, the cochlear lumen appeared patent on HRCT.

Certainly, CT is the best modality to assess for ossification, but a small degree of ossification may be overlooked on CT. Meanwhile MRI is more useful for investigating fibrosis, hence our suggestion that both CT and MRI should be performed in workup.

Changes in the text: No changes made.

Reference: Seidman DA, Chute PM, Parisier S. Temporal bone imaging for cochlear implantation. Laryngoscope. 1994 May;104(5 Pt 1):562-5. doi: 10.1002/lary.5541040510.

Minor issues

Comment 1: Line 55 - suggest otic capsule violating Reply 1: Changed as suggested Changes in the text: added capsule

Comment 2: Line 59 - suggest 7 to 25 times instead of "x" Reply 2: Changed as suggested Changes in the text: 7 to 25 times

Comment 3: Line 73 - suggest "patients" instead of "patient" Reply 3: Corrected Changes in the text: patients

Comment 4: Line 77 - Capitalise "However" Reply 4: Changed as suggested. Changes in the text: separated into two sentences, capitalize However

Comment 5: Line 79 - Suggest "The aim of this study is to evaluate...." Reply 5: Changed as suggested

Changes in the text: We evaluated changed to The aim of this study is to evaluate

Comment 6: Line 93 - plural for "fracture" Reply 6: changed as suggested Changes in the text: temporal bone fractures

Comment 7: Line 114 - what phoneme measure is used? What is the presentation level in dB? Reply 7: CVC phoneme. Speech testing performed at 65dB Changes in the text: updated sentence to include CVC and 65dB. Also added further line in methods: "Speech perception testing was performed at 65dB."

Comment 8: Line 129 - remove "broadly"

Reply 8: removed broadly Changes in the text: Patient age at insertion ranged from 21 years old to 80 years old.

Comment 9: Line 130 - confusing and needs rewording

Reply 9: Separated into two sentences to describe unilateral and bilateral fractures separately Changes in the text: Unilateral temporal bone fractures were present in nine patients. Five patients had bilateral fractures, due to assault (2 patients), fall (1 patient) and motor vehicle accident (2 patients).

Comment 10: Line 157 - suggest "known to be protective"

Reply 10: changed as suggested

Changes in the text: Both patients were implanted with CI512, with a perimodiolar electrode array which is known to be protective against facial nerve stimulation (11).

Reviewer B

The authors have presented their experience of cochlear implantation in patients following temporal bone trauma. The study reaches very sensible conclusions.

Comment 1: The comment (Line 219.) "For single sided deafness, the outcomes of implantation of an otic capsule violating fracture do not justify surgery" is a very important one, and if anything should be expanded on in the discussion, referenced, and added to the conclusion - even if the authors' experience with capsule violating fractures in single-sided deafness is small (n=1). Reply 1:

In retrospect, this recommendation is too strong given our limited data set. There were only two patients implanted for single sided deafness in our study, with one patient with an otic capsule sparing fracture performing well (CVC word score 65% and CVC phoneme score 84% at 12 months), while the other patient with an otic capsule violating fracture failed to attend any follow up.

Previous systematic reviews have also failed to give a recommendation, citing a "paucity of data." (Cowan et al.)

As such, we have changed our recommendation regarding single sided deafness, suggesting that it

be may be contraindicated in the presence of an otic capsule violating fracture given the poorer audiological outcomes in otic capsule violating fractures in general demonstrated in our study. Changes in the text:

Sentence regarding implantation for single sided deafness removed. Replaced with new paragraph: (lines 311-312):

"Implantation in the setting of single sided deafness should be considered cautiously, and may be contraindicated in the presence of an otic capsule violating fracture given the poorer audiological outcomes. Only two patients with single sided deafness were implanted in our study, with one patient with an otic capsule sparing fracture performing well (CVC word score 65% and CVC phoneme score 84% at 12 months), while one patient with an otic capsule violating fracture failed to attend any follow up."

Comment 2: In the first paragraph, "The preferred contemporary classification system nowadays is to classify a fracture as either otic capsule sparing or violating, which ..." should be considered to replace "They are now instead classified as otic capsule sparing or otic violating, which".

Reply 2: Change as suggested

Changes in the text: The preferred contemporary classification system nowadays is to instead classify a fracture as either otic capsule sparing or otic capsule violating, which more accurately predicts the outcomes of temporal bone trauma (2)

Comment 3: Line 54 should have "well" or "strongly" inserted between "correlate" and "with". Reply 3: Changed as suggested

Changes in the text: Temporal bone fractures were classically described as either longitudinal (80%) or transverse (20%) (3), however this classification failed to correlate well with clinical sequelae.

Comment 4: Line 64 should see "clearly suffer a profound quality of life imposition." replace "have devastating impacts".

Reply 4: changed as suggested

Changes in the text: Those patients unfortunate enough to have bilateral otic capsule violating fractures with hearing loss clearly suffer a profound quality of life imposition.

Comment 5: "In 2016 our centre published data from a large cohort of patients (n=382 patients), and found that 75% of adults met this definition of success after 12 months of use." should be considered to replace "In our centre, 75% of adults with post lingual hearing loss of all causes score greater than 55% on CVC phonemes after 12 months of use" (Line 115.).

Reply 5: Changed as suggested

Changes in the text: In 2016 our centre published data from a large cohort of patients (n=382 patients), and found that 75% of adults met this definition of success after 12 months of use.

Editorial Comments

Comment 1. The authors make good the explanation of the limitations of CT in Reviewer 1/comment 3 but then make no changes to the text. The average reader is likely to have the same query as the reviewer and it is changes to the text that is required here – NOT a reply to the reviewer.

Please simply update the text with the data and reference quoted.

Reply 1: As discussed in previous comments, text updated.

Changes in the text: CT imaging may overlook ossification. Siedman et al (15) found intraoperative ossification that was not identified on HRCT in 22% of cases. In 5 of 18 cases in their experience, the round window membrane was found to be ossified with a patent cochlear lumen. In 7 of 18 cases, ossification was found to extend for up to 2mm into the cochlear lumen. In 6 cases, 3-9mm of the basal turn was occluded. In all of these cases, the cochlear lumen appeared patent on HRCT.

As such, pre-operative imaging with both CT and MRI is essential in these patients, as it can predict the occurrence of perioperative adverse events by identifying both bony obstruction and fluid signal abnormalities.

Comment 2. Page 2, line 37, "than both the control group (33.8% vs 63.7%, p value 0.0005)", the details of the control group should be described in the Methods-Abstract.

Reply 2: Control group description added

Changes in the text: Audiological outcomes were compared to a control group of 1414 adult patients undergoing cochlear implantation for post lingual deafness.

Comment 3: Page 4, line 83, "to determine how outcomes compare to those expected for other indications", the objective is still vague. Please report the exact outcomes of interest here.

Reply 3: Changed line to discuss audiological outcomes and adverse events

Changes in the text: "The aim of this study is to evaluate cochlear implantation in this group, to determine whether audiological outcomes and adverse events are affected by the presence of a previous temporal bone fracture."

Comment 4. Please provide more detailed eligibility information on the target population. The authors only provided the exclusion criteria of the larger cohort. Simultaneously, it would be better if the authors draw a flow diagram to report the number of participants at each stage, from the selection of potential eligible ones, the final included ones, the numbers in the follow-up stage and with reasons for exclusion.

Reply 4: The description of both the target and control population have been brought together, to confirm that the exclusion criteria apply to both groups.

Changes in the text: The Cochlear Implant database was analysed for implantation in patients with an indication reported as head injury or trauma which yielded 48 patients. A chart review was performed, to determine clear evidence of temporal bone fractures on pre-operative imaging. A total of 14 adult patients with post lingual hearing loss were identified to have had cochlear implantation following temporal bone fracture between January 2000 to June 2020, with audiological data available for analysis for 13 patients.

A control group was also identified from the database, with 1414 adult patients with post lingual hearing loss implanted from January 2000 to June 2020 with otherwise normal cochlear anatomy. Patients were excluded from the study if they had documented otosclerosis as aetiology, were non-English speakers, patients with psychiatric or medical conditions precluding formal testing, and those patients that received a research device.

Comment 5. We couldn't find the source of the "larger cohort". Please add some necessary information here (such as the setting).

Reply 5: The control group was also drawn from the same Cochlear Implant database. This has been made clearer in the text, and the description of the control group brought to sit along side the description of the target group.

Changes in the text: See Comment 4 for updated paragraphs

Comment 6. The authors should delete Figure 1, since this information could be found in the main text and the qualitative description is enough. What's more, six kinds of aetiologies were provided in the figure, but only three of them were described in the Results section. In addition to this, the numbers of falling and motor vehicle accident differs between main text and Figure 1. Please checked thoroughly and adapted accordingly. Similarly, remove Figures 2 and 3. We note the adverse event were already described in Table 1. Then, the authors would renumber the figures mentioned in the text.

Reply 6: Figures 1, 2 and 3 removed. Actiology information updated within the text.

Changes in the text: Unilateral temporal bone fractures were present in nine patients, due to fall (3 patients), motor vehicle accident (2 patients), train accident (2 patients), bicycle accident (1 patient) and unknown cause (1 patient). Five patients had bilateral fractures, due to assault (2 patients), fall (1 patient) and motor vehicle accident (2 patients).

Comment 7. For Figures 4 and 5, could the authors consider changing them into the tables? We couldn't make visual comparison of the groups directly in the current format. Here is an example for your reference. The authors could create the tables in another way.

	Otic fracture	 Otic fractu	-	Control group	P ₁	P ₂
3-month				36%		
12-month				65%		

Table 2. CVC Word Scores (percentage) by follow up duration

P1: otic capsule sparing fractures compared to the control group

P2: otic capsule violating fractures compared to the control group

Reply 7: We were trying to provide a visual representation of the data, however given this isn't easy to interpret we have converted to a table.

Changes in the text: Provided a new table, Table 2, to represent the group means and their statistical comparison.

Table 2: CVC Word and Phoneme Scores (%) by Fracture Type

	Otic capsule sparing fracture	Otic capsule violating fracture	Control group	P _{1*}	P ₂	P ₃
Mean CVC Word score (%) At last follow up	58.1	15.5	41.9	0.091	0.003	0.001

Mean CVC	78.8	33.8	63.7	0.097	0.000	0.002
Phoneme score						
(%)						
At last follow up						

P1: Otic capsule sparing fractures compared to control group

P2: Otic capsule violating fractures compared to control group

P₃: Otic capsule sparing fractures compared to otic violating sparing fractures

*p-values in bold reach statistical significance

Comment 8. Page 9, lines 208-215, "There was a statistically significant strong correlation between age at implantation and both CVC word (-0.763; sig 0. 001) and phoneme scores (-0.773; p value 0.001) ...CVC phoneme scores (-0.422; p value 0.117))", "r" was missing in this paragraph. Please change it to "...both CVC word (r=-0.763; p value 0. 001)...".

Reply 8: Corrected in the text

Changes in the text: Corrected to add r= prior to scores. This was also corrected in the abstract.

Comment 9. Please add the methods of follow-up. For ease of reading, it's suggested to add the subheadings for the Methods and Results sections. The authors could refer to the STROBE reporting checklist.

Reply 9 Updated timing of follow up in Methods section.

Changes in the text: Follow up was performed at 3 and 12 months to assess audiological outcomes and ongoing use.

Comment 10. Page 6, line 129, "and found that 75% of adults met this definition of success after 12 months of use (10)", the actual individual number should be added, not just the percentages. Reply 10: Updated to include the number of patients

Changes in the text: In 2016 our centre published data from a large cohort of patients (n=382 patients), and found that 75% (n=288 patients) of adults met this definition of success after 12 months of use (10).

Comment 11. Page 5, line 91, "with over 5000 patients treated since its inception in 1982", this information may not be important.

Reply 11: Information removed.

Changes in the text: Suggested phrase removed.

Comment 12. Please mark "NA" in the blanks in Table 1.

Reply 12: Rather than mark NA, have adjusted the blanks to be more reflective of the relevant findings. The blank cells under "Imaging findings", have been marked as nil significant to reflect the lack of significant imaging findings. The blank cells under "Adverse events" have been marked as "None" to reflect the absence of an adverse event.

Changes in the text: as above

Comment 13. "pt" should be defined when first mentioned.

Reply 13: Rather than continue to use the definition, have used the full word patient or patients. Changes in the text: Pt changed to patient or patients.