Cochlear implant user perceptions of magnetic resonance imaging

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Abstract

Objectives: To characterise opinions about needing to undergo MRI within the population of current cochlear implant (CI) users.

Background: Magnetic resonance imaging (MRI) is the preferred technique for many clinical diagnostic needs. A CI contains an implanted magnet and metal components, causing safety concerns around MRI, carrying risks of severe discomfort, and, ultimately, magnet displacement.

Methods: A global online survey of 310 CI users was conducted between 22nd July and 13th September 2020.

Results: Only 55% of respondents had been told whether their model of CI could undergo MRI. 31% of respondents considered MRI when deciding whether to receive a CI, and 28% when deciding which CI model to have. 64% reported concerns related to their CI if needing MRI compared to 29% reporting concerns unrelated to their CI. Willingness to undergo MRI reduced when considering magnet removal, splinting, bandaging, or local anaesthesia, and reduced further when considering lasting discomfort or inability to use their CI, or when considering a reduction in image quality because of their CI. The single most influential factor was the possibility of damaging their CI (63%). 59% of respondents would consider minor surgery to upgrade their retaining magnet to one of a rotating design.

Discussion: These findings highlight the heterogeneity of views and beliefs of CI users about MRI. CI user consultation of this sort is scarce, meaning the views of CI users are often neglected.

Conclusion: We suggest several opportunities for improving the dissemination of current and accurate CI-related information for CI users.

Keywords:

cochlear implants; magnetic resonance imaging; safety; user consultation; patient perceptions; diagnostic medical imaging

Introduction

Magnetic resonance imaging (MRI) is a widely available, non-invasive diagnostic imaging technique, addressing many clinical questions. A cochlear implant (CI) is a prosthetic device that provides auditory input for deaf individuals. Children who are born deaf ideally receive a CI in the first year of life. As such, a CI is often used for a lifetime.

The presence of the magnet and other ferromagnetic material within the CI creates safety and practicality issues around undergoing MRI scanning. CI manufacturers publish associated safety protocols for scanning these individuals. These protocols often include procedures that are recommended prior to MR scanning, such as removing the internal retaining magnet, applying a splint to the scalp adjacent to the internal retaining magnet which is then tightly bandaged around the head, and administering local anaesthetic. Even when these protocols are followed, MRI can be very uncomfortable, or painful, and in some cases CI users are unable to complete image acquisition [1]. Further, the measures themselves are uncomfortable and inconvenient for the patient, as magnet removal/replacement surgeries require healing time without the use of their CI and pose an infection risk, and the tight bandages are themselves uncomfortable.

Even when all necessary measures are followed, the risks of severe discomfort, and ultimately magnet displacement are not negligible [2,3,4,5]. A reported 33% of MRI scans in patients with CIs result in complications [1] despite at least 80% of those patients being fitted with the FDA-approved bandaging. Where complications occurred, 60% required additional surgery and 40% could not complete scanning due to pain [1]. A retrospective study of the MAUDE (FDA Manufacturer and User Facility Device Experience) database [4], reported 624 adverse events involving auditory implants, of which 592 involved CIs. 384 of events involved auditory implant magnet displacement, and a further 48 incidents reported only pain. Complication rates as low as 14% [6] and 3.5% [7] have also been reported, as well as magnet dislocation rates of 11%, and pain occurring in 17% of scans. It is also worth noting that patients described pain as preferable to magnet removal [4]. However, magnet displacement often causes soft-tissue damage, which is in turn associated with a prolonged healing period, during which the CI cannot be used.

Unintended acoustic stimulation can result from the implant's interaction with the electromagnetic fields present during scanning [8,9,10]. Further, when imaging the head of a patient with a CI, clinical image quality is confounded by substantial image distortions, even with the magnet removed [11,12], and so on balance imaging of the head is often avoided. The extent and location of these image distortions depend on the positioning of the CI, which could be factored into surgical planning to anticipate any future need for MRI based on individual patient needs [13]. However, MRI is often avoided altogether in favour of other imaging techniques that are less diagnostically powerful and/or use ionising radiation; e.g. computed tomography (CT) or positron emission tomography (PET).

New generations of CIs contain implanted magnets with a rotating component, specifically designed such that they experience significantly less torque when placed in a magnetic field. Some existing implants can be retro-fitted with a replacement rotating magnet so as to update an existing device. As such, individuals with this new generation of retaining magnets do not have to undergo magnet removal (although for some conditions requiring visualisation of the internal auditory meatus, this is still beneficial [14]), splinting and bandaging of the head, or significant levels of discomfort. However, the overwhelming majority of the approximately 736,900 registered devices implanted worldwide as of December 2019 [15] are significantly less MRI compatible than this newer generation of devices, and therefore MRI compatibility remains an important consideration for existing CI recipients.

With a wide variety of levels of MRI compatibility across the devices in the currently implanted population, and the spread of highly unsettling anecdotal evidence for the dangers of MRI for CI users, there is a wide variation in the current opinions and understandings held by CI users. Opinion surveys of CI users are commonplace, and typically focus on aspects of speech perception or quality of life (e.g. [16]). A retrospective survey of CI users reported only 9.8% of respondents as having undergone MRI [17]. As such, many clinicians and CI users may not seriously consider MRI a necessity when making surgical decisions. Further, too little attention is paid to the prevention of complications in the radiological setting [17]. No existing work explores the opinions of CI users regarding the hypothetical prospect of undergoing MRI, or indeed any aspect of the expectations of CI users in the radiological setting.

The primary objectives of the study were to quantify what proportion of CI users were willing to consider undergoing MRI, and to quantitatively determine to what degree their concerns were related to their CI, and/or the procedures needed before undergoing MRI. A secondary objective was to assess whether CI users would be willing to undergo minor surgery to update the implant retaining magnet as a pre-emptive or prophylactic measure should they hypothetically need to undergo MRI at some point in the future. To achieve these objectives, we conducted a global online survey of CI users.

Materials and Methods

Participants

Experimental procedures complied with the World Medical Association's Declaration of Helsinki. Ethical approval was provided by the London Fulham Research Ethics Committee (reference 19/LO/1724). Study participants gave informed consent online prior to participating in the study. Participants read an introduction stating that they could close the survey window at any point to end their contribution to the study. No identifying information was sought in the survey questions. Only completed survey responses were included in the sample. The study was advertised widely on Facebook, Twitter and Reddit, in addition to specific hearing and CI online forums. A total of 310 participants completed the survey between 22nd July and 13th September 2020. Due to the descriptive purpose of the study, no formal sample size calculations were performed.

Survey design

The survey questions, in English, were designed by the research team. The objective was to characterise the understanding and attitudes of CI users towards MRI. To give context and background to these figures, questions were divided into five sections. The first section covered the respondent's history of CI use, how many CIs they currently had, or whether they were currently awaiting implantation surgery. The survey asked the date(s) of implantation and any re-implantation, their current model(s) and recency of update. The second section covered their opinions around their ability to undergo MRI, and whether this was a factor for them in deciding whether to accept a CI. Following this, the third section asked about their concerns around undergoing MRI as a CI user, and their awareness and any concerns they had around procedures performed prior to the scan. The fourth and penultimate section asked the participant about their awareness of any risks of undergoing MRI as a CI user and

whether they would agree to undergoing MRI in different scenarios. Finally, participants were asked if they would consider undergoing minor surgery to replace their internal retaining magnet with one that could undergo MRI more safely.

A majority of questions were multiple choice, with an open-ended "other" option where necessary. Some questions used a 5-item Likert scale from "very uncomfortable" to "very comfortable". These measures constrained the respondents to selecting a pre-defined option or options, to facilitate quantitative analysis. The survey was implemented using Jisc online surveys (onlinesurveys.ac.uk).

Patient and public involvement

The survey was developed in consultation with CI users through a patient and public involvement approach. A small sample of CI users were given background information about the purpose of the research, and then asked to read a draft of the survey questions and provide feedback. As a result of this feedback, questions were added, removed, or amended to improve clarity and correct errors or ambiguities. The sample individuals were subsequently given a draft of the participant information leaflet and also asked for feedback on that. Finally, they were asked if they would have taken part in the study if offered the opportunity, and all said they would be willing to do so.

Data processing and analysis

Survey responses were imported into SPSS version 26 (IBM, New York, USA) for data processing and inspection. For quantitative questions, the data were analysed using descriptive statistics and reported in terms of the percentage of respondents who chose each available option. Free-text responses were handled using informal thematic analyses, whereby visual inspection was used to identify themes, and the frequency with which those themes occurred was counted.

Results

Characteristics of the sample

There were 313 respondents, of whom 309 were current CI users (227 unilateral and 79 bilateral) and one was awaiting CI surgery at the time of completing the survey. The three remaining respondents were either not awaiting CI surgery and did not use CIs, or did not

complete the consent procedure, and were asked no further questions. The dataset comprises responses from 310 individuals who completed the survey. The sample received their first implants between 1987 and 2020, with the median date being 2013 and the mean (± standard deviation) being 2011±8 years. Of the 79 respondents with a second CI, the period between implantations was 5±5 years, with a range of 0 to 22 years, a median of 2 years and a mode of 0 years. Only 17 individuals in the sample had been re-implanted, with a mean period of 5±6 years between their initial implantation and their re-implantation. Respondents reported that their implants were manufactured by Cochlear (n=190), Advanced Bionics (n=82), MED-EL (n=35), Neurelec (n=1), Oticon (n=1) or that they did not know (n=4). A total of 12 participants reported that they currently had implant with a new rotating magnet design.

CI users self-reported ability to undergo MRI

55% of respondents (n = 171) said they had never been told that they might need an MRI scan (42% had been told this, the rest did not know or declined to answer). 46% of respondents (n = 144) said they had been told that they should never have an MRI scan (43% had not been told this, the rest did not know or declined to answer). 55% of respondents (n = 169) had been told whether their model of CI could undergo MRI, whereas 25% had not been told whether they could undergo MRI or not (the rest did not know or declined to answer).

Nearly two thirds of participants had not considered MRI at all during the implantation process, and nearly one third had considered MRI when making these decisions. 63% (n = 195) did not consider their ability to have an MRI scan in the future when deciding whether or not to receive a CI (31% of respondents did consider this factor, and the rest did not know or declined to answer). Further, 66% of respondents (n = 204) did not consider their ability to have an MRI scan when deciding which model of CI to have, with only 28% of respondents taking this into account when deciding which model to have (the rest did not know or declined to answer).

Concerns around having an MRI scan

Figure 1A shows the frequency with which respondents reported having concerns about undergoing MRI, both related and unrelated to their CI. The most commonly reported concern *not related to their CI* was the safety of MRI (n=72 respondents), followed by claustrophobia (n=29), metallic implants other than their CI (n=21), keeping still during the

scan (n=12), scanner acoustic noise (n=4) and removing jewellery (n=3). When asked what their greatest concern was, again the most frequent response was the safety of MRI (n=60), followed by claustrophobia (n=13), metallic implants other than their CI (n=8), keeping still during the scan (n=2), and scanner acoustic noise (n=1). Responses given by those who selected "other" (n=10) included electrical hypersensitivity, being unable to hear instructions, and another prosthesis.

Approximately a quarter of participants reported feeling very uncomfortable with the prospect of undergoing MRI, with slightly fewer respondents reporting the same concerns about the procedures required to prepare their CI for undergoing MRI (Figure 1B). Figure 2 shows free text responses to the question about concerns participants had related to undergoing MRI with a CI in place. The greatest concerns were the potential for damage to the CI, consequent communication issues without their CI, and MRI being unsafe or that they had been told not to. Participants were concerned about migration or movement of internal CI components and about the surgical removal of internal CI components and about experiencing pain or injury during the scan. Some participants reported that their own model of CI was not MRI compatible, or that there was insufficient need to undergo MRI. Some participants expressed concerns about the knowledge or training of MRI staff, or the adequacy of procedures in place to make MRI safe for them.

Procedures associated with MRI

More respondents were uncomfortable with undergoing these procedures than were uncomfortable with the prospect of undergoing MRI (Figure 1B). As shown in Figure 3, 81% of respondents were aware of the practice of surgically removing the CI retaining magnet prior to an MRI scan, but only 51% were willing to undergo the procedure. Conversely, while only 50% and 20%, respectively, were aware of the practice of affixing a splint to the CI with a bandage around the head, and of administering local anaesthetic to the implant site, a larger proportion of 57% and 34% were willing to consider undergoing these procedures.

Perceived risks and benefits of MRI

72% of respondents (n = 224) were aware of risks of MRI scans (20% were not, the rest did not know or declined to answer). Figure 4 shows the free text responses to this question. Concerns were based around the movement of internal CI components causing pain or injury,

heating, discomfort, damage to their implant, or specifically to the retaining magnet. They expressed an understanding that this may result in the need to undergo further surgery and an associated period of recovery without the use of their CI. Participants also articulated concerns that there may be an MRI artefact rendering the images useless. The most frequently cited sources of information for the risks associated with a CI user undergoing MRI were their audiologist, specialist or surgical team (n=93), the manufacturer brochure or information supplied with the implant (n=36), CI manufacturer websites (n=9), published literature or articles (n=11), the MRI team (n=4), formal training or their own expertise or knowledge (n=6), online CI groups, forums and social media (n=24), the internet and websites more broadly (n=23), and other CI users (n=17).

Respondents were more likely to be aware of the risks associated with undergoing MRI than they were with the chance of image artefacts resulting from the CI distorting the image. Only 42% (n = 130) were aware of the possibility of image artefacts (47% unaware of image artefacts, the rest did not know or declined to answer). The most frequent sources of information about CI artefacts on MR images were their audiologist, specialist or surgical team (n=22), the manufacturer brochure or information supplied with the implant (n=28), CI manufacturer websites (n=22), published literature or articles (n=3), the MRI team (n=5), formal training or their own expertise or knowledge (n=14), online CI groups, forums and social media (n=11), the internet and websites more broadly (n=13), and other CI users (n=2).

When asked which single factor would most strongly affect their decision whether or not to have an MRI scan, 66% (n = 204) said that damaging their device was the greatest factor, followed by undergoing procedures prior to the scan (n=64; 21%), being unable to use their device for any period following the scan (n=17; 5%), the possibility of experiencing discomfort (n=14; 5%) and finally the quality of the resulting images (n=11; 4%).

Willingness to hypothetically agree to MRI

Figure 5 shows the proportion of respondents saying they would consider undergoing MRI under varying circumstances. Respondents were more likely to agree to MRI if no preparation procedures were required, than if they did need to undergo such procedures. Adding in the risk of discomfort during or after the scan, or of a period of being unable to use the CI to allow for healing, reduced the number of respondents that agreed to undergo MRI

further. The possibility of poor image quality resulting from the proximity of their CI to the region of imaging interest further decreased the certainty of respondents, with a corresponding increase in the number of "I don't know" responses.

Willingness to consider magnet replacement surgery

59% of respondents (n = 182) said they would consider undergoing minor surgery to upgrade their internal retaining magnet to one that would be safer to MRI scan this option, with only 10% saying they would not consider this (the rest said they did not know or declined to answer; final bar on Figure 5). Figure 6 shows the responses given when participants were asked to explain the reasoning behind their answer to this question, as organised by their answer to the previous question. In responses from those who said they would consider the surgery, the main themes included peace of mind, futureproofing, it being a better solution than the alternative, and being useful in case of an emergency. Respondents who said they would not consider the minor surgery typically expressed concerns around undergoing further elective surgery or felt they would wait until the need arose. Of the respondents who said they did not know whether they would consider the surgery or not, their reasons also comprised concerns around undergoing unnecessary surgery or waiting until the need arose, coupled with a need for further information and time for consideration.

Summary of key findings

A majority of respondents had been told whether their model of CI could undergo MRI, but far fewer respondents considered MRI when deciding whether to receive a CI, or which CI model to have. Approximately double the number of respondents reported concerns related to their CI if needing to undergo MRI than reported concerns unrelated to their CI. Willingness to undergo MRI reduced when considering magnet removal, splinting, bandaging, or local anaesthesia, and reduced further when considering lasting discomfort or inability to use their CI, or when considering a reduction in image quality because of their CI. The single most influential factor was the possibility of damaging their CI. A majority of respondents would consider minor surgery to upgrade their retaining magnet to one of a rotating design, if they did not have this already.

Discussion

CI magnet displacements are often reported despite all reasonable precautions being taken [18,19,20,21]. With the prevalence of performing MRI in CI users estimated at less than 10% [17], many clinicians overlook the potential for future difficulty in this population. Among respondents, concerns about undergoing MRI were more likely to be related to their CI than to other factors. Despite this, only 28% considered the prospect of MRI when deciding which CI to receive. Given the increasing ubiquity of MRI in clinical medicine and research, it may be beneficial to raise awareness of issues related to MRI compatibility within the CI user population.

Concerns around the potential for damaging their device reflect the reliance of the CI user on their device for communication and are arguably well-founded. The concerns expressed around migration, or surgical removal, of the entire CI device, or concerns around the diligence of staff conducting MRI scans in terms of understanding that they have a CI, being trained in how to treat a CI user, and choosing to correctly follow protocol perhaps highlight a need for better information resources to be provided to CI users about how MRI is planned and carried out in the case of a CI user and what the relevant risks and benefits of MRI are. The sources of information CI users were consulting were mostly reliable sources, such as materials produced by manufacturers or clinicians. Some respondents did cite potentially unregulated and unreliable internet sources or social media. The provision of trusted information sources online may therefore be warranted to fully support potential and existing CI users.

This article reinforces the need to consider the beliefs and perceptions of CI users when making design decisions in future generations of CI models. One participant stated: “Would they be recommending MRI scans if it were not for my CI?”, demonstrating concern about the impact of their auditory prosthesis on other aspects of their health or their access to other healthcare technologies. The high proportion of individuals who would consider upgrading their internal retaining magnet reflects a desire for remaining up to date, attaining peace of mind, and that having an MRI scan may be useful in an emergency. This may suggest that many CI users are highly technologically literate. However, it is also the case that this study was conducted online, and as such may have been biased towards recruiting a sample of particularly technology-savvy individuals. As surgical techniques have improved over time,

together with post-surgical procedures and thus recovery times, the reluctance to undergo further surgery due to previous experiences or concerns about complications may be less prohibitive to new CI users compared to those who were implanted a considerable time ago. A small number of respondents mentioned needing to relearn how to hear or expressed a scepticism of magnet replacement being minor surgery, again highlighting the potential need for better penetration of relevant, accessible, and current information within the CI user community. Finally, the assumption of a few respondents that alternative imaging modalities offer comparable information to MRI likely reflects a general lack of understanding of diagnostic medicine. These findings may be of interest to CI manufacturers, surgeons, and clinicians as many of these misunderstandings could in part be addressed by clearer or more complete information from stakeholders.

Conclusion

This survey of CI users has demonstrated an awareness of MRI compatibility: some CI users consider it as part of their decision making around which device to receive. However, only about half the CI users surveyed had been told whether their model of CI could undergo MRI. Concerns about MRI more frequently related to their CI than to other factors. The proportion of respondents who were willing to undergo MRI reduced when asked to consider undergoing magnet removal, splinting, bandaging, or local anaesthesia, reduced further when asked to consider the possibility of a period of discomfort or without the use of their CI, or the possibility of reduced image quality because of their CI.

The current study has potential implications for the counselling of patients prior to CI surgery, specifically around the issue of MRI compatibility and issues that relate to future access to MRI. The fact that most respondents were willing to undergo minor surgery to replace their retaining magnet with one of a rotating design suggests that implant recipients see device compatibility and potential future health needs as important factors that are relevant to their use of a CI. Existing CI users will benefit from being more informed about the MRI compatibility of their current device(s), and future implant recipients will benefit from being informed about any differences in the MRI compatibility of the device(s) they are asked to choose between or which will be provided to them. In turn, clinicians need to be more informed about the importance of discussing MRI compatibility of the array of devices

available with their patients, and have easy access to suitable information and training resources.

CI user consultation in relation to medical imaging is scarce. This article presents findings that reinforce the notion that MR compatibility is important to CI users and identifies several opportunities for improving the dissemination of relevant, accessible, and current information about CIs within the global population of CI users.

Abbreviations

CI=cochlear implant; MRI=magnetic resonance imaging

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Figures

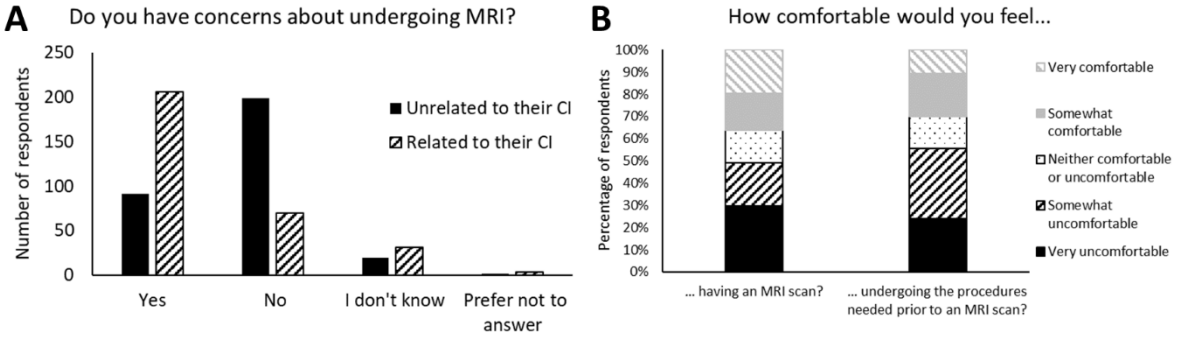

Figure 1A: The frequency with which respondents reported concerns about undergoing MRI, separated be whether or not those concerns related to their CI (n=310). B: The reported frequency of comfort or discomfort reported by participants in relation to undergoing MRI, or undergoing the procedures required to prepare their CI for undergoing MRI (n=310).

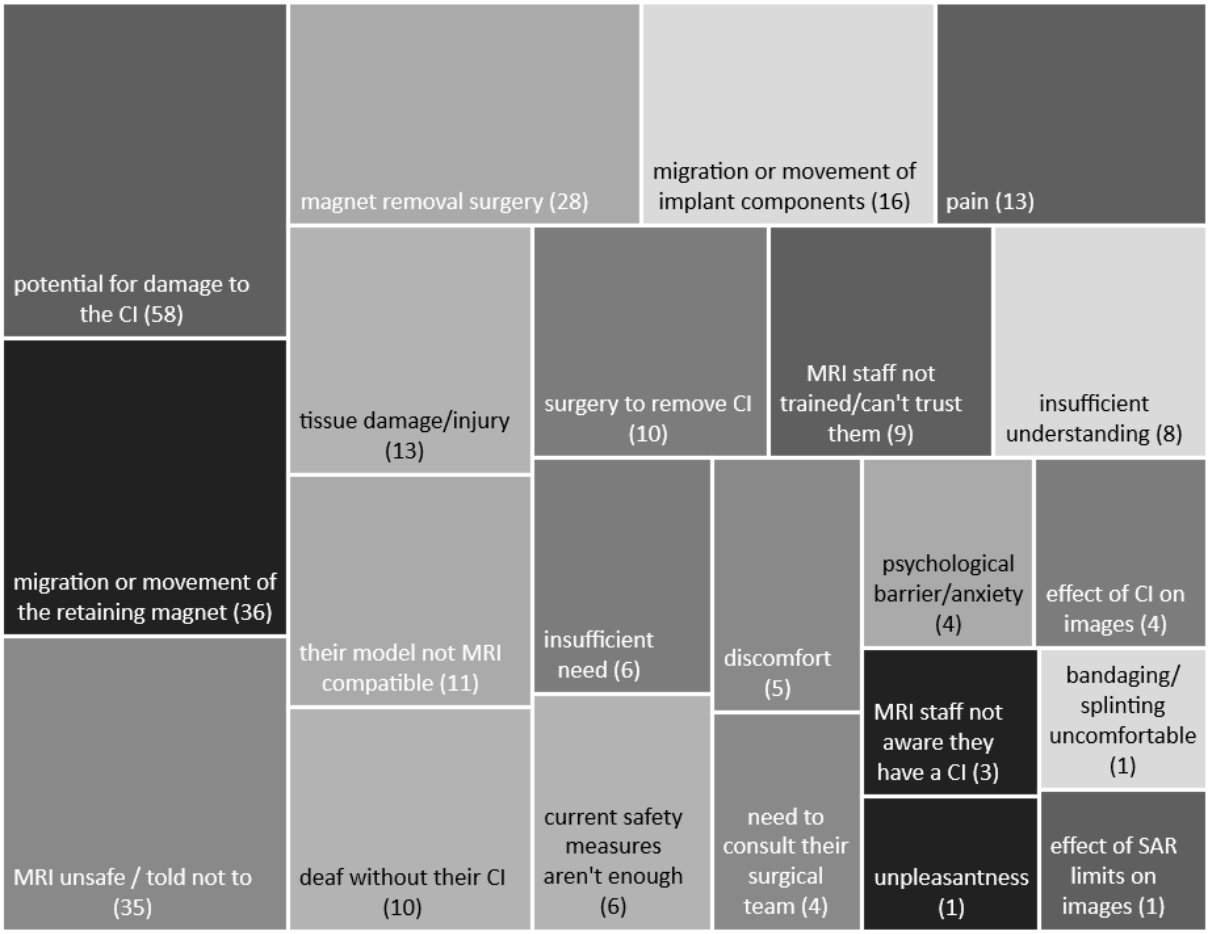

Figure 2: Visual representation of the informal thematic analysis of the textual responses from study participants when asked to briefly describe their concerns about undergoing MRI with a cochlear implant.

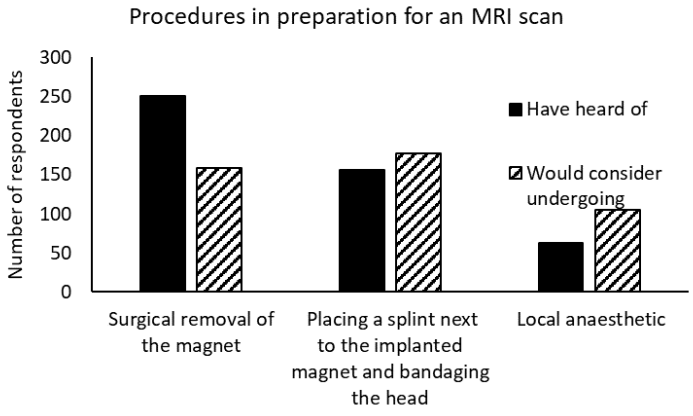

Figure 3: Respondents' awareness of, and willingness to undergo, procedures in preparation for an MRI scan (n=310).

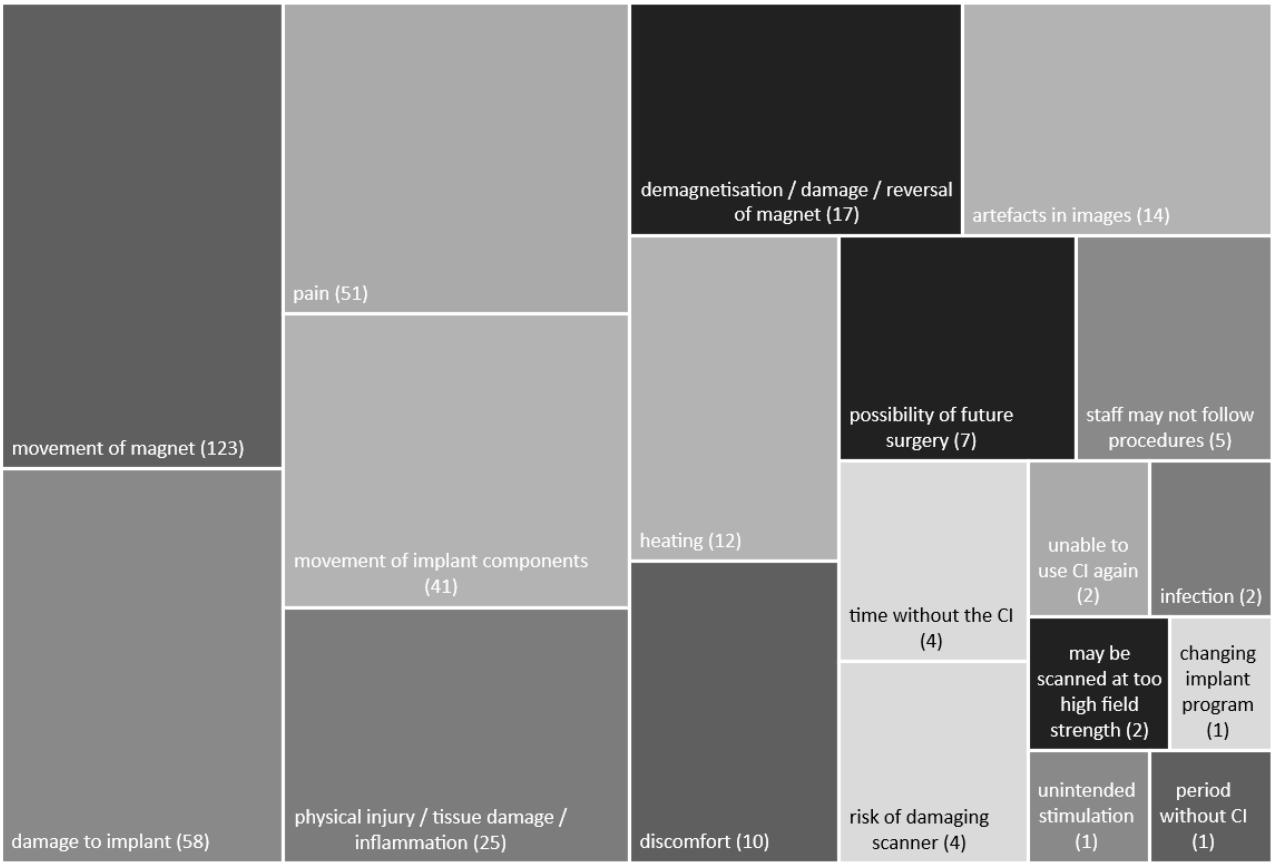

Figure 4: Informal thematic analysis of the textual responses from study participants when asked to briefly describe the risks associated with undergoing MRI as a cochlear implant user.

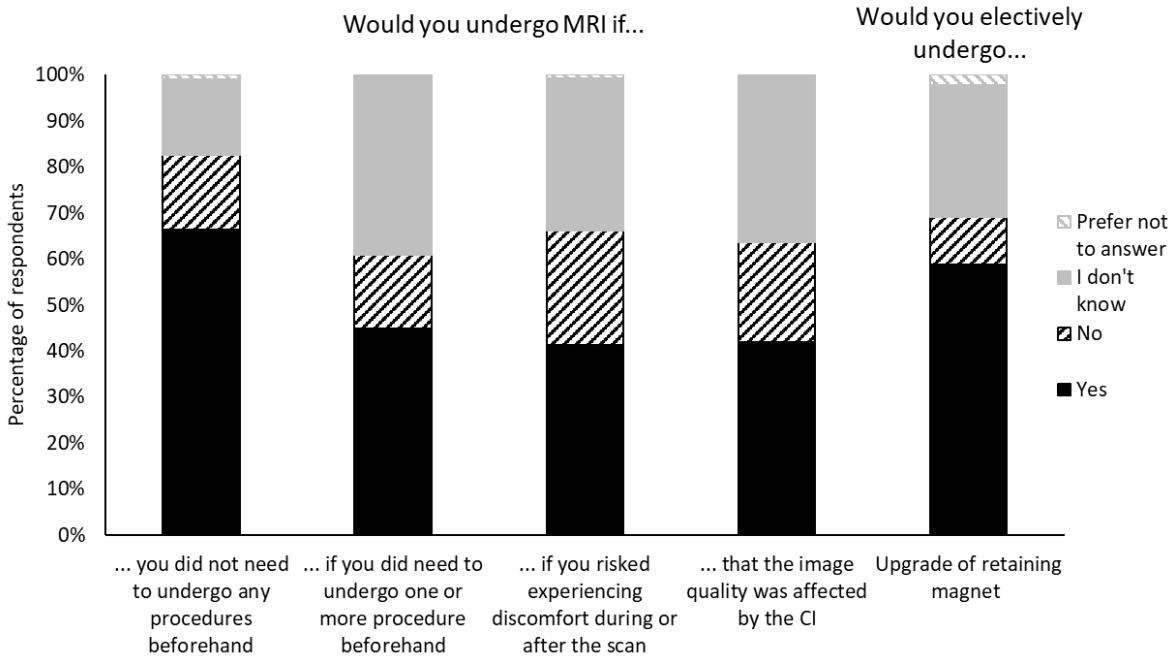

Figure 5: Willingness of respondents to undergo MRI under different conditions, i.e. with and without the possibility of enduring the procedures used to prepare the CI for MRI, and with the additional risk of discomfort or poor image quality (n=310). The final column on the right shows the willingness of respondents to undergo minor surgery to prophylactically update the implanted retaining magnet in order to improve the experience during a hypothetical future MRI scan (n=310).

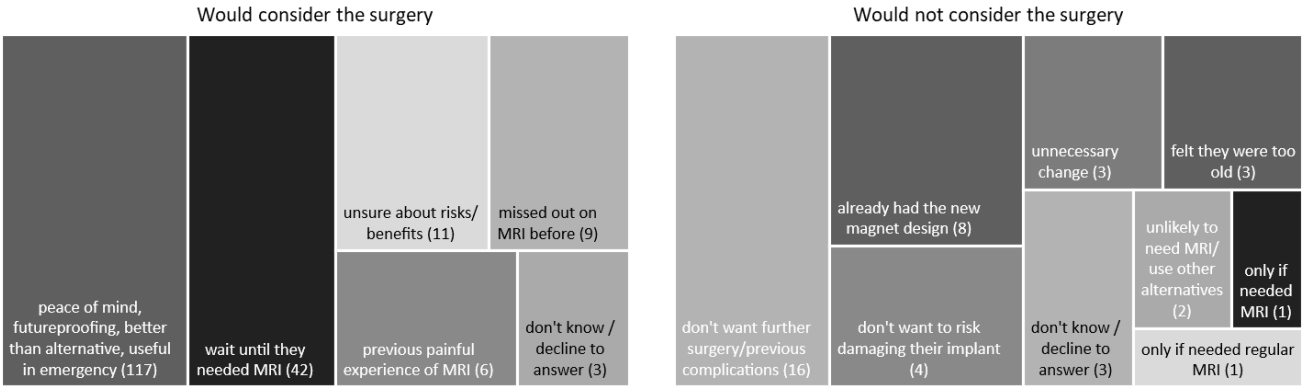

Figure 6: Informal thematic analysis of the textual responses from study participants when asked to briefly explain their answer to the question about whether or not they would consider elective surgery to upgrade their internal retaining magnet to a more MRI-compatible one.