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ORIGINAL ARTICLE

Patient-reported outcomes measures (PROMs) following a piezocision-assisted versus conventional orthodontic treatments: a randomized controlled trial in adults

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Abstract

Objective To explore patient-related outcomes measures (PROMs) of piezocision-assisted orthodontic treatment compared to a conventional orthodontic treatment using customized appliance.

Materials and methods Twenty-four adult patients requiring orthodontic treatment for mild-to-moderate overcrowding in both jaws were randomly assigned to a test group, treated with a piezocision-assisted orthodontic treatment, or to a control group, where piezocision was not applied. The patient-related outcomes were recorded using a 0–10 visual analog scale (VAS). Daily analgesic consumption and pain level were also recorded following the placement of the orthodontic appliance in both groups and after the piezocision procedure in the test group. Moreover, levels of apprehension and satisfaction were also assessed in both groups.

Results In the piezocision group, over the 7-day period, paracetamol consumption was comparable after the placement of the orthodontic appliance and after the piezocision surgery. Pain levels after the orthodontic and the surgical procedure decreased with time ($p < 0.0001$) but remained globally higher after piezocision ($p = 0.0056$). Significantly, more patients of the piezocision group reported that they would undergo the treatment again ($p = 0.033$) and that they greatly appreciated the duration of treatment ($p = 0.0008$). However, the level of apprehension was significantly higher in the piezocision group compared to the test group ($p = 0.012$).

Conclusions Although, the degree of apprehension before the surgery and higher pain level in the piezocision group, PROMs emphasized similar pain killer consumption in both group and revealed high acceptance and satisfaction with piezocision approach.

Clinical relevance The benefit of piezocision-assisted orthodontic treatment seems to be relevant from a patient perspective.

Trial registration NCT03406130

Keywords Piezocision · Piezosurgery · Accelerated orthodontic treatment · Patient-reported outcome measures (PROMs) · Pain level

Introduction

Reducing orthodontic treatment time has always been a major objective in orthodontics, especially in adult patients.

Many adjunctive interventions appear to be effective in promoting tooth movement [1]. The osteotomy technique, initially described in 1959 by Köle [2–4] and further developed by Wilcko et al., was proposed in order to accelerate tooth movement. The biological concept is to induce a so-called rapid acceleratory phenomenon (RAP) [5], which is characterized by a decrease of the mineral content of the bone and an acceleration of the bone turn over responsible of the faster tooth displacement [6–8]. It requires full flap opening and

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invasive bone osteotomies, which induce post-operative morbidity and discomfort. Nowadays, surgical cortectomy techniques have largely evolved into flapless technique and less invasive surgical approach such as piezocision [9–14].

Piezocision consists in a localized piezoelectric alveolar decortication through minor incision and without raising a flap [11]. Using the protocol described by Dibart et al. [11], the effectiveness of piezocision was demonstrated in several preclinical and clinical studies and revealed an overall treatment time decreased on average by a factor of 1.5 compared with the conventional approach [15–20]. The patient-related outcomes measures (PROMs) have been increasingly reported in the dental field and are of great interest for the validation of a new technique [21]. The benefit of piezocision from a patient prospective was poorly investigated, and as his procedure is not mandatory to complete the orthodontic treatment, it would be relevant to explore patient's perception of pain, opinion, and expectation [22–24]. A recent systematic review [25] showed that the pain-discomfort levels influenced significantly the overall orthodontic treatment satisfaction and therefore would be relevant in investigating PROMs for piezocision procedures.

One previous RCT [15] had a part of PROMs in their trail. Charavet et al. [15] demonstrated an acceptable level of acceptance and satisfaction using self-ligating brackets and a piezocision protocol without sutures. However, currently, new technology and computer-aided design and computer-aided manufacturing (CAD/CAM) permit the engineering of custom-made orthodontic appliances, which seems to be a relevant combination with the piezocision procedure to influence positively the treatment duration [26]. Additionally, the reduction of scar formation may be obtained by the uses of sutures [15]. These two parameters remain not investigated regarding the impact on the patient's perceptions of pain, acceptance, and satisfaction.

The aim of this study was also to set up a clinical trial investigating PROMs following a piezocision procedure involving sutures and using CAD/CAM-customized orthodontic appliances. The primary objective was to determine pain level after piezocision. The secondary objectives were to investigate the level of apprehension related to the procedure, the intake of pain killers, and the overall treatment satisfaction.

Materials and methods

Registration

The study was approved by the Liege University Hospital ethical committee (file number: B707201629875) and was registered with ClinicalTrails.gov (Identifier: NCT03406130). All patients were verbally informed of the purposes, risks, benefits, and monitoring of the study, and they all signed an informed consent form.

Experimental design

The study was designed as a randomized controlled trial (RCT) conducted at the Dental Department of Liege, University Hospital, Belgium, to compare PROMs between a conventional orthodontic treatment (control group) and a piezocision-assisted orthodontic treatment (test group). Twenty-four consecutive adult patients, who met the inclusion criteria, were enrolled from January to November 2016. Subjects were randomly assigned to the control group or to the test group. Figure 1 represents the PRISMA flow diagram.

The orthodontic treatments and the piezocision surgery were performed by two calibrated orthodontists and two calibrated periodontists, respectively. The study objectives, the surgical and orthodontic procedures, and the assessment method were explained and reviewed in two calibration meetings.

Sample size and randomization

With a sample size of 12 patients in each group, a power calculation showed that a difference of 2.5 points in the pain

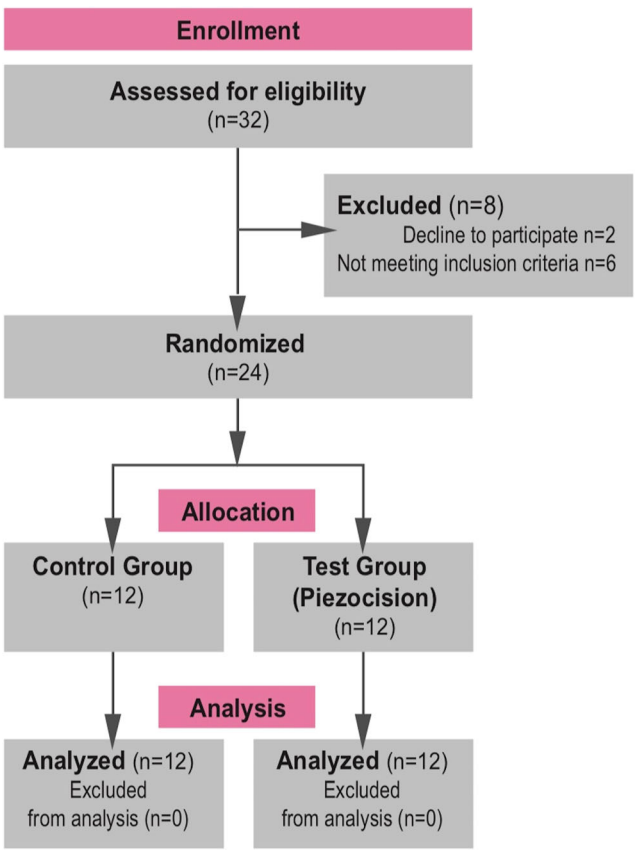

Fig. 1 Prisma flow diagram

VAS could be discerned between the two groups with a power of 80% assuming a two-sided normal test, a standard deviation of 2.5 points, and a statistical significance level of 5%. Sealed envelopes containing the random allocation of each patient to one or the other group were prepared by an independent team and opened as patients accrued. The 24 numbers were randomized into 4 blocks of 6 patients (3 controls and 3 tests).

Inclusion/exclusion criteria

The inclusion criteria were as follows:

(1) Adult patients with completed growth according to Baccetti et al. method [27]
(2) Minimal-to-moderate maxillary and mandibular anterior crowding at baseline (irregularity index ≤ 6) requiring maxillary and mandible orthodontic treatment
(3) American Society of Anesthesiologists (ASA) stage I or II (I = normal healthy patient; II = patient with mild systemic disease)

The exclusion criteria were as follows:

(1) Inadequate dento-oral health (presence of periodontal diseases, periapical infection, untreated caries)
(2) History of periodontitis with a loss of alveolar support > 10% gingival and recession > 2 mm
(3) Smoking
(4) Altered bone metabolism (due to anti-resorptive drug, steroid, or immunosuppressant use)
(5) Pregnancy

Orthodontic and piezocision surgical procedures

Metal-customized brackets (Insignia SL, Ormco, USA) were bonded in each patient according to the manufacturer's guidelines. The following sequence of arches was used: 0.014-in, 0.018-in, 0.014 × 0.025-in, and 0.018 × 0.025-in copper nickel-titanium archwires were used for alignment, and 0.019 × 0.025-in stainless steel archwires for fine-tuning. Patients were recalled every 2 weeks, and archwires were changed only when full bracket engagement was reached. After the removal, appliances, fixes, and removable retainers were placed. In the test group, piezocision surgery was performed with a Piezotome (Acteon, Merignac, France) according to the protocol described by Charavet et al. [15] 2 weeks after the placement of the orthodontic appliance. After local anesthesia, incisions (varying from 5 to 8 mm) were created and vertical corticotomies (5 mm long and 3 mm deep) were performed with the Piezotome. Single-interrupted sutures were made on each incision with a resorbable material (Vicryl rapid 5.0, Ethicon, Germany) (Fig. 2). Combined hard or soft tissue augmentations were not considered to avoid bias.

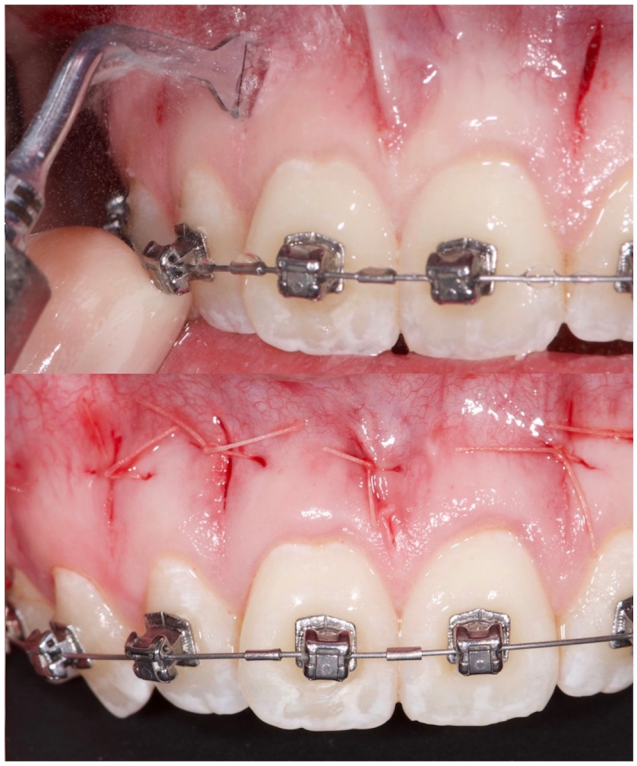

Fig. 2 Piezocision surgery. 3 mm long–5 mm depth corticotomies

Medications procedure

Patients were advised to take analgesics (paracetamol 500 mg) only if necessary and to record their daily intake.

Anti-inflammatory drugs were not permitted to avoid interference with the RAP effect. Careful tooth brushing and the use of a mouthwash twice daily (chlorhexidine 0.2% Perio-Aid, Dentaid, the Netherlands) were recommended for 7 days.

Pretreatment data

The following parameters were collected at baseline in each patient: age, gender, and space analyses on study model using a digital caliper. Full periodontal data was also collected.

Outcome data

All the patient-centered outcomes were recorded by questionnaire using a 0–10-cm visual analog scale (VAS). The two orthodontists provided a comprehensive explanation of the use of the VAS and the way to capture the outcome measure to each patient according to Wewers and Lowe [28] and they collected the questionnaires after the completion.

The following outcomes measures were assessed in each patient:

- Level of apprehension before bonding the orthodontic appliances and before piezocision procedure was scored from 0 to 10 with higher values indicating higher apprehension.
- Pain level was assessed on a 0–10 VAS with higher scores indicating more severe pain, and was recorded on a daily basis for 7 days after placement of the orthodontic appliance but also after piezocision surgery in the test group.
- Paracetamol consumption was recorded daily for 7 days, respectively, after placement of the orthodontic appliance in both groups and after piezocision surgery in the test group.
- Patient satisfaction parameters were evaluated after treatment completion as follows:

– Level of satisfaction in terms of the final result,
– Treatment duration,
– Recommendation of the procedure to a friend, and
– Willingness to undergo the treatment again.

Additionally, a possible correlation between baseline patient characteristics and outcome data was investigated.

Statistical analyses

Data were presented as mean ± standard deviation (SD) or as median and the interquartile range (IQR) for skewed distributions. The control and test groups were compared by the Kruskal-Wallis test. The time evolution of pain scores after piezocision surgery and after bonding of the appliances in patients of the test group was analyzed by linear mixed-effects models (GLMM). The same approach was used for paracetamol consumption. The results were considered significant at the 5% critical level ($p < 0.05$). The calculations were performed with the SAS version 9.4 and R version 3.0.3 software.

Results

Baseline characteristics

The age of the 24 patients (9 males and 15 females) enrolled in the trial was 27.9 ± 7.6 years (Table 1 and Fig. 1). Space analyses on the study models showed a mean crowing of 2.3 ± 1.2 mm in the maxilla and of 3.1 ± 1.7 mm in the mandible. Level of overcrowding (maxilla $p = 0.30$, mandible $p = 0.084$), age ($p = 0.76$), gender ($p = 0.99$), and all periodontal parameters were homogeneous between the two groups, except for the papilla bleeding index which was slightly higher in the piezocision group ($p = 0.043$). All patients were followed up until treatment completion.

Pain level

At placement of the orthodontic appliance, the pain score was 3.9 ± 3.0 in the control group and 4.3 ± 2.6 in the test group ($p = 0.70$) and significantly decreased thereafter in each group ($p < 0.0001$). Pain recorded the day after piezocision surgery (6.8 ± 2.8) was significantly higher than after placement of the orthodontic appliance (4.3 ± 2.6) ($p = 0.012$). However, these values decreased significantly thereafter ($p < 0.0001$) but remained globally higher after piezocision surgery ($p = 0.0056$) (Fig. 3).

Paracetamol consumption

After the placement of the orthodontic appliance, paracetamol consumption was 0.79 ± 0.75 in the control group compared to 1.0 ± 0.99 in the test group. The difference was not significant ($p = 0.57$). After this procedure, the daily consumption of paracetamol decreased significantly in each group ($p < 0.0001$). After 1 week, total paracetamol consumption was 2.0 ± 2.0 in the control group and 3.5 ± 3.5 in the test group ($p = 0.10$).

After the piezocision surgery, in the test group, the total paracetamol consumption was comparable after orthodontic appliance placement (3.5 ± 3.5 g) and after piezocision surgery (4.7 ± 4.0 g) ($p = 0.45$). Furthermore, the daily consumption of paracetamol decreased significantly after each procedure ($p < 0.0001$), somewhat faster after piezocision surgery ($p = 0.036$) but remained globally higher after piezocision ($p = 0.0087$) (Fig. 4).

Level of apprehension

The level of apprehension before bonding the orthodontic appliance was the same in both groups: 3.5 ± 2.6 for controls and 3.0 ± 2.0 for treated patients ($p = 0.64$). In the piezocision group (Fig. 5), however, the level of apprehension before the piezocision procedure started was significantly higher than before bonding the orthodontic appliance (5.7 ± 2.7 vs. 3.0 ± 2.0; $p = 0.012$).

Correlation between patient characteristics and outcomes

The pain level after placement of the orthodontic appliance was positively correlated with the level of crowding at the mandible ($p = 0.023$), while apprehension before the placement of the orthodontic appliance was significantly correlated to the level of crowding at the maxilla ($p = 0.045$). For the other patient-related outcomes including gender and age, no correlation was found.

Table 1 Patient characteristics (baseline)

	Control group ($N = 12$) Mean ± SD	Piezocision group ($N = 12$) Mean ± SD	p value
Age (years)	2737	2938	0.76
Sex (men/women)	34%/66%	42%/58%	1.0
Space analyses (mm)			
Maxilla	2.0 ± 1.2	2.5 ± 1.1	0.30
Mandible	3.1 ± 1.6	3.0 ± 1.8	0.084
Periodontal data			
Recession depth/patient (mm)	1.0 ± 2.0	0.13 ± 0.3	0.19
Plaque index	0.67 ± 0.52	0.97 ± 0.73	0.26
Papilla bleeding index	1.0 ± 0.58	1.5 ± 0.59	0.043
Root resorption score	0.42 ± 1.2	0.42 ± 1.0	1.0
Pocket depth score	0.14 ± 0.31	0.40 ± 0.42	0.094

Overall patient satisfaction after treatment completion

At the end of the treatment, the level of satisfaction in terms of final result was the same in the two groups ($p = 0.47$) and so was the proportion of patients who would recommend the treatment to a friend ($p = 0.37$). Interestingly, there were more patients reporting that they would undergo the treatment again in the piezocision group than in the control group ($p = 0.033$).

Finally, significantly, more patients mentioned that they were satisfied by the duration of treatment in the piezocision group compared to the conventional group ($p = 0.0008$) (Fig. 6).

The overall treatment time was significantly lower in the test group compared with the control group (p value = 0.0027) as described in details in a recent manuscript [20].

Discussion

The present randomized controlled clinical trial compared PROMs following a piezocision-assisted orthodontic treatment to conventional orthodontic treatment in two homogeneous adult patient groups, according to a patient recall every 2 weeks. The objective was to explore the benefit of piezocision from a patient perspective.

Pain level and paracetamol consumption following a piezocision procedure

Based on a scale from 0 to 10, moderate pain levels (6.8) were found after the piezocision while mild pain levels (4.3) were observed after the placement of the orthodontic appliance. However, these results should be related to the pain killer intake and therefore be interpreted cautiously as the pain levels were recorded under the recommendation that patients should take paracetamol whenever it was needed. The difference was significant for only for 2 days, and as of day 3, the pain level dropped below 4.0 and no further difference was observed. At contrary, looking at the paracetamol consumption, no significant difference was observed after piezocision and after bonding appliances. These results support the idea that acceptable pain levels can be sustained following piezocision without any additional paracetamol consumption.

Similar studies using more traumatic approach such as corticotomies found that about half of the patients presented pain levels after the surgery that were “extreme” at day 1, “moderate-to-severe” at day 3, and “mild-to-moderate” after 1 week [29]. Although the measuring methods are different compared with our study, it can be extrapolated that the post-operative morbidity was limited in intensity and in time with the piezocision technique. Furthermore, in a comparable RCT [15] involving a protocol of piezocision without sutures, the pain level after piezocision reached 6.0 and was therefore similar to the present results. Therefore, the application of sutures does not seem to decrease the post-operative pain.

Moreover, in their study, Strippoli et al. [30] found very low pain levels when prescribing 500 mg of paracetamol immediately after guided piezocorticision, every 4 h for the next 48 h and as needed thereafter. Such a protocol may then be recommended on a routine base in order to minimize post-operative discomfort.

The limited pain levels found in this study may be related to the combination of—the flapless approach and—the piezoelectric surgery. Indeed, some flapless implant surgery studies showed less operative pain, swelling, and analgesic consumption and were preferred by the patients compared to open flap implant surgery [31, 32]. In other clinical utilization such as lower wisdom tooth removal, the use of the piezoelectric device also demonstrated a decrease in post-operative pain and swelling compare to conventional hand piece approach [33, 34]. Piezosurgery was preferred by the patient’s due to an

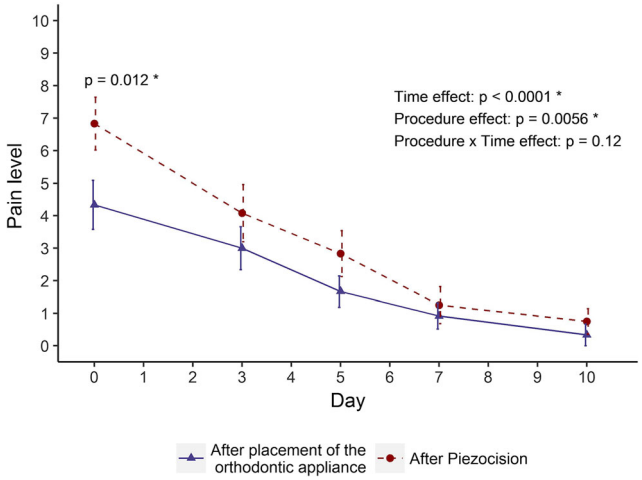

Fig. 3 Mean (± SE) pain level after piezocision surgery and after orthodontic appliance placement in the 12 patients of the piezocision group

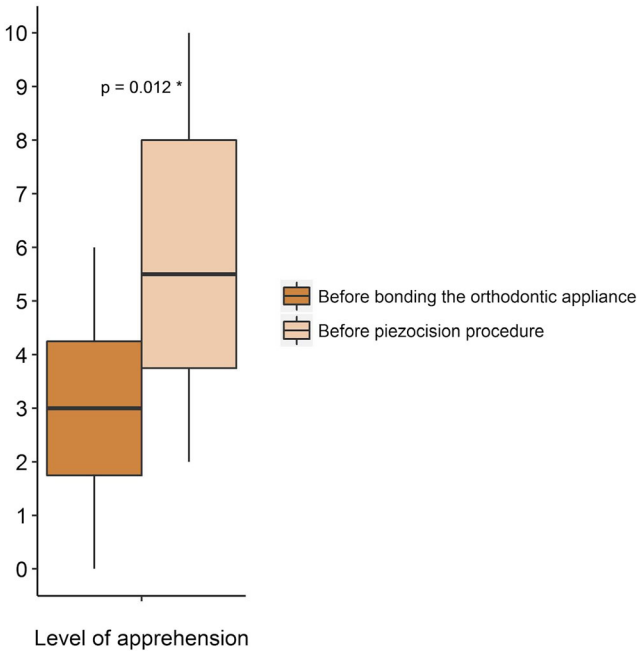

Fig. 5 The level of apprehension before bonding the orthodontic appliance and before the piezocision procedure ($p = 0.012$)

improvement of comfort by a decrease in vibration and noise [34], which can negatively influence the stress and the anxiety of the patients [35].

Finally, gender or age was not found as a predictor of pain perception and paracetamol consumption in the present study, although this point remains controversial in the literature [36].

Apprehension and satisfaction

In the present study, a certain level of apprehension was observed both before the placement of the orthodontic appliance and the piezocision surgery although the scores were higher before the surgical step (3.5 vs. 5.7). Each patient had a full explanation of the entire procedure as much as needed including the purpose, the risks, the benefits, and the monitoring and

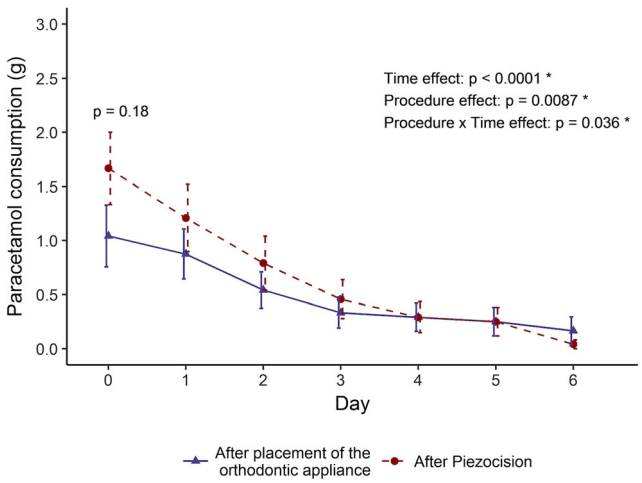

Fig. 4 Mean (± SE) paracetamol consumption after piezocision surgery and after orthodontic appliance placement in the 12 patients of the piezocision group

these results are in agreement with the study of Cabbar et al. [37], who demonstrated that verbal information with written information does not prevent completely the apprehension although the patient's cooperation is optimized. It remains therefore difficult to completely avoid the level of apprehension before intra-oral surgical interventions. After treatment completion, a high level of satisfaction was observed in both groups and significantly more patients reported that they would undergo the treatment again in the piezocision group. These results confirm in a RCT the observations of previous publications [15, 30, 38, 39]. By contrast, the available data about patient's acceptance of corticotomy-assisted orthodontics displayed low level of acceptance [40]. Therefore, minimally invasive protocol of the piezocision surgery seems to increase patient acceptance. Finally, the level of satisfaction regarding the treatment time, which is after all the main goal of applying such a technique, was significantly better in the piezocision group, related to the overall treatment time which was significantly lower in the test group compared to the control group [20]. The same conclusion was obtained in a previous RCT [15]. Indeed, the piezocision procedure following the orthodontics and periodontics guidelines of Dibart et al. [11] demonstrated a significant decrease of the orthodontic treatment time by 43% in cases of minor overcrowdings [15] and by 59% in cases of severe overcrowdings when combining with extractions [41]. In other clinical indications, orthodontic traction of upper canine was 1.5- to 2-fold faster when applying piezocision [18, 19].

It is important to mention that the piezocision procedure entails a patient recall every 2 weeks and hence an additional

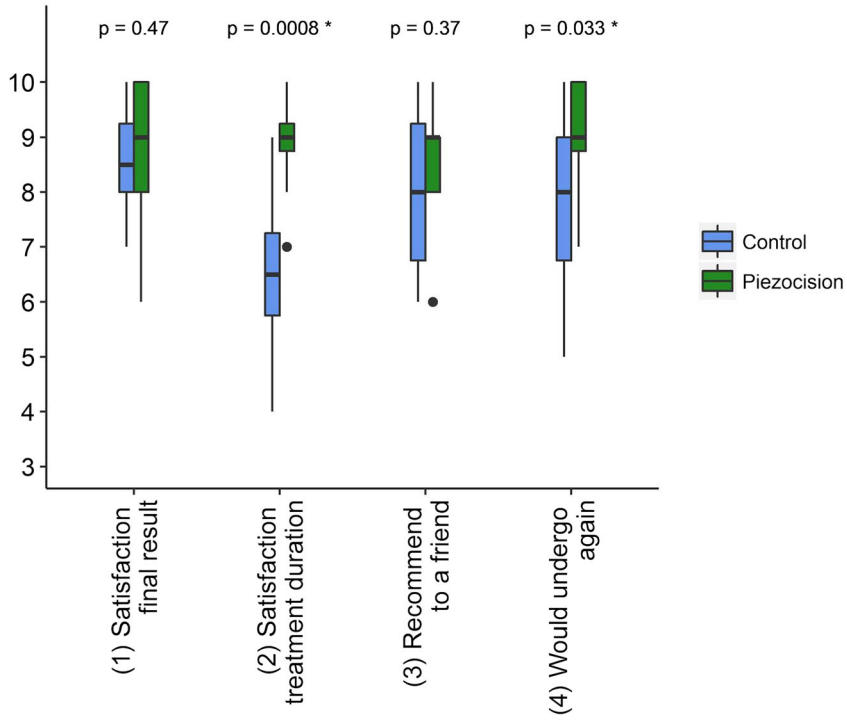

Fig. 6 In both groups, after the treatment completion, the patients were asked 4 questions: (1) levels of satisfaction in terms of the final result, (2) treatment duration, (3) if the patient would recommend the procedure to a friend, (4) if they would undergo the treatment again

financial and time burden. The rational to recall patients every 2 weeks when applying the piezocision technique, as recommended in publications considering piezocision [11, 14, 15, 19, 20, 42], is related to: The maintenance of the RAP effect [5, 6, 16], specifically the biological response responsible for the acceleration of tooth displacement. The limited period in which the piezocision procedure is effective in accelerating the orthodontic tooth movement [15, 20]. This must be mentioned to the patient prior to the treatment.

So, the absence of periodontal and radiographic adverse events, apart from the presence of minor scars [20], and the significant reduction of the orthodontic treatment time, provided a high patient satisfaction and acceptance concerning the piezocision surgery.

Limitations

Although the result of the present study should be interpreted cautiously considering that the patients were not blinded regarding their groups, the present study seems to demonstrate that PROMs following a piezocision-assisted orthodontic treatment was satisfactory. Furthermore, the orthodontic operator could not be entirely blinded since it was impossible to hide the piezocision scars when visible.

The visual analog scale (VAS) has been described as a valid, easy-to-use, and reproducible measurement tool [43–45] to evaluate subjective observations [28]. A comprehensible explanation of the use of the VAS and the way it can capture the outcome measure was provided to each patient according to Wewers and Lowe [28] to avoid any inability to conceptually understand the method [28]. This assessment tool has been used successfully in previously published piezocision RCTs [15, 30].

Finally, there is a need to evaluate the ratio cost/benefit, which was lacking in the current assessment.

Conclusion

Within the limits of the present study, PROMs emphasized a higher the degree of apprehension and higher pain level in the piezocision group. However, the pain killer consumption was similar in both groups. Study data also demonstrated an excellent patient satisfaction and acceptance regarding piezocision despite the imposed recall visits every 2 weeks.

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Compliance with ethical standards

Ethical approval All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

The randomized controlled trial as a whole received approval of the Ethics Committee of the University Hospital Liege (file number: B707201629875). The study was registered with ClinicalTrails.gov (Identifier: NCT03406130).

Informed consent All patients were verbally informed of the purpose of the study and they all signed an informed consent form.

Conflict of interest The authors declare that they have no conflict of interest.

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