The influence of radiotherapy on outcomes for auricular osseointegrated implants

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1 | INTRODUCTION

Following surgical removal of the pinna for malignancy or craniofacial trauma, reconstruction with an auricular prosthesis provides an acceptable cosmetic option. The development of osseointegrated implants for the mounting of such auricular prostheses has significantly improved functional outcomes and aesthetics for patients.1-5

Given the accepted effectiveness of osseointegrated implants, the risk factors associated with their failure are now being studied. Determinants of implant survival include their premature loading,6 chronic inflammation of the peri-implant soft tissues 4 and a prior history of radiation therapy to the mastoid or temporal bone.7 In particular, the effect of radiation is one identified determinant of implant survival; however, there is a paucity of published evidence assessing its influence amongst large cohorts, with the limited prevailing literature being case series and reports.1,7-9 Furthermore, these papers study implants that hold a bone conduction device (BCD), which is generally placed in healthy bone. The practice in our institution has been to place titanium implants at the same time as the surgical resection of temporal bone and or external auditory canal (EAC)/auricular cancer. These implants, for some, are exposed to postoperative radiotherapy (RTx) and are therefore at risk of compromised osseointegration and subsequent, implant failure. However, the influence of radiotherapy on the ability of osseointegration is yet to be appropriately explored in a contemporaneous cohort of patients.

The main objective of this study was to assess for prosthesis-retaining implant-related problems between patients who did and did not receive RTx following the resection of their auricular cancer. This will help clinicians make evidence-based decisions as to the benefits and timing of RTx on the outcomes for auricular osseointegrated implants.

2 | METHODS

All notes of patients listed for a unilateral auricular prosthesis after auricular resection due to head and neck cancer between April 1999 and April 2018 at the Queen Elizabeth Hospital Birmingham were reviewed. Patient receiving implants for auricular prosthesis had 2 or 3 implants inserted, with only 2 uncovered for prosthesis loading. Our primary outcome was to assess implant and patient survival between the irradiated and non-irradiated cohorts. Findings were reported in accordance with the STROBE reporting guidelines.

2.1 Radiotherapy

The average radiotherapy dose (median; IQR) was 52.8 Gy (50.0-60.0) and the average fractions were 20.0 (20.0-30.0). Radiotherapy was provided as adjuvant therapy.

2.2 Statistical analysis

We compared a range of factors between the irradiated and non-irradiated populations, using Mann-Whitney U tests for continuous variables and chi-square tests for nominal variables. A range of outcome measures was then compared between the groups, with Kaplan-Meier curves for implant survival. Statistical analysis was
performed with IBM spss Statistics version 21 for Mac. Statistical significance was defined as being $P < .05$.

### RESULTS

Data were analysed for 123 patients with osseointegrated implants: 33 received adjuvant RTx while 90 received no RTx. Median follow-up (IQR) for the cohort was 3.25 years (1.19-7.23). Table 1 details the baseline demographics for this cohort. Overall compared to the non-RTx cohort, patients that received RTx were more likely to be younger ($P = .018$), female ($P = .043$), to have been diagnosed prior to 2010 (45.5%, $P = .020$), to have had a diagnosis of squamous cell carcinoma ($P = .036$), to have undergone free flap and temporal bone resection and received adjuvant chemotherapy ($P < .001$).

#### 3.1 Implant loading

While all 123 patients who underwent a pinnectomy and the placement of osseointegrated implants, loading of the implant with an auricular prosthesis was only observed in 85 patients. As only 2 of the 3 inserted implants were uncovered for loading, this meant that 164 implants had a prosthesis fitted.

Thirty-eight patients failed to have their implants loaded, with the commonest reasons for non-loading including (non-RTx vs RTx) (Table 2): disease recurrence (17.4% vs 26.7%) and patient death (43.5% vs 33.3%).

Overall radiotherapy was found to be predictive of implant non-loading in univariate analysis (HR: 0.32, 95% CI: 0.14-0.76, $P = .009$). Other factors within the baseline characteristics that were predictive of non-loading included temporal bone resection (TBR) ($P = .046$), with patients who had received a TBR less likely to have their prosthesis loaded (Table 3).

#### 3.2 Implant failure

A total 12 out of 85 (14.1%) patients had failure of their osseointegrated implants after loading. All these patients had 2 implants loaded: with 2 patients having both implants failing, and 10 having only 1 implant failure. This gave a total of 14/164 (8.5%) implant failures. Median time to implant failure was 4.5 years (IQR: 3.33-7.65). Overall, in univariate analysis, no significant difference in implant survival was observed between the radiotherapy (4 out of 33) and non-radiotherapy cohorts (9 out of 90) ($P = .546$).

### DISCUSSION

In our long-term analysis of 123 patients, we identified a 91.5% survival for loaded auricular implants. In univariate analysis, RTx failed to significantly influence long-term implant survival ($P = .789$).
a multivariate analysis. Finally, Wright et al assessed Thirty-nine implants, placed in 16 patients. No surgical complications, implant failures or prosthetic failures were encountered.

Our practice to date has been to place the osseointegrated implants at the primary cancer resection surgery. This sequence, of placing osseointegrated implants at the time of primary cancer resection, was done in order to hopefully have good osseointegration before postoperative radiotherapy is delivered. Our team felt that this would give a more stable implant and reduce the risk of implant failure. However, this review has not demonstrated a significantly higher rate of implant loss in the irradiated group (when RTx was provided as an adjuvant therapy after the implants were placed).

Furthermore, our findings show a significant number of patients fail to have their implants loaded with a prosthesis with the most important reasons for this including (non-RTx vs RTx): disease recurrence (17.4% vs 26.7%) and patient death (43.5% vs 33.3%). The high proportion of patients refusing implants due to their preference is quite staggering and indicates a lack of effective communication between clinicians and patients as to the process of implant insertion and prosthesis loading. Furthermore, knowing there is higher rate of non-use with TBR indicates that this could be a point where we could opt to not place the implants—that is doing a temporal bone resection means we should really think about the risk of non-use when placing at the primary surgery. Therefore, it is essential to include the patient within this decision in order to reduce non-loading of the implants.

Given our findings, we now recommend that implants should be planned and sited following completion of surgical and postoperative radiotherapy in conjunction with CT imaging and input from the facial prosthetists for the group requiring temporal bone resection surgery. While more research is required, our analysis indicates that this may be performed at a later procedure following any adjuvant cancer treatment and done as a single-stage surgery much like bone-anchored hearing implant surgery. Most certainly, we plan to continue closely studying this group of patients and compare the implant outcomes and survival when placed later following completion of all cancer-related treatment to ensure that patients are not disadvantaged by this change in practice.

The results of this study must be interpreted considering its limitations. First, this is a retrospective, single-centre study, and the limitations of this study design must be acknowledged (ie, institutional biases may not be accounted for). Furthermore, all patients at our centre received radiotherapy prior to the second-stage placement of skin penetrating abutments and loading of their implants. These patients were compared to a cohort of patients who received no radiotherapy. It would have been useful to have had a 3rd group of patients who received radiotherapy and then had their osseointegrated implants placed at a later date in a single-stage procedure, which is the process we have now adopted and plan to report on in due course. This would have provided a more comprehensive overview on the influence of RTx on outcomes after implant insertion.

From our initial results, osseointegrated implants for ear prostheses do not have a significantly higher failure rate when adjuvant RTx is given. In preventing the non-use of previously placed implants, we now recommend inserting the implants following completing of treatment as a single-stage surgery and in close consultation with the patient. Extended follow-up, with larger cohorts of patients, is required to explore the influence of RTx in more detail.

**CONFLICT OF INTEREST**
The authors declare no conflicts of interest.

**AUTHOR CONTRIBUTIONS**PM designed the study; AA, JC, SE and PM extracted the data; AA and PM analysed and interpreted the data; AA, MV, MH and PM wrote original draft; and all authors reviewed the manuscript.

**ETHICAL APPROVAL**This was a retrospective review of practice and so ethical approval was not sought.

**DATA AVAILABILITY STATEMENT**The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

### TABLE 2 Reasons for not loading the implant with a prosthesis

| Reason for non-loading | Non-RTx (n = 23) | RTx (n = 15) |
|------------------------|------------------|--------------|
| Disease recurrence     | 4 (17.4%)        | 4 (26.7%)    |
| Patient death          | 10 (43.5%)       | 5 (33.3%)    |
| Patient choosing not to have prosthesis placed | 7 (30.4%) | 6 (40.0%) |
| Patient too unwell for second-stage placement of abutments and construction of prosthesis | 2 (8.7%) | 0 (0.0%) |

Abbreviation: RTx, Radiotherapy.

### TABLE 3 Loading between the temporal bone resection and non-temporal bone resection patients

| TBR | Non-TBR | P-value |
|-----|---------|---------|
| Prosthesis not loaded | 17 (41.5%) | 19 (23.8%) | P = .044 |
| Prosthesis loaded | 24 (58.5%) | 61 (76.3%) |

Note: P-values from chi-square tests, as applicable. Bold P-values are significant at P < .05.

Abbreviation: TBR, temporal bone resection.
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How to cite this article: Arshad A, Chan J, Edmondson S, Vijverberg M, Hol MKS, Monksfield P. The influence of radiotherapy on outcomes for auricular osseointegrated implants. Clin Otolaryngol. 2021;46:650–653. https://doi.org/10.1111/coa.13698