WEARABLE TECHNOLOGY

https://aber.apacsci.com/index.php/wt/index

2020

Volume 1

Issue 2

ISSN 2810-9783

ISSN 2810-9783

9 772810 978206 02 >

Asia Pacific
Academy of Science Pte. Ltd.

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Volume 1 Issue 2 • 2020

Wearable Technology

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Table of Contents

Editorial

Original Research Article

Case Report

Wearable Technology (2020) Volume 1 Issue 2, *pp.* 1.
doi: 10.54517/wt.v1i2.1679

EDITORIAL

Implants are medical devices designed and manufactured to enhance an existing biological structure, support a damaged biological structure, or even replace a missing one. They are extensively used in surgery around our bodies, such as limbs, ears, mouth, etc.

Prof. Kátia de Freitas Alvarenga from São Paulo University located in Brazil was invited to write an implant-related article for *Wearable Technology*. Her team showed us a story about the function of cochlear implants in hearing impairment caused by Kearns-Sayre syndrome (KSS). The effects of AASI (a kind of individual sound amplification device) were compared in a pair of twin sisters.

Zoila Katherine Salazar Torres and her colleagues tried to determine the prevalence and related factors of permanent pacemaker implantation in adult patients in the cardiology department of José Calasco Artega hospital in 2017, by conducting a randomized cross-sectional study on 422 patients over 18 years old in the cardiology department of "José Carrasco Arteaga" hospital in Cuenca, Ecuador.

What's more, oral implants and calcaneo-stop implants research were also collected in this issue. Implants research in English-speaking developed countries is spread all over the world. Here, we hope to help researchers know more about the implant-related research situation in Spanish-speaking countries.

Managing Editor
Dr. Yina Xu

Wearable Technology (2020) Volume 1 Issue 2, *pp.* 2–6.
doi: 10.54517/wt.v1i2.1657

ORIGINAL RESEARCH ARTICLE

Implantation of permanent pacemakers in Cuenca–Ecuador, from 2017 to 2018

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ABSTRACT

Introduction: In recent years, the placement frequency of permanent pacemakers has increased due to some risk factors, some of which are carried out through cables. **Objective:** To determine the prevalence and related factors of permanent pacemaker implantation in adult patients in the cardiology department of José Calasco Artega hospital in 2017. **Methods:** a randomized cross–sectional study was conducted on 422 patients over 18 years old in the cardiology department of "José Carrasco Arteaga" hospital in Cuenca, Ecuador from January to December 2017. Information is processed in SPSS software version 24. Descriptive statistical analysis based on frequency and percentage was used to measure the statistical correlation with odds ratio (or) within 95% confidence interval. When $p<0.05$, it was considered to be statistically significant. **Results:** The implantation rate of cardiac pacemaker was 7.1%, and the average age was 65.52 years (DS±14.77), mainly male. The risk factors associated with pacemaker implantation were atrioventricular block or 42.56 (95% confidence interval: 16.06–112.73, p=0.000); Sinoatrial node disease or 59.34 (95% CI: 11.67–301.93, P=0.000) and others or 0.017 (95% confidence interval: 0.00–0.05, p=0.000). Atrial fibrillation was not statistically significant or 1.71 (95% confidence interval: 0.62–4.71, p=0.354). **Conclusion:** The prevalence of pacemaker implantation is 7.1%, which is related to atrioventricular block, which is the main risk factor, followed by nodular diseases.

Keywords: pacemaker; prevalence; risk factors

1. Introduction

At present, the use of permanent pacemakers has increased in recent years, secondary to various risk factors, some of which are modicable[1]. This is a medical procedure implemented since the 1950s. At present, it has completely changed the management of some diseases through minimally invasive technology and low complication rate[2].

Unlike developing countries without specific data, the frequency of implementation in developed countries is 200 to 1000 per million inhabitants[3]. Previous studies have shown that the most common cause of implantation is still conduction disorder, of

ARTICLE INFO
Received: April 8, 2020 | Accepted: May 20, 2020 | Available online: June 6, 2020

CITATION
Secaira Neira BE, Espinosa Espinosa HM, Martin LE, et al. Implantation of permanent pacemaker in Cuenca–Ecuador, from 2017 to 2018. Wearable Technology 2020; 1(2): 2–6.

which the most prominent 85% are sinoatrial node dysfunction and complete atrioventricular block[4,5]. In developed countries such as the United States and Europe, the prevalence of pacemaker implantation is 30% to 50%[4]; According to the records of the Spanish Society of Cardiology in 2017, this proportion in Spain is 32.1%, so it is still a globally representative problem[5].

In Ecuador, Dr. Abel Gilbert Ponton of Guayaquil specialized hospital conducted a study. In 2017, Izaguirre S determined 15% of the prevalence of pacemaker implantation through his research[6].

2. Materials and methods

A cross–sectional and retrospective study was conducted by reviewing the clinical history of the AS400 system in José Carrasco Arteaga hospital and collecting information using a form pre- established by the author. The sample consisted of 422 patients over the age of 18, who were randomly selected and met the inclusion criteria.

The information is processed by SPSS version 24 (Windows statistical product and service solution). Descriptive statistics is used for analysis to determine the absolute frequency and percentage. The statistical correlation and odds ratio (or) are measured within the 95% confidence interval. When $p<0.05$, it is considered to be statistically significant.

3. Results

Among the adults treated in the cardiology department of "José Carrasco Arteaga" hospital, the pacemaker implantation rate was 7.1%; 5.2% were carriers and 88.7% were not implanted (**Figure 1**). As for the sociodemographic variables of pacemaker implantation, 266 men (63.0%) were dominant, of which 5.7% were implanted with permanent pacemakers. The average age was 65.52 ± 14.77 years, including 223 elderly (52.9%) and 22 permanent pacemaker implants (5.2%). 322 cases (76.3%) were urban residents. According to marital status, the most common group was 286 (67.8%). The main education was 177 people (41.9%) in primary school, of which 16 (3.85%) received permanent pacemaker implantation. Finally, the most common occupation is 164 retirees (38.9%), of which 19 (4.5%) need to install such equipment. (**Table 1**).

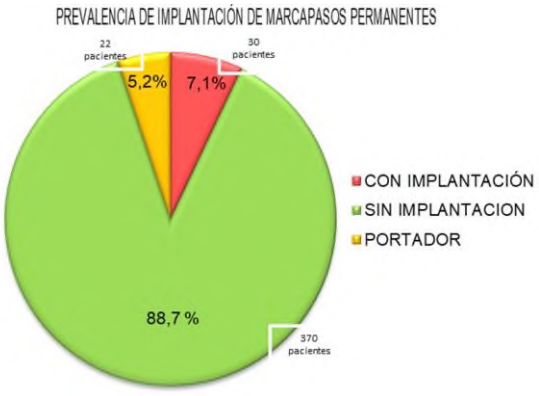

Figure 1. XRD Prevalence of permanent pacemaker implantation. José calasco altega hospital, 2017.
Source: database. Editor: Author

Atrioventricular block and permanent pacemaker implantation or 42.56 (95% confidence interval: 16.06–112.73 $p<0.001$); Sinoatrial node disease or 59.34 (95% confidence interval: 11.66–301936; $P<0.001$). Unlike atrial fibrillation, atrial fibrillation was not statistically significant or: 1.71 (95% confidence interval 0.62–4.71, $P=0.354$). Although according to our study, other categories and our study were interpreted as the protective factor or 0.017 (95% CI 0.00–0.08), this phenomenon only applies to the placement of these devices, not to the progression of cardiac structural diseases (**Table 2**).

Table 1. Prevalence of permanent pacemaker implantation. José Calasco Altega hospital, 2017

Variable	Implantation of yes	Pacemaker not	Carrier	Total	Total
Gender					
Female	6 (1.4%)	145 (34.4%)	5 (1.2%)	156 (37.0%)	0.574
Male	24 (5.7%)	225 (53.3%)	17 (4.0%)	266 (63.0%)	
Age * year					
18–39	0 (0.0%)	30 (7.1%)	(0.5%)	32 (7.6)	
40–64	8 (1.9%)	149 (35.3%)	10 (2.4%)	167 (39.6%)	0.003
Over 65	22 (5.2%)	191 (45.2%)	10 (2.3%)	223 (52.9%)	
Residence					
Countryside	10 (2.4%)	88 (20.9%)	2 (0.5%)	100 (23.7%)	0.046
Urban	20 (4.7%)	282 (06.8%)	20 (4.7%)	322 (7(5.3%)	
Marital status					
Single	2 (0.5%)	28 (6.6%)	2 (0.5%)	32 (7.0%)	
European Union of banks for reconstruction and development	0 (0.0%)	8 (1.9%)	0 (0.0%)	8 (1.9%)	
Married	18 (4.3%)	251 (59.5%)	17 (4.0%)	286 (67.8%)	0.152
Divorced	2 (0.5%)	26 (6.2%)	0(0.0%)	28 (6.6%)	
Widower	8 (1.9%)	57 (13.5%)	3(0.7%)	68 (10.1%)	
Teaching level					
Illiteracy	0 (0.0%)	8 (1.9%)	0 (0.0%)	8 (1.9%)	
Primary	16 (3.8%)	153 (36.3%)	8 (1.9%)	177 (41.9%)	0.235
Secondary	9 (2.1%)	121 (28.6%)	7 (1.7%)	137 (32.5%)	
Superior	5 (1.2%)	88 (20.8%)	7 (1.6%)	100 (23.7)	
Eye movement					
Student	0 (0.0%)	3 (0.7%)	0 (0.0%)	3 (0.7%)	
Public Dependent	0 (0.0%)	220 (5.2%)	1 (0.2%)	23 (5.5%)	
Private teeth	2 (0.5%)	40 (9.5%)	3 (0.7%)	45 (10.7%)	0.382
Uncorrelated	7 (1.7%)	100 (23.7%)	6 (1.4%)	113 (26.8%)	
Retired	19 (4.5%)	136 (32.2%)	9 (2.1%)	164 (38.9%)	
None	2 (0.5%)	69 (16.4%)	(0.7%)	74 (17.5%)	

Table 2. Factors related to permanent pacemaker implantation. José calasco altega hospital, 2017

Related factors	Implantation of yes		Pacemaker not		OR	95% confidence interval		P value
	N=30	%=7,1	N=392	%=92,9				
AV block								
Yes	15	3.55	9	2.1	42.56	10.06	112.73	0,000
No	15	3.56	383	90.8				
Sinus node								
Yes	7	1.66	2	0.5	59.34	11.67	301.93	0,000
No	23	5.45	390	92.4				
Atrial fibrillation								
Yes	5	0.7	41	9.7	1.71	0.62	4.71	0,354
No	25	6.4	351	83.2				
Other								
Yes	3	0.71	340	80.6	0.017	0.00	0.05	0,000
No	27	6.40	52	12.3				

4. Discussion

Our study showed that the prevalence of permanent pacemaker implantation was 7.1%, similar to the study conducted by Pellegrini C et al. In Germany in 2018, which showed that 9.9% of patients used this pacemaker[7], which may be due to the prevalence of cardiogenic diseases, including those risk factors indicating pacemakers.

At the national level, the Izaguirre study conducted in Guayaquil, Ecuador, in 2016 found that the prevalence of pacemaker implantation was higher, at 15%. This may be because the complexity and solving ability of this hospital are higher, so the number of cases is more, not to mention that this population has similar socio demographic characteristics with the population we studied.

Based on the sociodemographic variables analyzed, it was observed that:

More than half of the study samples were 266 men (63.0%), of which 24 (5.7%) were implanted with pacemakers; Similar to the study of Ruiz e.et al., Peru in 2015, 64% of them are men, which may be because men are more prone to cardiovascular disease[8].

Permanent pacemaker implantation was most common in 223 people over 65 years old (52.9%); Pacemakers were implanted in 22 cases (5.2%); Like the 2009 study of Femenia F et al. In Argentina, the study found that the prevalence of pacemaker implantation in the age group over 65 increased by 59.89%, This may be because risk factors and the likelihood of progression of these diseases increase with age.

In terms of marital status, 286 (67.8%) were married and 18 (4.3%) were implanted with pacemakers; This result was confirmed by Diaz m et al. In Quito, Ecuador in 2015, 56% of patients were married[9].

According to occupation, 164 patients (38.9%) were retired patients, of which 4.5% were implanted with pacemakers; This was followed by 1.7% in the independent group and 0.5% in the private dependence group.

The above research shows that for pacemaker implantation, they must meet some standards recognized by the European clinical practice guidelines for pacemaker and cardiac resynchronization therapy.

In our study, we observed association with atrioventricular block or 42.56 (95% confidence interval: 16.06–112.73, P=0.000), similar to the results of international studies, which confirmed this statistically significant association (or 9.95% CI: 2.30–42.95 p value 0.002 (P=0.057)[10,11]. Sinoatrial node disease or 59.34 (95% confidence interval: 11.67–30.1936 P=0.000) established this association and considered it a risk factor, which is consistent with the study conducted by Fernandez and collaborators in Buenos Aires, Argentina or 2.09 (95% CI 1.09–3.07 P=0.025[10,11]).

According to our study, atrial fibrillation was considered a risk factor[12] (or 1.71; 95% CI: 0.62–4.71), but it was not statistically significant (P 0.354). Cosedis et al. Confirmed this in the 2012 study in the United States, which pointed out that the initial treatment of atrial fibrillation is drug treatment and ablation (P=0.007), and pacemaker implantation is the last treatment measure[13].

5. Conclusions

The prevalence of pacemaker implantation is 7.1%, which is related to atrioventricular block, which is the main risk factor, followed by nodular diseases.

Conflict of interest

The authors declare no conflict of interest.

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Wearable Technology (2020) Volume 1 Issue 2, *pp.* 7–13.
doi: 10.54517/wt.v1i2.1659

ORIGINAL RESEARCH ARTICLE

Prevalence and characteristics of findings related implant in panoramic X-rays

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ABSTRACT

Introduction: In Colombia, the latest oral health study shows that about 70% of the population suffer from partial edentulism, while 5.2% lose all teeth between the ages of 65 and 79. Implant rehabilitation is an increasingly and widely used option, which requires clinical and X-ray follow-up. Panoramic X-ray examination is a low-cost option. In this case, the area of bone loss, the middle and distal angle of the implant, the relationship with the anatomical structure and the related lesions of periimplant inflammation can be observed. Data on X-ray findings associated with dental implants need to be reported and analyzed to determine risk factors for success in patients using these implants. **Objective:** To determine the prevalence and characteristics of findings related to osseointegrated implants in panoramic X-ray films. **Methods:** Descriptive cross-sectional observation was used to select 10,000 digital panoramic photos from the radiation center in Bogota, Colombia, of which 543 were related to the presence of implants. The position, angle and distance from adjacent structures of each implant were evaluated using program ClínicalView® (Orthopantomograph OP200D, Instrumentarium, USA). **Result:** The X-ray frequency of implants was 5.43%. There were 1,791 implants, with an average of 3.2 X-rays per time. They have a higher proportion in the maxilla and are located on the crest at an angle of 10.3 degrees. 32% of patients had implant/tooth or implant/implant distance below the optimal value. 40.9% of the patients were repaired, and 1.2% of the patients had periodontitis. **Conclusion:** The high proportion of modified implants has a risk factor that affects their long-term survival, whether due to angle, ridge or ridge location, adjacent teeth or other implants, or because they are irreparable.

Keywords: X-ray examination findings; panoramic X-ray film; dental implants

1. Introduction

Tooth loss is a related problem, which not only affects aesthetics and chewing, but also related to tooth position change, bone resorption, tooth extrusion, periodontal disease and pronunciation[1]. According to the National Oral Health Study (ENSABIV)[2], in Colombia, 45% of dental patients who attend dentistry fortooth loss. By age, 3.9% of the teeth in the 15 to19 years old group were missing or suitable for extraction, the tooth loss in the 35 to 44 years old group increased to 8 teeth per person, and the loss in the over 55-year-old group was 16.2 teeth per person. The same study found that the prevalence of edentulity was 25% in both jaws and 7%

ARTICLE INFO
Received: May 6, 2020 | Accepted: June 25, 2020 | Available online: July 11, 2020

CITATION
Sánchez SB, Ciodaro AR, Martínez Laverde DM, et al. Prevalence and characteristics of findings related implant in panoramic X-rays. Wearable Technology 2020; 1(2): 7–13.

in the lower jaw in Colombia.

There are several methods of clinical treatment for patients with partial or complete edentulosis, using fixed, movable and complete restorations, and its success depends on the location, availability or absence of dental columns. In this sense, implant is considered an option, which can provide a variety of spinal positioning according to the number and quality of patients' bones. The successful placement and rehabilitation of implants depend on the diagnosis and correlation of clinical and imaging results, including CT and panoramic X-ray, to plan the treatment and follow-up of conventional implants[3]. The evaluation before and after implantation includes evaluation of anatomical structure, detection of disease, estimation of bone quantity and quality, angle of alveolar ridge and insertion path close to natural teeth or other traditional oral implants; and these items must be evaluated immediately after surgery[4].

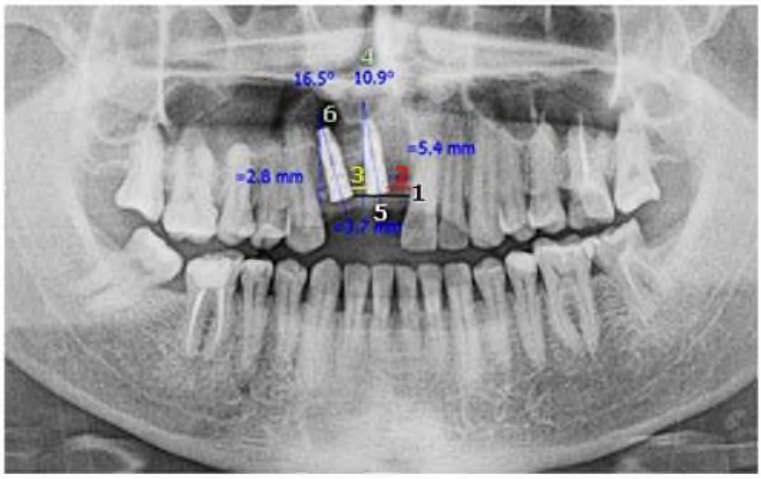
Post implant monitoring is carried out through clinical examination, which examines activity, inflammation, infection and panoramic radiology. Although the sensitivity and specificity of these examinations are limited, they allow the suspicion of related bone injury[5]. It is very useful in long-term research because it shows the data of periimplant inflammation, The relationship between the implant and adjacent teeth or implants, and the proximity to adjacent structures (such as maxillary sinus or mandibular canal)[6,7]. Implant repair should be evaluated to identify and quantify relevant risk factors and their impact on the oral morbidity profile, especially in the context of the increasing popularity of this technology. The aim was to determine the prevalence and characteristics of panoramic X-ray findings associated with osseointegrated implants.

2. Methods

A descriptive observational study was conducted with the approval of the Research and Ethics Committee of the Facultyoff Dentistry of the Pontifica Universidad Javeriana. In order to facilitate sampling, 10,000 digital panoramic X-rays were selected from the radiation center of Bogota, of which 543 were related to the presence of implants. Digital X-rays, including those over 18 years of age, have sufficient density, clarity, contrast or focus. These X-rays show no evidence of vertical and horizontal distortion, nor artifacts such as unremoved prostheses or other injuries that do not allow the correct display of complete images.

The observation was conducted by two researchers, who were maxillofacial surgeons trained in bone integration and used the computer of the school's dental clinic. After the X-ray film is selected according to the inclusion criteria, each digital panoramic X-ray film is systematically and orderly measured and divided into four areas: 1-upper right corner, 2-upper left corner, 3-lower left corner and 4-lower right corner, using the Clinic Viewprogram® 9.3 (Orthopantomograph OP200D, Instrumentarium, USA). This program allows you to measure the image directly from the previously defined points, as shown in the figure. The measures taken were as follows: the distance between the evaluated implant and adjacent teeth or implants and its angle relative to a line parallel to the bone midline drawn through the anterior nasal spine and chin points (**Figure 1**).

The results are listed in an Excel spreadsheet, including general data on age and gender. In addition to recording the number of implants, the following characteristics were studied: implant type (conventional, paraosseous or zygomatic), location (maxillary or mandibular anterior teeth are defined as the area between central and lateral teeth, central teeth, canine and premolar, and posterior molars), angle, presence of periimplant injury (bone loss of more than 2 mm around the implant, distance between the implant and adjacent teeth and implants, rehabilitation of maxilla, mandible or both and complete edentulous jaw). For inter group comparison, chi-square test was used and odds ratio was calculated while seeking the relationship between variables, $P<0.05$ was accepted as significance value.



(1): According to the position of alveolar bone; **(2)**: Distance from adjacent teeth; **(3)**: Distance from adjacent implants; **(4)**: At an angle to the center line; **(5)**: With or without artificial crown; **(6)**: Whether there is peri-implant injury.

Figure 1. Description of the measures taken to describe the characteristics of the implant on the panoramic X-ray film.

The results are listed in an Excel spreadsheet, including general data on age and gender. In addition to recording the number of implants, the following characteristics were studied: implant type (conventional, paraosseous or zygomatic), location (maxillary or mandibular anterior teeth are defined as the area between central and lateral teeth, central teeth, canine and premolar, and posterior molars), angle, presence of periimplant injury (bone loss of more than 2 mm around the implant, distance between the implant and adjacent teeth and implants, rehabilitation of maxilla, mandible or both and complete edentulous jaw). For inter group comparison, chi-square test was used and odds ratio was calculated while seeking the relationship between variables, $P<0.05$ was accepted as significance value.

3. Results

Of the 10,000 X-rays analyzed, the average age of the patients was 38.4 years (SD: ± 15.4), male accounted for 42.4%, the lowest age was 18 years old, and the highest age was 92 years old. In the study population, when X-rays showed at least one implant, the prevalence of dental implants was 5.43% (a total of 1,791 implants), with an average of 3.2 implants per X-ray. Of the 543 implant X-rays, 45% were male and 55% were female, with an average age of 52. There was no statistically significant difference between men and women.

In 1,791 implants, the study variables were characterized. According to the type of implant, 98.9% were terminal bones, including cheekbones (18 implants) and 1.1% juxtaposed bones. There were 5 cases of 18 zygomatic implants without pathological changes. Eight patients received 12 juxtaosseous implants, each with changes between 1 and 3, and some showed signs of bone loss.

According to the location, at the maxillary level, 57.62% (1,032) of the implants were mainly located in the premolar area (419 implants). The number of mandibles decreased to 42.38% (759), mainly distributed in the posterior part. The anatomical locations of the implants are summarized in **Table 1**.

Table 1. Locate the implant according to the anatomical area

Anatomical area	N	%
Anterior maxilla	406	22.7
Middle maxilla	419	23.4
Posterior maxilla	207	11.6
Anterior mandible	152	8.5
Middle mandible	238	13.2
Posterior mandible	369	20.6

The analysis of implant angle showed that the average angle of anterior teeth was 10.3°, the standard deviation was ± 8.95°, that of premolars was ± 10.48°, and that of posterior segments was ± 10.88°. 2.06% (37) of conventional implants had an angle greater than 30°; 59.5% of them were located

on the ridge and 40.5% on the ridge; of these, 15 implants have been repaired and 2 have some damage around them. When calculating the odds ratio, it was found that the risk of periimplant inflammation increased by 4.7 times for implants with a mid-distal angle greater than 30 degrees.

The frequency of X-ray examination consistent with the lesions around the implants was 1.22% of the total number of implants. There was no gender difference, but it increased significantly with the increase of patients' age.

Table 2 summarizes the status of implants relative to bones, teeth and adjacent implants. The analysis of these risk factors showed that in terms of tooth spacing, 14.9% of implants were less than 1.5 mm from adjacent teeth, and 21.7% were less than 3 mm from adjacent implants. The X-ray results of four implants were consistent with the surrounding lesions, and the distance between implants and teeth was less than 1.5 mm. The calculation of odds ratio showed that the X-ray findings consistent with peri implant lesions increased by 2.3 times where the ideal distance was not maintained.

Table 2. Relationship between implant location and adjacent structures

Location of	N	%
Suprascrestal	918	51.3
crestal	733	40.9
Infracrestal	140	7.8
Total	1,791	100
Distance between teeth		
Distance < 1.5 mm, far from adjacent teeth	112	6.3
Distance > 1.5 mm, distant teeth	482	26.9
Distance adjacent to mesial teeth < 1.5 mm	156	8.7
Distance > 1.5mm and proximal middle adjacent teeth	611	34.1
No adjacent teeth	430	24
Total	1,791	100
Distance between plants		
Distance < 3.0 mm, distal adjacent implant	153	8.5
Distance > 3.0 mm adjacent to distal implant	478	26.7
Distance < 3.0 mm with adjacent mesial implants	237	13.2
Distance > 3.0 mm with near median adjacent implants	689	38.5
Non adhesive implant	234	13.1
Total	1,791	100

In terms of repair, 40.9% (734) of the implants were repaired, 51.6% were located on the supracrestal, 42.7% on the crestal and 5.7% on the infracrestal. By observing the repaired implants, 89% (655) of the patients had a pair of occlusal relationships, making their functions normal. 96 fixed dentures were found in 543 X-rays, of which 23 were implant supported dentures and 73 were implant supported dentures, although most were repaired separately.

Other studies showed that 4.2% of implant images correspond to the total upper and lower edentulas, who used 1 to 13, with an average of 5.4 implants per patient. 4.9% of patients with total edentulous maxilla used an average of 4.7 implants, ranging from 1 to 12, while 2.9% of patients with lower edentulous maxilla used an average of 4.9 implants, ranging from 1 to 11.

4. Discussion

The National Oral Health Study[2] reported that only 0.17% of Colombians have dental implants, which is due to economic constraints and the existence of other faster and more affordable repair solutions to solve the aesthetic and functional problems of edentulism. In our sample, the frequency of implants increased by 5.43% over the total Colombian population because it analyzed urban areas and individuals with better dental services.

These epidemiological data are important because they are the basis for assessing implant behavior and its impact on oral health for they analyze the risk factors associated with implant loss. Radiological variables[8] related to implant survival and prognosis, such as location, distal angle, bone relationship and periimplant lesions, were observed, of which variables depended on the appropriate distribution of implant anchorage and masticatory force[9].

The placement of the implant in the anterior maxillary region indicates that although the loss of posterior teeth in the maxilla and mandible is greater[2], the patient initially needs to restore its aesthetic part. It is well known that the rehabilitation of posterior sectoris the primary task of occlusal stability and prevention of joint injury, although the results of this study show that these implants sometimes do not have antagonists, resulting in their loss of function.

This evidence proposes angle implants to seek the maximum bone stability and survival of long-term prostheses, which are usually accepted in the range of 30 degrees to 35 degrees; these reports support the high predictability and preservation of implants and protheses supported on them[10]. For cheekbones, the average angle can be between 35 degrees and 45.7 degrees, with high stability and life span[11], when there is a large angle, there is excessive stress at the bone crest-platform interface of the implant, and this loss will gradually disappear if the stress is not reduced[12]. In this study, only the middle and distal angle of the implant can be seen through two-dimensional imaging, which is usually within the acceptable range of evidence supporting masticatory load. It is worth noting that implants with a larger angle also have greater bone loss being at the crestal and supracrestal level. In fact, the possibility of damage around the implant is greater[13].

As for the distance between the tooth and the implant, in order to maintain the integrity of the nipple and obtain the best aesthetic effect, the distance between the two implants should not be less than 3 mm, and the distance between the tooth and the implant should not be less than 1.5 mm[8]. However, animal studies have shown that the distance between implant and tooth can lead to resorption and necrosis of dental pulp. In fact, these are the reasons of lawsuit for malpractice in clinical practice[14,15].

In the sample of this study, the distance between 85.1% of implants and adjacent teeth was greater than or equal to 1.5 mm, and 78.3% of implants and adjacent implants were greater than or equal to 3 mm; The above results show that most implants show a good prognosis due to this factor, especially in the anterior teeth, and the aesthetic results between the final rehabilitation of implants and appropriate nipple formation. Although 21.7% of implant to implant measurements are lower than those in the literature, the absorption of crest bone is controversial over time between implants with a distance of 1.8 mm or less. Considering that the implant bone interface and the height of alveolar bone relative to the implant platform will also affect the ridge or supraridge position of the implant, and may reduce the long-term life of the implant[17–20].

In addition, ridge bone loss, platform exposure and implant thread are the risk factors for the development of peri implant inflammation, which is related to the accumulation of plaque on the implant surface[21–22]. However, within the limitations of the tools used in this study, clinical conclusions cannot be drawn and these findings cannot be clinically relevant.

Another aspect of this study is that the rehabil-

itation rate of these implants is only 40.9% (734%), which may be due to the large cost of repair, or because the implants can correctly integrate the bone, but not necessarily through their position or angle, because one of the limitations of panoramic images is the vestibular tongue analysis of the implants.

The X-ray findings consistent with the periimplant lesions in the top area of the implant were 1.2%, which was consistent with other clinical studies, in which the prevalence of periimplant inflammation was about 1.7%. These may be caused by overheating of bone during milling and damage close to the top of adjacent teeth[23–25]. It is also obvious that the X-ray results related to periimplant increase with age, which confirms the findings of other authors[13].

5. Conclusions

Considering the limitations of being a radiological study, it can be concluded that there are risk factors for the loss of a large number of implants analyzed, such as angle values greater than the repair correctness reported in the literature, position errors in extreme proximity to teeth or implants, and age.

Conflict of interest

The authors declare that there is no conflict of interest in the development of this research project.

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Wearable Technology (2020) Volume 1 Issue 2, *pp.* 14–19.
doi: 10.54517/wt.v1i2.1661

ORIGINAL RESEARCH ARTICLE

Simulation study of calcaneal insertion in the treatment of children's flat foot

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ABSTRACT

One of the correction methods of children's flat foot is calcaneal insertion. The purpose of this work is to determine the performance of calcaneal stop by using two bioco MPatible materials. The Finite Element Method (FEM) is used. The material analysis is AISI 316L steel and Ti-6Al-4V titanium alloy. Using Cuban anthropometric models, loads were calculated based on foot biomechanics and body weight of boys and girls aged 10 and 12. The results show that the implant model ensures the mechanical strength of the two materials. The difference between the two stresses is 4.44 MPa, accounting for 5% of the difference. Both materials have enough mechanical strength reserves because the maximum stress is less than the elastic limit of the material and ensures the mechanical strength of the calcaneal stop design.

Keywords: finite element method; calcaneal insertion point; flat foot; biomechanics

1. Introduction

The foot is an important part of the body because it ensures our flexibility and balance. One of the most common causes affecting the foot is known as flat feet. Some conservative alternatives, such as the use of orthopedic shoes, brackets and insoles, have been used for flat foot correction. And only in cases where the previous treatments do not work, surgical correction is indicated[1,2].

One known technique is the so-called calcaneal stop, which includes placing a screw in the tarsal sinus (bone) to maintain the formation of the plantar fornix[1,3]. The purpose of using calcaneal insertion implant is to correct the flat foot immediately after surgery. Orthopedic surgeons have evaluated its results as a good treatment option with less complications and good surgical effect[4,5].

There are various types of calcaneal insertion implants, also known as prostheses, screws or devices. The mechanical properties of the element made of the human body must meet the conditions of its exposure. Titanium and its alloys and some stainless steel are used for this implant. Research on new materials such as those that are absorbed by

ARTICLE INFO
Received: June 8, 2020 | Accepted: July 19, 2020 | Available online: August 4, 2020

CITATION
Nápoles-Padrón E, Pacheco-González JP, González-Carbone RA, et al. Simulation study of calcaneal insertion in the treatment of children's flat foot. Wearable Technology 2020; 1(2): 14–19.

the body are among the current trends[6,7]. The mechanical strength of these orthopedic implants can be evaluated by biomechanical research and numerical methods, in order to further improve the design or material substitution decision-making.

Among these methods, finite element method (FEM) is an indispensable modeling tool in many engineering fields and other branches of science and technology. In the past decade, the use of FEM in health fields such as disease prognosis and glaucoma has increased[8,9], in examining the stress and deformation of dental implants[10], and fatigue analysis of spinal pedicle screws[11]. Research on feet using FEM appears in specialized scientific literature, such as fractures and injuries in this part of the human body[12,13], work related to gait level[14] and diseases related to diabetic feet[15,16]. For the benefit of preventive medicine, research prior to the use of new screws is convenient. Therefore, the purpose of this work is to evaluate the behavior of stress, deformation and displacement in calcaneal implant stopper using FEM for children's flat foot correction, so as to make decisions based on the evaluation of mechanical strength.

2. Methods and materials

The finite element method is used as a modeling method to study stress, strain and displacement. The implementation steps of FEM are composed of geometric model, load model, material model and grid model[17]. Then it describes the process of obtaining components from the model.

2.1. Geometric model

Patent US 8267977 B2[18] was selected as a result of the search for patents related to calcaneal implant stop to evaluate the characteristics, performance and technical specifications that best meet the needs of the study. According to the recommendations of orthopedic experts, this geometry makes the surgical process simpler and less invasive to bone and surrounding tissues, as shown in **Figure 1**.

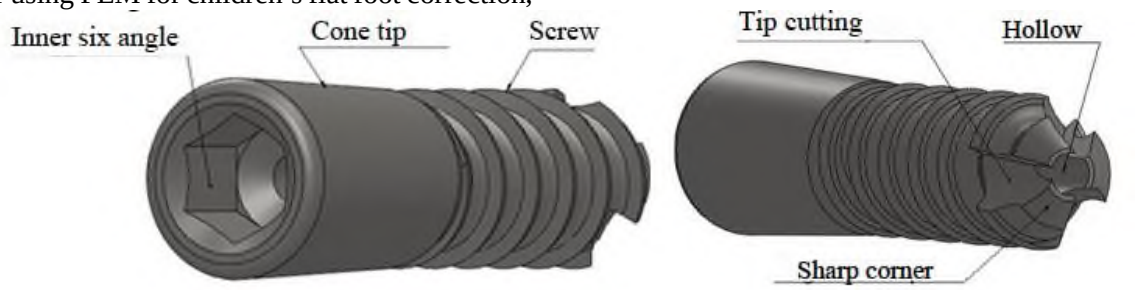


Figure 1. Geometric model of calcaneal insertion.

The head of the device is a smooth cone, which serves as a buffer for the heel and is used to correct the flat foot. The latter has a hexagon inside for screw implantation. Screws are the type used for cancellous bone to ensure the self-tightness of bone and prevent screw loosening. The tip has three 120° displacement cuts. This type of tip replaces the use of drill bit. Through a through-hole intubation at the longitudinal end, the screw can be placed correctly, and only a small incision needs to be made on the skin. Finally, the angle of the screw end ends at an angle of 90°, which helps to place the implant at the beginning of implantation.

2.2. Load model

The load on the implant depends on the child's weight. There is a relationship between boys' weight and age. According to the percentile data and chart of Cuban boys' weight from male and female age groups[19], the maximum percentile weight of boys and girls aged 10 and 12 was selected to ensure the maximum load on the implant.

On the other hand, the plantar dome has three arches and supporting points. The load on the support point is uneven. In the upright, vertical and stationary position, 50% or 60% of the weight can

affect the calcaneus, while 50% or 40% of the weight can affect the anterolateral and anterolateral support. It is considered that in an upright, vertical and immobile position, 50% or 60% of the weight can be placed on the calcaneus, while in the antero-external and antero-internal supports 50% or 40%[20,21]. **Figure 2** shows the support point of the foot and the load distributed according to the weight of the person. The authors believe that the force acting on the implant is 60% of the child's body weight. **Table 1** shows the weight, load and percentage information corresponding to the calcaneus. The maximum load is 330.7 N, which is suitable for 12-year-old girls. It is the load used to analyze the strength and stiffness of implants.

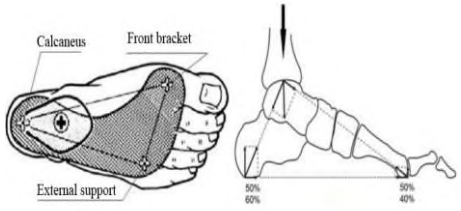
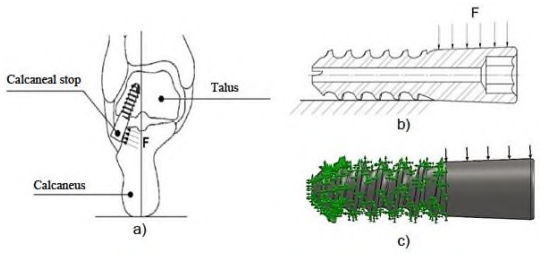


Figure 2. Foot support points and load distribution[20,21].

Table 1. Force ratio acting on the implant in each case

	Weight (kg)		Total load (n)		60%(N)	
Age	Masculine	Feminine	Masculine	Feminine	Masculine	Feminine
10	43.7	45.5	428.6	446.2	257.2	267.7
12	49.2	56.2	482.5	551.1	289.5	330.7

During the simulation, it should be considered that the screw is screwed on the calcaneus and the head is in contact with the calcaneus to form the plantar dome and correct the flat foot, **Figure 3a**. Therefore, the screw will be embedded in the screw area to simulate a consistent connection with the bone, while a distributed load is applied to the head, the value of which is discussed in the previous paragraph. **Figure 3b** shows the model loads and boundary conditions applied to the model.



(a) The insertion mode of the implant to realize that the plantar dome curls on the calcaneus and the head performs the cushioning function

(b) The representation of the load condition, which applies the distributed load on the head and is embedded into the screw

(c) The load model is represented in the simulation software, and the green arrow eliminates the movement

Figure 3. The load model of the calcaneal implant stops according to the position of the foot.

2.3. Material model

The materials used for modeling are titanium alloy (Ti-6Al-4V) and AISI 316L stainless steel. Because of their mechanical strength, elastic limit, fatigue strength, wear resistance and fracture toughness, these two metal materials are widely used in the manufacture of orthopedic implants to replace or fix bones or joints. Both are bio-compatible and are accepted by living tissues.

According to ASTM standards, titanium alloy containing 6% aluminum and 4% vanadium is classified as grade 5, which is the most ductile alloy in grade 5. This is why it is one of the most recommended and commercialized implant manufacturing because of its high corrosion resistance and relatively low density than steel[22]. In addition, compared with other biocompatible metal materials, AISI 316L stainless steel of surgical quality is suitable for the manufacture of implants because of its durability and low cost. Among other properties, it has been widely studied and has many international standards that specify its chemical composition, recommendations on which implant to use, and mechanical properties determined according to the method of acquisition, Annealing by plastic deformation[23]. These materials are homogeneous and linearly isotropic, and their most common properties are shown in **Table 2**.

Table 2. Mechanical properties of selected materials

Attribute	AISI 316L steel	Ti-6Al-4V Alloy
Modulus of elasticity (MPa)	200,000	110,000
Shear modulus (MPa)	82,000	41,023.81
Elastic limit (MPa)	200-500	795
Poisson coefficient	0.265	0.31
Maximum deformation (%)	55-60	10
Density (g/cm^3)	7.9	4.5

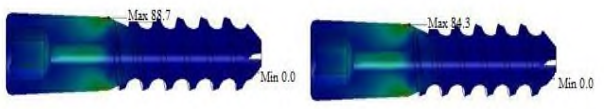
2.4. Grid model

Mesh generation is very important for element analysis and research. For this type of parts, *the* software recommends using solid mesh type (tetrahedron) and standard mesh (automatic three-dimensional). There are 9,934 elements and 16,479 nodes in total, as shown in **Figure 4**.

Figure 4. Insertion point of calcaneal reticular implant.

3. Results and discussion

The study used two of the most commonly used surgical implant materials to study the mechanical strength of implants. The highest von Mises equivalent stresses have a value of 88.73 MPa for the implant made of AISI 316L steel (**Figure 5a)** and 84.29 MPa for those made of Titanium Ti-6Al-4V alloy (**Figure 5b**). The difference between the two stresses is 4.44 MPa, accounting for 5%. Therefore, according to the engineering standard, the difference is not significant. As shown in **Figure 5**, the maximum equivalent stress is located between the screw head and the screw transition zone. At this point, the diameter of the cone head is small and is the end of the depression. This result is consistent with the behavior of the cantilever beam, in which the stress increases towards the outer edge of the geometry, and the maximum value appears in the area near the bottom. This is a key part of this work.



(a) AISI 316L stainless steel is 88.73 MPa **(b)** titanioti-6al-4v alloy is 84.29 MPa

Figure 5. Calcaneal implant insertion and other effects.

The elastic limit of titanium alloy can reach 795 MPa[22], while the elastic limit of AISI 316L steel depends on its state (annealing or plastic deformtion), ranging from 200 MPa to 500 MPa[24]. Both materials have very good design factors because in all possible cases, the stress is less than the elastic limit of the material and ensures the mechanical strength of the calcaneal stopper design.

The deformations have a maximum value of 3.741x10-4 for 316L steel (**Figure 6a**) and 7.024x10-4 for Ti-6Al-4V titanium alloy (**Figure 6b**). These deformations occur in the transition region between the screw head and the screw, which matches the distribution of equivalent stress. The deformation of alloy steel is about half that of titanium alloy.

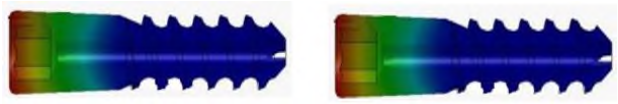
(a) AISI 316L stainless steel 3,741×10-4 **(b)** titanium alloy Ti-6Al-4V 7,024×10-4

Figure 6. The load deformation diagram of calcaneal implant dead center.

This is because the elastic modulus of titanium

alloy is twice that of alloy steel, as shown in **Table 2**. Therefore, the unit deformation of titanium should be twice that of stainless steel. The equivalent stress difference between the implant and the two materials is less than 5%. Therefore, according to the law of elasticity, the proportional relationship between stress and strain is satisfied.

The maximum displacement of AISI 316L steel (**Figure 7a**) is 3,913 μm and that of Ti-6Al-4V titanium alloy (**Figure 7b**) is 7,394 μm. This displacement occurs at the end of the screw head, in the area of the maximum diameter of the cone. The results show that the stiffness of titanium alloy implant is low. These two displacements are insignificant co MPared with the displacement printed on the calcaneus by the implant. In order to form the plantar fornix, the calcaneus and calcaneus need to be separated by a few millimeters.



(a) AISI 316L stainless steel 3,913 μm, **(b)** Ti-6Al-4V titanium alloy 7,394 μm

Figure 7. Displacement diagram of insertion stop of calcaneus.

From the modeling results, AISI 316L stainless steel and titanium alloy can be used because they can resist the working conditions to which the implant will be exposed, because the elastic limit of both materials is much higher than the stress generated in the implant. It should be noted that AISI 316L stainless steel implants should be removed after the correction period, because the corrosion of these liquids will degrade the material after long-term exposure to body fluids[25].

The position of the maximum equivalent stress close to the screw thread is consistent with the report in[11], which analyzes the analysis of Ti-6Al-4V titanium alloy pedicle internal fixation. Different loading conditions are analyzed, and the fillet part of the thread is restrained concave.

The main limiting factor of the analyzed model is that it does not include the influence of fluctuating load during walking. However, AISI 316L has a minimum safety factor of 2.38, so it can be assumed that the screw can resist fatigue conditions. The safety factor of titanium alloy Ti-6Al-4V is greater than 9. In addition, in further analysis, the screw bone interaction after the screw is inserted into the foot model should be considered, and the friction effect between bone and screw should be considered.

4. Conclusions

The implant model ensures the mechanical strength of the studied material. The maximum equivalent stress of AISI 316L steel implant is 88.73 MPa, and that of Ti-6Al-4V titanium alloy implant is 84.29 MPa. The percentage difference between the two tensions is 5%. Both materials have enough reserves in terms of mechanical strength, because they are far less than the elastic limit of the material and ensure the mechanical strength of the calcaneal stopper design.

Conflict of interest

The authors declare no conflict of interest.

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Wearable Technology (2020) Volume 1 Issue 2, *pp.* 20–27.
doi:10.54517/wt.v1i2.1670

ORIGINAL RESEARCH ARTICLE

Bioethical thinking of cochlear implant in the treatment of deafness

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ABSTRACT

Otolaryngologists engaged in cochlear implant surgery are very careful to require a variety of complex medical and clinical examinations in order to make a clear diagnosis and perform surgery to improve hearing and speaking. From a biomedical point of view, this is not controversial. However, in the analysis, if the personal, social, family and environmental factors of deaf people are not considered as important as pathology, the wanted results may be undermined. This reflective article highlights these situations, which are part of the bioethics view and considered to be a necessary supplement to the rehabilitation of deafness. The dilemma and conflict in bioethics are defined so as to put the pathology of deafness, the deaf and their environment in the framework of the concept of overall health and the doctors' responsibility, then to reach the bioethics principles of Beauchamp and Childress. Its purpose is to show that cochlear implantation can be attributed to a valuable cutting-edge technology operation behavior, and the prejudices and values of this medical technology must be surpassed and understood, which directly or indirectly, positively or negatively affect the deaf.

Keywords: bioethics; deafness; cochlear implant.

1. Introduction

If the hearing loss is not serious or profound, it can be corrected by surgery, low, medium or high-tech prostheses or hearing aids. When hearing loss is severe, or when there is scab, i.e. complete deafness or the use of prosthetics has no positive impact, then use other communication methods: Oral communication through lip reading, or sign language communication in the absence of oral communication. In fact, in Europe and other countries with similar advanced health and education, more than 90% of 1 million affected people communicate orally and 6% to 8% use sign language[1].

However, in addition to the above alternatives, for people with hearing impairment or loss of hearing due to disease or trauma, cochlear implant technology opens up opportunities to obtain hearing ability in the absence of hearing, restore hearing

ARTICLE INFO
Received: July 22, 2020 | Accepted: August 30, 2020 | Available online: September 15, 2020

CITATION
Urbano Bucheli FD. Bioethical thinking of cochlear implant in the treatment of deafness. Wearable Technology 2020; 1(2): 20–27.

ability in the conditionof hearing loss, or amelioratesevere hearing impairment, which could not have been achieved many years ago.

Cochlear implant is a cutting-edge electronic technology system, which is used for medical and surgical treatment of the above cases for deaf rehabilitation. In order to makecochlear implants succeed, candidates must fully comply with the required protocols and, most importantly, undergo rigorous hearing and language rehabilitation after surgery. The ultimate goal of cochlear implantation is to obtain auditory interaction in order to develop appropriate oral English. If this is not possible, cochlear implantation is meaningless. Therefore, the agreement on the selection of patients with cochlear implantation must be fully observed.

The protocol for cochlear implant patients clearly stipulates many necessary tests for medical research and hearing pathological diagnosis, as well as the evaluation and results of hearing and speaking[2,3]. However, there is little application in social, family, psychological and educational aspects, as well as in the bioethics of the deaf and their family core. These factors are basic and necessary and need to be considered like other medical examinations in order to have a positive impact on the quality of life of cochlear implant patients.

Neither biomedical care with the help of scientific progress nor technical or technical assistance alone is sufficient to manage patients with the above-mentioned deaf mutes. It also requires other aspects that have been identified, such as arriving on time and in an appropriate way. It must also consider aspects related to bioethical dilemmas and conflicts in the management of deaf mutes and cochlear rehabilitation patients, so as to improve their quality of life.

Although cochlear implant surgery is an important part of the rehabilitation process, the surgery itself does not correct deafness. Continuous and selective hearing and language rehabilitation is required after surgery for one or more years to obtain, restore or correct hearing and language loss. Interdisciplinary team management is the basis for achieving the best results.

In Spain, the best timeof cochlear implantation for deaf children is 0–3 years old, and their hearing and language levels have improved by 90% to 95%. Among them, 80% to 90% children have developed hearing and language skills, just like children with normal hearing. Among adults, 80% have improved hearing, quality of life, mental health and social life[4]. Although not all deaf people are candidates for these cochlear implants, 40% of live born deaf people are considered candidates for cochlear implants. These results indicate the usefulness of this type of implant for deaf people who fully meet the requirements of the protocol and the requirements of rehabilitation and follow-up treatment.

2. Dilemma and conflict

All implant operations, especially those for deafness and cochlear implant treatment, require serious bioethical reflection. As described below, especially when doctors face real and inevitable conflict situations, many questions may be raised before deciding to implant or not.

Ethical dilemma is a brief historical narrative. In this narrative, a possible situation appears in the real field, but it is conflicting at the moral level. The actor is required to either solve the conflict rationally or analyze the solution chosen by the protagonist of the story. Generally speaking, this situation gives onlyone choice: the protagonist is facing a decisive situation, in which there are only two options (a) or (b), both of which are equally feasible and defensible[5].

For Beauchamp and Childress[6], the only way to fulfil one obligation is to breach another. Either way, allobligations must be breached. It is wrong and misleading to say that under such circumstances, we must take these two actions at the same time. We must fulfil this obligation, which, according to the circumstances, takes precedence over what we are fully obliged to fulfil in the absence of conflict. The conflict between moral requirements and

self-interest sometimes leads to practical difficulties, not moral difficulties. If moral reasons conflict with non-moral reasons, it is difficult to determine priorities even if there is no moral dilemma[6].

In order to make specific moral judgments, it is often necessary not only to resort to more general rules or principles, but also to specify and weigh the rules according to specific circumstances. In the process of regulating and measuring standards, as well as in making specific judgments, it is necessary to take into account beliefs, cultural expectations, the most likely results, precedents and similar issues about the world in order to supplement and measure standards, principles and theories[6].

In medicine, there are usually balanced judgments. These principles have not changed in the whole history. For example, doctors should not use patients for their own interests, and the interests of patients should be the primary consideration. Entrepreneurs are not always bound by rules such as customer interests. The difference between medical and business ethics stems from the above rule, i.e. the weighted judgment of doctor-patient relationship[6].

For Beauchamp and chaidris, the so-called comprehensive reflective balance is achieved by evaluating the advantages and disadvantages of all relevant moral judgments, principles or theories, i.e. incorporate the widest possible range of legitimate moral beliefs, including the most difficult situations experienced. The characteristics of this process are ideal: no matter how wide the range of beliefs is, there is no reason to believe that the process of polishing, adjustment and consistency will end or be improved. Any set of theoretical generalizations obtained through reflective balance may be inconsistent with weighted judgment, and the only appropriate model of moral theory is to be as close to overall consistency as possible[6].

3. Deaf people and their environment

Deafness is a disease invisible to the naked eye. However, its impact on personal emotional, social and educational development is unimaginable. The isolation that a person may suffer because he or she is unable to establish free and normal contact with others is a huge obstacle to his or her full participation in life, which will produce huge rust in many cases. In the face of reality, deafness inevitably leads to personal isolation, and it often leads to an increase in loneliness[7].

Through hearing, we can perceive the background sound or environmental noise. It is a warning signal that can express sentiment, emotion and thought. Deafness hinders the emotional and social development of deaf children and adults, limiting their expression of thoughts and feelings and their understanding of their surroundings[7].

Understanding and comprehending the situation of deaf people and their families must be complemented by adequate information on possible solutions and the risk of violations of their rights. Therefore, it is necessary to seek the possible help of other disciplines to solve the problems related to this pathology. The role of voice, psychological and social workers in addressing these issues is crucial.

4. Comprehensive health care and deafness

If we regard the change of health as a disease of the body, it is necessary to understand the body beyond the biological conditions. This means that changes take place in other different situations, such as social and family areas. It must also take into account the characteristics of freedom embodied in human reality. This freedom in personal, social and economic structures[8].

Comprehensive health is considered a right enshrined in Article 26 of the UN *Universal Declaration of Human Rights*[9]. The right to health is not only the right to be free from disease, but also the ability to be in a welfare state and planning for the future. Man is not just a biological entity. Living

does not mean that an organic system works like a well lubricated machine. It is a person who is developing his physiological and biological abilities. Therefore, it is also related to their culture, relationships, society, history, projection and moral abilities[10]. Therefore, in this case, listening, hearingand developing a language does not just mean maintaining the function of biological organs and systems. They mean living a healthy life, i.e. the condition of being able to develop all the abilities of human being, no matter how many or less.

5. Doctors and doctors' responsibilities

From the perspective of Hippocratic medicine, the reasons why practicing medicine is related to goodness and charity are well founded. Hedonism ethics finds the legitimacy of human behavior in the process of pursuing good. Since the time of Hippocrates, doctors have traditionally repeated the practice of oath, i.e. to let God or any entity higher than themselves as witnesses and judges of their actions, and committed to providing absolute benefits to their patients[10]. However, "such advanced technological medicine emphasizes biological reductionism, which reflects the epistemological deviation of what human medicine was, is and should be"[8]. In the world of modern medicine, it was called "life medicine" by Mainetti[11]. Patients and doctors are conquered by the necessity of technology: This is why most of the time, one person and another's decision will experience this charm. Doctors must be responsible for the use of this drug and be aware of the limitations and the dangers involved in the use of technical measurement procedures which involve and exacerbate the possession of drugs in life[12].

From the perspective of our analysis, welfare must start with defending the right to health, which is more important than the right to disease care. It must enable people to exercise their rights so that they can live a healthy life. There is no doubt that respecting the right of patients to live a healthy life, the right to be cured when they lose their health, and the right to participate in these two behaviors must be put into practice unconditionally. This can be interpreted as an absolute benefit to humans[10].

6. Bioethics and its principles

Reverend Fritz Jahris known as the "father of bioethics"[12] because he first used the term "bioethics" in an editorial published in the German Journal of natural science Kosmos in 1927[14]. He later developed his view of universal bioethical orders in small-scale publications to replace Kant's formal absolute orders[15].

American biologist Van Rensselaer Potter of the University of Wisconsin[16] may not be aware of this when explaining the conflict caused by technical knowledge and its application in medicine and the emergence of planetary ecological challenges. Potter described the conflict as follows: If two cultures seem unable to talk to each other-Science and humanities, if this is one of the reasons why the future looks suspicious, then we may build a bridge for the future. As a new subject combining biological knowledge with human value system knowledge, I define "biology" as biological knowledge, i.e. life system science. I choose "ethics" to represent the knowledge of human value system[16].

In 1978, Tom Beauchamp published the Belmont Report without excluding other bioethical theories. A few years later, he co-authored the Book *Principles of biomedical ethics* with James Childress and founded his theory of principles. This theory is particularly dominant in the United States and provides a basis for the purpose of this article. In this article, cochlear implant, as a kind of technical knowledge, creates difficulties and conflicts, and doctors and patients are committed to this treatment.

Cochlear implants need bioethical analysis to comply with beneficial and harmless bioethical principles, which correspond to medical management, mainly the obligation to treat when possible without causing further problems. Respecting the principle of patient autonomy, which explains freedom and free decision, their ambition to obtain or not

to obtain these technological benefits, and the principle of justice. They must reflect society, through the state, in their role to provide timely and fair existing technology to all those who need it[6,8].

These principles are not formulated as a strictor rigid rule. Cases include the weight of each principle in a particular case. Beauchamp and Childress[6]set out a preliminary obligation to perform, unless it conflicts with another equivalent obligation. As mentioned above, this leads to a trade-off between principles to find the reason why it must prevail.

7. Respect for the principle of autonomy

Beauchamp and Childress define autonomy as a rule that requires respect for the ability of autonomous decision makers[6]. These authors refer to the ability to make decisions without being influenced by others, as well as the correct understanding and significance of the situation. Therefore, autonomy means the possibility of independence and autonomy in elections, acting according to one's will without being influenced by others[6].

In order to make autonomy possible, Beauchamp and Childress pointed out that three criteria need to be met: Intentionality, understanding and lack of influence in deciding action. Autonomy is considered part of the theory of rights because it allows the use of these rights in decisions about ownership and the exercise of these rights. Since autonomy is seen as a right in health science, individuals must give informed consent to investigation procedures, interventions or actions against individuals.

Although autonomy is the recognition of individual self-management ability, there are some difficulties in its application because the conditions of self-control do not always exist. For example, it covers people who have difficulties in making decisions, such as minors, persons with mental or cognitive disabilities or older persons. Adults with sufficient intelligence but relying on others or technical language beyond comprehension are also limited. In this case, because the information and circumstances do not allow understanding, the decision will not have so much autonomy. It should be added that autonomy is exercised within a social framework, its values are culturally clear, and there are social and relational practices. Therefore, the essence of this concept must include care and respect for the individual[17].

With regard to cochlear implant, the most sensitive point about respecting the principle of autonomy is the decision made by parents or guardians in favor or against whether cochlear implant is needed. For Joel Feinberg, these rights must now be protected in order to be exercised in adulthood[18]. The decision of parents as legal guardians is legal, but not about autonomy, so there is a need to protect the scope of children's future decisions. However, if this protection is implemented on children, it may be late for cochlear implants.

Deaf mute children also have their declared rights. In order to respect these rights, we must start with respecting individual freedom. However, it cannot exist if society does not consider it vulnerable[19]. Most deaf children are not born in the world of deaf people. Therefore, the level of interest of them or their guardians should be reasonable. As cautious people, they should choose the world of deaf people. If children are born in the deaf world, it is different, because their parents are deaf, and they believe that their deaf is the basis of their education and integration into the culture they manage. However, no one has the right to limit physical capacity indefinitely, for whatever reason, as do children born in deaf communities[20]. In school-age children, when their intellectual ability makes it possible, even if it has no legal significance, their wishes or decisions must be taken into account.

8. No malice principle

This principle was originally proposed by Beauchamp and Childress and is known as the "obligation not to harm others"[6]. In this sense, it is

consistent with the Hippocratic maxim "at least don't hurt". Injury is defined as a bad thing done to a person. It usually refers to an event, state or event that is unfavorable to someone. The author constructs the concept of injury according to the concepts of pain, disability or death. This principle includes both non-injury and prevention of pain or suffering. It is of great significance in medical ethics and research because it believes that despite the existence of informed consent, damage to personal health or living conditions should not be recognized[6].

For the author, the principle of doing good or promoting good takes precedence over the principle of interest, taking into account the obligation not to cause harm[6]. However, in some cases, non-malicious obligations are more stringent than charitable obligations, even if the most utilitarian results are obtained through charitable acts. Beauchamp and Childress warned that caution should be exercised in prioritizing the above axioms, as charitable acts do not always occur after acts that do not cause harm. Although non-malicious acts may prevail over other principles, it depends on the specific circumstances. In other words, non-malice only needs to avoid intentional injury and take actions to prevent and avoid injury and promote goodness in charity activities.

The author envisages the concept of "due care", i.e. full and appropriate care to avoid damage based on a reasonable and careful assessment of the situation[6]. This is the framework of negligence, known as "lack of proper care". The term can be understood as deliberately and unreasonably imposing a risk of damage, or inadvertently and unknowingly providing a risk, both of which are morally reprehensible but assessed on conditions that mitigate responsibility[6].

Beauchamp and Childress also include the meaning of non-malice in their specifications when considering the decision to treat or not to treat[6]. In addition, non-harmfulness takes into account the use of ordinary or special treatment according to the frequency of use or habit. From a moral point of view, the most important point must be whether treatment is beneficial to anyone receiving treatment or, more specifically, whether it will make them feel stressed.

The author considers whether intentional behavior can lead to foreseeable adverse effects[6]. In this case, the effects of good and evil must be seen. Therefore, good and evil, whether direct or indirect, must be treated and defended independently. Therefore, the motivation of the behavior should also be considered, which may help to solve its intention.

9. Charity principle

For Beauchamp and Childress, this principle includes "all forms of action aimed at the benefit of others"[6]. Charity principle is a moral obligation to do good to others. Although not all charitable acts are inevitable, some forms are inevitable. The following are prudent and valuable decisions on the indications of cochlear implantation.

The concept of charity has changed, especially in the doctor-patient relationship and the recognition of individual autonomy. For the author, active charity is the obligation to provide benefits, and the utility principle is the principle to examine the risks and benefits of behavior. This is because charitable activities may have a negative impact. Therefore, the decisions taken must measure the difficulties that may arise in order to take the most appropriate action[6].

In dealing with this principle, it is particularly note worthy to take into account the conflict between paternalism and autonomy. The charitable behavior of health workers is often what they think is most suitable for patients, including behavior that may exceed the wishes of patients, without respecting the autonomy they are entitled to[6].

The ethical dilemma of paternalism is to determine whether the interventions taken are morally justified and what happens in these interventions.

Generally speaking, it is through laws or rules to regulate paternalistic behavior, especially when the ability of individuals to make appropriate decisions is limited[6].

Beauchamp and Childress's charitable principles are also based on the best consideration of the benefits, risks and costs involved in health care, which must be weighed. Its definition of cost is economic, i.e. based on the resources needed to realize profits. Risk is considered to be possible damage in the future, thereby impeding people's well-being, health or life[6].

Benefits refer to values such as health or life that can take action, as well as reducing and preventing risks. His position is based on the principle of utility and proposes three common tools in the use of health policy, research and medical technology: Cost-benefit analysis or risk-benefit[6].

10. Principle of Justice

Fairness is a set of rules to ensure the fair distribution of benefits, risks and costs. Justice is a principle that transcends the personal sphere and can be introduced at the social level. Although it involves individual rights, it involves the protection of individual rights in different situations[6].

Beauchamp and Childress interpret it as "just, fair and appropriate treatment based on due or obligation to individuals"[6]. These authors cite the term "distributive justice" to recognize that "just, fair and appropriate distribution is determined by reasonable rules in social cooperation"[6].

In addition, they indicated that their implementation involved policies to allocate or restrict resources in terms of ownership, taxes, benefits, privileges or opportunities. In other words, they believe that distributive justice is the distribution of all political or civil rights and responsibilities in a society. An important aspect of Beauchamp and Childress's method is the principle of justice. On the one hand, it puts forward forms and materials. There must be a balance between the two, especially when the conditions existing in an environment are not sufficient to meet the needs of all members of a social group. In this regard, the exercise of the principle of justice can be changed, modified or reduced[6].

In a non-philosophical sense, the principle of material justice stipulates the characteristics of equal treatment in health care according to basic needs, which is the primary standard of distribution[6].

Distributive justice has always been a problem of seeking theoretical resources, which helps to determine the forms of distribution that can be taken, including the utilitarian theory of pursuing the maximization of social welfare, and individual rights is based on this premise. Therefore, its significance lies in the pursuit of the greatest public interest, on which the sense of justice will be based[6].

This principle is important for health policy and its impact on equitable access and distribution. For Beauchamp and Childress, there are two reasons for the right to health. On the one hand, there is collective social protection, i.e. giving priority to health care in the government's political agenda, providing basic services to citizens, and recovering social investment in the training of health personnel and technological development[6]. It also includes consideration of the "fair opportunity rule". His view is that individuals should not enjoy social benefits because of uncontrollable personal property, nor should they deny those who do not own such property[6].

All doctors using biotechnology must be aware that budgets for health are often insufficient to meet the needs of patients and health professionals for modern biotechnology. The aspirations of these people, whether fair or not, must be limited, because they are regulated by the state, where discrimination, inequality and inequality arise. In democracies, they try to avoid this situation by carrying out human rights mandates, but paradoxically, the market economy operated by these countries uses currency as an important tool of legal discrimination. Therefore, money has become the main legal source of discrimination and inequality in all societies[21].

11. Conclusions

Many dilemmas and conflicts of cochlear implantation may affect different analysis principles. The same dilemma, in addition to becoming a doctor, can also be bioethical. For cochlear implant, before making any decision, otolaryngologists must carefully consider the considerations described in each principle and carefully analyze these factors, because it will have a positive or negative impact on deaf people. Medical indications do not necessarily mean bioethical indications.

Cochlear implant is a high-tech operation, which has a good effect on deaf people who need and meet the requirements of the agreement. In order to obtain the best results, this should be the wish of every doctor who orders or performs implants. It must be considered that the biomedical program itself isnot the only reason for the success or failure of the process.

Conflict of interest

The author declares no conflict of interest.

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Wearable Technology (2020) Volume 1 Issue 2, *pp.* 28–32.
doi: 10.54517/wt.v1i2.1664

Asia Pacific Academy of Science Pte. Ltd.

CASE REPORT

Extra short implants in jaws with extreme vertical resorption: Case series

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ABSTRACT

Introduction: The use of in vitro implants can repair severe resorption. This sometimes requires the use of prostheses in the most extreme cases, when the proportion of crown implants is not ideal, to reach 2:1 or 3:1. Materials and methods: Clinical analysis was carried out on implants with a residual of 5.5 mm or less and more than 6 months. Chi square test was used for categorical variables and student test was used for continuous variables. Then, a linear fitting regression model is established. **Results:** Six patients received in vitro implantation. 21.2% of the patients in the study were male and 78.8% were female, with an average age of 57 years. The average crown planting ratio was 3.19 (+/–0.24). The average bone loss of the implant was 0.86 mm (+/–0.33) in the near median position and 0.83 mm (+/–0.47) in the anterior position. There was no statistically significant difference in the functional proportion of proximal and distal bone loss (P = 0.224). **Conclusion:** According to the data provided in this study, even if the crown implant.

Keywords: dental implants; atrophy; bone resorption; oral rehabilitation

1. Introduction

The treatment of posterior alveolar ridge defects in patients with severe maxillary bone resorption is a challenge for every surgeon. In these cases, there are different bone regeneration techniques, such as transplantation with or without membrane and bone traction[1–5]. In many cases, the grafts are reabsorbed to varying degrees. Resorption usually occurs due to the presence of severely atrophic blood vessels and cell density differences in these areas. In addition, there is very thin soft tissue in these areas, which makes it difficult to obtain good gingival coverage and one-time closure without tension or suture dehiscence when placing a large number of grafts[6–8].

In vivo explants were created to address the need to simply repair these subsequent parts while avoiding the more complex assistive techniques described above. The main problem when using these implants is whether the survival rate is equivalent to that of other implants with larger length, and how to solve these problems to ensure that the whole implant performs well in biomechanics.

According to relevant published studies, the

ARTICLE INFO
Received: April 10, 2020 | Accepted: May 26, 2020 | Available online: June 11, 2020

CITATION
Anitua E. Extra short implants in jaws with extreme vertical resorption: Case series. Wearable Technology 2020; 1(2): 28–32.

survival rate of short implants can be comparable to that of "traditional length" implants (following the cautious scheme formulated by the team of Anitua et al.), in which the atrophy is very serious and the implants are in vitro[9,10]. The data of these implants published by our research group showed that the survival rate was 98.2%[11] during an average follow up of two years.

The treatment plan developed for these implants includes the following steps: Biological milling (no watering at low speed) to form an implant bed, which relates to the repair of the implant. The implant bed contains an intermediate component (across telial multi IM), which produces the "overall" behavior of the system, produces better load transfer to the bone, and maintains tightness to ensure that there are no bacteria in the interface[12–18]. In this way, the length of the epithelium is combined with the length of the implant, which reduces the lever arm of the prosthesis and thus the ridge stress.

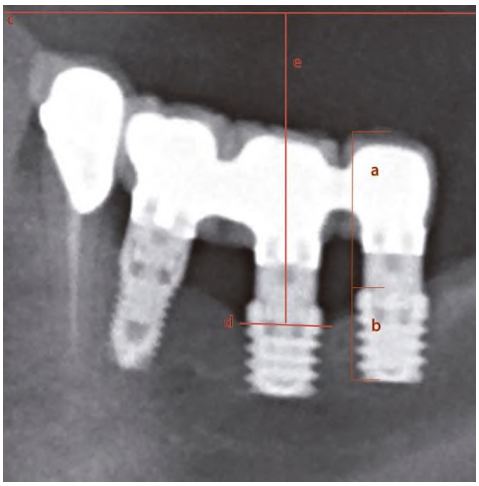
Based on a series of cases, this paper attempts to retrospectively evaluate the behavior of these implanted and repaired in vitro implants in the area of extreme bone resorption by analyzing the rate of marginal bone loss and the effect of prosthesis on joints.

2. Materials and methods

A retrospective study was conducted by selecting patients with ultra-long implants located in the posterior segment of the mandible. In these patients, due to the extreme resorption of bone, the implant needs to be inserted, and the minimum loading time is 6 months. In all patients, demographic variables, harmful habits (tobacco and alcohol), prosthesis data (crown implantation rate, prosthesis type related to the number of parts and manufacturing materials) and marginal bone loss (measured at the proximal and distal ends of the implant) were collected.

To determine the proportion of crown implants, we measured crown height gap (CHS) and bone loss using calibrated panoramic X-rays. All patients were positioned according to a strict protocol. Once the X-ray is obtained, the length of the X-ray is calibrated using specific software (sidexis, Sirona dental systems, Bensheim, Germany), which is the same as the length of the dental implant. Through the calibration measurement, the actual measurement of X-ray can be carried out (1:1 scale).

The crown implant ratio was determined by dividing the length of the implant by the length of the prosthesis placed on it. The crown height of the long axis of premolars and the middle crown area from the vestibular sulcus (interdental sulcus) of molars to the implant platform were measured. The measuring line must be completely perpendicular to the implant platform and at an angle of 90° to the implant platform (**Figure 1**).



Potential bone atrophy was observed in both maxillae when the removable prosthesis was removed

Figure 1. Measure the height of the crown (a) relative to the implant (b) and the height from the implant platform (d) to the eye plane (c).

In order to determine whether there are statistically significant differences between the two groups, Chi square test was used for categorical variables and student T-test was used for continuous variables. $P < 0.05$ was considered as the statistical significance of the statistical test used.

3. Results

We recruited six patients over the age of 18 who received in vivo implants. 21.2% of the subjects were male and 78.8% were female, with an average

age of 57 years. In any case, assisted surgical techniques were not used in implant surgery, and all implants were performed in two operations with a waiting time of up to three months.

The average crown implant ratio of implants was 3.19 (+/– 0.24 mm), ranging from 3 mm to 3.64 mm. All implants included in the study were ferulized, forming a bridge between two to four implants. 100% of cases were mainly screw fixation. All implants were repaired with a system consisting of percutaneous im (Tute, Spanish Institute of Biotechnology), which is connected to the prosthesis bolted to it.

The median bone loss of the studied implants was 0.86 mm (+/–0.33). The mean bone loss at the distal end of the implant was 0.83 mm (+/–0.4). When the proximal, middle and distal bone loss were analyzed according to the ratio of crown to implant, there was no statistically significant difference (P = 0.224). The mean follows up time was 19.2 months (+/– 4.6 months), ranging from 14 to 25 months. During follow up, no adverse events of prosthesis or implant were observed. **Figure 2–11** shows a clinical case in the study.

Figure 2. Patients with lower partial edentulous and upper complete edentulous (using removable dentures).

Figure 3. Bone atrophy in patients with upper and lower removable dentures.

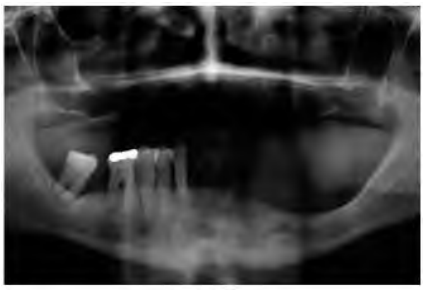
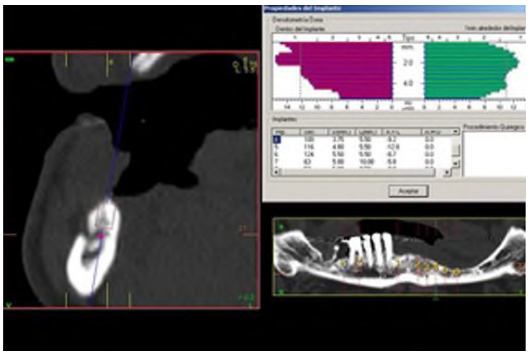


Figure 4. X-ray plain film of patients with lower edentulous and upper total edentulous.

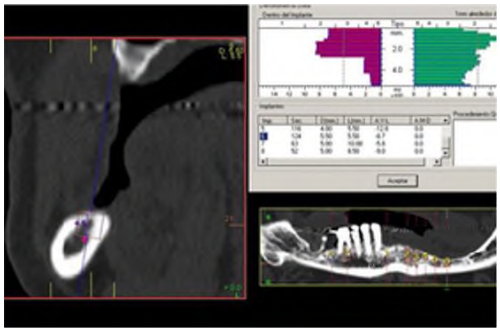
Figures 5. Research on garment modeling.

Figures 6. Research on garment modeling.



You can observe severe mandibular height atrophy at the back of the third quadrant, and then insert an ultrashort implant there

Figures 7. Planning dental CT with bti-scan III diagnostic software.



You can observe severe mandibular height atrophy at the back of the third quadrant, and then insert an ultrashort implant there

Figures 8. Planning dental CT with bti-scan III diagnostic software.

The postoperative X-ray after the implantation of the upper and lower implants further showed that the patient had performed maxillary sinus lifting in order to insert more implants in the rear of the maxilla in the future. It can be demonstrated that the in vitro implants in the third quadrant are submerged, while the remaining implants in this quadrant and the implants in the front of the fourth quadrant are placed in an immediately loaded prosthesis

Figure 9. X-ray examination after upper and lower implant implantation.

After three months, the remaining lower implants were wrapped in the prosthesis and loaded with body explants

Figure 10. X-ray after implant implantation.

Figure 11. X-ray examination 5 years after implantation.

4. Discussion

Developing a protocol for this type of implant to accommodate this limitation (severe vertical shrinkage) is essential to achieve a success rate compared to “conventional length” implants. This prototype was used in all papers published by the team of Anitua et al., and the survival rate of in vitro implantation was 98.2%[11].

According to the data of traditional prosthesis, this unfavorable implant crown ratio (3:1) may have a serious impact on in vitro implants, but the data provided in this study can’t confirm this hypothesis. Other studies in this area have reached the same conclusion that there is no relationship between adverse proportion and ridge bone loss, although they do not assess extreme imbalance as in this study[19–22].

In this study, the implant was ferulate as part of the bridge. According to other studies in this area[23,24], this ferulization reduces the risk of bone loss and makes the biomechanical function of the joint better. Therefore, it can be suggested that prosthesis replacement in this way may be the key to the crown implantation of this implant than the unfavorable implant.

5. Conclusions

According to the data provided in this study, the use of in vitro implants with a crown implant ratio of 3 or more is not a risk factor for ridge bone loss or prosthesis or implant failure. Ferulization of explants improves biomechanical behavior under unfavorable crown implant ratio, which may be a suggestion worthy of consideration in this case.

Conflict of interest

The author declares no conflict of interest.

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Wearable Technology (2020) Volume 1 Issue 2, *pp.* 33–41.
doi: 10.54517/wt.v1i2.1669

Asia Pacific Academy of Science Pte. Ltd.

CASE REPORT

Cochlear implant in Kearns-Sayre syndrome: A case study of twin sisters

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ABSTRACT

Hearing loss may be related to several factors, including hearing loss resulting from certain genetic syndromes. Kearns-Sayre syndrome is characterized by mutations in mitochondrial DNA (Deoxyribonucleic Acid), responsible for the production of energy (adenosine triphosphate-ATP), which is extremely important for the development of structures that require it, such as the cochlea. The case was followed up at the hospital since 2000, due to the progressive characteristic of hearing loss found in audiological tests and findings in cases related to the syndrome. The intervention with individual sound amplification devices proved to be of little benefit for good oral communication of one of the patients, who was diagnosed with bilateral profound hearing loss. Thus, after discussions in clinical meetings, the team opted for the indication of the cochlear implant for the patient, according to the current criteria for indication of this surgery, and with which it obtained good results. His twin sister, who presented good results with hearing aids, will continue in audiological follow-up, to verify the evolution of the case and discuss a new approach, if necessary. Patients with suspected or diagnosed Kearns-Sayre syndrome should seek audiological diagnosis, because it is a possible progressive hearing loss, requiring rehabilitation with the use of hearing devices. Maintaining oral communication is extremely important because, in these cases, other functions will be impaired, such as muscle tone and vision.

Keywords: hearing loss; cochlear implant; syndrome; diseases in twins; audiology

1. Introduction

Several causes of hearing loss are reported in the literature and, regardless of the etiology, it is important that the diagnosis and intervention are performed early. Approximately 30% of genetic hearing losses occur associated with a syndrome[1,2].

Kearns-Sayre syndrome (KS) is related to ge-

ARTICLE INFO
Received: August 15, 2020 | Accepted: September 19, 2020 | Available online: October 7, 2020

CITATION
Oliveira LS, Brosco KC, Oliveira EB, et al. Cochlear implant in Kearns-Sayre syndrome: A case study of twin sisters. Wearable Technology 2020; 1(2): 33–41.

netic mutation in mitochondrial DNA. Mitochondria is an intracellular organelle that has its own genome (DNA)[2], and multiple deletions of this genome are possible[3]. The inheritance of the mitochondrial genome is maternal, because during fertilization the tail of the sperm, which contains the mitochondria, is displaced during penetration into the egg. In KS syndrome, part of the zygote DNA is not formed, but these mutations can also occur spontaneously[4].

The main function of mitochondria is to provide energy to cells in the form of ATP (Adenosine Triphosphate) and some organs require higher energy and are most affected by cases of mutations in the DNA. Among these organs are nerve, muscle, optic, endocrine and auditory cells. The cochlea is an organ that requires a lot of energy, therefore mutations in the mDNA of hair cells can cause bilateral, symmetrical and progressive sensorineural hearing loss (SNHL)[2,4,5].

KS syndrome was first described by Kearns and Sayre in 1959[6], in a case report that presented with external ophthalmoplegia, pigmentary retinopathy and cardiac conduction disorder (CCD). It is a rare syndrome and it is estimated that the appearance of cases occurs in 1.6 for every 100,000 individuals[7].

Diagnosis occurs through the observation of a triad: Progressive external ophthalmoplegia, pigmentary retinopathy and CCD. The first signs and characteristics of the syndrome usually appear before the age of 20, as observed in the literature[3,6–10]. In addition, it is possible to perform genetic testing, mainly seeking information related to DNA, where multiple deletions or mutations are found in cases of KS syndrome[11,12].

In the literature[9], there are reports of the presence of KS syndrome in twin siblings: there was no presence of risk factors and, at 19 years of age, both began to present symptoms of the syndrome, such as eyelid ptosis and sensorineural hearing loss (SNHL).

Regarding progressive hearing loss, the literature recommended monitoring patients with this suspicion at least every two months to check if there was progression. The authors also described that electrophysiological examinations in children help in the best conduct for the adaptation of individual sound amplification devices (ISADS)[13,14]. It is believed that this monitoring is necessary to avoid loss of sensory and, consequently, cognitive auditory information, which can lead to delay in auditory and language development.

Few studies related to KS syndrome have focused on the diagnosis of hearing loss and do not correlate this finding in twin children. However, some authors argue that the most appropriate audiological intervention in cases of progressive hearing loss in patients with KS syndrome and others related to DNA mutations would be cochlear implant (CI)[15].

The present study aimed to report the case of twin sisters with KS syndrome, from their audiological diagnosis to the intervention.

1.1. Conducting the research

The study was initiated after approval by the Research Ethics Committee of the Hospital for Rehabilitation of Craniofacial Anomalies of the University of São Paulo, Campus Bauru: 090311/2015, CAE 42447215.8.0000.5441. This is a longitudinal descriptive study of twin sisters with KS syndrome and audiological diagnosis of sensorineural hearing loss, carried out by the interdisciplinary team of a hospital. Cases are described as Twin 1 (T1) and Twin 2 (T2).

The patients were registered at the hospital in June 2000 and have been followed up ever since. Therefore, in order to demonstrate more accurately the progression of hearing loss and the results of the intervention, we chose to describe two moments of the evaluation: Time of admission to the hospital: first audiological diagnosis, performed in June 2000, when they were 11 years old; the last attendance reported in the medical record, up to the time of the start of the research, performed in August 2014 and March 2015 for T1, and in August 2014 for T2, and

they were 25 years old then.

1.2. Patients

The mother of the patients, when registering them in the hospital in June 2000, signed the Free and Informed Consent Form, authorizing the consultation of the data from the medical records, for scientific subjects. In the year of this study, in 2015, patients and their families were informed that the research would be carried out through the analysis of documents attached to the hospital's medical records and thus obtained the existing permission for the development of the research.

2. Presentation of the clinical case

2.1. Medical evaluation

The first consultation at the hospital was performed by an otolaryngologist, who found complaints and characteristics typical of KS syndrome on clinical examination. During the anamnesis, the mother reported other evaluations and diagnoses made by doctors from her home city, such as astigmatism, hyperopia, visual fatigue, decreased muscle mass with preserved strength, myopathic face, slight restriction of eye motricity and alteration in muscle tone.

The patients (T1 and T2) were referred for the realization of the genetic test, to know the suspicion of the syndrome, already verified by another institution and informed by the mother, through document, to the multidisciplinary team, who reported all these data in the medical records, in the form of anamnesis and evolution of the case.

2.2. Audiological diagnosis

Twin 1

The following data were reported by the mother, in a speech-language pathology anamnesis, during the first consultation in June 2000, when the patient was 11 years old.

—There is no family history related to hearing loss and syndromes.

—There were no complications during pregnancy.

—Report of mumps and chickenpox, near 3 years of age.

— Neuropsychomotor and language development according to age, however, without previous specialized evaluations.

—Hearing complaints started at 10 years of age. Patient T1 began to respond to her own name when her voice was very strong and also reported bilateral tinnitus.

In relation to audiological tests, objective tests were analyzed, such as immittance testing, transient otoacoustic emissions and distortion product otoacoustic emissions (TEOAE and DPOAE) and auditory brainstem evoked potential (BAEP), and subjective tests, such as pure tone audiometry (PTA) and speech perception tests (SPT) (**Table 1**).

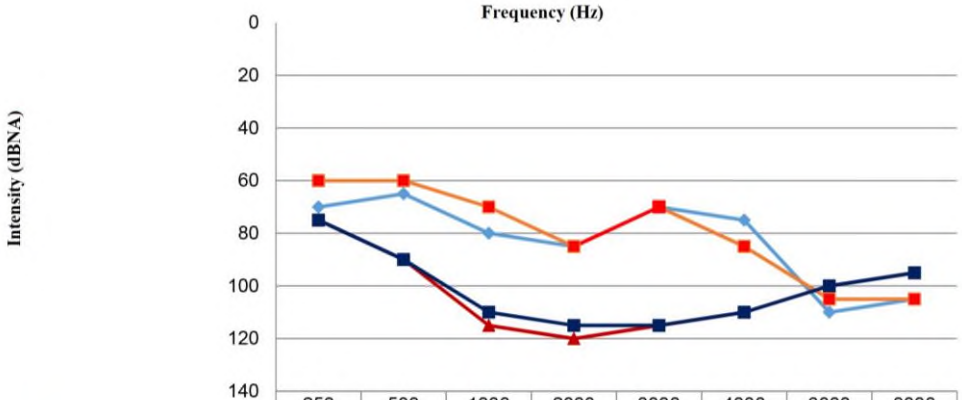
Table 1. Results of objective tests for the hearing of Twin 1 (2000 and 2014)

Examination performed	Right ear (RE)	Left ear (LE)
Imitanciometry	Type A curve Absent reflections in 2000 and 2014	Type A curve Absent reflections in 2000 and 2014
TEOAE and DPOAE	No record in the medical records in 2000 Absent in 2014	No record in the medical records in 2000 Absent in 2014
BAEP click	No record in medical records in 2000 Absent in 2014	No record in medical records in 2000 Absent in 2014

Legend: TEOAE = Transient Evoked Otoacoustic Emissions; DPOAE = Distortion Product Otoacoustic Emissions; BAEP = Brainstem Auditory Evoked Potential.

The results of the subjective tests were compatible with the electrophysiological tests, in both evaluation moments, as shown in **Figure 1**.

In 2000, after the exams, professionals were able to diagnose hearing loss as severe bilateral sensorineural hearing loss (SNHL) and thus adapt the individual sound amplification device (ISAD) and perform the respective validation and verification tests. However, in 2014, there was a significant progression of the degree of hearing loss, which became of deep bilateral degree, requiring replacing the hearing aid with another, higher and more recent technology, as well as redoing the verification tests (**Figure 2**).



	250	500	1000	2000	3000	4000	6000	8000
Left Ear (2000)	70	65	80	85	70	75	110	105
Right Ear (2000)	60	60	70	85	70	85	105	105
Left Ear (2014)	75	90	115	120	115	110	100	95
Right Ear (2014)	75	90	110	115	115	110	100	95

Figure 1. Threshold tonal audiometry-Twin 1.

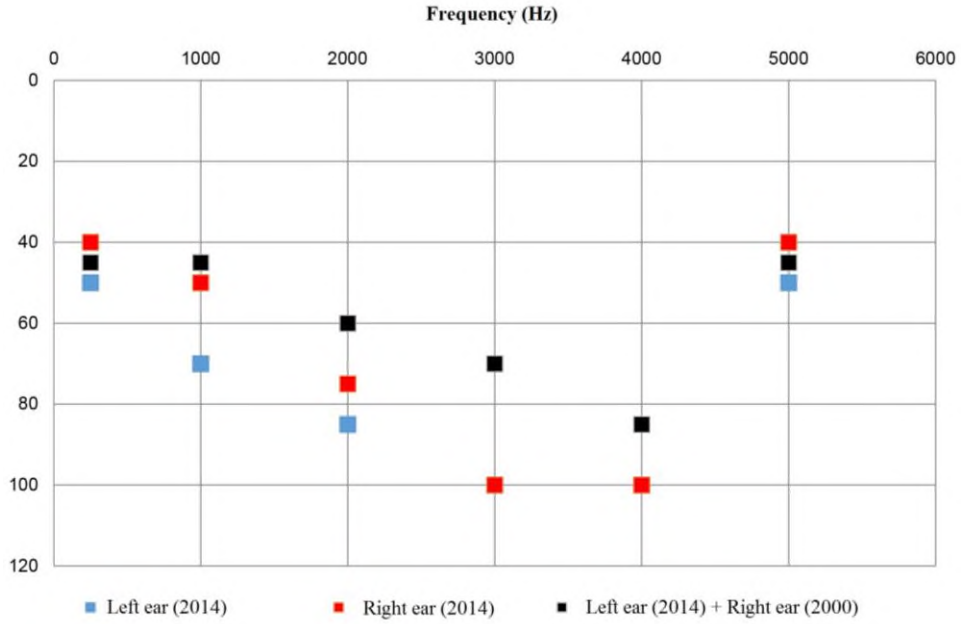


Figure 2. Research of the amplified threshold with individual sound amplification apparatus-Twin 1.

In 2000, it was not yet common in the hospital to apply the speech perception test (SPT) with hearing aids in all patients. They were performed only in those whose cases would be presented in a meeting, for discussion about cochlear implant surgery (CI). For this reason, in the medical records of patient T1, SPT evaluation was found only in 2014. The right ear score (RE) was: Detection of Ling test sounds for /a/, /u/, /i/ and /m/=100% and for /s/ and /ʃ/=0%; name recognition=100%; question/statement breakdown=0%; identification of vocabulary extension=44%; identification of the

length of sentences=60% and identification of sentences=0%.

In the left ear (LE), the score found was: Detection of Ling test sounds for /a/, /i/, /u/ and /m/=100% and for /s/ and /ʃ/=0%; name discrimination=90%; question/statement breakdown=0%; identification of vocabulary extension = 28%; identification of the length of sentences=30% and identification of sentences=0%.

Despite the progression of hearing loss, Twin 1 had good vocabulary and oral language, since the hearing loss was post-lingual. Specific language tests were not included in the medical records. It is believed that the reason is the fact that the patient was already in adolescence in 2000 and later in adulthood in 2014, and there are no specific language protocols in the hospital sector to evaluate these age groups.

After the exams, the case was selected to be discussed by the multidisciplinary team, regarding the need for surgery for cochlear implant (CI). Several criteria were addressed, from the analysis of other professionals, such as social worker, psychologist, otolaryngologist and speech therapist, and from the SUS and hospital criteria at the time.

Regarding the speech therapy analysis, the main criterion for the indication of surgery was the low result in the speech perception tests in closed set and difficulty in open set. In addition, professionals were concerned about not having other hearing aid replacement options in the future if the hearing loss progressed. In addition, the team physicians emphasized that the patient was losing other functions, including vision. Therefore, it was necessary to maintain good oral communication in order to preserve their quality of life, despite the other difficulties caused by the syndrome.

Therefore, we chose to perform CI surgery on the left side, which decided by surgeons, and the activation occurred in February 2015 (**Figure 3**).

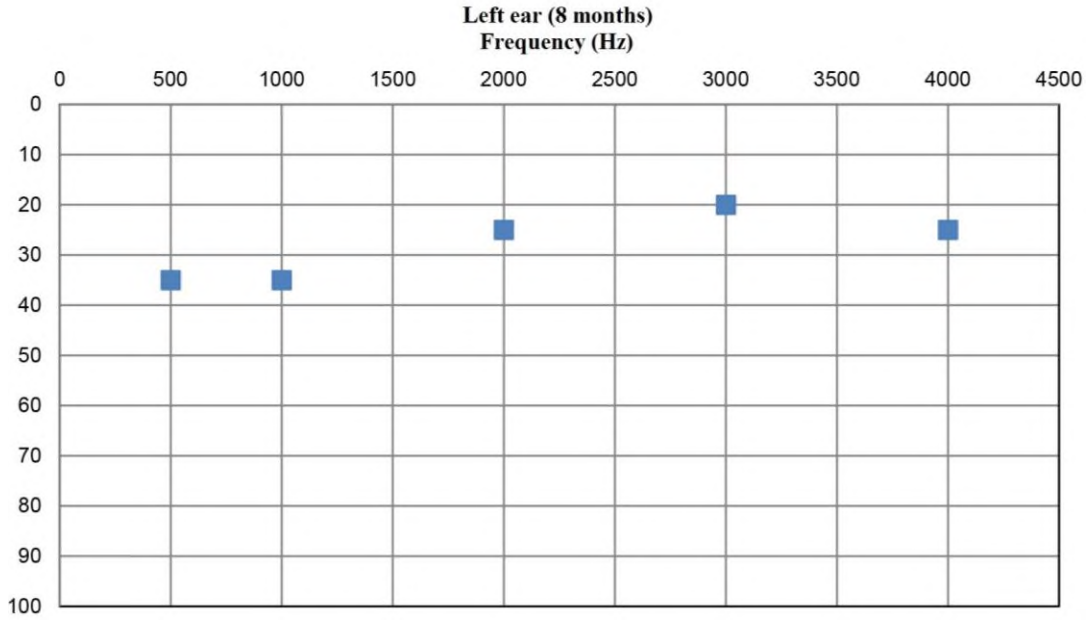


Figure 3. Research of the amplified threshold with cochlear implant–Twin 1.

Regarding the SPT with CI, performed one month after activation, in March 2015, the patient detected all the sounds of the Ling test, but could not perform other speech tests, complaining that she had not yet gotten used to all the sounds, because the CI was very different from the hearing aid, which she used for 15 years. The best results appeared eight months after activation, when, then, the patient performed the SPT in an open set, with a result of 45% for the list of sentences. However, regular follow-ups are still made for new approaches and guidelines.

Twin 2

The data presented below, as well as for Twin 1, were reported by the mother in a speech-language pathology anamnesis during the first visit in June 2000, and the patient was 11 years old then.

—There is no family history related to hearing loss and syndromes.

—There were no complications during pregnancy and childbirth.

—She contracted mumps and chickenpox near 3 years old.

—Neuropsychomotor and language development, according to age, however, without previous specialized evaluations.

—Hearing complaints started at 10 years old. Patient T2 started to respond to her own name only when her voice was very strong and also reported bilateral tinnitus.

In relation to audiological tests, objective tests were analyzed, such as immittance, transient otoacoustic emissions and distortion product (TEOAE and DPOAE) and brainstem auditory evoked potential (BAEP), and subjective tests, such as pure tone audiometry (PTA) and speech perception tests (SPT) (**Table 2**).

Table 2. Results of objective tests for the hearingof Twin 2 (2000 and 2014)

Examination performed	Right ear (RE)	Left ear (LE)
Imitatiometry	Type A curve Absent reflections in 2000 and 2014	Type A curve Absent reflections in 2000 and 2014
TEOAE and DPOAE	No record in the medical records in 2000 Absent in 2014	No record in the medical records in 2000 Absent in 2014
BAEP click	Absent in 2000 Absent in 2014	Absent in 2000 Absent in 2014

Legend: TEOAE = Transient Evoked Otoacoustic Emissions; DPOAE = Distortion Product Otoacoustic Emissions; BAEP = Brainstem Auditory Evoked Potential.

The results of the subjective tests were compatible with the electrophysiological tests, in both evaluation moments, as shown in **Figure 4**.

After all evaluations, in 2000, when Twin 2 was 11 years old, the professionals diagnosed the patient with mild sensorineural hearing loss (SNHL) in the left ear and moderate in the right ear. Therefore, the fitting of hearing aids compatible with this type of hearing loss was performed, as well as validation and verification tests.

In 2014, when the patient was 25 years old, progression of hearing loss was observed, as shown in **Figure 4**. Thus, the diagnosis became severe bilateral SNHL, which made it necessary to replace the hearing aid and perform new tests to verify its benefits (**Figure 5**).

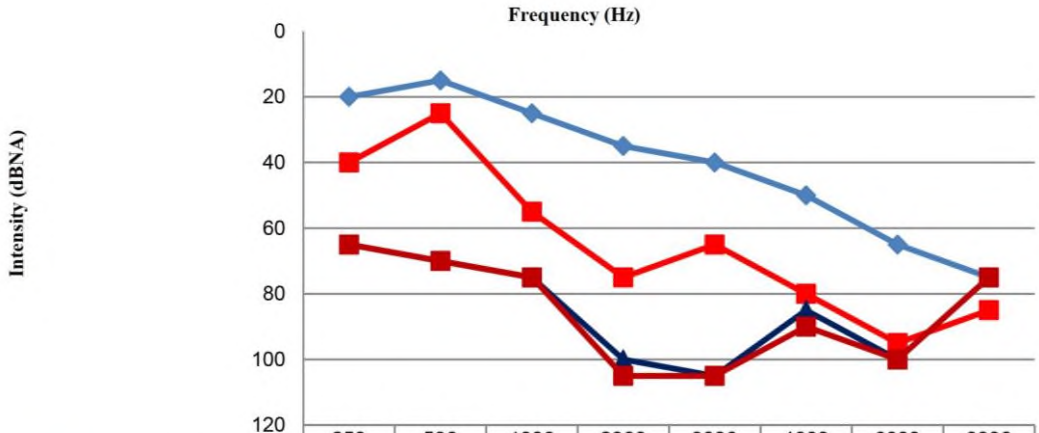
Regarding the SPT with hearing aids, performed in 2014, the patient was able to perform all tests in a closed set and obtained a result of 80% in RE and 97% in LE, for the tests in an open set (list of sentences).

Despite Patient T1 was experiencing hearing loss, Patient T2 had good vocabulary and oral language, since hearing loss was post-lingual. Specific language tests were not included in the medical records.

The reason was thought to be that the patient was already in adolescence in 2000 and later became an adult in 2014, and the hospital department did not have specific language protocols to assess these age groups.

The case was also selected for a multi-disciplinary meeting to discuss the CI, including to compare the results with those of Twin 1. All professionals, such as social worker, psychologist, otolaryngologist and speech therapist informed the results of their evaluations and, based on this information and the criteria established by SUS and

the hospital in 2014, Twin 2 were not indicated for CI surgery.



	250	500	1000	2000	3000	4000	6000	8000
Left Ear (2000)	20	15	25	35	40	50	65	75
Right Ear (2000)	40	25	55	75	65	80	95	85
Left Ear (2014)	65	70	75	100	105	85	100	75
Right Ear (2014)	65	70	75	105	105	90	100	75

Figure 4. Threshold tonal audiometry-Twin 2.

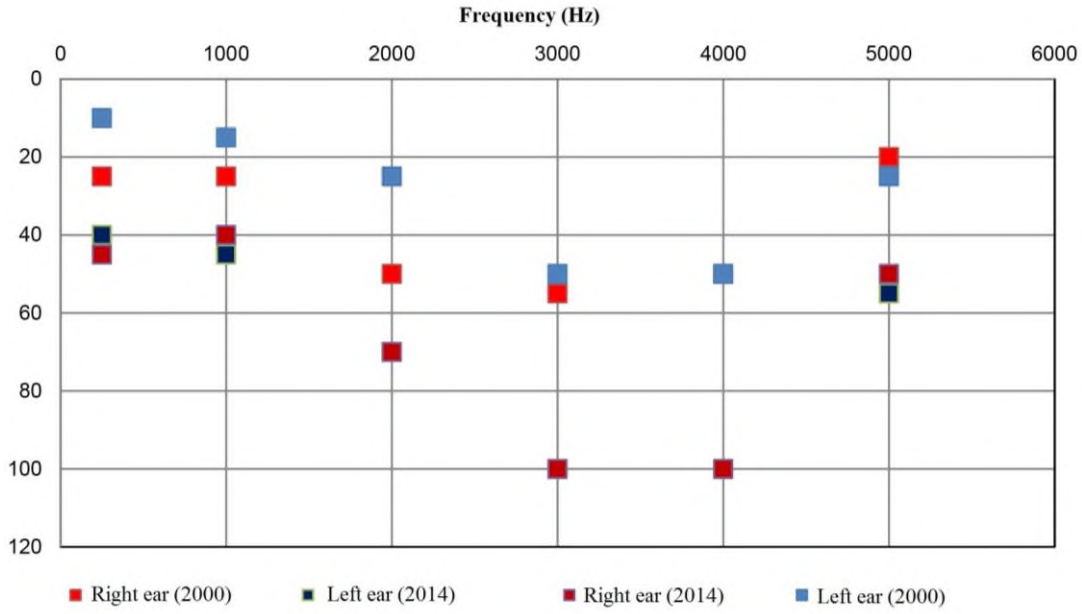


Figure 5. Research of the amplified threshold with individual sound amplification apparatus-Twin 2.

Regarding the speech therapy evaluation, the main factor that did not indicate CI was a good percentage of correct answers in the SPT with hearing aids, demonstrating that the device still provided a benefit. Thus, it was decided to keep Twin 2 in audiological follow-up and verify if the hearing loss will progress. Even if this may happen, professionals believe that there are still other options for hearing aid replacement to maintain good oral communication of the patient, which makes it unnecessary, at the moment, to undergo surgery, since the benefits of CI are very similar to those that the hearing aid still provides. However, as soon as the hearing aid does not provide the same benefits, the case of Twin 2 will be discussed again by a multidisciplinary team, regarding the need for CI, to

prevent progressive loss from aggravating the patient's current good communication.

All data related to the discussion of Case T1 and Case T2 by the multidisciplinary team were collected from the medical records and from interviews with the professionals responsible for the cases.

3. Discussion

The literature[7] described the case of twin siblings with KS syndrome, showing the absence of risk factors associated with preconception and early childhood, as both developed normally until years old, when the first symptoms of visual changes and hearing impairment began to appear. These findings were consistent with those of the present study, as the sisters also did not have any complaints or symptoms until the age of 10 years. Other studies[2,4,5] also mentioned the onset of symptoms and diagnosis before 20 years old.

In terms of audiometric testing, a diagnosis of SNHL was obtained, as well as a progression of hearing thresholds, one of the typical features of patients with hearing loss due to KS syndrome, which in most cases is sensorineural, symmetrical and progressive[1,2]. Therefore, audiological diagnosis and early intervention, as well as follow-up every two or three months, were considered extremely important to verify the progression of hearing loss and determine the optimal behavior related to hearing aid adaptation[13,14]. Thus, delay in auditory and language development can be avoided.

The etiology of the syndrome remained controversial in the literature. In the cases studied (T1 and T2), the only early complications in children were a diagnosis of mumps and chickenpox. However, these viral infections usually did not leave serious sequelae after treatment. Therefore, it was believed that the syndrome may have occurred due to genetic mutations.

Another factor that indicated the presence of genetic mutation, in the case of this study, was bilateral, symmetrical and progressive hearing loss, because it demonstrated alteration in the cochlea, in agreement with the literature, regarding the genetic mutation of the mDNA, which impairs the supply of energy (ATP), especially to the organs that need it most, such as the cochlea[1,2].

According to the authors[15,16], in cases of hearing loss due to mitochondrial disease, the best intervention option was CI, because of the progressive nature of these losses. In the present study, this was also the case in Patient T1, where the auditory benefit verified in the test was not obtained after the diagnosis of profound SNHL, even after the replacement of the hearing aid, which was the main reason for the CI indication. In the case of T2, despite the progression of the hearing loss, even with the use of hearing aids, from 2000 to 2014, the patient presented a good speech perception condition, that was, there was still an auditory benefit only with the use of hearing aids, but due to the characteristics of this case, the patient would continue to be monitored.

Authors[15] reported the case of patients with KS syndrome who underwent CI. The responses regarding speech recognition and electrophysiological tests with CI were very similar to those of CI patients who did not have the syndrome.

It was believed that the patient who already uses CI (Twin 1), together with contralateral hearing aid, added to speech rehabilitation, could present even more satisfactory results in relation to speech recognition, and maintain good oral communication.

4. Conclusions

Subjects with suspected KS syndrome should be evaluated to confirm the syndrome and have an early hearing evaluation, as if necessary rehabilitation with hearing aids and/or cochlear implants, coupled with speech therapy, can bring beneficial outcomes.

Conflict of interest

The authors declare no conflict of interest.

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