

AOS Grant Review

Principal Investigator(s): Adrian James

Application Title: Development of novel surgical instruments for endoscopic ear surgery

Reviewer Assignment (check one): ☒ Primary Reviewer ☐ Secondary Reviewer

OVERALL IMPACT

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following five scored review criteria, and additional review criteria. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

Overall Impact Write a paragraph summarizing the factors that informed your Overall Impact score.

Score (1-9): 7

NARRATIVE: The investigators propose a systematic approach to development of instruments to facilitate learning and conduct of middle ear surgery using an endoscopic approach. The research plan describes a reasonable sequence for product development, utilizing collaboration between engineers and surgeons at the University of Toronto, but does not give adequate detail to ensure reviewer that the plan will be successful. Although product development would be helpful and potentially innovative, the overall impact on patient care is limited.

SCORED REVIEW CRITERIA

Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each.

1. Significance Score (1-9): 6

Strengths

- There are some advantages of endoscopic ear surgery techniques over traditional techniques, including lack of postauricular incision. Instruments that would make this technique more accessible by a larger percentage of otologic surgeons would be helpful.

Weaknesses

- As a plausible alternative strategy, instrument development could be sponsored by company partner that could then refine and produce the instruments in consultation with otologists

2. Investigator(s) Score (1-9): 5

Strengths

- Investigative team seems well resourced to do the projected studies, within the Institute of Biomaterial and Biomedical Engineering of the University of Toronto

Weaknesses

- Not clear that the investigative team is better suited to carry out studies than appropriate industry sponsor.

3. Innovation Score (1-9): 5

Strengths

- Endoscopic surgery techniques are innovative and the development of instruments that could make these techniques more accessible to the majority of surgeons could be helpful.

Weaknesses

- This is not a high impact game-changer in terms of patient care. There is no evidence that surgical procedures carried out using endoscopic techniques are fundamentally better in terms of quality care or resource utilization than traditional techniques.

4. [Approach](#) Score (1-9): 7**Strengths**

- Conceptually laid out well with information gathering, device development, and testing stages, which seem reasonable.

Weaknesses

- The proposal is cursory, and gives little detail about how these aims would be achieved. The 'needs assessment' is qualitative and it is not clear what information is added given the PI's personal and teaching experience. No examples are given of prior such studies and how they impacted project development.
- Details on QFD are inadequate, given that this is bridge between needs assessment and instrument development. Do the investigators have access to a virtual temporal bone dissection system that can produce specimens from clinical CT scans? This is not referenced or described.

5. [Environment](#) Score (1-9): 5**Strengths**

- Collaboration between engineers and surgeons is useful for this project.

Weaknesses

- There is a lack of information regarding what resources are available for product development and testing

ADDITIONAL REVIEW CRITERIA

As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items.

[Protections for Human Subjects](#)

Click Here to Select

Comments (Required Unless Not Applicable):

- Proposal focuses on development of surgical tools but does mention at the end that instruments considered safe and suitable to utilize in the OR will be evaluated in patients, according to the hospital policy on surgical innovation. Further description not provided.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

<p>Click Here to Select</p> <p>Comments (Required Unless Not Applicable):</p> <ul style="list-style-type: none"> ○ N/A

Vertebrate Animals
<p>Click Here to Select</p> <p>Comments (Required Unless Not Applicable):</p> <ul style="list-style-type: none"> • N/A

Resubmission
<p>Comments (if applicable):</p> <ul style="list-style-type: none"> • N/A

Renewal
<p>Comments (if applicable):</p> <ul style="list-style-type: none"> • N/A

Revision
<p>Comments (if applicable):</p> <ul style="list-style-type: none"> • N/A

ADDITIONAL REVIEW CONSIDERATIONS

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact/priority score.

Budget and Period of Support
<p>Recommended budget modifications or possible overlap identified:</p> <ul style="list-style-type: none"> • Appropriate budget; no concerns

ADDITIONAL COMMENTS TO APPLICANT

Reviewers may provide guidance to the applicant or recommend against resubmission without fundamental revision.

Additional Comments to Applicant (Optional)

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