Randomized controlled trial

**Self-reported pain after orthodontic treatments: a randomized controlled study on the effects of two follow-up procedures**

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**Summary**

**Objectives:** To assess the effects of a follow-up text message and a telephone call after bonding on participants’ self-reported level of pain.

**Materials and methods:** Eighty-four participants were randomly assigned to one of three trial arms. Randomization was performed by the Department of Epidemiology and Biostatistics of IRCCS G.Gaslini. Participants were enrolled from patients with a permanent dentition who were beginning fixed no extraction treatment at the Orthodontic Department, Gaslini Hospital. Participants completed baseline questionnaires to assess their levels of pain prior to treatment. After the initial appointment, participants were completed a pain questionnaire at the same time, daily, for 7 days. The first group, served as control, did not receive any post-procedure communication; the second group received a structured text message; and the third group received a structured telephone call. Participants were blinded to group assignment.

**Limitations:** A larger sample size should have been considered in order to increase the ability to generalize this study’s results.

**Results:** Participants in both the telephone call group and the text message group reported lower level of pain than participants in the control group with a larger and more consistent effect for the telephone call group. Most participants reported a higher level of pain during the first 48 hours post-bonding. The analgesic’s consumption significantly correlated with the level of pain during the previous 24 hours. Female participants appeared to be more sensitive to pain than male participants.

**Conclusions:** A telephone follow-up after orthodontic treatment may be an effective procedure to reduce participants’ level of pain.

**Protocol:** The research protocol was approved by the Italian Comitato Etico Regionale della Liguria-sezione 3^ c/o IRCCS- Istituto G.Gaslini 845/2014.

**Registration:** 182 Reg 2014, 16/09/2014 Comitato Etico Regione Liguria, Sez.3.
Introduction

Pain in orthodontics

Orthodontic appliances may be uncomfortable and usually require a period of physical and psychological adjustment. Studies in the literature have shown that in many cases, the lack of treatment completion may be explained by the pain associated with orthodontic procedures (1, 2). Prospective studies assessing both children and adults have shown that approximately 94% of participants experienced pain during orthodontic treatments with a higher intensity during the first 24 hours, albeit the duration of the pain differed among participants (2).

Scheuer et al. (3) have demonstrated that the extent of tissue damage cannot fully explain the degree of perceived pain and that the correlation between pain stimulus and the individual experience of pain is usually low. A recent systematic review conducted by Jian et al. (4) concluded that there is insufficient evidence to determine whether or not there is a difference between type of arch wires with regard to speed of alignment or pain. Similarly, other investigators (5–7) have pointed out the lack of any significant correlation between the magnitude of perceived pain and the degree of crowding, measured using the Little index (8) and the vertical displacement of maxillary canine.

On the other hand, a significant correlation has been demonstrated between psychological factors and perception of pain. The Gate Control Theory (9), which integrates sensory aspects of pain with cognitive, behavioural, and psychological factors, indicates that both anxiety and stress are directly correlated with the perception of pain. Post-procedure interventions, which aim at reducing individual anxiety and stress, may influence the subjective perception of pain and facilitate health-related lifestyle changes (10–12). A follow-up procedure, which provides encouragement and reassurance after orthodontic treatments, may be helpful in reducing the patients’ feeling of uncertainty and anxiety. Bartlett et al. (11) and Keith et al. (12) have recently demonstrated that a telephone call or a text message from a health care provider during the first hours following orthodontic treatment significantly decrease post-procedural pain and anxiety.

The aim of this study was to investigate the effects of a structured telephone call and of a structured text message on the perception and of pain in a cohort of participants who underwent orthodontic treatments.

Materials and methods

Guidelines

The study was conducted according to current guidelines CONSORT 2010 (13).

Trial design

Participants were enrolled from patients who were beginning fixed orthodontic treatment at the Orthodontic Department, Gaslini Hospital, Genova, between July and October 2014. Ninety-six subjects were examined and 88 patients fulfilled the inclusion and exclusion criteria. Among these 88 patients, 84 patients and their parents consented to participate in the study and they were randomly allocated to the three groups:

1. fifteen male and fifteen female participants with a mean age of $13.5 \pm 1.7$ were assigned to the control group (group 1);
2. twelve male and 16 female participants with a mean age of $12.8 \pm 1.5$ to the text message group (group 2);
3. 16 male and 10 female participants with a mean age of $13.6 \pm 1.7$ to the telephone group (group 3).

Ethical issue

The methods of the present study were detailed in a research protocol that was approved by the Italian Comitato Etico Regionale della Liguria – Sezione 3^ c/o IRCCS - Istituto G. Gaslini (845/2014). Prior to participation, informed consent was obtained from all participants and from the parents of children younger than 18 years old.

Subjects, eligibility criteria and setting

Study setting and eligibility criteria

Inclusion criteria were:

1. participants’ age between 10 and 19 years,
2. access to a mobile phone,
3. orthodontic treatment with fixed maxillary self-ligating appliances,
4. no extraction treatment,
5. no previous orthodontic treatment,
6. no chronic usage of analgesic medications,
7. no previous pain-related pathology or disease,
8. permanent dentition.

The structure of the message, received by group 2, was consistent with that reported by Keith et al. (12) and it offered encouragement and enquiring about participants’ well-being after their initial orthodontic treatment.

The structure of the call, made to group 3, consisted of the following aspects: 1. to thank for participating in the study and for attending the previous orthodontic appointment; 2. to explain possible reasons of pain or discomfort; 3. to encourage appropriate dental hygiene; 4. to recommend adequate use of painkillers/analgesics; and 5. to stress the importance of a positive attitude towards orthodontic treatment.

The questionnaire, completed by all patients, was previously validated (11, 12), contained clear instructions for its completion and consisted of a number of dichotomous questions related to the socio-demographic characteristics of the participants (e.g. age, gender), to the individual experience of pain and discomfort, including a 100-mm self-assessment visual analogue scale, and to the use of analgesics during the previous 24 hours.

Randomization method

Participants were randomly assigned to one of three intervention trial arms by the Department of Epidemiology and Biostatistics of IRCCS G.Gaslini.

Treatment protocol and process

Group 1 served as control and participants did not receive any kind of structured follow-up. Participants in group 2 received a structured text message. Participants in group 3 received a structured telephone call after few hours from orthodontic appliance placement. Phone calls and text message were performed 5–7 hours after the bonding by the orthodontists.

Following the study protocol proposed by Keith et al. (12), all patients were bonded with fixed self-ligating maxillary appliances but, depending on the degree of crowding, some variation of the initial arch wire may have occurred in certain cases. This was not accounted for during the randomization process. Before the bonding, a so-called “zero time questionnaire” was completed by the
participants to evaluate the perception of pain at baseline, prior to the beginning of orthodontic treatment. A subsequent questionnaire was completed by the participants at home approximately 4 hours after bonding and then daily for the next 7 days. This questionnaire was categorized as follows: T1 = questionnaire completed 1 day after bonding, T2 = questionnaire completed 2 days after bonding, T3 = questionnaire completed 3 days after bonding, T4 = questionnaire completed 4 days after bonding, T5 = questionnaire completed 5 days after bonding, T6 = questionnaire completed 6 days after bonding, and T7 = questionnaire completed 7 days after bonding. All completed questionnaires were collected at the next orthodontic appointment.

The participants and their caregivers in case of youngsters were informed on the possible consequences of orthodontic treatment, such as pain, ulcers, difficulty in chewing hard food, and subsequent changes in the daily diet. They also received instructions on oral hygiene procedures and remedies that could reduce discomfort.

The degree of perceived pain after orthodontic treatment was assessed by evaluating the intensity of the pain, the use of painkillers, and the participants’ anticipation regarding potential problems, which could arise from orthodontic treatment.

Blinding
Participants were blinded to group assignment and were not made aware that the text message or the telephone call was part of the study. A blinded examiner performed data collection and analysis.

Statistical analyses
Sample size calculation
A power calculation indicated that for a type I alpha risk of 0.05 and a power of 80%, a sample of 28 participants per group would be required.

Statistics
For continuous variables, data were expressed as mean and standard deviation or median and range of variability, while for categorical variables, data were expressed as absolute and relative frequencies. The normality of variables distribution was assessed using the Komogorov–Smirnov test and a non-parametric statistical approach was considered appropriate. Continuous variables were compared between groups using the Kruskal–Wallis and Mann–Whitney U-tests. The chi-square test or the Fisher Exact test was used to assess the association between categorical variables. The Spearman correlation coefficient was also computed. All P-values were calculated using a two-tailed test. A P-value less than 0.05 was considered statistically significant. Statistical analyses were performed using SPSS, version 18, for Windows (SPSS Inc., Chicago, Illinois, USA). The statistician, who performed all statistical analyses, was blinded to name of participants and group assignment.

Harms
There are no harms associated with the protocol of this study.

Results
Participant flow
Eight patients (four in the control group, two in the text message group, and two in the telephone call group) did not return the questionnaires and therefore were not included in the statistical analyses (Figure 1).

Baseline findings
Sample demographic features
There were no statistically significant baseline differences in the participants’ demographic characteristics between the three study groups (Table 1).

Participants’ expectation of braces at T0
Overall, about 70% of participants were convinced that orthodontic treatment could cause pain and discomfort, 58% were concerned about possible changes in dietary habits and oral hygiene, 31% were worried that orthodontic appliances could affect normal speech, and 7% were convinced to be taunted.

Primary outcomes
Perception of pain
The majority of participants (88%) reported pain during the first 24 hours after bonding. The proportion dropped to 50% after 3 days and continued to decrease gradually after Day 4 (Figure 2).

During the first 3 days after orthodontic treatment, fewer participants in both the telephone group and the text message group reported pain compared with those in the control group, but no statistical differences were detected between groups.

Degree of pain
For all groups, higher values of pain were recorded in the first 24 hours with peaks of 97/100 mm, which decreased gradually in the next few days.

At Day 1 and Day 2 after bonding, participants in both the telephone call group and the text message group reported a lower, but not significantly different, mean level of pain compared to participants in the control group. Table 2 shows that participants in the telephone call group reported a significant reduction of pain compared to those in the control group at Day 3 (P = 0.02), Day 5 (P = 0.03), and Day 6 (P = 0.006). A statistically significant difference was also observed between the control group and the text message group at Day 6 after bonding (P = 0.03) but not at any other assessment (Table 2 and Figure 3).

Secondary outcomes
Gender difference in response to pain
With regard to the perception of pain, differences were observed between female and male participants. Female participants tended to report higher levels of pain compared with male participants even though these differences were statistically significant only at Day 5 (P = 0.005) and Day 6 (P = 0.04; Figure 4).

Use of analgesics
Overall, the proportion of participants who reported analgesics usage after orthodontic treatment was 37% at Day 1, 24% at Day 2, 9% between Days 3 and 6, and 1% at Day 7. No statistically significant group differences were detected. At T1, there is a significant correlation between the consumption of analgesic compared with no analgesic consumption (P = 0.003); this correlation became not significant after Day 1.

Discussion
We analysed the effects of two structured orthodontic follow-up procedures, a telephone call and a text message, on pain perception and oral hygiene compliance during the 7 days after the application of orthodontic appliance. The questionnaire used was a validated instrument (11, 12), with simple and clear instructions, easy to complete even by young patients (14, 15). In order to avoid the influence
of past experiences on pain perception, we enrolled only patients who did not receive previous treatment with orthodontic appliances.

We found that a telephone call to patients following initial appliance placement resulted in reduced levels of pain. From Day 3, participants in the telephone call group reported a significant reduction of pain compared to those in the control group. These findings are in line with those reported by Bartlett et al. (11) who observed that a telephone call following an initial orthodontic procedure resulted in a decreased perception of reported pain. We did not find the same impact for a text message who other investigators have reported in the literature. In particular, our results differ from those of Keith et al. (12), who observed lower levels of pain among patients who received a text message compared with those who did not. Different results could be explained by cultural differences in reaction to pain and in communication style. People of Italian or Jewish origin, for instance, are apt to report pain before people of northern European descendant and to tolerate less intense levels of laboratory-induced pain before refusing to continue (16, 17). Moreover, French, Italians, and Latin Americans prefer a more empathic and emotional communication like the verbal one. People from America and northern
Europe, in contrast, pay secondary attention to the emotional component of the communication style and react positively also to written approach (18).

A possible explanation for the reduced levels of reported pain we observed could be that usually from Day 3 the periodontal ligament compression decreases and the association between pain stimulus and patient’s pain perception is weaker. Significant correlation has been demonstrated between psychological factors and individual perception of pain. Psychological approaches, such as the cognitive restructuring method, which provide encouragement and reassurance to reduce patients’ anxiety and feeling of uncertainty, have been proposed in the literature (10). It is therefore plausible that a follow-up intervention, which aims at reducing individual anxiety and stress, may have a positive impact on the individual perception of pain (10–12). In our study, a verbal communication approach (i.e. spoken words) proved to be more powerful than a written approach.

The theory of Token Economy (19) maintains that both positive and negative reinforcements are essential to obtain a proper behaviour and to avoid the extinction process described by Skinner (20). The lack of compliance may be explained by the pain associated with orthodontic procedures and by the absence of adequate encouragement. We believe that post-procedure interventions may facilitate health-related lifestyle changes, reduce the individual perception of pain (negative stimulus), and promote correct habits (positive stimulus).

Similar to the findings of other studies in the current literature, in our study, the majority of participants reported pain during the first 24 hours after bonding (3–7, 21–23).

Table 2. Different degree of pain perception among the three trial arms.

<table>
<thead>
<tr>
<th>Time of pain measurement</th>
<th>Groups (1 = control, 2 = SMS, 3 = call)</th>
<th>N</th>
<th>Mean ± SD</th>
</tr>
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<tbody>
<tr>
<td>Baseline</td>
<td>1</td>
<td>30</td>
<td>0.73 ± 1.8</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>28</td>
<td>1.68 ± 5.7</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>30</td>
<td>0.69 ± 2.6</td>
</tr>
<tr>
<td>T1</td>
<td>1</td>
<td>26</td>
<td>48.5 ± 23.6</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>26</td>
<td>43 ± 28.4</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>24</td>
<td>36.2 ± 22.9</td>
</tr>
<tr>
<td>T2</td>
<td>1</td>
<td>26</td>
<td>38.9 ± 23.1</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>26</td>
<td>34.5 ± 28.4</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>24</td>
<td>28 ± 24.9</td>
</tr>
<tr>
<td>T3</td>
<td>1</td>
<td>26</td>
<td>26.3 ± 21.4*</td>
</tr>
<tr>
<td></td>
<td>2</td>
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<td>18.6 ± 20.7</td>
</tr>
<tr>
<td></td>
<td>3</td>
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<td>15.2 ± 21.2</td>
</tr>
<tr>
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<td>26</td>
<td>16.1 ± 16.3</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>26</td>
<td>16.5 ± 19.7</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>24</td>
<td>10.1 ± 18.1</td>
</tr>
<tr>
<td>T5</td>
<td>1</td>
<td>26</td>
<td>10.1 ± 12.8**</td>
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<tr>
<td></td>
<td>2</td>
<td>26</td>
<td>10.1 ± 17.6</td>
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<tr>
<td></td>
<td>3</td>
<td>24</td>
<td>7 ± 17</td>
</tr>
<tr>
<td>T6</td>
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<td>26</td>
<td>9.3 ± 13.1****</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>26</td>
<td>4.1 ± 8.1*****</td>
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<td>1.3 ± 2.3</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>24</td>
<td>5.5 ± 16</td>
</tr>
</tbody>
</table>

*Control versus phone call, P = 0.02.
**Control versus phone call, P = 0.03.
***Control versus phone call, P = 0.006.
****Control versus SMS, P = 0.03.
We observed a statistically significant correlation between the use of analgesics and pain only at Day 1. As suggested by Jones and Chan (7) and Feinmann et al. (24), patients often take tablets in order to reduce their anxiety and stress.

We also found that compared to male participants, female participants reported higher levels of pain at Day 5 and Day 6. This finding is consistent with other reports in the literature, which demonstrate that women are more sensitive to perception of pain (3, 21–24).

Limitations
Even though a certain degree of bias exists in any randomized clinical trial, we tried to minimize major potential biases. In particular, all our results were analysed by an independent statistician who was blinded to the name of participants and groups assignment.

Further investigations should involve a larger sample to generalize the results and should include patients of various cultural and ethnic groups in order to limit the influence of culture-specific differences on the results.

Conclusions
Our study demonstrated that from the Day 3 after the bonding, a post-procedure phone call may reduce the perception of pain. Our sample of patients showed more sensitivity to a verbal communication rather than a written approach.

We believe that patient motivation is a crucial factor to reduce the perception of pain.

References