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Original Article

Thermal Characteristics of Different Types of Cochlear Implants in Pediatric Cochlear Implant Users: A Comparative Digital-Infrared Thermal Imaging Analysis

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BACKGROUND: This study aimed to evaluate thermal characteristics of different types of pediatric cochlear implants

METHODS: A total of 39 pediatric patients using Med-El (Synchrony®), Cochlear (Nucleus®), or Advanced Bionics (HiRes 90K®) type of cochlear implants were included. A digital infrared thermal imaging analysis was performed to measure the heating over the implant and the tissue heating of the skin below and around the device, while skin thickness and visual analog scale scores were also recorded.

RESULTS: Over the implant, heating values were significantly higher in the on-mode vs. off-mode of device for each type of implant (P ranged from <.05 to <.001). The implants groups were similar in terms of skin thickness, visual analog scale scores, on-mode values for heating over the implant, and the heating of the skin (below or around the device; <36°C for each), while the off-mode values for heating over the implant were significantly higher in the Med-El (Synchrony®) implants compared to other implants (median 31.75 vs. 31.30 and 30.20°C, $P = .001$). Skin thickness was negatively correlated with the heating over the implant (off-mode, $r = -0.708$, $P < .001$) and heating of the skin (around the device, $r = -0.479$, $P = .028$) in Advanced Bionics (HiRes 90K®) implants.

CONCLUSION: Our findings emphasize that there is no hazard or discomfort from a cochlear implant in terms of heating of skin and no significant difference between 3 implant types in terms of skin thickness or tissue heating, whereas indicate the increased likelihood of thermal characteristics of implant to differ with respect to skin thickness in Advanced Bionics (HiRes 90K®) users.

KEYWORDS: Cochlear implant, heating, over the implant, tissue heating, skin, infrared thermal imaging analysis

INTRODUCTION

Unilateral or bilateral cochlear implantation is considered a well-defined and safe surgical procedure for hearing rehabilitation of patients who have severe to profound sensorineural hearing loss and demonstrate limited benefit from conventional hearing aids.[1-3] Owing to extension of the indications for cochlear implantation and the safety and efficacy of this modality of hearing rehabilitation, there has been a significant increase in the number of implanted patients all over the world, including the pediatric patients.[1,2,4-6]

Introduction of improved surgical techniques with use of smaller incisions and miniaturized and biocompatible implants enabled a remarkable decrease in the global complication rate (from 39% to 9%) after cochlear implantation.[4-7]

Cochlear implant transmitter coils emit radiofrequency (RF) energy to the head, similar to mobile phones;[8] RF is a form of electromagnetic energy that induces dermal heating and collagen shrinkage with a subsequent contraction resulting in tissue tightening.[9] However, most of the studies investigated the complications associated with either the surgical technique or implantation of a foreign body or device failure, with limited data on the possible tissue effects of RF on skin, despite the likelihood of chronic electromagnetic energy exposure to cause an increase in skin temperature over the implant.[2,8]

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In addition, while the skin overlying a cochlear implant protects from external damage and infection,[2] the skin damage and related discomfort, pain, or thermal sensations may also occur in cochlear implant users via skin contact with surfaces beyond the moderate temperature (5°C and 40°C).[10]

Infrared thermography is a safe, noncontact, and noninvasive digital infrared thermal imaging method widely applied in clinical practice being based on assessment the skin heat pattern due to heat vibration as recorded in the form of thermographic images.[11,12]

As the cochlear implant technology is indicated in increasingly young patients,[1] this study aimed to provide real-life data on thermal characteristics (heating of device during on and off modes and skin tissue heating below and around the device) of the different types of implants via digital infrared thermal imaging analysis in pediatric cochlear implant users.

METHODS

Study Population

A total of 39 pediatric cochlear implant users who had bilateral (n = 27) or unilateral (n = 12) cochlear implants for at least 1 year were included in this study. Being 4-14 years of age and using 1 of the 3 types of cochlear implants including Med-El (Synchrony®), Cochlear (Nucleus®), and Advanced Bionics (HiRes 90K®) were the inclusion criteria of the study.

Written informed consent was obtained from parent/legal guardian of each patient following a detailed explanation of the objectives and protocol. The study was conducted in accordance with the ethical principles stated in the "Declaration of Helsinki" and approved by the Istanbul Training and Research Hospital Clinical Research Ethics Committee (Date of approval: April 16, 2021, Protocol No: 2806).

MAIN POINTS

- This study evaluated the heat changes over the implant during off- and on-modes and the tissue heating of the skin below (under the external processor) and around (on-mode) the device via digital infrared thermal imaging analysis in pediatric cochlear implant users
- A significant increase was noted in heating over the implant from off-mode to on-mode (for 8 hours) of device for each type of implants, while the off-mode values for heating over the implant were significantly higher in the Med-El (Synchrony®) implants
- The skin temperature measured below and around the device was similar in each device and below 36°C, along with similarly low visual analog scale scores reported by implant users regardless of the type of implant.
- The skin thickness was not correlated with heating over the implant (on-mode or off-mode) or heating of the skin (below or around the device) in Med-El (Synchrony®) and Cochlear (Nucleus®) implants, whereas in Advanced Bionics (HiRes 90K®) implants, skin thickness was negatively correlated with the heating over the implant (off-mode) and the heating of the skin around the device.
- Our findings emphasize that there is no hazard or discomfort from a cochlear implant in terms of heating of skin and no significant difference between 3 implant types in terms of skin thickness or tissue heating, whereas indicate the increased likelihood of thermal characteristics of implant to differ with respect to skin thickness in Advanced Bionics (HiRes 90K®) users

Implantation Surgery

All surgeries were performed by the same surgeon experienced in cochlear implantation using a standard surgery procedure and subperiosteal pocket technique for subcutaneous placement of internal processor. The hair on the area of implantation on the temporoparietal scalp is cut. Then, 50% diluted lidocaine with adrenaline (2%) is infiltrated to the surgical zone 10 minutes before the operation. The location of the implant is marked at the intersection of 2 lines, one marked between the temporoparietal line on the superior side and the lambdoidal suture on the inferior side and the other drawn at a 45° angle. A small vertical skin incision is made 2 cm away from the retro-auricular sulcus. The flap is elevated anteriorly on the avascular plane up to the external ear canal. The periosteal incisions are performed superiorly at the level of the superior temporoparietal line and inferiorly at the mastoid tip, and both incisions are united anterior to the skin incision. The superior incision is extended approximately 1 cm posterior. Anterior-based Palva flap is elevated up to the external ear canal. Using a Freer elevator, a pocket is created, which is approximately 5 mm wider than the marked skin area, in the subperiosteal plane on the parietal region. In the next step, a classic technique of cortical mastoidectomy and posterior tympanotomy was performed, and a cochleostomy is done after drilling of the round window niche. The internal receiver-stimulator (IRS) is placed into the prepared subperiosteal pocket, and the electrodes are inserted into the cochlea. If a reference electrode is present, it is placed into the temporal area in a subperiosteal plane. The periosteal flap is sutured to shut down cables. The skin incision line lies posterior to the periosteal incision which may result in the exposing of the device. To prevent this complication, overlapping of the 2 suture lines is avoided.

Digital Infrared Thermal Imaging Analysis

A digital infrared thermal imaging analysis was performed via Fluke TiS60 Infrared Camera (Fluke Biomedical, Everett, Washington, USA) to measure the heating over the implant (the part of external processor not contacting with the skin) in on- and off-modes of device and the tissue heating of the skin below (under the external processor) and around (in on mode) the device in cochlear implant users (Figure 1). The 3 types of implants were compared in terms of thermal imaging findings. The measurements during "on mode" of the device were performed after 8 hours of usage.

Skin thickness over the implant was measured via Obagi Skin Pinch test and categorized as thin (<1 cm), normal (1-2 cm), and thick (>2 cm), while visual analog scale (VAS) scores were also recorded in implant users.

Infrared Thermal Imaging Analysis

The infrared thermography evaluation was performed via Fluke TiS60 Infrared Camera, using the general temperature differences (NETDs); 50-Hz sampling rate; optics: germanium lens; f 20; and f/1.5. The camera was positioned at 0.50 m away from the facial region to obtain the maximum spatial resolution. The thermographic images were recorded at a rate of 10 images per second and consequently re-aligned by the use of an edge-detection-based method implemented with an in-house software package. A thermal video

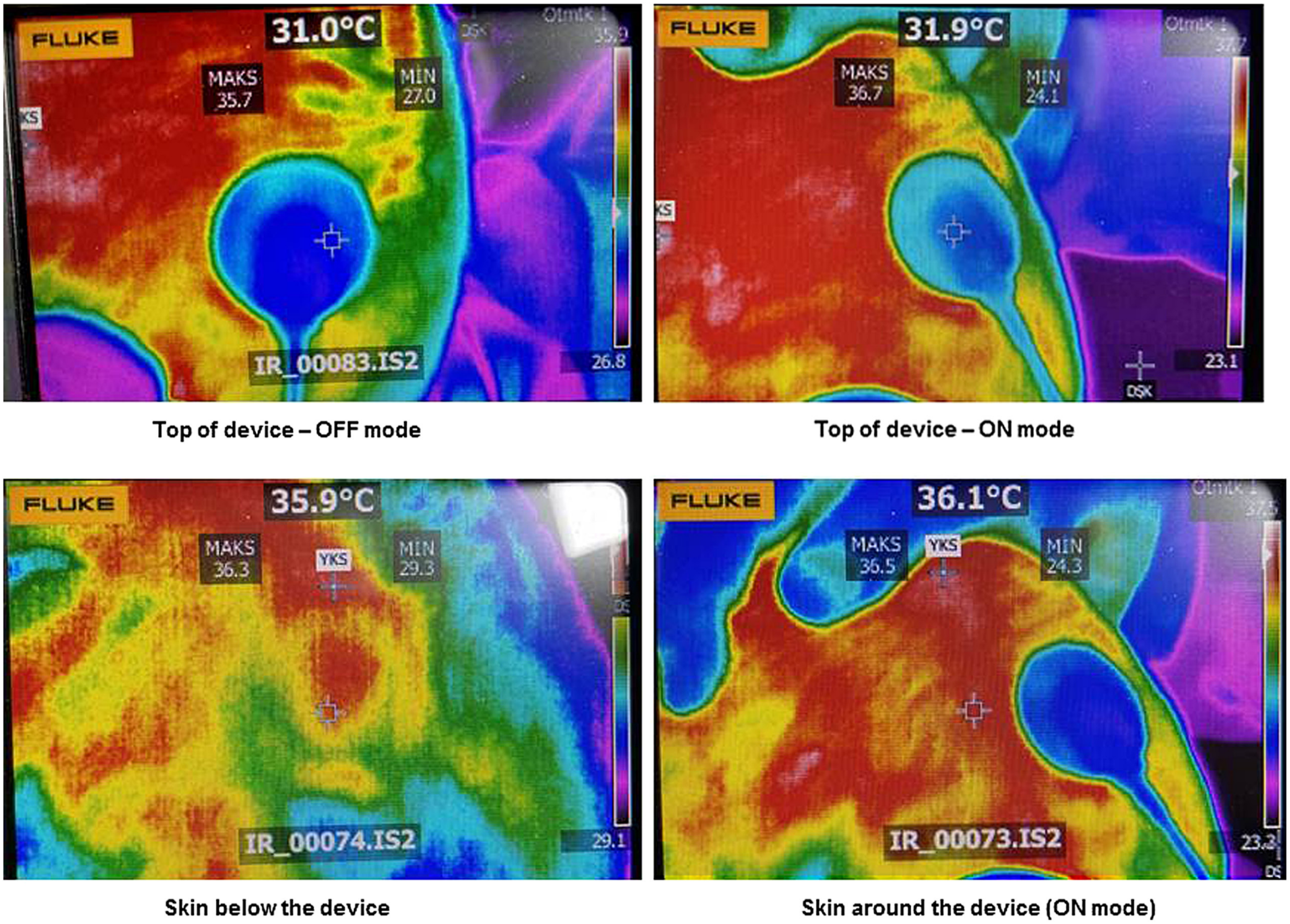

Figure 1. The digital infrared thermal imaging analysis.

was recorded, and the photos were developed via dedicated software. Thermographic data measurements were performed by the software package FLIR QuickReport v.1.2 (FLIR Systems Inc., North Billerica, Mass, USA).

Statistical Analysis

Statistical analysis was made using International Business Machines Statistical Package for the Social Sciences software for Windows, Version 22.0 (IBM Corp., Armonk, NY, USA). Chi-square (χ^2) test was used for the comparison of categorical data. The numerical data were analyzed using Kruskal–Wallis test and repeated measures of ANOVA, while change over time was evaluated by Wilcoxon test. Correlation analysis was performed using Spearman's correlation test. Data were expressed as mean ± standard deviation (SD) and median where appropriate. $P < .05$ was considered statistically significant.

RESULTS

Patient Demographics and Skin Thickness Over the Implant

Mean ± SD patient age was 7.2 ± 2.4 years, and 66.7% of patients were boys. No significant difference was noted between implant types in terms of patient demographics (Table 1).

No significant difference was noted between implant groups in terms of skin thickness over the implant (Table 1).

Heating Over the Implant (On- and Off-Modes) in 3 Brands

For the top of device not contacting the skin, heating values measured during the on-mode of device were significantly higher than off-mode values for Med-El (Synchrony®), Cochlear (Nucleus®), and Advanced Bionics (HiRes 90K®) implants ($P < .05$, $P = .001$, and $P < .001$, respectively) (Table 2 and Figure 2).

The 3 types of implants had similar on-mode values for heating over the implant, while the off-mode values for heating over the implant were significantly higher in the Med-El (Synchrony®) implants compared to Cochlear (Nucleus®) and Advanced Bionics (HiRes 90K®) implants (median 31.75 vs. 31.30 and 30.20°C, $P = .001$) (Table 2).

No significant correlation was noted between skin thickness and heating over the implant during on-mode in any implant. Heating over the implant during off-mode was negatively correlated with skin thickness ($r = -0.708$, $P < .001$) only for the Advanced Bionics (HiRes 90K®) implants (Table 2).

Tissue Heating of the Skin Below (Under the External Processor) and Around (in On-Mode) the Device

No significant difference was noted between 3 types of cochlear implants in terms of heating of the skin below the device (external

Table 1. Patient Demographics and Skin Thickness

	Total (n = 39)	Med-El (Synchrony®) (n = 14)	Cochlear (Nucleus®) (n = 12)	Advanced Bionics (HiRes 90K®) (n = 13)	*P*
Age (year), mean ± SD	7.2 ± 2.4	7.2 ± 2.5	8.2 ± 2.3	6.2 ± 2.0	.100[1]
Gender, n (%)					
Girl	13 (33.3)	4 (28.6)	7 (58.3)	2 (15.4)	.066[2]
Boy	26 (66.7)	10 (71.4)	5 (41.7)	11 (84.6)	
Skin thickness over the implant, n (%)					
Thin (<1 cm)	22 (33.3)	6 (25.0)	8 (38.1)	8 (38.1)	.547[2]
Normal (1-2 cm)	40 (60.6)	16 (66.7)	11 (52.4)	13 (61.9)	
Thick (>2 cm)	4 (6.1)	2 (8.3)	2 (9.5)	0 (0.0)	

[1]ANOVA, [2]χ^2 test.
SD, standard deviation.

processor) or the skin surrounding the device (on-mode). The median recorded values were below 36°C (Table 3).

The skin thickness was not significantly correlated with heating of the skin below the device (external processor) in any type of implants, while the heating of the skin surrounding the device (on-mode) was negatively correlated with skin thickness ($r = -0.479$, $P = .028$) in the Advanced Bionics (HiRes 90K®) implants (Table 3).

Mean VAS scores were 0.17, 0.1, and 0.0 in Med-El (Synchrony®), Cochlear (Nucleus®), and Advanced Bionics (HiRes 90K®) users, respectively, with no significant difference between implant types (Table 3).

No significant correlation was noted between VAS scores and tissue heating of the skin below (under the external processor) and around (in on-mode) the device (Table 3).

DISCUSSION

Our findings revealed a significant increase in heating over the implant (the part with no skin contact) from off-mode to on-mode (for 8 hours) of device for each implant brand studied, while the Med-El (Synchrony®) seems to have the highest off-mode resting temperature than other implants. The skin temperature measured below (under the external processor) and around (in on-mode) the device was similar in each device and below 36°C. Alongside the similar values for the skin thickness over the implant between the implant groups, skin thickness was not correlated with either the heating over the implant (on-mode) or the heating of the skin below the device (external processor) in any type of implant. However, only in the Advanced Bionics (HiRes 90K®) implants, skin thickness was negatively correlated both with the heating of the skin surrounding the device (on-mode) and the heating over the implant (off-mode).

The skin plays a principle homeothermic role in maintenance of internal body temperature at around 37°C.[10] Similar to changes in the whole-body temperature, local heating of skin also causes vasodilation and sweating, given a sufficient response time, while the reaction of skin to contact with hot surfaces may also depend upon the initial condition of the skin.[10] The exposure of human cells to temperatures above around 43°C is considered to induce heat damage if exposure is sufficiently long.[10] Hence, while "safe upper limit" levels for internal body temperature are less than around 38.5°C, for the local skin temperatures, the skin temperature in contact with

Table 2. Heating Measured over the Implant in On- and Off-Modes of the Device and Correlation with Skin Thickness

		Med-El (Synchrony®)	Cochlear (Nucleus®)	Advanced Bionics (HiRes 90K®)	*P*
Heating over the implant (part of external processor not contacting with the skin; °C), mean ± SD (median)					
Off-mode		31.74 ± 1.17 (31.75)	30.76 ± 1.68 (31.30)	30.24 ± 1.03 (30.20)	**.001[1]**
On-mode		32.59 ± 1.27 (32.45)	32.85 ± 1.18 (32.60)	32.39 ± 0.98 (32.40)	.434[1]
P^2		**.005**	**.001**	**<.001**	
Correlation of the skin thickness with "heating over the implant"					
Off-mode	*r*	0.063	-0.298	−0.708	
	P^3	.768	.190	**<.001**	
On-mode	*r*	−0.043	−0.225	−0.381	
	P^3	.842	.327	.088	

[1]ANOVA, [2]Wilcoxon test, [3]Spearman correlation test.
SD, standard deviation.
Values in bold indicate statistical significance ($P < .05$).

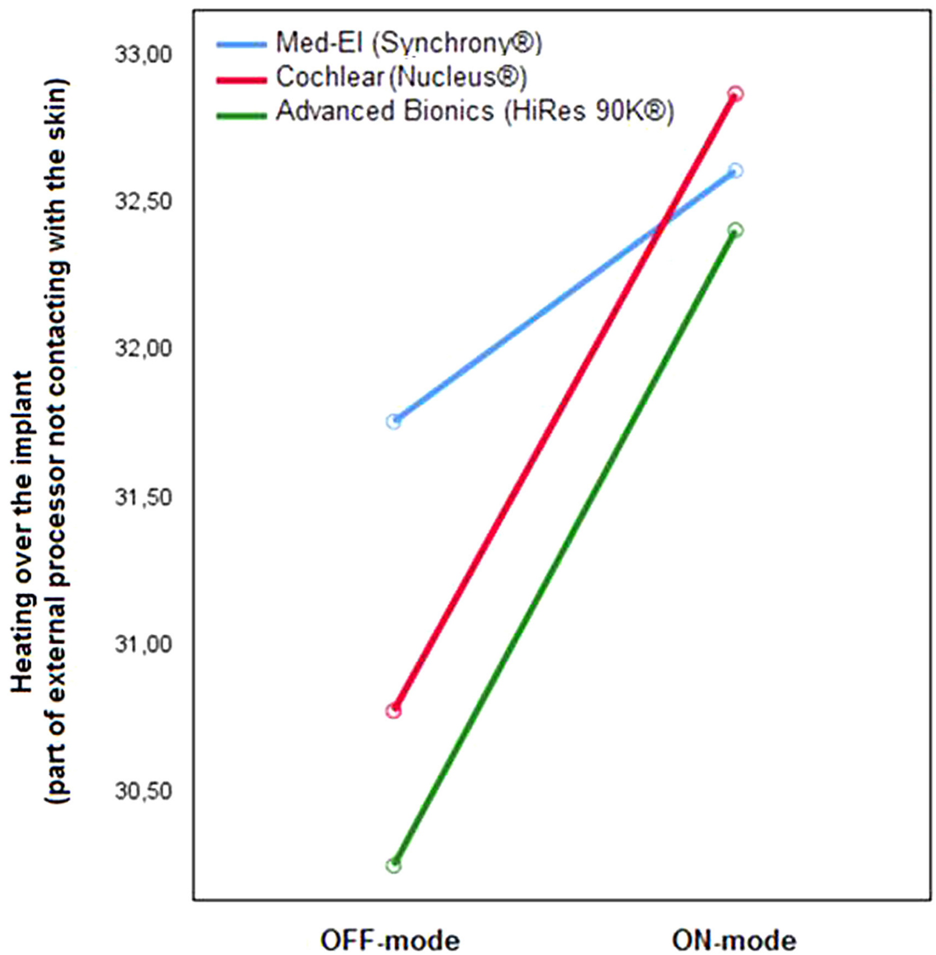

Figure 2. Heating measured over the implant in on- and off-modes of devices.

Table 3. Tissue Heating of the Skin Below (under the External Processor) and Around (in On-Mode) the Device and Correlation with Skin Thickness

		Med-El (Synchrony®)	Cochlear (Nucleus®)	Advanced Bionics (HiRes 90K®)	*P*
Heating of the skin below the device (external processor, °C), mean ± SD (median)		35.73 ± 1.28 (36.00)	35.86 ± 1.37 (35.80)	36.02 ± 1.09 (36.00)	.832[1]
Heating of the skin surrounding the device (on-mode, °C), mean ± SD (median)		35.17 ± 1.86 (35.90)	35.51 ± 1.18 (35.30)	35.14 ± 1.49 (34.90)	.699[1]
Correlation of the skin thickness with "heating of the skin"					
Heating of the skin below the device (external processor, °C)	*r*	−0.238	0.328	−0.431	
	P[2]	.263	.147	.051	
Heating of the skin surrounding the device (on-mode, °C)	*r*	−0.267	0.181	−0.479	
	P[2]	.207	.432	**.028**	
VAS scores during on-mode, mean ± SD		0.17 ± 0.38 (0.00)	0.10 ± 0.30 (0.00)	0.00 ± 0.00 (0.00)	.156[1]
Correlation of the VAS scores with heating of the skin					
Heating of the skin below the device (external processor, °C)	*r*	0.040	0.094	N/A[3]	
	P[2]	.851	.685		
Heating of the skin surrounding the device (on-mode, °C)	r	−0.081	−0.134		
	P[2]	.707	.562		

[1]Kruskal–Wallis test, [2]Spearman Correlation Test, [3]Correlation analysis could not be performed since VAS scores were 0.0 in this group.
VAS, visual analog scale; SD, standard deviation.
Values in bold indicate statistical significance ($P < .05$).

a solid surface <43°C is considered safe to avoid the discomfort and pain sensations with no skin damage.[10] Our findings indicate similarly low VAS scores with each type of implant, along with no significant correlation of VAS scores with the tissue heating of the skin below (under the external processor) and around (in- or on-mode) the device.

In a study investigating the effects of RF on skin, the authors reported an edema-based expansion of the papillary dermis and vascular congestion followed by an increase in the skin thickness, while an increase in cellularity, mucopolysaccharide accumulation, and collagen and elastic fibers were also noted in tissue examination.[13] Hence, given that cochlear implant transmitter coils emit RF energy to the head, chronic electromagnetic energy exposure in cochlear implant users has also been suggested to be associated with an increase in skin temperature over the implant.[2,8] Our findings regarding the skin temperature under the external processors of the device or around the device after 8 hours of on-mode, which was below 36°C for each type of implant, emphasize that there is no hazard or discomfort from a cochlear implant in terms of heating of skin, which seems also lower than the heating found in mobile phones.[8,14]

Nonetheless, it should be noted that skin reaction to contact with a hot solid surface depends upon the rate of heat transfer from the surface to the skin and thus the factors related to the nature of the skin and the surface such as the number of layers, the roughness, wetness/dryness, temperature or cleanness of the surface, specific heat, thermal conductivity, density, and material thickness.[10] In addition, implant surgery technique has also been associated with skin alterations.[15] In the current study, the skin thickness over the implant was in the normal range in most of implant users along with no significant difference between users of different implants in terms of skin thickness. In addition, no significant correlation was noted between the skin thickness and heating over the implant (on-mode) or the heating of the skin below the device (external processor) in any type of implant, while the heating of the skin surrounding the device (on-mode) and the heating over the implant (off-mode) were negatively correlated with skin thickness only in the Advanced Bionics (HiRes 90K®) type of implants.

In a past study with 15 patients who were examined by thermography (the Agema thermovision system) after cochlear implantation, the authors reported no significant alterations in the skin covering the implant and emphasized that while most types of incisions respect the patterns of blood circulation, the retroauricular C-incision may cause problems and postoperative scars can be regarded as places of minor resistance in terms of the blood circulation of the skin above the implant.[15]

Nonetheless, our findings revealed a significant increase in heating over the implant (not contacting with skin) in each device with 8 hours of on-mode, while the Med-El (Synchrony®) seems to have the highest off-mode resting temperature than other implants. The negative correlation of skin thickness with the heating of the skin surrounding the device (on-mode) and the heating over the implant (off-mode) only in the Advanced Bionics (HiRes 90K®) type of implants seem notable given that Advanced Bionics (HiRes 90K®) has the highest stimulation rate (83 000 pulses per second-pps) as compared with Med-El (Synchrony®, 50 704 pps) and Cochlear (Nucleus®, 32 000 pps).[16-19]

Indeed, given that the more marked rise of maximum temperature on the side of the face after 6 minutes of continuous contact with a mobile phone operating in the 900 MHz vs. 835 MHz band (4.5 vs. 2.3°C) and differences in inoperative (−0.7°C), transmitting at full power (+2.6°C) and in stand-by mode (+2.0°C) recordings of skin temperature, direct RF heating of the skin during mobile phone contact is considered to contribute only a small part of the temperature rise, while heat conduction from the handset is the main factors responsible for the temperature rise.[14]

Notably, in a past study investigating the effect of scattered radiofrequency fields in cochlear implant users when these persons are subject to mobile phone type exposure, authors reported that with a 900 MHz half-wave dipole antenna producing continuous wave (CW) 250 mW power, the maximum temperature increase was 0.33°C in skin adjacent to the hook and for the 1800 MHz antenna, operating at 125 mW, the maximum temperature change was 0.16°C.[20] The authors concluded that the effects in the cochlea were insignificant given that the wearer complies with the radiofrequency safety limits for 900-1800 MHz mobile phone type exposure and the resultant temperature increase is well below the maximum rise of 1°C and thus raises no cause for concern.[20]

CONCLUSION

In conclusion, our findings revealed a significant increase in heating over the implant (the part with no skin contact) from off-mode to on-mode (for 8 hours) of device for each type of implants studied. The skin temperature measured below (under the external processor) and around (in on-mode) the device was similar in each device and below 36°C, while VAS scores were also similarly low in implant users. The skin thickness was not correlated with heating over the implant (on-mode or off-mode) or heating of the skin (below or around the device) in Med-El (Synchrony®) and Cochlear (Nucleus®) implants, whereas in Advanced Bionics (HiRes 90K®) implants, skin thickness was negatively correlated with the heating over the implant (off-mode) and the heating of the skin around the device. Hence, our findings emphasize that there is no hazard or discomfort from a cochlear implant in terms of heating of skin and no significant difference between 3 implant types in terms of skin thickness or tissue heating, whereas indicate the increased likelihood of thermal characteristics of implant to differ with respect to skin thickness in Advanced Bionics (HiRes 90K®) users.

Ethics Committee Approval: The study was approved by the Istanbul Training and Research Hospital Clinical Research Ethics Committee (Date of approval: April 16, 2021, Protocol No: 2806).

Informed Consent: Written informed consent was obtained from parent/legal guardian of each patient following a detailed explanation of the objectives and protocol.

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Analysis and/or Interpretation: E.Y., Ok.O, N.S., Oz.O., O.Y / Writing – E.Y.; Critical Review – Ok.O, N.S., Oz.O., O.Y.

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