Immediate implant placement influenced by musical flow: A prospective randomized controlled clinical trial

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Research Article

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Abstract

Objectives

The purpose of this study was to test how musical flow using baroque (BM) and classical era music (CM) as a non-pharmacological therapy can control anxiety and pain levels among patients undergoing IPI (Immediate post-extraction implants).

Material and Methods

78 patients who required an IPI were enrolled in this randomized clinical trial. Each patient was assigned to one of the three experimental groups with a simple randomization: Group I (n=26) listened to BM; Group II (n=27) listened to CM; and Group III (n=25) did not listen to music and was the control group (C). The physiological dependent variables analyzed were SBP, DBP, HR and SpO2. The psychological dependent variable analyzed was MDAS and VAS, measured before and after surgery. In all cases, the level of statistical significance was set at p < 0.01.

Results

Statistically significant differences were found in the SBP decrease in the CM group (p=.001, CI=1.9716-6.5840) and the BM group (p=.003, CI=1.4450-6.4396). Anxiety levels during the intervention decreased in both groups that listened to music: BM group (p=.002, CI=.645-2.662) and CM group (p=.000, CI=1.523-3.884).

Conclusion

Patients undergoing IPI placement surgery can register lower levels of SPB when listening to BM and CM, improving their anxiety levels.

Clinical relevance

The evidence on the effect of music as a non-pharmacological tool in reducing anxiety during dental implant surgery is very scarce. Only two randomized clinical trials have been previously published (Gülnahar & Kupeli, 2020 and Esteban Pellicer et al., 2022). The present study is the first to be published on immediate post-extraction implants.

Trial Registration Number:

NCT05052034

https://beta.clinicaltrials.gov/study/NCT05052034?distance=50&cond=%20NCT05052034&rank=1

Introduction
Tooth loss in the anterior maxillary area has a negative influence on the patient's esthetics, and may compromise hard and soft tissues\textsuperscript{1,2}. Surgery by means of IPI in the esthetic area by means of a flapless technique is a surgical procedure that presents positive results\textsuperscript{3,4}, being a widely used technique, preserving hard and soft tissues and maintaining the patient's esthetics\textsuperscript{5,6}. This minimally invasive procedure improves patient comfort and reduces treatment time compared to deferred implants.

However, many patients requiring this type of treatment present increasing levels of fear and anxiety, which can be as high as 76%\textsuperscript{7,8}. This can make it difficult to carry out the treatment properly.

Music has proven to be an effective tool in the management and control of anxiety during some surgical procedures\textsuperscript{9,10}, being a safe and non-invasive therapy. However, to date, there is no suitable musical flow in this type of surgery to reduce patients' intraoperative anxiety and fear\textsuperscript{11}.

The purpose of this study was to test musical flow in a clinical setting as a non-pharmacological therapy, testing how baroque and classical music can reduce intraoperative anxiety and pain experienced by patients undergoing IPI. The influence of music regarding changes in systolic BP (SBP), diastolic BP (DBP), oxygen saturation (SpO2) and heart rate (HR) during dental extraction and subsequent dental implant placement was evaluated. In addition, they sought to identify the effects of musical intervention on perioperative anxiety levels and patient perception of pain. The investigators hypothesize that musical intervention will induce minor changes in patient vital signs during IPI, and musical intervention will decrease perioperative anxiety levels and pain perceptions in patients undergoing implant surgery.

**Materials & Methods**

**Study design**

To address the research purpose, the investigators designed and implemented a prospective randomized controlled clinical trial (RCT) double-blind, with a parallel design and simple randomization using the computer algorithm program (http://www.random.org). This study was designed and conducted in accordance with the ethical principles stipulated by the Helsinki Declaration of the World Medical Association (version VI, 2002), and the additional requirements of Spanish legislation. Approval was obtained from the Ethics Committee of European University of Madrid, which assigned the internal code CIPI/21/005. All patients signed an informed consent form. And it was registered in the ClinicalTrials.gov database with ID NCT05052034.

The study population sample was composed of all the subjects who came for evaluation and management and required placement of an immediate post-extraction single-tooth implant in the esthetic zone between teeth 1.4 and 2.4, between February 2021 and May 2022, in the European University of Madrid, Spain. For this reason, it was not necessary to carry out a sampling, but rather 100% of the patients who met the inclusion criteria for the study were included. The 15-month interval was considered adequate since it included sufficient variability in patient types. Of the 84 patients in this 15-month
interval, 3 refused to participate in the study, and 3 others were excluded because they did not meet any of the conditions for inclusion in the study. The final sample was 78 patients (Fig. 1).

To be included in the study sample, patients had to be over 18 years of age and Spanish-speakers who required the extraction of an anterior tooth between 1.4 and 2.4 and a post-extraction implant could be placed at the same time. Patients were excluded if they required surgery with flap lifting and bone regeneration, not being able to perform a flapless technique. In addition, all cases that required a connective tissue graft on the same day of surgery were excluded because they had a thin gingival phenotype, due to a greater morbidity and duration of treatment. Also excluded were all patients diagnosed with mental illness (dementia), with psychiatric disorders, under anxiolytic treatment, with visual or motor loss or with any disability that made it impossible to fill out the forms provided, and the visual analog scale (VAS). Patients under medical treatment that could interfere with the anesthesia used during the oral surgery procedure were also excluded.

The patients were randomly divided into three groups:

- Group I (n=26) who listened to baroque music (BM).
- Group II (n=27) who listened to classical music (CM).
- Group III (n=25) who did not listen to music and acted as the control group (C).

No patient had ever undergone such a surgical procedure before.

The patients received all the information regarding the study and signed an informed consent which stated that the study would not interfere with the correct completion of the treatment. Each patient was given a brief explanation about possible complications, as well as direct, intraoperative communication with the surgeon when necessary. All patients were blinded in each music group, and each patient could choose to stop being part of the study and discontinue the music at any time.

There was a calibrated, blinded dental observer who randomized and collected and quantified the data. In addition, all surgeries were performed by the same practitioner,

thus, minimizing different subjective criteria that could modify or alter the patient's level of intraoperative anxiety.

**Surgical procedure**

Post-extraction single-tooth implants were placed in the upper arch, including central incisors, lateral incisors, canines and first premolars.

All the post-extraction implants selected for the study met the following requirements: all had a class I socket, with sufficient remaining palatal bone for the adequate performance of the surgery; the gingival margin of all the teeth to be extracted had adequate conditions for the treatment, type I or II as described
by Elian et al. 13. The type II sockets chosen were those subclassified as type IIa and IIb, discarding type IIc with greater apical hard tissue involvement 14. Patients who required any type of improvement of the peri-implant phenotype through surgery with connective tissue grafts were rescheduled for a second surgical phase 15.

The same methodology was followed throughout each group. The usual diagnostic tests were performed before IPI. The surgical area was anesthetized via mucosal infiltration, using in all cases articaine at 4% and epinephrine 1/200,000 (Artinibsa, Inibsa, Barcelona, Spain). After a 3-minute pause, a curette was used to check that all the tissue was correctly anesthetized, injecting new infiltrative anesthesia, when necessary, never exceeding 4 carpules of anesthesia in total. Subsequently, the supracrestal gingival fibers were cut with a 15c scalpel and the tooth to be extracted was luxated. The tooth extraction was performed atraumatically, always avoiding vestibulo-palatal movements that could affect the vestibular bone table and require additional bone regeneration with the raising of a flap.

Once the dental extraction was completed, an exhaustive curettage of the alveolus followed.

The implants were placed following the sequence recommended by the manufacturer (Galimplant, Dental Implant System, Sarria, Spain). They were placed subcrestal, between 3-4 mm from the future gingival margin, following the recommendations of Linkevicius et al., 2009 16. Bone regeneration was performed crestal to the vestibular gap using a flapless technique, and then sutured with a 5/0 monofilament suture (Braun, Barcelona, Spain). In cases where primary stability > 25 Ncm (Newton-centimeter) was obtained, an immediate provisionalization was performed as described by Gonzalez-Martín et al. 6. In cases where sufficient primary stability was not achieved, a Maryland-type provisional bridge was cemented. This did not influence the results of the study in any way (Fig. 2).

**Musical intervention and data collection methods**

The musical intervention and data collection for the measurement of anxiety and pain in this study was performed in the same way as described by Esteban Pellicer et al. 11. In summary, music listening was done using Sony WH-CH510 headphones (Sony Corporation, Tokyo, Japan) connected via Bluetooth to an iPhone X device (Apple, California, USA) also connected to the Spotify App. The BM group listened to pieces by different composers (J. Pachelbel, A. Vivaldi, J.S. Bach and T. Albinoni); the CM group listened to music by W.A. Mozart.

A constant average volume was always maintained, without exceeding 60 Db.

The variables studied were recorded using the Modified Dental Anxiety Scale (MDAS) 17 to assess an initial anxiety level. During the surgical procedure the following vital signs were taken as primary predictor variables: systolic blood pressure (SBP), diastolic blood pressure (DBP), heart rate (HR) and oxygen saturation (SpO₂). Each of these parameters was recorded twice consecutively to improve accuracy due to their variability. The blood pressure monitor used to take SBP, DBP and HR was an OMRON M2 (Omron
Healthcare, Kyoto, Japan). Oxygen saturation was recorded using the Lovia Lox100A pulse oximeter (Noto-Tech Electronics, Shenzen, China).

Once the patient was seated on the dental chair and before starting the intervention, the first vitals recording was made. Then the patient began to listen to music according to a randomly selected group and was anesthetized (second recording of constants). After verifying the desired anesthetic effect, the tooth was luxated and extracted, and curettage of the alveolus was performed exhaustively. Subsequently, the bone bed was reamed with the first surgical drill (third recording) and the fourth recording took place once the treatment was completed. Finally, the headphones were removed, and the patient completed the VAS form as previously described. Subsequently, the patients answered the following questions: do you think the music helped you to relax; would you have chosen another type of music; for the next visits, would you prefer to listen to music again (Table 3).

Finally, the patient was given the usual post-surgical guidelines.

**Data Analysis**

The dependent variables were divided into physiological variables and psychological variables. The physiological dependent variables analysed were systolic and diastolic blood pressure, heart rate and oxygen saturation, being recorded at four different times during surgery. The ANOVA test compared each of these variables between the three experimental groups. The psychological dependent variable analyzed was the degree of anxiety, measured by the self-completed Modified Dental Anxiety Scale and VAS (measured before and after surgery). The paired t-test compared degree of anxiety before and after surgery. For the comparison between qualitative variables, the Chi square test was used. In all cases, the level of statistical significance was set at $p < .01$. The statistical analysis was performed using the IBM SPSS version 23 package program (IBM Software).

**Results**

Seventy-eight subjects were included in the study conducted between Feb 2021 and May 2022, with a mean age of 45.7 ± 15.2, 47.4% were men and 52.6% were women. When comparing the scores on MDAS prior to the intervention between the three experimental groups (C, CM and BM), no significant differences were obtained ($p = .831$, CI = 9.16–11.17) (Fig. 3). No differences were found for sex ($p = .358$) or age ($p = .473$) (Table 1). There were also no differences in the SBP results before starting treatment between groups ($p = .634$; F = .459), which could be considered homogeneous. Statistically significant differences in SBP decrease were found between the three experimental groups after anesthesia ($p = .005$; F = 5.808) and at mid-treatment ($p = .006$; F = 5.478). The decrease in mean SBP during treatment was in CM group ($p = .001$, CI = 1.9716–6.5840) and BM group ($p = .003$, CI = 1.4450–6.4396) (Fig. 4). No differences were found in the C group ($p = .536$, CI=-3.6037-1.9237). There were no statistically significant differences found in DBP, SpO2 or HR.
Table 1
Demographic data

<table>
<thead>
<tr>
<th>Anxiety Level</th>
<th>Control Group (C)</th>
<th>Baroque Music (BM)</th>
<th>Classicism Music (CM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>M</td>
<td>SD</td>
<td>M</td>
<td>SD</td>
</tr>
<tr>
<td>Gender</td>
<td>Male</td>
<td>8.4</td>
<td>3.134</td>
</tr>
<tr>
<td>Female</td>
<td>10.73</td>
<td>4.317</td>
<td>9.67</td>
</tr>
<tr>
<td>p value</td>
<td>.386</td>
<td>.691</td>
<td>.364</td>
</tr>
<tr>
<td>&gt; 45</td>
<td>9.75</td>
<td>4.673</td>
<td>12.78</td>
</tr>
<tr>
<td>p value</td>
<td>.954</td>
<td>.054</td>
<td>.386</td>
</tr>
<tr>
<td>Yes</td>
<td>10.73</td>
<td>5.65</td>
<td>10.88</td>
</tr>
<tr>
<td>p value</td>
<td>.313</td>
<td>.308</td>
<td>.008*</td>
</tr>
</tbody>
</table>

M mean value; SD standard deviation. * (p<.01)

The decrease in anxiety levels during treatment was statistically significant in the experimental groups that listened to music: BM group (p = .002, CI = .645-2.662) and CM group (p = .000, CI = 1.523–3.884). There were no differences in C group (p = .022, CI = .192-2.288) (Table 2). No statistically significant differences were found in pain perception between groups (p = .590, F = .531).

Table 2
VAS for Anxiety (Before & After) and Pain between groups.

<table>
<thead>
<tr>
<th>Groups</th>
<th>Anxiety Level Before Treatment</th>
<th>Anxiety Level After Treatment</th>
<th>Pain Level</th>
<th>P value</th>
<th>M</th>
<th>SD</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control Group (C)</td>
<td>2.88</td>
<td>1.64</td>
<td>1.12</td>
<td>2.007</td>
<td>.590</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baroque Music (BM)</td>
<td>3.31</td>
<td>1.65</td>
<td>1.15</td>
<td>1.461</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Classicalism Music (CM)</td>
<td>4.41</td>
<td>1.7</td>
<td>0.74</td>
<td>1.347</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>p value</td>
<td>.188</td>
<td>.993</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

VAS Visual Analog Scale; M mean value; SD standard deviation. * (p<.01)
Regarding musical style, there was no statistically significant difference in anxiety reduction between BM and CM (p = .172, CI=-.471 – 2.570).

Patients in the two experimental groups who underwent auditory listening felt that the music helped them to relax (p = .000), and they would prefer to listen to music again at their next visits (p = .000) (Table 3).

Table 3. Patient response on listening to music during surgery

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>DK/NA</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you think the music helped you relax?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Baroque Music</strong></td>
<td>23</td>
<td>3</td>
<td>0</td>
<td>.000*</td>
</tr>
<tr>
<td><strong>Classicism Music</strong></td>
<td>23</td>
<td>1</td>
<td>3</td>
<td>.000*</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>46</td>
<td>4</td>
<td>3</td>
<td>.000*</td>
</tr>
</tbody>
</table>

| Would you have chosen another kind of music? |     |    |       |         |
| **Baroque Music**                          | 5   | 20 | 0     | .003*   |
| **Classicism Music**                       | 9   | 15 | 4     | .221    |
| **TOTAL**                                  | 14  | 35 | 4     | .003*   |

| For future visits, would you prefer to listen to music again? |     |    |       |         |
| **Baroque Music**                          | 24  | 1  | 1     | .000*   |
| **Classicism Music**                       | 25  | 1  | 1     | .000*   |
| **TOTAL**                                  | 49  | 2  | 2     | .000*   |

DK don´t know; NA no answer; * (p<.01).

**Discussion**

The purpose of this study was to test how musical flow using baroque (BM) and classical era music (CM) as a non-pharmacological therapy can control anxiety and pain levels among patients undergoing IPI with a flapless technique.

The following two hypotheses were tested: will musical intervention induce some changes in patients’ vital signs during dental implant surgery, and will musical intervention decrease perioperative anxiety levels and perceptions of pain in patients undergoing IPI?
Current scientific evidence encourages us to perform immediate implant treatment using the flapless technique instead of delayed implants whenever possible\(^2\text{--}^5\). Immediate provisionalization limits bone resorption\(^1^8,1^9\) and improves soft tissue stabilization, improving the patient's pink esthetics\(^2^0\) and the gingival phenotype\(^1^5\).

However, performing a double surgery with simultaneous tooth extraction and placement of dental implant may involve a high level of anxiety in patients\(^1^0,2^1\).

The latest studies encourage the implementation of musical flow in dental offices using certain types of music in treatments that generate anxiety, such as dental implants, where satisfactory results are achieved in reducing the level of anxiety in patients\(^1^1,2^2\).

Listening to music can influence both psychological and physiological aspects, even promoting neuronal neuroplasticity\(^2^3\). The management and control of anxiety and pain levels experienced by patients undergoing IPI is a basic aspect that the dentist and the dental staff should be aware of.

Some articles have been published with good results using musical hearing in patients undergoing dental extractions\(^1^0,2^4\text{--}^2^7\). However, the evidence in patients undergoing dental implants is scarce\(^1^1,2^1\).

The effect of music on vital signs has been studied, but the reduction of blood pressure in patients undergoing these treatments is still unclear. In a systematic review by Monteiro et al.,\(^2^8\) they found only one study in which there was a statistically significant decrease in systolic blood pressure. The present study adds to the scientific evidence new favorable results on the statistically significant decrease in systolic blood pressure in patients undergoing tooth extraction and implant placement, being the first to study this type of combined treatment.

During oral surgery, there is an increase in heart rate\(^2^9\). Classical music seems to reduce heart rate\(^3^0\), especially at the time of administering anesthesia\(^3^1\), although the present study found no statistically significant differences.

Likewise, several authors concluded that listening to music can even positively affect the perception of pain during surgery\(^3^2,3^3\), in contrast to this research where no statistically significant differences were observed.

**Conclusion**

A lower level of anxiety during IPI was reported in the groups that listened to classical and baroque music using headphones among the Spanish patients. The addition of musical flow in an individualized way on each patient in dental clinics is a useful non-pharmacological therapy to reduce anxiety and fear in patients, and incorporates the possibility of monitoring vital signs mainly in patients at increased risk of cardiovascular disease.
Some limitations of this study could be the number of songs used. As a follow-up study, we recommend a multicenter study, including patients requiring connective tissue grafting and evaluating the influence of a third surgery at the same time.

**Declarations**

**Declaration section**

No applicable

**Author contribution**

L.A. Esteban Pellicer: wrote the manuscript tex, prepared figures

J.L. Martínez Rubio: prepared figures

E. Casañas: reviewed the manuscript

A.J. Conde Villar: wrote and reviewed the manuscript

**Ethical approval and Consent to participate**

CIPI/21/005

Written informed consent

**Funding**

“No funding was obtained for this study”.

**Conflict of interests**

The authors deny interest conflict

**References**


**Figures**
Figure 1

CONSORT Flow Diagram for Trial Participation
Figure 2

Surgical procedure of IPI performed on all patients in the study. a: image of monitored patient under musical intervention; b: initial CBCT; c: intraoral image of tooth 1. 4; d: post-extraction socket; e: extracted tooth with vertical fracture; f: insertion of the first surgical drill; g: three-dimensional positioning of implant using a flapless technique; h: placement of an esthetic anti-rotational straight abutment; i: customization of immediate provisional; j: immediate provisional prosthesis; k: pink esthetic and emergence profile; l: intraoral image of definitive prosthesis; m: final CBCT.
Figure 3

Box plot represents the degree of pre-surgery anxiety by group, showing a homogeneous sample. The p-values did not have a statistically significant difference (p=.831).
Figure 4

Comparison of mean systolic blood pressure values during immediate dental implant placement surgery between groups. Statistically significant results were found in the decrease of SBP in CM and BM group ($p=.001$ and $p=.003$, respectively).