ORIGINAL SCIENTIFIC ARTICLE

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Comparison of tooth movement with aligners with and without acceleration devices

Part 2: Oral health-related quality of life and pain in patients with acceleration devices

Key words *acceleration devices, aligner, oral health-related photobiomodulation, quality of life and pain, vibration therapy,*

Objective: *The purpose of this study was to evaluate the oral health-related quality of life and pain in patients with acceleration devices during orthodontic treatment with Invisalign.*

Methods: *Thirty patients were randomly assigned to three groups: control group (without additional accelerating devices, changing aligners every 7 days); Acceledent group (with Acceledent accelerating device aligners, changing every 6 days); Orthopulse group (with Orthopulse accelerating device aligners, changing every 6 days).*

The Oral Health Impact Profile (OHIP) questionnaire was used after the orthodontic treatment to measure the OHIP. This was a modified self-administered short version of the German Oral Health Impact Profile (OHIP-G16) questionnaire.

Results: *Due to the reduced number of patients included in the study, as well as the individual differences in the groups, no sufficient statistical data could be obtained, but only trends stated. One trend seemed to be reduced pain both at the beginning of a new pair of aligners and during the orthodontic treatment in the Acceledent group and the Orthopulse group.*

Conclusion: *The accelerated orthodontic treatment using the Invisalign system, with the help of vibrating or low-level light emitting devices, may reduce pain.*

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Introduction

In society, especially with adult patients, there is a growing desire for an aesthetic and functional way to straighten teeth as quickly and inconspicuously as possible, without pain. Brackets that adhere to the external tooth surfaces in a fixed multi-band device are aesthetically disturbing, even with the transparent or tooth-coloured materials that can be used today. In past decades, orthodontics has made great progress, with a great deal of research and innovative ideas to offer patients more comfort and improved aesthetics with the same quality of treatment.

Description of Invisalign

Invisalign has been on the German market for more than 15 years and has expanded the possibilities of orthodontic treatment. At the beginning of the treatment, impressions or an intraoral scan of the teeth are performed, and the data is read by Align Technology's ClinCheck software. The software calculates an individual treatment process based on the orthodontist's treatment plan and demonstrates the final probable target position of the teeth. The treating practitioner can, of course, make manual and individual changes to the proposed treatment process.

The scanned position of the teeth serves as the basis for the production of the transparent plastic aligners for the maxillary and mandibular arches. Aligners are worn by the patient for at least 22 h a day and are changed independently at regular intervals. The alternating rhythm is determined by the attending practitioner on the basis of the present dental findings (age of the patient, previous periodontal disease, etc.) and varies according to the individual therapeutic needs of each patient. The aligners can be removed to eat, drink and brush your teeth. This offers the possibility of optimal oral hygiene and patient comfort. Additional composite attachments on which the aligners grip are fixed on the teeth by the treating practitioner to achieve a targeted movement of the teeth. The range of treatment options has changed over the years from small to more complicated and complex orthodontic treatments.

As a result of the progress of the Invisalign System and the resulting therapy of more complicated cases, the treatment duration is usually many months to years, with an alternating rhythm of the aligners of 6 to 14 days. Especially for adult patients, the long treatment period with its associated aesthetic impairment is often one of the reasons for patients avoiding orthodontic treatment, prematurely finishing an orthodontic treatment, or steadily decreasing their compliance during treatment.

There are many research approaches to address this problem. For example, authors report on surgical interventions that speed up the rebuilding processes in the tooth-holding apparatus during tooth movement[1-3]. A far gentler variant might be the stimulation of the reconstruction process by vibrating devices. In orthopaedics, this method of treatment has been widespread since the end of the 1980s, since it can achieve considerable success in osteoporosis and the healing of bone fractures. The use of photobiomodulation and lasers is another alternative to obtain faster tooth movements during orthodontic treatments[4,5] and has been described to obtain a reduced pain level during orthodontics[6,7].

Orthodontic treatment with vibrating devices (e.g. Acceledent)

Vibrating devices have been used in orthopaedics since the mid-1980s. The mechanical stimulation can improve bone density in osteoporosis and accelerate the healing of bone fractures. The vibrations stimulate bone activity; osteoblasts and osteoclasts are increasingly producing the bone. In orthodontics, teeth in the tooth-holding apparatus are moved to a new position.

The total tooth retaining apparatus consisting of the root cement, the Sharpey fibres, the alveolar bone and the gingiva must react to the applied pressure of a fixed or removable appliance. On the side of the pressure application, bone is reduced by osteoclasts and on the side of the pressure elimination it is built up with the aid of the osteoblasts. The so-called 'remodelling' is to be supported and stimulated by the vibrations of vibrating devices.

The vibrating AcceleDent device is held in the oral cavity between the teeth with the help of the jaw muscles and the vibration is thus transferred to the tooth-holding apparatus. Patients are instructed to use the device for a minimum of 20 min per day. The device can be read and controlled on the computer by the orthodontist thanks to an integrated chip.

The effectiveness of mechanical stimulation to accelerate tooth movements has already been confirmed *in vitro* in rats and monkeys, as well as *in vivo* in combination with multiband appliances. In Germany, vibrating devices are not yet widely used in orthodontics. However, studies from other countries show promising results *in vitro* and *in vivo*. In experiments in rats, a 15% accelerated tooth movement was observed within 21 days using a vibrating device for 8 min per day compared with rats from a control group, which were only subjected to static pressure on the teeth[8]. However, these treatment successes have so far only been described in animal studies[9] and in combination with fixed appliances[10] and others in a few publications[11-13].

In the literature, however, there have been very few studies in which an orthodontic treatment with Invisalign in connection with vibrating devices has been investigated in

a larger patient group. Further randomised clinical trials are needed to achieve more meaningful results.

Until now, the potential risks of the use, as well as the actual effectiveness of this process, have not been sufficiently investigated[14].

Orthodontic treatment with low-level light therapy (e.g. Orthopulse)

Low-level laser (light) therapy (LLLT) – also known as photobiomodulation[15] – has been used since 1967 to enhance tissue healing and regeneration and to relieve pain, inflammation and swelling. Photobiomodulation uses light-emitting diodes or low-energy lasers that emit light in the visible red to near-infrared range[16]. The effective wavelength range is between ~590 nm and 1000 nm[15-18], and is called the near-infrared range (NIR). An effective tissue penetration of light is maximised from approximately 650 nm to 1200 nm. The energy density (fluence, dose or energy) is generally between 1 and 20 J/cm^2. The power density (irradiance) can vary depending on the actual light source and spot size, from 5 to 50 mW/cm^2. Much higher irradiances up to 1 W/cm^2 can be used for nerve inhibition and pain relief[18].

Photobiomodulation is effective if delivered to normal cells or tissue before the actual insult or trauma, in a pre-conditioning mode[16]. Muscles are protected using photobiomodulation before intense exercise[19], also showing a positive effect during muscle regeneration through the gene expression modulation related to the inflammatory process and the formation of new muscle fibres[20]. The treatment of painful muscles is useful for patients with temporomandibular disorders (TMD) if muscular problems such as trigger points are present.

The origin of a trigger point is ischemia, which can be treated with injection, or currently more with manual techniques[21]. Photobiomodulation is another effective tool to treat ischemia in the muscle. Photobiomodulation promotes synovial fibroblast proliferation and can reduce pain and inflammation in joints[22], which can be helpful in TMD patients with an arthrogenic origin. Under photobiomodulation treatment, muscles are protected and nerves feel less pain. Photobiomodulation can even protect against heart attack[19].

Many studies have shown the effect of photobiomodulation on proliferation and the differentiation of cells contributing to bone regeneration[5,24]. In a literature review based on 240 articles published between 2001 and 2014, Amid et al[25] concluded that photobiomodulation exerts a biostimulatory effect on bone tissue and enhances osteoblastic proliferation and differentiation of cells.

Experimental tooth movement in rats with an orthodontic force applied to the molars in combination with irradiation of the molar area with a low-energy laser showed a RANK expression in osteoclast precursor cells[26]. The effect of photobiomodulation on root resorption during orthodontic treatment in patients was measured using cone beam computed tomography (CBCT). The results showed that photobiomodulation did not cause root resorption greater than the normal range[27]. Other studies also concluded that photobiomodulation has the potential to accelerate orthodontic tooth movement and has inhibitory effects on orthodontically induced resorptive activity[28]. The influence of photobiomodulation on orthodontic tooth movements with fixed appliances or coils was studied in patients as well[17,25,29,30] or with the Invisalign System[30]. They showed an increase in the tooth movement of those patients treated additionally with photobiomodulation. However, the potential risks of the use of this process as well as its actual effectiveness have been insufficiently investigated[14].

Invisalign (invisible) is an orthodontic treatment system with removable, transparent aligners for the maxillary and mandibular arches. The system was introduced to the German market in 1981 and from the outset met the requirements of a much less discerning apparatus, but still had considerable weaknesses in the execution of more complicated orthodontic treatments. With further research and development of the system – e.g. in combination with elastic bands and special attachments – it is now possible to solve even complex treatments such as for Class II and III or extraction cases.

Materials and methods

Strategy

In this prospective, randomised pilot study, adult patients who planned to start their orthodontic treatment with aligners were selected by chance and were randomly assigned to three different groups: a control group without any use of additional acceleration devices, the “AcceleDent” group

that used the AcceleDent acceleration device, and the "Orthopulse" group that used the Orthopulse acceleration device. The included patients were treated without any differentiation as to initial findings, severity of malocclusion, type of movement, etc. Moreover, the aim of this randomised pilot study was to include patients with various characteristics with regard to age, grade and type of malocclusion, etc, in order to obviate selection bias and achieve a wide patient base for cross-sectional data. However, due to the low number of patients included in this study, no varied statistical analysis could be obtained.

The questionnaires were administered in the middle of the study after the setting of the 10th aligner.

Oral health awareness was evaluated by asking what patients could do to keep their teeth healthy or to improve their oral health. Patients were also asked why they opted for orthodontic treatment. They could choose between aesthetic reasons, TMD, problems while eating, or recommendations from family or friends.

All patients in the Invisalign control group were non-smokers; one in 10 in the AcceleDent and Orthopulse groups were occasional smokers.

The oral health impact profile (OHIP) included the following questions:

- Have you had trouble pronouncing any words because of problems with your teeth, mouth or aligners?
- Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or aligners?
- Have you had painful aching in your mouth?
- Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or aligners?
- Have you been self-conscious because of your teeth, mouth or aligners?
- Have you felt tense because of problems with your teeth, mouth or aligners?
- Has your diet been unsatisfactory because of problems with your teeth, mouth or aligners?
- Have you had to interrupt meals because of problems with your teeth, mouth or aligners?
- Have you found it difficult to relax because of problems with your teeth, mouth or aligners?
- Have you been a bit embarrassed because of problems with your teeth, mouth or aligners?
- Have you been a bit irritable with other people because of problems with your teeth, mouth or aligners?
- Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or aligners?
- Have you felt that life in general was less satisfying because of problems with your teeth, mouth or aligners?
- Have you been totally unable to function because of problems with your teeth, mouth or aligners?

Patients were asked about levels of pain at the beginning with a new aligner, if and when the pain got remarkably better after getting a new pair of aligners, and the overall pain felt during the whole orthodontic treatment.

The groups using accelerating devices (AcceleDent, Orthopulse) were also asked how much they liked the additional device, if they would recommend the device, how much they would spend on the device, if they felt uncomfortable while using the device, if it was hard to remind themselves to use the device, if pain occurred, if the pain changed during the treatment with the device and finally, if they felt well informed about its use.

The figures in this article show the results of the questionnaire.

Oral health-related quality of life

Originally developed in Australia, the OHIP questionnaire is used internationally to determine health-related quality of life. The questionnaire was translated into the German language (-G) and contains 49 questions in the original version, but in practice is a shortened version with 14 questions (OHIP-G14)[32]. The questionnaire encompasses a variety of questions that can be used to assess specific areas such as functional limitations of the masticatory system, orofacial pain, dentofacial aesthetics and psychosocial influence of oral health by the patient's own subjective perception. The questions can be answered with one of five frequency details and can be summed up with the corresponding point values – "never" = 0, "hardly" = 1, "from time to time" = 2, "often" = 3 and "very often" = 4. Therefore, the sum can vary from the extremes of 0 (no restrictions; all questions answered with "never") to 56 (maximum restriction by the treatment; all questions answered with "very often"). Filling out the questionnaire took patients approximately 2 to 3 min.

The 14 questions provide a quick overview of the psychosocial impairment caused by the dental treatment and provide the practitioner with information that will help to

achieve patient satisfaction. The OHIP has been scientifically investigated in several national and international studies with regard to its meaningfulness. This questionnaire was administered at the end of treatment.

Pain scale

The pain scale is a quick and easy-to-understand test for each patient to visualise the pain they have experienced. On a scale with values from 0 (no pain) to 10 (worst possible pain), the patient is asked to enter the subjectively felt pain. This can be used in the form of a visual analogue scale or a numerical rating scale. The subjective pain intensity of each patient can be used to measure the therapy success at several points in the treatment and, if necessary, to adapt the treatment accordingly.

Questions and answers

The current data situation does not allow us to safely assume reliable knowledge about the accelerated treatment success and patient comfort in orthodontic treatments with Invisalign, supported by vibrating devices such as AcceleDent or the combination with low-level light therapy, such as the Orthopulse device. An accelerated orthodontic treatment with the Invisalign System, with the help of vibrating or low-level light emitting devices that could even reduce the pain, could open up new possibilities for practitioners as well as for patients.

The key issues of this study have therefore been the following:

1. Is the same amount of tooth movement possible without any additional device (aligner change every 7 days with Invisalign only), in conjunction with a vibrating device (aligner change every 6 days) or with a PBM device (aligner change every 5 days)? (See part 1 of this article series: The comparison of the tooth movement with aligner without and with acceleration devices (Journal of Aligner Orthodontics 2018;2:141–150).
2. Is the oral health-related quality of life better in an orthodontic Invisalign treatment with an additional accelerating device (vibrating or PBM) than without such a device?
3. Is the pain reduced during an orthodontic treatment with Invisalign with the use of a vibrating or PBM device?

Table 1 Comparison of the number of participants according to gender.

	Control group	AcceleDent	Orthopulse
Male	1	3	2
Female	9	7	8
Total	10	10	10

Results

The control group (without additional accelerating devices and aligner changes every 7 days) comprised one male and nine female patients with an average age of 34.4 (range – 35 to 61). The patients in the AcceleDent group included three males and seven females, with an average age of 33.8 years (range – 20 to 60 years), while the Orthopulse group comprised 10 patients – eight females and two males – with an average age of 35.1 years (range – 22 to 52) (Table 1).

Results of the questionnaire

Orthodontic treatment with Invisalign (control group) (Figs 1 to 5)

Patients

Youngest: 24 years

Oldest: 61 years

Mid: 35.5 years

Change of aligners in the control group: Every 7 days

1. **How much can you do to keep your teeth healthy or to improve your oral health? (Fig 1).**
2. **Why did you make the decision to get an orthodontic treatment?**

   Aesthetic reasons: 21.5%

   TMD: 28.5%

   Problems while eating: 50%

   Recommended by family/friends: 0%

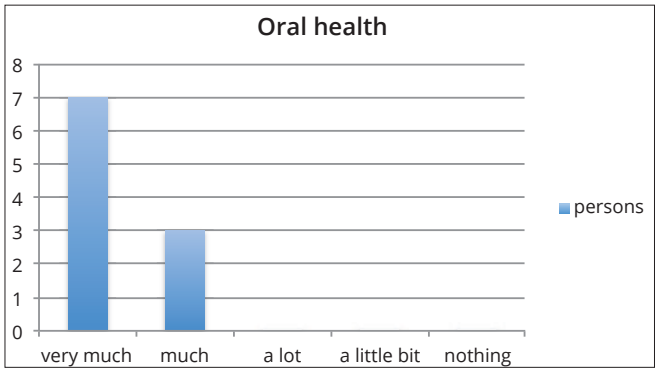

Fig 1 How much can you do to keep your teeth healthy or to improve your oral health?

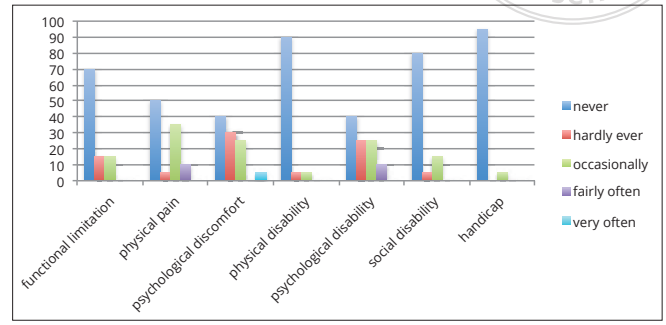

Fig 2 OHIP at the beginning of treatment.

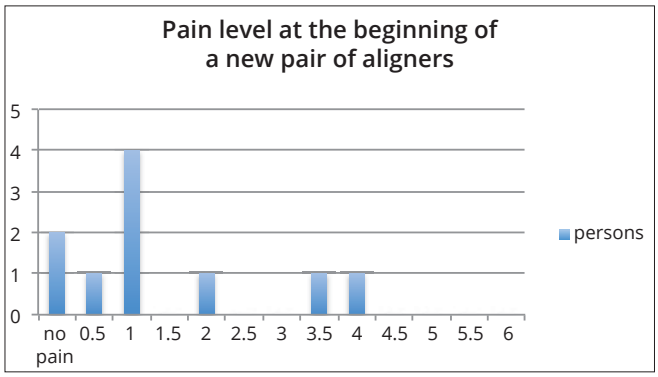

Fig 3 How do you rate the pain at the beginning of a new pair of aligners and the orthodontic treatment in general?

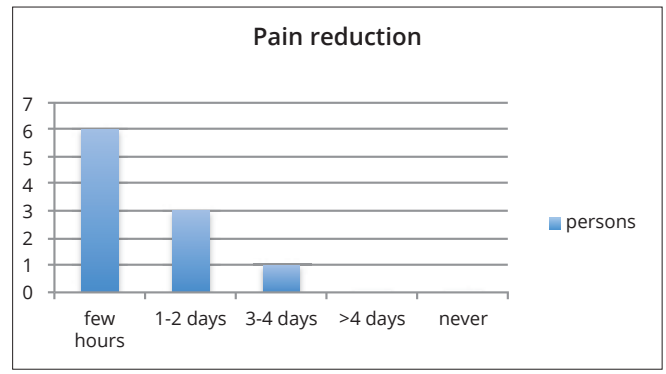

Fig 4 When does the pain get remarkably better after getting a new pair of aligners?

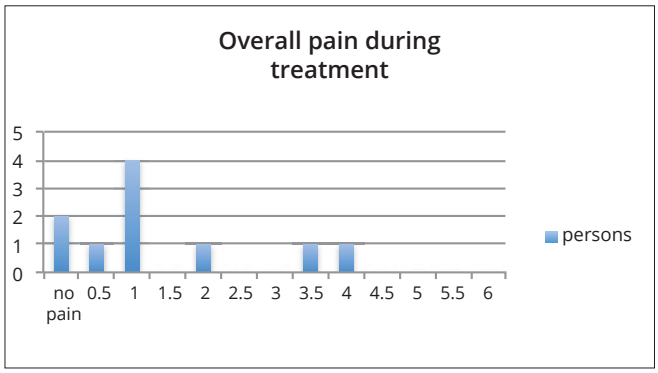

Fig 5 How much pain do you experience overall during the orthodontic treatment?
Subscales 1-7
Functional limitation: 1-9 (2, 6)*
Physical pain: 10-18 (10, 16)
Psychological discomfort: 19-23 (20, 23)
Physical disability: 24-32 (29, 32)
Psychological disability: 33-38 (35, 38)
Social disability 39-43 (42, 43)
Handicap: 44-49 (47, 48)
* Numbers in parenthesis are questions that can be found in the OHIP-G14, two from every subscale.

3. **Do you smoke cigarettes? If yes, how many and since when?**
   No: 100%
4. to 17. **OHIP at the beginning of treatment (Fig 2).**
18. **How do you rate the pain at the beginning of a new pair of aligners and the orthodontic treatment in general? (Fig 3).**
19. **When does the pain get remarkably better after getting a new pair of aligners? (Fig 4).**
20. **How much pain do you have overall during the orthodontic treatment? (Fig 5).**

Table 2 OHIP at the beginning of treatment (orthodontic treatment with Invisalign [control group; Figs 1 to 5]).

No.	Question	Never (0)	Hardly ever (1)	Occasionally (2)	Fairly often (3)	Very often (4)
2	Have you had trouble pronouncing any words because of problems with your teeth, mouth or aligners?	50	20	30	0	0
6	Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or aligners?	90	10	0	0	0
10	Have you had painful aching in your mouth?	30	10	40	20	0
16	Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or aligners?	70	0	30	0	0
20	Have you been self-conscious because of your teeth, mouth or aligners?	40	30	20	0	10
23	Have you felt tense because of problems with your teeth, mouth or aligners?	40	30	30	0	0
29	Has your diet been unsatisfactory because of problems with your teeth, mouth or aligners?	80	10	10	0	0
32	Have you had to interrupt meals because of problems with your teeth, mouth or aligners?	100	0	0	0	0
35	Have you found it difficult to relax because of problems with your teeth, mouth or aligners?	60	20	0	20	0
38	Have you been a bit embarrassed because of problems with your teeth, mouth or aligners?	20	30	50	0	0
42	Have you been a bit irritable with other people because of problems with your teeth, mouth or aligners?	80	10	10	0	0
43	Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or aligners?	80	0	20	0	0
47	Have you felt that life in general was less satisfying because of problems with your teeth, mouth or aligners?	90	0	10	0	0
48	Have you been totally unable to function because of problems with your teeth, mouth or aligners?	100	0	0	0	0

Table 3 OHIP score of patients in test group (orthodontic treatment with Invisalign [control group; Figs 1 to 5]).

Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7	Patient 8	Patient 9	Patient 10
4	13	3	12	17	2	6	5	8	14
* Possible maximum: 56; high points: high impact on quality of life.									

Results of the questionnaire – orthodontic treatment with Invisalign and AcceleDent (Figs 6 to 11)

Patients:

Youngest: 20 years

Oldest: 60 years

Mid: 33.8 years

Change of aligner in the control group: every 7 days

With Acceledent: every 6 days

Scans and photos

- At the beginning
- With aligner 5 (+ -1)
- With aligner 10 (+ -3)
- With aligner 20 (+ -3)

1. **How much can you do to keep your teeth healthy or to improve your oral health?**
2. **Why did you make the decision to have orthodontic treatment?**
   Aesthetic reasons: 70%
   TMD: 30%
   Problems while eating: 0%
   Recommended by family/friends: 0%
3. **Do you smoke cigarettes? If yes, how many and since when?**
   No: 90%
   Yes: 10% (25 for 45 years)

4. to 17. OHIP.

18. **How do you rate the pain at the beginning of a new pair of aligners and the orthodontic treatment in general?**

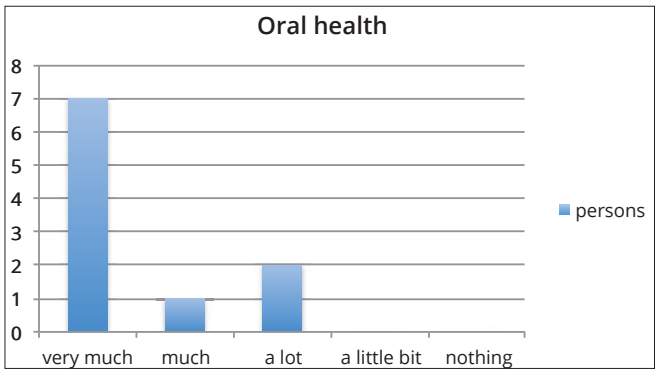

Fig 6 How much can you do to keep your teeth healthy or to improve your oral health?

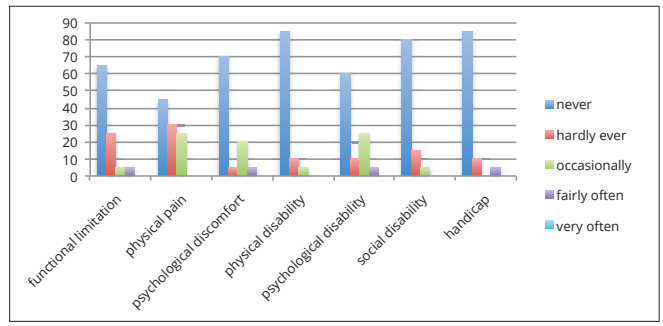

Fig 7 Subscales 1-7:
1 Functional limitation 1-9 (2, 6)
2 Physical pain 10-18 (10, 16)
3 Psychological discomfort 19-23 (20, 23)
4 Physical disability 24-32 (29, 32)
5 Psychological disability 33-38 (35, 38)
6 Social disability 39-43 (42, 43)
7 Handicap 44-49 (47, 48)

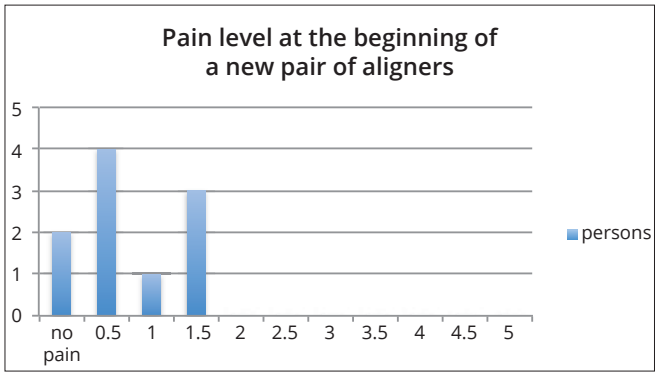

Fig 8 How do you rate the pain at the beginning of a new pair of aligners and the orthodontic treatment in general?

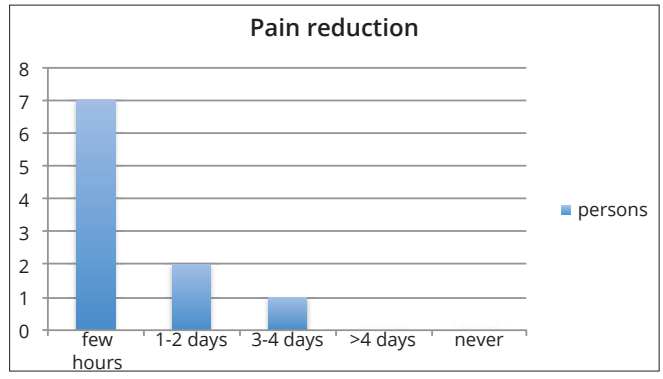

Fig 9 When does the pain get remarkably better after getting a new pair of aligners?

Table 4 OHIP at the beginning of treatment (results of the questionnaire – orthodontic treatment with Invisalign and AcceleDent [Figs 6 to 11]).

No.	Question	Never (0)	Hardly ever (1)	Occasionally (2)	Fairly often (3)	Very often (4)
2	Have you had trouble pronouncing any words because of problems with your teeth, mouth or aligners?	40	40	10	10	0
6	Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or aligners?	90	10	0	0	0
10	Have you had painful aching in your mouth?	30	50	20	0	0
16	Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or aligners?	60	10	30	0	0
20	Have you been self-conscious because of your teeth, mouth or aligners?	60	10	30	0	0
23	Have you felt tense because of problems with your teeth, mouth or aligners?	80	0	10	10	0
29	Has your diet been unsatisfactory because of problems with your teeth, mouth or aligners?	80	20	0	0	0
32	Have you had to interrupt meals because of problems with your teeth, mouth or aligners?	90	0	10	0	0
35	Have you found it difficult to relax because of problems with your teeth, mouth or aligners?	70	10	10	10	0
38	Have you been a bit embarrassed because of problems with your teeth, mouth or aligners?	50	10	40	0	0
42	Have you been a bit irritable with other people because of problems with your teeth, mouth or aligners?	90	10	0	0	0
43	Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or aligners?	70	20	10	0	0
47	Have you felt that life in general was less satisfying because of problems with your teeth, mouth or aligners?	80	20	0	0	0
48	Have you been totally unable to function because of problems with your teeth, mouth or aligners?	90	0	0	10	0

Table 5 OHIP score of patients in test group (results of the questionnaire – orthodontic treatment with Invisalign and AcceleDent [Figs 6 to 11]).

Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7	Patient 8	Patient 9	Patient 10
19	1	7	10	5	6	2	2	1	14
Possible maximum: 56; high points: high impact on quality of life.									

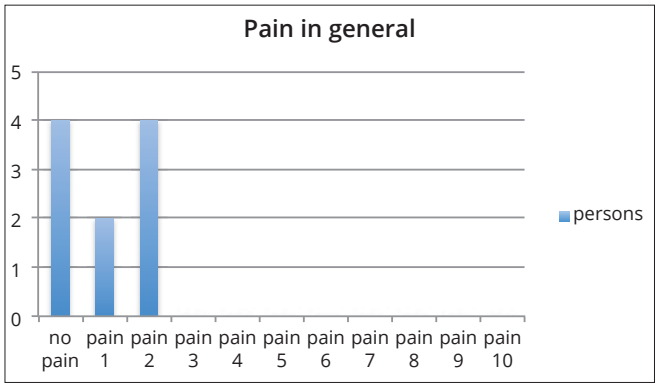

Fig 10 How much pain do you have overall during the orthodontic treatment?

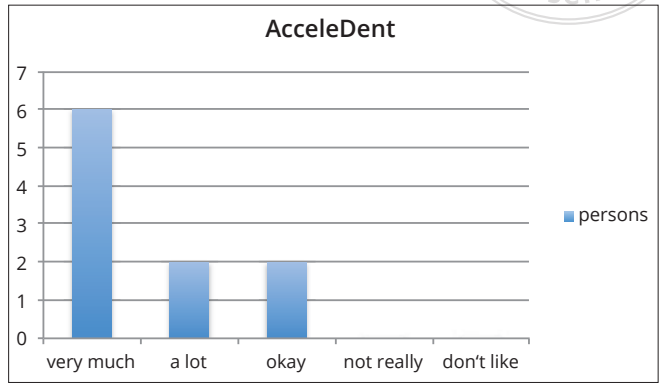

Fig 11 How much do you like AcceleDent?

19. **At what point does the pain get remarkably better after getting a new pair of aligners?**
20. **How much pain do you have overall during the orthodontic treatment (Fig 10)?**
21. **How much do you like AcceleDent (Fig 11)?**
22. **Would you recommend AcceleDent?**
    Yes: 100%
    No: 0%
23. **How much would you spend on a vibrating device?**
    3x 200€, 4x 500€, 2x 1000€, 1x 2000€
24. **Did you feel uncomfortable during the use of the AcceleDent device?**
    Yes: 30%
    No: 70%
    Mouthpiece too big: 2
    Saliva was triggered: 2
    Feeling embarrassed: 1
    Device did not work the way it should: 1
    Triggered retching at the start: 1
25. **Was it hard to remind yourself to use the AcceleDent once a day for 20 min?**
    No: 100%
26. **Did you have pain implicitly during the use of the AcceleDent device?**
    No: 60%
    No, and it actually relieved the pain during orthodontic treatment: 20%
    Yes, on a pain scale from 1 to 10 it was a pain of 2, because the muscles of the jaw where aching at the beginning: 10%
27. **Were you well informed about AcceleDent?**
    Yes: 100%

Results of the questionnaire – orthodontic treatment with Invisalign and Orthopulse (Figs 12 to 19)

Patients:

Youngest: 22 years

Oldest: 52 years

Mid: 35.1 years

1. **How much can you do to keep your teeth healthy or to improve your oral health?**
2. **Why did you make the decision to get an orthodontic treatment?**
   Aesthetic reasons: 29.4%
   TMD: 29.4%
   Problems while eating: 29.4%
   Recommended by family/friends: 11.7%
3. **Do you smoke cigarettes? If yes, how many and since when?**
   No: 90%
   Yes: 10% (2 per day for 10 years)

4. to 17. **OHIP at the beginning of treatment.**

18. **How do you rate the pain at the beginning of a new pair of aligners and the orthodontic treatment in general?**
19. **When does the pain get remarkably better after getting a new pair of aligners?**
20. **How much pain do you have overall during the orthodontic treatment?**
21. **How much do you like Orthopulse?**

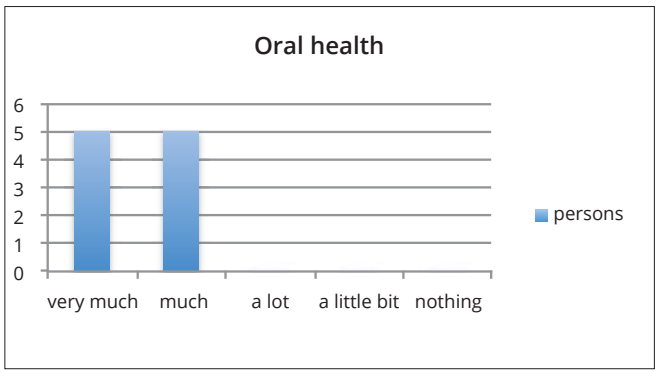

Fig 12 How much can you do to keep your teeth healthy or to improve your oral health?

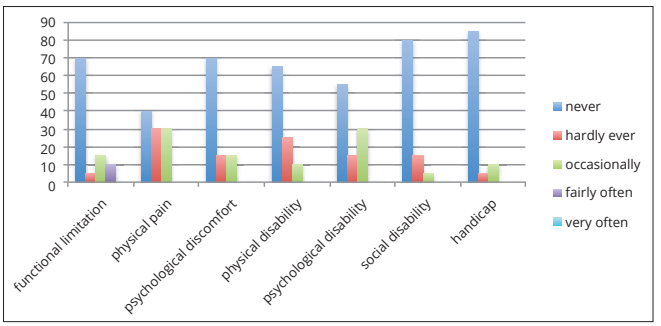

Fig 13 Subscales:
1 Functional limitation 1-9 (2, 6)
2 Physical pain 10-18 (10, 16)
3 Psychological discomfort 19-23 (20, 23)
4 Physical disability 24-32 (29, 32)
5 Psychological disability 33-38 (35, 38)
6 Social disability 39-43 (42, 43)
7 Handicap 44-49 (47, 48)
Numbers in parenthesis are the questions that can be found in the OHIP-G14, two from every subscale.

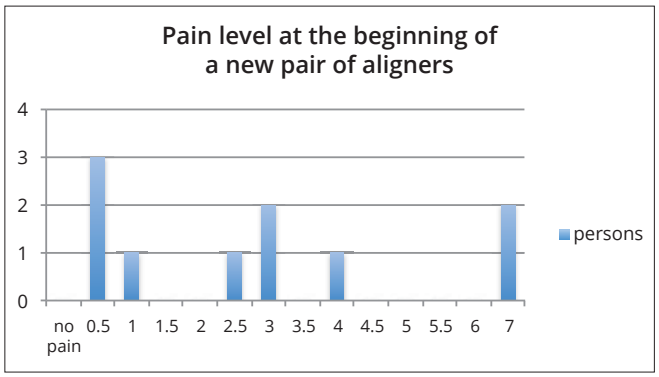

Fig 14 How do you rate the pain at the beginning of a new pair of aligners and the orthodontic treatment in general?

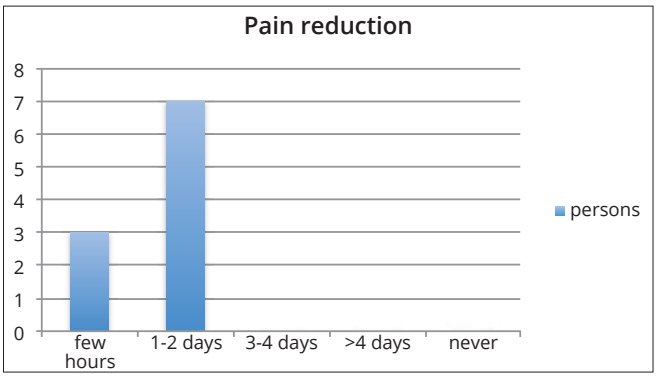

Fig 15 When does the pain get remarkably better after getting a new pair of aligners?

Table 6 OHIP at the beginning of treatment (results of the questionnaire – orthodontic treatment with Invisalign and Orthopulse [Figs 12 to 19]).

No.	Question	Never (0)	Hardly ever (1)	Occasionally (2)	Fairly often (3)	Very often (4)
2	Have you had trouble pronouncing any words because of problems with your teeth, mouth or aligners?	50	0	30	20	0
6	Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or aligners?	90	10	0	0	0
10	Have you had painful aching in your mouth?	30	30	40	0	0
16	Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or aligners?	50	30	20	0	0
20	Have you been self-conscious because of your teeth, mouth or aligners?	70	0	30	0	0
23	Have you felt tense because of problems with your teeth, mouth or aligners?	70	30	0	0	0
29	Has your diet been unsatisfactory because of problems with your teeth, mouth or aligners?	60	30	10	0	0
32	Have you had to interrupt meals because of problems with your teeth, mouth or aligners?	70	20	10	0	0
35	Have you found it difficult to relax because of problems with your teeth, mouth or aligners?	50	20	30	0	0
38	Have you been embarrassed because of problems with your teeth, mouth or aligners?	60	10	30	0	0
42	Have you been a bit irritable with other people because of problems with your teeth, mouth or aligners?	90	0	10	0	0
43	Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or aligners?	70	30	0	0	0
47	Have you felt that life in general was less satisfying because of problems with your teeth, mouth or aligners?	70	10	20	0	0
48	Have you been totally unable to function because of problems with your teeth, mouth or aligners?	100	0	0	0	0

Table 7 OHIP score of patients in test group (results of the questionnaire – orthodontic treatment with Invisalign and Orthopulse [Figs 12 to 19]).

Patient 1	Patient 2	Patient 3	Patient 4	Patient 5	Patient 6	Patient 7	Patient 8	Patient 9	Patient 10
6	11	0	14	16	15	4	3	0	5
Possible maximum: 56; high points: high impact on quality of life.									

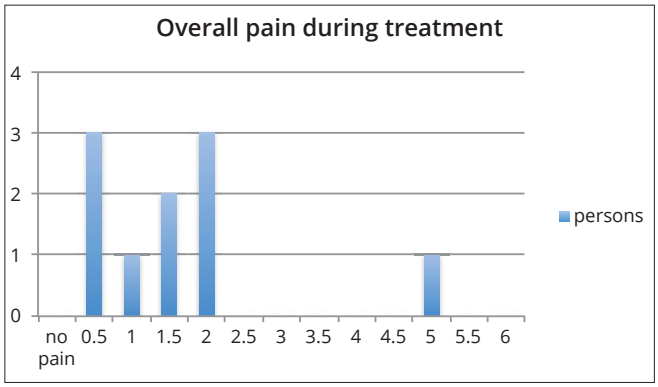

Fig 16 How much pain do you have all over during the orthodontic treatment?

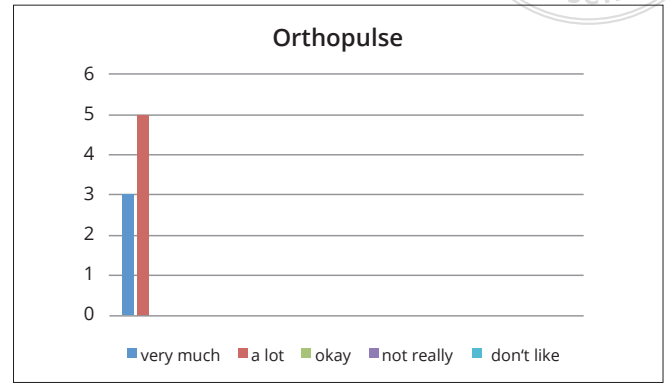

Fig 17 How much do you like Orthopulse?

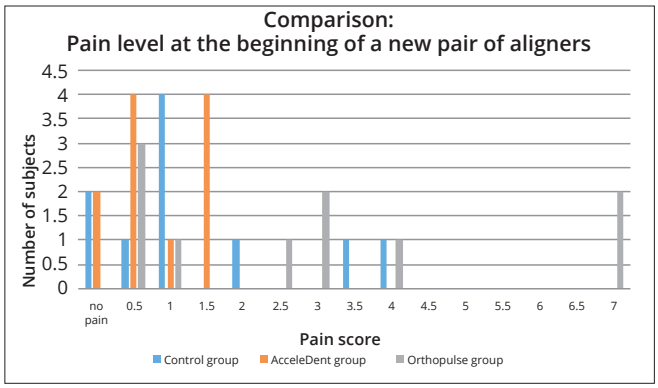

Fig 18 Comparison: Pain at the beginning of new aligners.

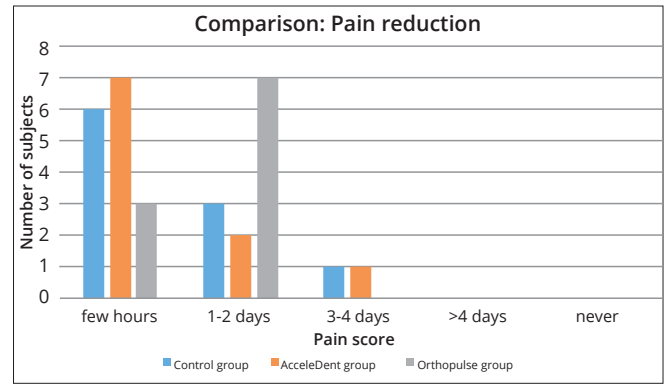

Fig 19 Comparison: Pain reduction.

22. **Would you recommend Orthopulse?**
    Yes: 7 out of 8
    No: 1 out of 8
23. **How much would you spend on an accelerating device?**
    2× nothing, 1× 200€, 3 X 200-250€, 1× 300-400€, 2× 300-500€, 1× 600€
24. **Did you feel uncomfortable during the use of Orthopulse?**
    No: 5 out of 8
    Yes: 2 out of 8
    Mouthpiece was too big: 2
    Saliva was triggered: 2
25. **Was it hard to remind yourself to use Orthopulse once a day for 10 min?**
    No: 100%
26. **Did you have pain implicitly during the use of Orthopulse?**
    No: 7 out of 8
    No (it actually relieved the pain during orthodontic treatment): 1 out of 8
27. **Did you feel well informed about Orthopulse?**
    Yes: 100%

Results

See Figures 18 and 19 for a comparison of the results regarding estimated pain at the beginning of a new pair of aligners and the pain reduction in the control group, the AcceleDent group and the Orthopulse group.

Discussion

In recent years, acceleration devices have gained an ever-growing importance. Acceleration appliances can be subdivided into surgical and non-surgical processes. This study concentrated on the non-surgical methods, the vibration therapy and the photobiomodulation under the use of incoherent light emitting diodes. A clear statement regarding the efficiency of accelerating dental tooth movement does not exist[14] for the vibration processes[33-37] or for the photobiomodulation process[35,38-40].

The questionnaire part of the study shows that the pain at the beginning of a new pair of aligners and the pain during orthodontic treatment tended to be slightly less when using AcceleDent and Orthopulse than without without the use of an acceleration device.

Conclusion

The use of acceleration devices during the orthodontic treatment showed a tendency for a reduction of orthodontic pain, as well as an improvement on the parameter of oral health-related quality of life when used with Invisalign. Benefits were apparent within the very first weeks of therapy and were maintained during the entire treatment. The acceleration devices were tolerated well by the participants of the present study. The evaluation of the questionnaires demonstrated a tendency for a decrease in pain intensity when using specific devices in addition to the orthodontic aligners, and important clinical parameters such as overall comfort, oral health, functional and emotional well-being also improved.

Between 70% and 75% of the participants using acceleration devices never or hardly ever perceived physical pain, while the percentage in the group without an additional appliance was 55%. The reported amount of psychological discomfort and psychological disability was significantly lower in the groups using acceleration devices than in the control group. Furthermore, the social disability was 95% in patients using the acceleration devices, while it was 85% in the control group.

These findings might show a tendency for acceleration devices offering less pain and increasing oral health-related quality of life compared with Invisalign treatment without additional devices. Due to the variety of malocclusion, gender and age, and especially the low number of patients included, a valid statistical analysis was not possible in this study. Therefore, the clinical effectiveness of the acceleration devices need to be investigated more extensively.

Acknowledgements

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