UNIVERSIDADE DE SÃO PAULO
HOSPITAL DE REABILITAÇÃO DE ANOMALIAS CRANIOFACIAS

LETÍCIA ALVES DA FONSECA AGUERA NUNES

Evaluation of cochlear implant receptor-stimulator migration using the bony bed technique without sutures: Objective measurements

Avaliação da migração do receptor-estimulador do implante coclear utilizando técnica com nicho ósseo sem suturas: medidas objetivas

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Orientador: Prof. Dr. Luiz Fernando Manzoni Lourençone
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Letícia Alves da Fonseca Aguera Nunes

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Aos meus pais, pilares do que venho me tornando, agradeço pelos valores ensinados e por fornecerem todo o alicerce necessário à minha construção acadêmica, profissional e pessoal.

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“Educação não transforma o mundo. Educação muda as pessoas. Pessoas transformam o mundo.”

Paulo Freire

RESUMO

RESUMO

Objetivos: Avaliar o deslocamento do receptor-estimulador em pacientes submetidos à cirurgia de implante coclear com a técnica de fixação com nicho ósseo sem suturas. Métodos: Este estudo prospectivo observacional incluiu 83 casos de cirurgias de implante coclear no Hospital de Reabilitação de Anomalias Craniofaciais da Universidade de São Paulo. Os pacientes abrangem faixa etária de 12 meses a 60 anos de idade. Os dados coletados correspondem à distância entre o ímã do receptor-estimulador (R-E) e três pontos anatômicos pré-determinados: ponta da apófise mastoídea (M), tragus (T) e o canto lateral do olho (O). Uma fita métrica em milímetros (mm) foi utilizada para a medição no momento pós-operatório imediato, e após um 1, 3, 6 e 12 meses de pós-operatório. Resultados: A média das medidas da distância do dispositivo até a M, T e O no pós-operatório imediato foram, respectivamente 98,23mm ± 10,12 (Média ± DP), 96,48mm ±10,62 e 142,52mm ± 10,36. Observando a evolução do posicionamento de R-E, nota-se que, quando há deslocamentos, eles ocorreram até 3 meses de pós-operatório, destacando-se a medida entre o R-E e M, que apresentou variação com significância estatística desde a primeira até a terceira medição. Medições feitas entre 3 e 12 meses de pós-operatório não apresentaram variação com significância estatística. Discussão: No presente estudo, o acesso às medidas objetivas seriadas possibilitou acompanhar os deslocamentos de forma detalhada, e notar que após 3 meses de pós-operatório, tais migrações não são estatisticamente significativas, porém, continuam ocorrendo e devem ser monitoradas. Conclusão: Os resultados deste estudo corroboram os achados da literatura: a técnica de nicho ósseo sem suturas traz estabilidade para o dispositivo, e consequentemente evita a sua migração.

Palavras-chave: implante coclear; receptor-estimulador; técnica cirúrgica; nicho ósseo; perda de audição; métodos de fixação.

ABSTRACT

ABSTRACT

Evaluation of cochlear implant receptor-stimulator migration using the bony bed technique without sutures: Objective measurements

Objective: To evaluate the migration of receptor stimulators in patients who underwent cochlear implant surgery using the bony bed technique without sutures. **Methods:** This prospective observational study included 83 patients who underwent cochlear implant surgery at the Hospital for Rehabilitation of Craniofacial Anomalies at the University of São Paulo. Patients were aged between 12 months and 60 years. Data collected included the distance between the receptor-stimulator magnet (RS) and three predetermined anatomical points: the tip of the mastoid apophysis (M), the tragus (T), and the lateral corner of the eye (E). A millimeter (mm) tape measure was used for measurements in the immediate postoperative period and at 1, 3, 6, and 12 months after surgery. **Results:** The mean measurements of the distances from the device to the M, T, and E in the immediate postoperative period were 98.23 mm ± 10.12 (mean ± SD), 96.48 mm ±10.62, and 142.52 mm ±10.36, respectively. The progression of RS positioning showed that migration occurred up to 3 months postoperatively, highlighting the measurement between RS and M, which presented a statistically significant variation between the first and third measurements. Measurements performed 3–12 months postoperatively showed no statistically significant variation. **Discussion:** The objective serial measurements performed in the present study showed the progression of RS migration, which was not statistically significant 3 months after implantation. **Conclusion:** The results of this study corroborate the literature: the bony bed technique without sutures provides stability to the device, consequently preventing its migration.

Keywords: cochlear implant; receptor-stimulator; surgical technique; bony bed; hearing loss; fixation methods.

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1 Introduction

1 INTRODUCTION

Cochlear implant (CI) surgery has become the standard treatment for patients with severe to profound sensorineural hearing loss who present little or no benefit from acoustic amplification. The mode of receptor-stimulator (RS) fixation has advanced over time but is still not standardized. Fixation methods have been investigated to achieve better surgical results. The main objective of this step is to avoid RS migration and possible complications. The surgeon should consider the final position of the device as below the scalp as a protruding device is more prone to trauma, especially in children; the surgeon should also consider the influence of coupling with the external receptor (Cuda, 2013).

The RS is a part of the internal component of the CI and is formed by the magnet and electronic components contained in a hermetically sealed titanium case and a transmission coil, involved in silicone **(Figure 1).** The RS will be connected to the electrode array that will be inserted into the cochlea.

Figure 2 – Receiver-Stimulator Models

Advanced Bionics® Cochlear® Med-El®

Source: http://www.implantecoclear.org.br

Several techniques have been described in the literature, including the use of heterologous materials for fixation, such as polypropylene mesh and screws, on the bony

bed, as well as techniques that do not use a bony bed, making only a subperiosteal fixation pocket, as shown by Alexander et al. (2011). According to Cuda (2013), the creation of a bony bed to make the device flatter in relation to the skull and more stable by suturing it to the surrounding bone was the first and, for a while, the standard approach. This step was mandatory when skin flaps and large exposures were used, which required a receptor-stimulator well anchored to the bone to prevent migration.

Internal device migration is associated with local infection, exposure to electrode wires, displacement of electrodes inserted into the cochlea, and implant extrusion (Jethanamest et al., 2014). RS migration is a CI complication that has not been explored in the literature but has recently become a subject of interest (Markodimitraki et al., 2020).

Studies on the most suitable RS fixation method have been published, but objective device migration measurements are scarce in the literature. The objective of this study was to evaluate RS migration with objective measurements in patients who underwent the bony bed technique without associated heterologous materials.

2 Objective

2 OBJECTIVE

To evaluate the migration of receptor stimulators in patients who underwent cochlear implant surgery using the bony bed fixation technique without sutures.

3 Article

3 ARTICLE

The article presented in this Dissertation was written according to the Cochlear Implants International instructions and guidelines for article submission.

Evaluation of cochlear implant receptor-stimulator migration using the bony bed technique without sutures: Objective measurements

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Abstract

Objective: To evaluate the migration of receptor stimulators in patients who underwent cochlear implant surgery using the bony bed technique without sutures. Methods: This prospective observational study included 83 patients who underwent cochlear implant surgery at the Hospital for Rehabilitation of Craniofacial Anomalies at the University of São Paulo. Patients were aged between 12 months and 60 years. Data collected included the distance between the receptor-stimulator magnet (RS) and three predetermined anatomical points: the tip of the mastoid apophysis (M), the tragus (T), and the lateral corner of the eye (E). A millimeter (mm) tape measure was used for measurements in the immediate postoperative period and at 1, 3, 6, and 12 months after surgery. Results: The mean measurements of the distances from the device to the M, T, and E in the immediate postoperative period were 98.23 mm ± 10.12 (mean ± SD), 96.48 mm ±10.62, and 142.52 mm ±10.36, respectively. The progression of RS positioning showed that migration occurred up to 3 months postoperatively, highlighting the measurement between RS and M, which presented a statistically significant variation between the first and third measurements. Measurements performed 3–12 months postoperatively showed no statistically significant variation. Discussion: The objective serial measurements performed in the present study showed the progression of RS migration, which was not statistically significant 3 months after implantation. Conclusion: The results of this study corroborate the literature: the bony bed technique without sutures provides stability to the device, consequently preventing its migration.

Keywords: cochlear implant; receptor-stimulator migration; bony bed; suture; surgery; hearing loss; acoustic amplification; fixation methods

Introduction

Cochlear implant (CI) surgery has become the standard treatment for patients with severe to profound sensorineural hearing loss who present little or no benefit from acoustic amplification. The mode of receptor-stimulator (RS) fixation has advanced over time but is still not standardized. Fixation methods have been investigated to achieve better surgical results. The main objective of this step is to avoid RS migration and possible complications. The surgeon should consider the final position of the device as below the scalp as a protruding device is more prone to trauma, especially in children; the surgeon should also consider the influence of coupling with the external receptor (Cuda, 2013).

Internal device migration is associated with local infection, exposure to electrode wires, displacement of electrodes inserted into the cochlea, and implant extrusion (Jethanamest et al., 2014). RS migration is a CI complication that has not been explored in the literature but has recently become a subject of interest (Markodimitraki et al., 2020).

Several techniques have been described in the literature, including the use of heterologous materials for fixation, such as polypropylene mesh and screws, on the bony bed, as well as techniques that do not use a bony bed, making only a subperiosteal fixation pocket, as shown by Alexander et al. (2011).

Studies on the most suitable RS fixation method have been published, but objective device migration measurements are scarce in the literature. The objective of this study was to evaluate RS migration with objective measurements in patients who underwent the bony bed technique without associated heterologous materials.

Materials and methods

Ethical aspects

This study was approved by the Research Ethics Committee of the Hospital for Rehabilitation of Craniofacial Anomalies of the University of São Paulo (*Universidade*

de São Paulo, USP). Participants older than 18 years signed an informed consent form (ICF), and patients younger than 18 years signed an assent form, which was associated with the ICF signed by their guardians.

Sample selection and characteristics

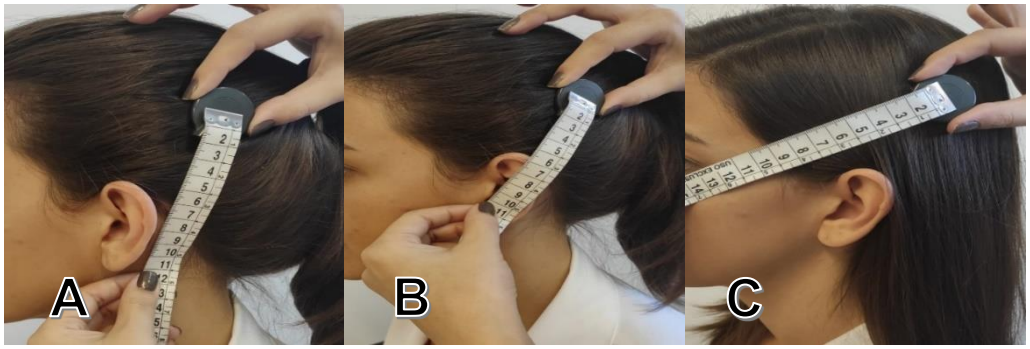
This prospective observational study included patients who underwent CI surgery at the Hospital for Rehabilitation of Craniofacial Anomalies at the University of São Paulo from November 2018 to July 2019. The study included patients of both sexes, aged between 12 months and 60 years. Only patients who underwent primary implantation surgery were included in the study.

Procedure

Standardized surgeries were performed by a team of three surgeons, and the authors were not one of them. The devices used were manufactured by Cochlear® (Sydney, Australia), Advanced Bionics® (Valencia, California, USA), and Med-El® (Innsbruck, Austria), the three brands available at the service where the study was conducted.

The data collected refer to the distance between the RS magnet and three predetermined anatomical points: the tip of the mastoid apophysis (M), the tragus (T), and the lateral corner of the ipsilateral eye (E) **(Figure 2),** the same points used by Güldiken et al. (2017). A millimeter tape measure was used for measurements in the immediate postoperative period and at 1, 3, 6, and 12 months after surgery. An external magnet was used to locate the internal magnet. These distances were compared during postoperative follow-up to identify possible device migration. Head circumference measurements were also recorded to adjust the cranial growth of the children to the distances from the reference points.

Figure 2 - Anatomical points for measuring the position of the receptor-stimulator (RS) magnet. A) RS magnet to mastoid apophysis; B) RS magnet to tragus; C) RS magnet to the lateral corner of the eye.

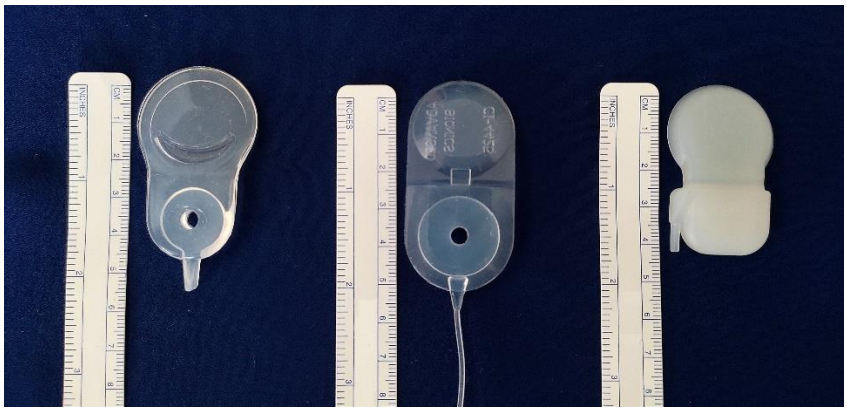


Source: Prepared by the author

Surgical technique

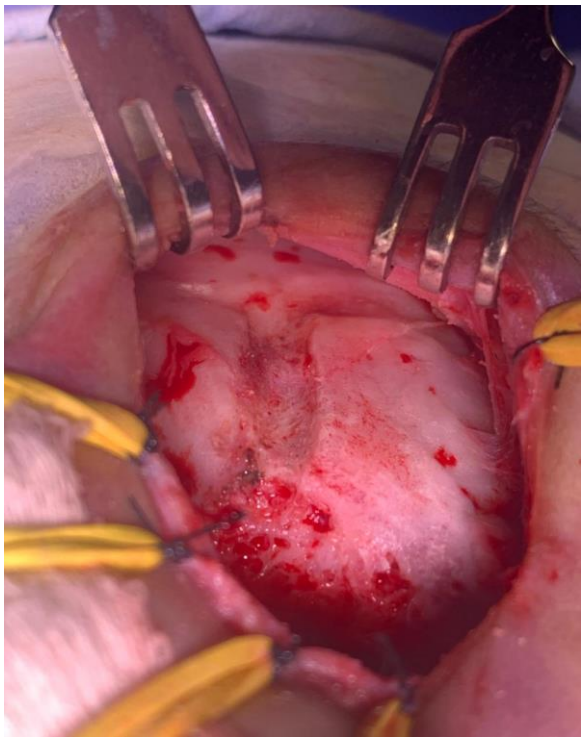
The surgical technique used by the team of surgeons was standardized, with a 4-cm linear retro-auricular skin incision creating a linear muscle-periosteal flap with exposure of the mastoid cortex. Subsequently, mastoidectomy and posterior tympanotomy were performed. Using a Freer periosteal elevator, a posterior subperiosteal pocket was created and sized using an implant RS surgical template **(Figure 3).** A 2-mm deep bony bed was then drilled, respecting the limits of the subperiosteal pocket. A 3-mm deep channel was made with a 3-mm diamond drill to accommodate the electrode array, connecting the recess to the mastoid cavity **(Figure 4)**. After the RS was positioned in the recess and the electrodes were inserted into the cochlea, the muscle-periosteal flap was closed using a 3-0 Vicryl® absorbable suture. The retroauricular incision was closed using 3-0 Vicryl® and 4-0 Monocryl®. Impedance and neural response telemetry were performed, and the distances previously described were measured.

Figure 3- Receptor-stimulator surgical templates. Brands: A) Cochlear®, B) Advanced Bionics®, C) Med-El®.



Source: Prepared by the author

Figure 4 - Lower edge of the bony bed and channel.



Source: Prepared by the author

Statistical analysis

A minimum sample size of 50 patients was estimated based on findings by Güldiken et al. (2017), which included an alpha of 5%, test power of 80, and expected variability of

12.34 mm.

Data on the date of surgery, age, sex, surgeon, implant brand, and position of the RS device were collected. Measurements were analyzed using paired t-tests in IBM SPSS Statistics software (version 22.0; Armonk, New York, USA). Statistical significance was set at $p < 0.05$.

Results

A total of 83 CIs were included in the study, which included 74 patients (9 patients with bilateral CI). The ages ranged from 1 to 60 years, including 63 (85.13%) children and adolescents (up to 18 years) and 11 (14.86%) adults. Thirty-three patients (44.59%) were women and 41 (55.4%) were men. One patient was excluded during the data collection period because of extrusion of the internal device, requiring explantation 2 months after surgery.

Devices from three main CI manufacturers were used: 61 (73.49%) from Advanced Bionics®, 14 (16.86%) from Med-El®, and 8 (9.63%) from Cochlear Corporation®.

Head circumference was analyzed over the 12-month follow-up period; 17 patients (22.9%) presented with head growth (not statistically significant).

The distances from the device to the M, T, and E were analyzed. In the immediate postoperative period (IPO), the mean distance from RS to M was 98.23 ± 10.12 mm (mean ± SD); from RS to T, 96.48 ± 10.62 mm; and from RS to E, 142.52 ± 10.36 mm. One month after surgery, the mean values were 96.34, 95.51, and 140.87, respectively. Three months postoperatively, the mean values were 95.64, 94.69, and 140.35, respectively. Six months after surgery, the mean values were 95.35, 94.12, and 140.04, respectively. Twelve months postoperatively, the mean values were 95.19, 94.28, and 139.67, respectively (Data in **Table 1)**.

Table 1 – Evolution of the means and medians of the distance from the device to the anatomical points

	RECEPTOR TO MASTOID (MM)		**RECEPTOR TO TRAGUS (MM)**		**RECEPTOR TO EYE (MM)**	
Measurement	Mean ± SD	Median (Interval)	Mean ± SD	Median (Interval)	Mean ± SD	Median (Interval)
Immediate Postop.	98.23 ± 10.12	98 (94 - 103)	96.48 ± 10.62	96 (89 - 98)	142.52 ± 10.36	143 (138 - 147)
After 1 month	96.34 ± 9.43	96 (94 - 104)	95.51 ± 9.93	95 (93 - 102)	140.87 ± 9.997	140 (131 - 142)
After 3 months	95.64 ± 9.51	95 (94 - 104)	94.69 ± 10.2	95 (86 - 96)	140.35 ± 10.13	140 (138 - 147)
After 6 months	95.35 ± 10.14	95 (88 - 97)	94.12 ± 10.6	95 (86 - 96)	140.04 ± 10.03	140 (134 - 144)
After 12 months	95.19 ± 10.31	95 (89 - 98)	94.28 ± 10.72	95 (86 - 96)	139.67 ± 9.78	140 (134 - 144)

SD: Standard Deviation

Source: Prepared by the author

Mean values were compared between IPO and 1 month after surgery, 1 and 3 months after surgery, 3 and 6 months after surgery, and 6 and 12 months after surgery **(Table 2).**

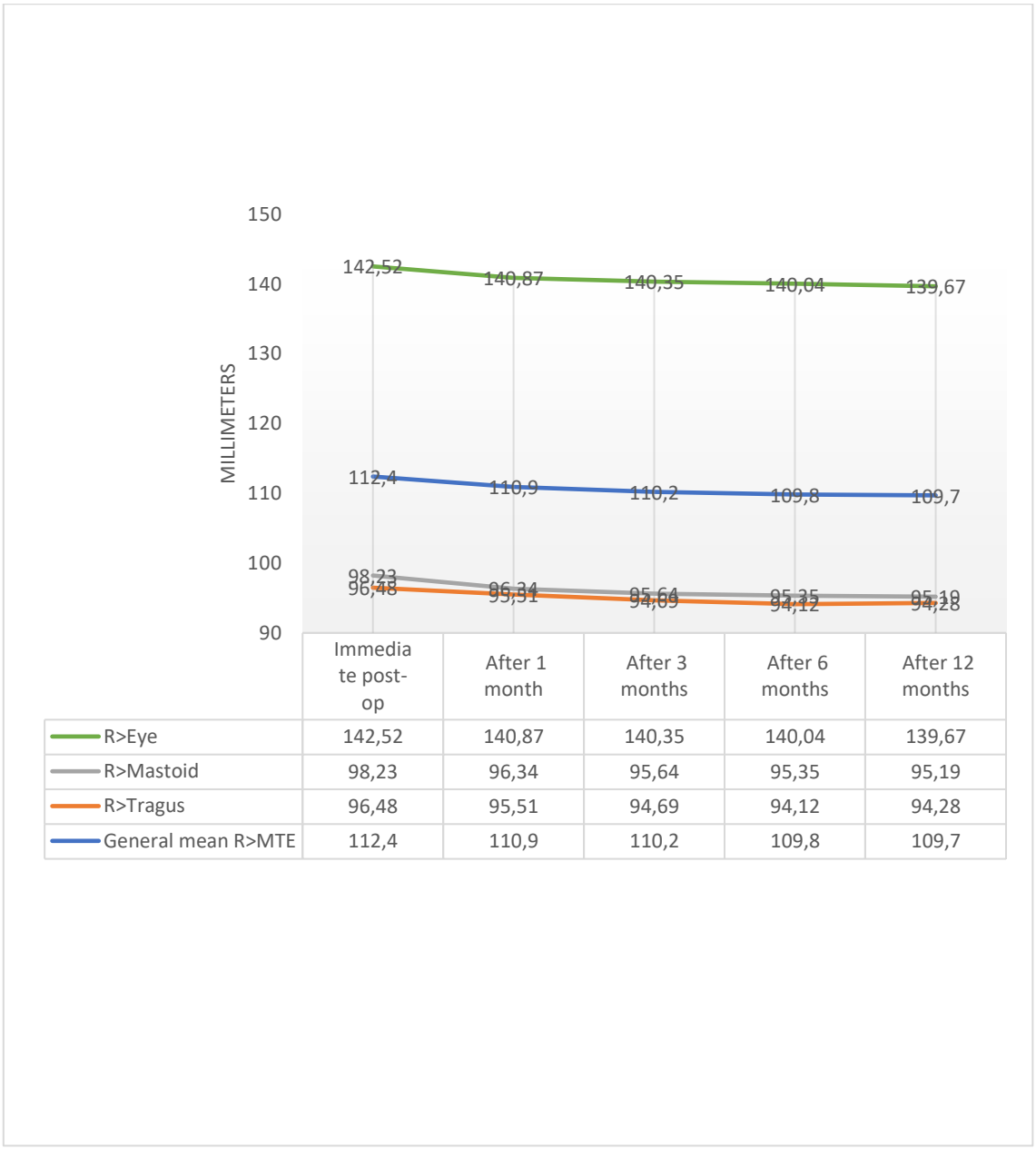
The distance between M and RS showed statistically significant migration until the first postoperative month ($p = 0.002$) and between the first and the third postoperative month ($p = 0.046$). The distance between T and RS showed statistically significant migration between the first and third postoperative months ($p = 0.022$). The distance between E and RS showed statistically significant migration only until the first postoperative month ($p = 0.003$) **(Table 2)**. The progression of measurements in each anatomical point is presented in **Figure 5**.

Table 2 – Migration between periods

			Analysis (P=0.05)	
MEASUREMENT	**COMPARISON**		**P-VALUE**	RESULT
Mastoid	Immediate post-op	After 1 month	0.002	There is a statistically significant difference between groups
	After 1 month	After 3 months	0.046	There is a statistically significant difference between groups
	After 3 months	After 6 months	0.194	There is no statistically significant difference between groups
	After 6 months	After 12 months	0.338	There is no statistically significant difference between groups
Tragus	Immediate post-op	After 1 month	0.062	There is no statistically significant difference between groups
	After 1 month	After 3 months	0.022	There is a statistically significant difference between groups
	After 3 months	After 6 months	0.055	There is no statistically significant difference between groups
	After 6 months	After 12 months	0.650	There is no statistically significant difference between groups
Eye	Immediate post-op	After 1 month	0.003	There is a statistically significant difference between groups
	After 1 month	After 3 months	0.084	There is no statistically significant difference between groups
	After 3 months	After 6 months	0.149	There is no statistically significant difference between groups
	After 6 months	After 12 months	0.078	There is no statistically significant difference between groups

Source: Prepared by the author

Figure 5 - Migration analysis - Mean between periods by measurement point and their general means.



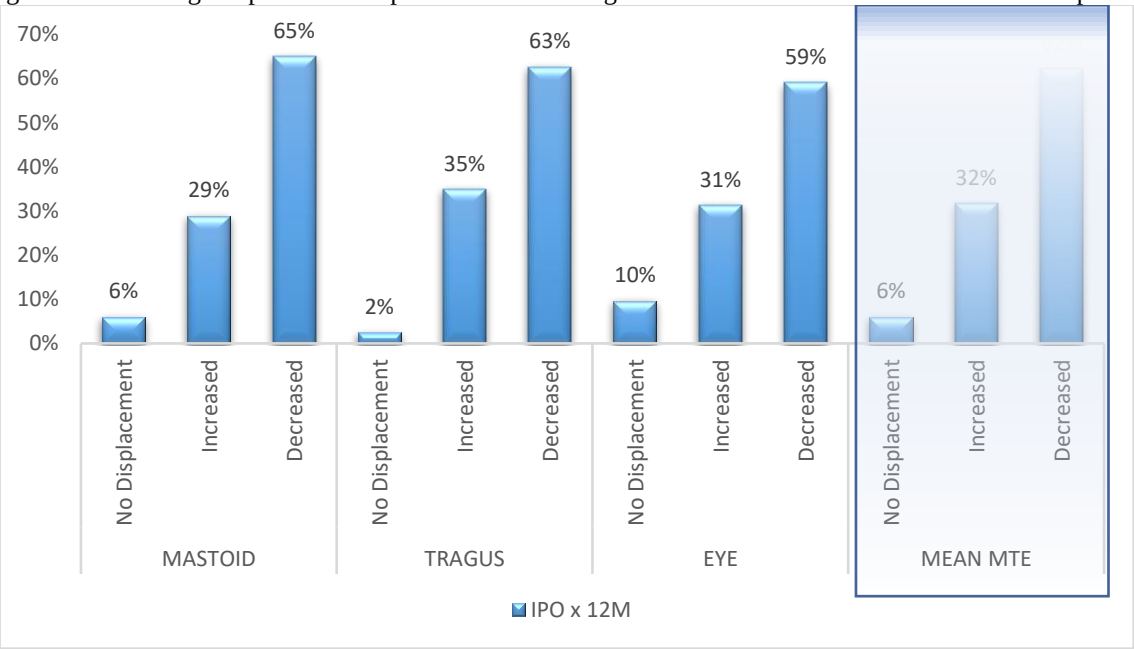
	Immediate post-op	After 1 month	After 3 months	After 6 months	After 12 months
R>Eye	142,52	140,87	140,35	140,04	139,67
R>Mastoid	98,23	96,34	95,64	95,35	95,19
R>Tragus	96,48	95,51	94,69	94,12	94,28
General mean R>MTE	112,4	110,9	110,2	109,8	109,7

Source: Prepared by the author

The progression of RS positioning showed that migration occurred up to 3 months postoperatively, highlighting the measurement between RS and M, which presented a statistically significant variation from the first to the third measurement. Measurements performed 3–12 months postoperatively showed no statistically significant variation.

The mean displacement between the three reference points (M, T, and E) after 12 months of follow-up showed that 52 cases (62%) had a decrease from the initial distance, which means that there was movement toward the ear, and 26 cases (32%) had an increase in relation to the initial distance, moving away from the ear. In five cases (6%), there was no migration. **(Figure 6)**. Of the cases with migration, 43 (55.1%) were >5 mm and the remaining cases (35- 44.8%) were <5 mm.

Figure 6 - Percentage of patients who presented device migration-decrease or increase from the initial point



Source: Prepared by the author

Discussion

The existing literature evidences the lack of consensus on the most appropriate technique for fixing CI RS. Current studies have reported no device migration with the techniques described, but objective descriptions of device positioning and follow-up are scarce.

This study sought objective measurements from the initial device positioning with follow-up on predetermined dates to detect displacement progression.

A study of 137 cases of CI using a subperiosteal surgical technique prospectively analyzed RS migrations using a ruler. The authors found migration greater than 1 cm in 11 patients (8%); two of the migrations were greater than 2 cm. Of these 11 patients, six showed clinical evidence of migration, and the other five had migration detected only with objective measurements. The authors did not consider migrations smaller than 1 cm. Follow-up was performed for 6 weeks postoperatively (Monksfield et al., 2012).

Similar to Monksfield et al., Maxwell and Cass (2019) used the subperiosteal technique and reported that almost all displacements found in their study were not clinically noticeable unless measured. They found 25,9% of device migration up to 6 months postoperatively and 19.4% after 6 months. The measurements were collected objectively with a tape measure, with only one distance measured between the RS magnet and the ear. A limitation of this study was its retrospective nature, with data collected from medical records presenting no standardized postoperative periods in patients with late displacements (Maxwell & Cass, 2019). Compared with the current study, the displacements were divided into greater or less than 5 mm. Of the cases with displacement, 43 (55.1%) were >5 mm and 35 (44.8%) were <5 mm. Regardless of the migration value, such movements were only noticed through objective measurements; there were no changes in clinical observations.

A study by Güldiken et al. (2017) used the subperiosteal pocket surgical technique and evaluated RS displacement with objective measurements in a pediatric population, reporting no statistically significant difference between device positions during surgery and after 6 months. This study was limited by the small sample size (32 patients) and the short postoperative follow-up. The results of the current study were similar, but statistically significant displacements were found, highlighting that measurements in the

present study were collected during surgery and 1, 3, 6, and 12 months after the operation, allowing a more detailed analysis of displacements (Güldiken et al., 2017).

A comparative study of surgical techniques by Pamuk et al. (2018) analyzed the bony bed technique with sutures versus the subperiosteal pocket technique to assess surgical revision rates; the bony bed technique group presented a lower revision rate and, therefore, was the technique preferred by the authors. No obvious migration was observed in the groups studied; however, this positioning was not objectively measured. In addition, the data were retrospectively collected.

Other authors assessed migration through clinical observation without objective measurements, including Gekeler et al. (2013), who used the bony bed technique without sutures and analyzed the presence or absence of device migration. They did not detect migration and considered the technique to be safe, simple, and cost effective. On the other hand, Jethanamest et al. (2014) used the subperiosteal pocket technique in 62 patients and evaluated device migration related to interference in the use of the external device. No objective measurements were collected, and migration was evaluated through clinical evidence of displacement using a retrospective analysis. The authors found no evident migration and considered the subperiosteal pocket technique without sutures safe. Such literature supports the idea that migration will not be detected unless it is objectively measured.

As there is currently no validated method to objectively measure RS position and displacement, in 2020 Markodimitraki et al. proposed an objective method to measure RS migration using predefined anatomical reference points, measuring the distance from the center of the device to the corner of the eye, tragus, mastoid angle, and mandible angle. Suspecting that CI internal device migration is an underreported condition, the authors aimed to validate this pilot project as a standardized measurement method.

In a recent systematic review published in 2021, Markodimitraki et al. analyzed the outcomes of seven articles related to RS migration. These studies included CI surgeries using both the bony bed technique and the subperiosteal pocket technique, reporting heterogeneous migration rates ranging from no migration detected to 69% migration. These data show the need for measurement standardization to follow the RS position.

All cited studies used clinical observations to assess displacements and found no differences in this outcome. However, studies that used objective measurements with rulers or positioning analysis through tomography found RS migration. It is worth emphasizing that current studies in the literature present samples of different sizes and characteristics and do not follow any patterns for comparison.

Several previous studies, with the exception of Monksfield et al. (2012), Dees et al. (2018), Güldiken et al. (2017), Maxwell & Cass (2019), reported displacements based on clinical evidence of migration in addition to analyzing short follow-up periods. In the present study, serial objective measurements made it possible to monitor displacements in detail and note that 3 months after surgery, these migrations were not statistically significant; however, they continue to occur and must be monitored.

Limitations of this study include being a prospective study with no specific control group and no comparison with other fixation techniques, therefore our results should not be generalized to techniques without a bony bed. Future studies could include additional analysis with comparisons of different techniques and regular objective measurement acquisitions. Nevertheless, we see implications of our results, which show that the CI fixation method is adequate. The bony bed technique involves no additional foreign material or lengthy steps that would increase cost or time of surgery. Additionally,

prospective analysis and regular follow-up intervals with recorded receiver-stimulator location measurements were made, making these results more reliable.

Conclusion

In the current study, implant displacements suggest that RS objective positioning could be a useful monitoring parameter during postoperative follow-up. Further, the results of this study corroborate the literature: the bony bed technique without sutures provides stability to the device, consequently preventing its migration and associated complications.

Acknowledgements

The authors would especially like to thank Juliane Cândido Henrique for her help with the statistical analysis and the entire team of professionals at the Hospital for Rehabilitation of Craniofacial Anomalies who collaborated to carry out this study, especially to Marina Matuella e Guilherme Trindade Batistão.

Disclosure

The authors report there are no competing interests to declare.

Data availability

The datasets generated for this study are available on request to the corresponding author.

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4 Final Considerations

4 FINAL CONSIDERATIONS

1. The bony bed technique without sutures provides stability to the device.
2. Serial objective measurements made it possible to monitor RS displacements in details.
3. Until 3 months after surgery, there are statistically significant displacements that wouldn't be noted if they weren't measured.
4. Three months after surgery, these migrations were not statistically significant; however, they continue to occur and must be monitored.
5. The methodology we use can be used in future studies and could include additional analysis with comparisons of different techniques.

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Appendix

APPENDIX A

DECLARATION OF EXCLUSIVE USE OF THE ARTICLE IN DISSERTATION/THESIS

We hereby declare that we are aware of the article **(Evaluation of cochlear implant receptor-stimulator migration using the bony bed technique without sutures: Objective measurements)** will be included in Dissertation of the student Letícia Alves da Fonseca Aguera Nunes were not used and may not be used in other works of Graduate Programs at Bauru School of Dentistry/ University of São Paulo.

Bauru, April 20th 2022

Luiz Fernando Manzoni Lourençone

Author

Signature

Alessandra Mazzo

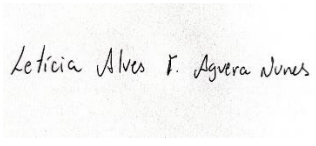
Author

Signature

Rubens Vuono de Brito Neto

Author

Signature



Letícia Alves da Fonseca Aguera Nunes

Author

Anexxes

ANNEX A - INFORMED CONSENT FORM

HOSPITAL DE REABILITAÇÃO DE ANOMALIAS CRANIOFACIAIS
UNIVERSIDADE DE SÃO PAULO

SEÇÃO SE IMPLANTE COCLEAR

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Convido o paciente _____- _____ ou os pais/responsáveis pelo menor _____- _____ para participação no estudo denominado “Avaliação do deslocamento do receptor-estimulador do implante coclear utilizando técnica com nicho ósseo sem suturas".

Este estudo será realizado no Hospital de Reabilitação de Anomalias Craniofaciais da Universidade de São Paulo e consiste na medida do posicionamento do componente interno do implante coclear, em pacientes submetidos à cirurgia de implante coclear neste serviço, com o objetivo de identificar possíveis deslocamentos do mesmo. É importante a detecção de mudanças na posição do dispositivo, já que existem relatos de complicações, como por exemplo a falha do funcionamento dos eletrodos do implante devido a deslocamentos.

Durante a pesquisa será feita a medição, com o uso de uma régua, da distância entre o dispositivo que fica abaixo do couro cabeludo e pontos de referência, sendo estes o canto lateral do olho, o tragus (estrutura da orelha externa) e a ponta da mastoide (osso atrás do pavilhão auricular).

Estas medidas serão analisadas para checar se há deslocamentos no dispositivo interno do implante coclear quando é usada técnica cirúrgica que confecciona uma “cama” no osso temporal do crânio, onde é alojado o este componente do implante.

Estas medições serão feitas logo após a cirurgia de implante coclear, com um mês, três meses, seis meses e um ano pós-operatório, datas estas compatíveis com o protocolo de acompanhamento do paciente com implante coclear. Não será necessário comparecimento a este serviço apenas para a

Rubricas:
Participante da pesquisa e/ou responsável legal: _____
Pesquisador Responsável: _____
Pesquisador Responsável: _____

coleta das medidas já citadas, sendo assim, a pesquisa não proporciona despesas adicionais para o participante.

Consideram-se riscos de origem psicológica ou emocional inerentes a esta pesquisa a possibilidade de desconforto durante a coleta das medidas, medo, vergonha, estresse, cansaço ao responder os termos de assentimento e consentimento, sentimento de discriminação em relação à deficiência auditiva. De ordem física e orgânica, consideram-se risco a possibilidade de lesões de pele decorrente do contato da fita métrica ou régua na pele, além de desconforto local. Durante o procedimento não se acrescenta risco cirúrgico adicional, uma vez que o mesmo já é realizado de rotina em nossas cirurgias de implante coclear.

O benefício proposto é a demonstração da estabilidade do receptor-estimulador de IC, com medidas objetivas, possibilitando detectar possíveis deslocamentos que poderá afetar o funcionamento do implante.

A qualquer momento o paciente ou responsável pelo paciente tem plena liberdade de recusar-se a participar ou retirar seu consentimento, em qualquer fase da pesquisa, sem prejuízos no acompanhamento e tratamento neste serviço. Será mantido o sigilo e privacidade dos participantes durante toda a pesquisa.

O participante ou seu responsável receberá uma via do Termo de Consentimento Livre e Esclarecido. Há a garantia de indenização diante de eventuais danos decorrentes da pesquisa.

Em caso de dúvidas sobre a participação na pesquisa ou sobre qualquer procedimento referente a este estudo, poderá ser feito contato com a pesquisadora Letícia Alves da Fonseca Aguera Nunes via e-mail (leticiaaguera@gmail.com) ou via telefone (22 999872350) e para denúncias ou reclamações entrar em contato com o Comitê de ética em Pesquisa- HRAC-USP à Rua Silvio Marchione, 3-20 - Vila Universitária - CEP 17012-900 - Bauru/SP, de segunda à sexta-feira das 8 às 18 h, ou pelo telefone (14) 3235-8421, e-mail: cephrac@usp.br.

Pelo presente instrumento que atende as exigências legais, eu, _____, portador da

Rubricas:
Participante da pesquisa e/ou responsável legal: _____
Pesquisador Responsável: _____
Pesquisador Responsável: _____

cédula de identidade _____, após leitura das informações contidas neste TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO, devidamente explicada pelos profissionais em seus detalhes, não restando quaisquer dúvidas a respeito do lida e explicado, firmo meu consentimento livre e esclarecido concordando com as informações contidas neste documento

Fica claro que, a qualquer momento, o participante da pesquisa pode retirar seu consentimento e deixar de participar do estudo, ciente de que todas as informações prestadas tornar-se-ão confidenciais e guardadas em sigilo profissional.

Por fim, a pesquisadora responsável pelo estudo, compromete-se a cumprir todas as exigências contidas na resolução do CNS/MS n.466 de dezembro de 2012, publicada em 13 de junho de 2013.

Por estar de acordo com o presente termo elaborado em duas vias (uma do participante e uma do pesquisador), assino este documento, que deverá ser rubricado em todas as suas páginas.

Bauru, SP, _____ de _____ de _____.

_____
_____
Assinatura do Participante da Pesquisa Assinatura do Pesquisador(a)

_____
Assinatura do Responsável pelo menor ou legalmente incapaz

(Participante da Pesquisa menor de 18 anos)

Rubricas:
Participante da pesquisa e/ou responsável legal: _____
Pesquisador Responsável: _____
Pesquisador Responsável: _____

ANNEX B - ASSENT FORM

HOSPITAL DE REABILITAÇÃO DE ANOMALIAS CRANIOFACIAIS
UNIVERSIDADE DE SÃO PAULO

SEÇÃO DE IMPLANTE COCLEAR

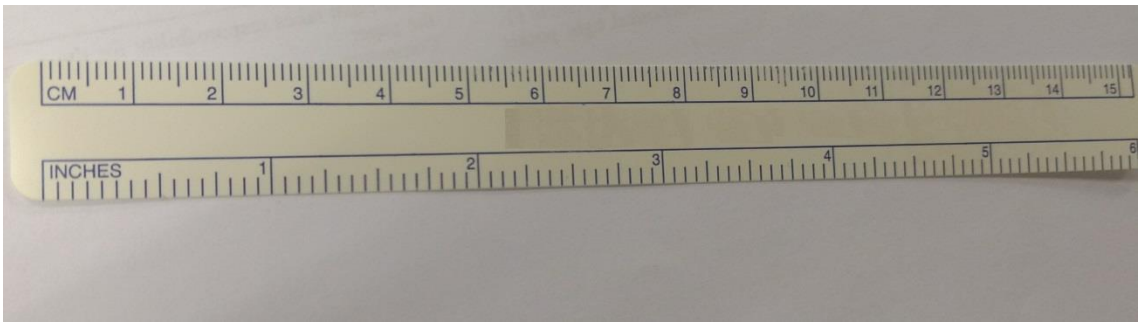
TERMO DE ASSENTIMENTO LIVRE E ESCLARECIDO

Olá, queria convidar você para participar de uma pesquisa para ver o local do seu implante coclear. Ele fica atrás da orelha e queremos ver se ele ficará nesse mesmo lugar.

Seus pais já concordaram com a participação, mas se você não quiser não tem problema, você poderá continuar usando o seu aparelho e vindo aqui nas consultas. Você pode pensar antes de decidir, ou mudar de opinião depois, também sem nenhum problema.

As medidas vão ser feitas aqui mesmo usando uma régua da sua antena do aparelhinho até seu rosto igual o desenho abaixo:

Rubricas:
Participante da pesquisa e/ou responsável legal: _____
Pesquisador Responsável: _____
Pesquisador Responsável: _____



O uso da régua é considerado seguro, mas é possível ocorrer alguma lesão no rosto caso você movimente o rosto durante a medida. Nós tomaremos os devidos cuidados para que isso não ocorra.

Existem também benefícios relacionados à pesquisa como a identificação precoce de algum problema com a localização do seu implante coclear.

Você não terá consultas extras para a pesquisa, pois as medições serão feitas quando vier para as consulta de acompanhamento do implante.

Ninguém saberá que você está participando da pesquisa, não falaremos a outras pessoas nem daremos a estranhos as informações que você nos der. Depois que a pesquisa acabar, os resultados serão informados a você e a seus pais e também poderá ser publicada em uma revista, livro ou conferência, mas sem identificar as crianças que participaram do estudo.

Caso aconteça algo errado, seus pais e você podem nos procurar pelos telefones (0xx14) 3235-8421 do comitê de pesquisa e (0xx22) 99987-2350 da pesquisadora Letícia Alves da Fonseca Aguera Nunes.

Acompanhei a explicação que foi feita à criança/adolescente sobre a pesquisa e o(a) mesmo(a) concordou em participar.

Assinatura dos pais/responsáveis: _____

Assinatura do pesquisador: _____

Data: ...../...../.....

Rubricas:
Participante da pesquisa e/ou responsável legal: _____
Pesquisador Responsável: _____
Pesquisador Responsável: _____

Rubricas:
Participante da pesquisa e/ou responsável legal: _____
Pesquisador Responsável: _____
Pesquisador Responsável: _____

ANNEX C

USP - HOSPITAL DE REABILITAÇÃO DE ANOMALIAS CRANIOFACIAIS

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Avaliação do deslocamento do receptor-estimulador do implante coclear utilizando técnica com nicho ósseo sem suturas

Pesquisador: Letícia Alves da Fonseca Aguera Nunes

Área Temática:

Versão: 1

CAAE: 00986218.9.0000.5441

Instituição Proponente: Hospital de Reabilitação de Anomalias Craniofaciais da USP

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 2.994.197

Apresentação do Projeto:

Trata-se de um projeto de Pesquisa de Atualização com o título "Avaliação do deslocamento do receptor-estimulador do implante coclear utilizando técnica com nicho ósseo sem suturas", de autoria de Leticia Alves da Fonseca Aguerra Nunes sob orientação de Dr. Luiz Fernando Manzoni Lourençone.

Será realizado um estudo prospectivo observacional realizado com pacientes submetidos à cirurgia de implante coclear no Hospital de Reabilitação de Anomalias Craniofaciais da Universidade de São Paulo, no período de novembro de 2018 a fevereiro de 2020. Os pacientes incluídos no estudo serão de ambos os sexos e de qualquer faixa etária, que farão a cirurgia de implante coclear. Estima-se amostra de 50 pacientes. Os dispositivos usados serão fabricados pela Cochlear® (Sidney, Austrália), Advanced Bionics® (Valencia, Califórnia, EUA) e Med-El® (Innsbruck, Austria).

Os dados serão coletados através da medição da posição do receptor-estimulador no momento pós-operatório imediato, com um mês, três meses, seis meses e um ano de pós-operatório. As distâncias avaliadas serão entre o ímã do receptor-estimulador e pontos anatômicos pré determinados, que correspondem ao canto lateral do olho ipsilateral, tragus e ponta da apófise mastoidea. Tais distâncias serão comparadas durante o seguimento pós-operatório visando identificar possíveis deslocamentos do dispositivo. Serão registradas, também, as medidas da circunferência cefálica para adequar o crescimento da cabeça durante a infância às distancias dos pontos de referência. O deslocamento mínimo considerado relevante será de 10 milímetros.

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Continuação do Parecer: 2.994.197

A técnica cirúrgica usada será padronizada com a incisão de pele retroauricular, confecção de retalho de Palva pediculado anteriormente, com exposição do periósteo do osso temporal e incisão periosteal. Então, será realizada a mastoidectomia e timpanotomia posterior antes da confecção do nicho ósseo para o implante. Será feita a elevação do periósteo e posicionamento de um molde na bolsa subperiosteal formada. Definindo-se os limites do molde, será feito o broqueamento ósseo até a completa acomodação do molde dentro do novo espaço formado. É feito um sulco conectando este nicho ósseo à cavidade mastoidea para a acomodação do fio condutor. Será feita, então, a exposição da janela redonda, o receptor-estimulador será posicionado no nicho ósseo e os eletrodos serão inseridos na cóclea. Nesta técnica, não serão feitas suturas para fixação do dispositivo.

Durante o procedimento não se acrescenta risco cirúrgico adicional, uma vez que o nicho ósseo já é realizado de rotina em nossas cirurgias de implante coclear.

Será aplicado o Termo de Consentimento Livre e Esclarecido (TCLE) aos participantes maiores de 18 anos e o Termo de Assentimento para os pacientes menores de 18 anos, associado ao TCLE assinado pelo responsável.

Objetivo da Pesquisa:

Objetivo Primário:

Avaliar o deslocamento do receptor-estimulador em pacientes submetidos à cirurgia de implante coclear com a técnica de fixação com nicho ósseo sem suturas.

Objetivo Secundário:

Quantificar o deslocamento do receptor-estimulador, caso existente, em pacientes submetidos à cirurgia de implante coclear usando a técnica de fixação com nicho ósseo sem suturas.

Avaliação dos Riscos e Benefícios:

Riscos:

Consideram-se riscos de origem psicológica ou emocional inerentes a esta pesquisa a possibilidade de desconforto durante a coleta das medidas, medo, vergonha, estresse, cansaço ao responder os termos de assentimento e consentimento, sentimento de discriminação em relação à deficiência auditiva. De ordem física e orgânica, consideram-se risco a possibilidade de lesões de pele decorrente do contato da fita métrica ou régua na pele, além de desconforto local.

Benefícios:

O benefício proposto é a demonstração da estabilidade do receptor-estimulador de IC, com

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Continuação do Parecer: 2.994.197

medidas objetivas, possibilitando detectar possíveis deslocamentos e consequentes falhas do IC. O seguimento dos participantes favorece a detecção precoce de possíveis alterações e abordagem precoce das mesmas, caso seja necessário.

Comentários e Considerações sobre a Pesquisa:

Trata-se de um estudo estudo prospectivo observacional que se baseia na aplicação de medidas inofensivas e sem qualquer procedimento invasivo. Tais procedimentos não ferem nenhuma norma ética que torne a pesquisa inviável. Por outro lado a pesquisa em questão poderá ajudar futuramente nos tratamentos dos usuários de implante coclear.

Considerações sobre os Termos de apresentação obrigatória:

Carta de encaminhamento;
Formulário HRAC;
Folha de Rosto da Plataforma Brasil;
Termo de Consentimento Livre e Esclarecido;
Termo de Assentimento;
Termo de Compromisso, Confidencialidade e Autorização de Utilização de Dados em Projetos de Pesquisa
Termo de Permissão para uso de Registros para Fins Científicos;
Termo de Compromisso de Tornar Públicos os Resultados da Pesquisa e Destinação de Materiais ou Dados Coletados;
Termo de Compromisso do Pesquisador Responsável.

Recomendações:

No TCLE:

- Corrigir "Seção Se Implante Coclear" por Seção De Implante Coclear"

- No parágrafo 11 corrigir a frase: "....não restando quaisquer dúvidas a respeito do LIDA e explicado...."

Conclusões ou Pendências e Lista de Inadequações:

Sugiro ao CEP aprovação do projeto.

Considerações Finais a critério do CEP:

O pesquisador deve atentar que o projeto de pesquisa aprovado por este CEP refere-se ao protocolo submetido para avaliação. Portanto, conforme a Resolução CNS 466/12, o pesquisador é

USP - HOSPITAL DE REABILITAÇÃO DE ANOMALIAS CRANIOFACIAIS

Continuação do Parecer: 2.994.197

responsável por "desenvolver o projeto conforme delineado", se caso houver alterações nesse projeto, este CEP deverá ser comunicado em emenda via Plataforma Brasil, para nova avaliação.

Cabe ao pesquisador notificar via Plataforma Brasil o relatório final para avaliação. Os Termos de Consentimento Livre e Esclarecidos e/ou outros Termos obrigatórios assinados pelos participantes da pesquisa deverão ser entregues ao CEP. Os relatórios semestrais devem ser notificados quando solicitados no parecer.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Outros	ChecklistLeticiaNunes77_2018.docx	21/10/2018 15:15:30	Renata Paciello Yamashita	Aceito
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1220538.pdf	11/10/2018 17:59:19		Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.docx	11/10/2018 17:56:40	Letícia Alves da Fonseca Aguera Nunes	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	Termo_de_Assentimento_13_a_18_anos.docx	11/10/2018 17:56:28	Letícia Alves da Fonseca Aguera Nunes	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	Termo_de_Assentimento_6_12_anos.docx	11/10/2018 17:56:12	Letícia Alves da Fonseca Aguera Nunes	Aceito
Outros	Term_Perm_Uso_Registro.pdf	11/10/2018 17:34:09	Letícia Alves da Fonseca Aguera Nunes	Aceito
Projeto Detalhado / Brochura Investigador	Projeto_Pesquisa.docx	11/10/2018 16:54:03	Letícia Alves da Fonseca Aguera Nunes	Aceito
Cronograma	CRONOGRAMA_DO_PROJETO.docx	11/10/2018 12:44:11	Letícia Alves da Fonseca Aguera Nunes	Aceito
Outros	Term_Comp_Tornar_Publico_Dest_Mat.pdf	04/10/2018 20:48:25	Letícia Alves da Fonseca Aguera Nunes	Aceito
Outros	Term_Comp_Confid_Autor_Dados.pdf	04/10/2018 20:46:32	Letícia Alves da Fonseca Aguera Nunes	Aceito
Outros	Formulario_Cadastro_HRAC.pdf	04/10/2018 20:44:02	Letícia Alves da Fonseca Aguera	Aceito

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Continuação do Parecer: 2.994.197

Outros	Formulario_Cadastro_HRAC.pdf	04/10/2018 20:44:02	Nunes	Aceito
Outros	Carta_Encaminhamento.pdf	04/10/2018 20:42:15	Letícia Alves da Fonseca Aguera Nunes	Aceito
Orçamento	Orcamento.docx	04/10/2018 20:39:49	Letícia Alves da Fonseca Aguera Nunes	Aceito
Declaração de Pesquisadores	Term_Comp_Pesq_Resp.pdf	04/10/2018 20:37:30	Letícia Alves da Fonseca Aguera Nunes	Aceito
Folha de Rosto	Folha_Rosto.pdf	04/10/2018 20:24:36	Letícia Alves da Fonseca Aguera Nunes	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

BAURU, 31 de Outubro de 2018

Assinado por:
Renata Paciello Yamashita
(Coordenador(a))