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ACUPUNCTURE REDUCES PAIN DURING INJECTION OF LOCAL ANAESTHETIC FOR PEDIATRIC DENTISTRY – A RANDOMIZED CROSSOVER TRIAL

Inaugural – Dissertation zur Erlangen des Akademischen Grades
Doktor der Zahnmedizin (Dr. med. dent)
der Universitätsmedizin
der Ernst-Moritz-Arndt-Universität Greifswald
2012

Vorgelegt von
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Geb. am 29.09.1978 in Hannover / Deutschland

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Tag der Disputation: 26.02.2014

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1 Introduction

Acupuncture treatment, practiced in China for more than 2000 years, represents an alternative to the conservative methods and instruments in Western medicine. Its demand has been considerably rising within the western population during the past decades. Especially young parents, irritated by negative headlines concerning the pharmaceutical industry and by the side effects listed on each package insert, are looking for a save alternative for their children as for themselves [Jindal V. et al., 2008]. With the research of acupuncture, as a complementary and alternative medicine (CAM) on the increase, it became more and more accepted by the Western medicine. In Germany, for instance, acupuncture treatment of several diseases is covered by medical insurance since 2007 according to the resolution by GBA (German Federal Joint Committee).

However, pain management with acupuncture is still in its infancy. Although acupuncture states a proven treatment for relieving pain in adults, the mechanism and physiological effects of acupuncture remain unclear [Lin JG and Chen WL, 2009; Huang CS and Tsai YF, 2009].

As for children, the amount of well-designed and high-quality studies concerning pain management is quite concise, mostly due to poor standardization, lack of randomization and small sample sizes [Libonate J. et al., 2008; Kundu A. and Berman B., 2007]. According to Jindal et al. 2008, research data of adults cannot simply be extrapolated, since the manifestation of pain in children differ from that of adults. Therefore, it remains difficult to draw conclusions on the basis of the available published clinical trials data concerning pediatric acupuncture so far, albeit proving to be promising.

This study, which deals with the reduction of procedural pain during the injection of the local anesthetic in pediatric dentistry using acupuncture, tries to meet the aforesaid problems by

- ensuring standardized data by using an equal pain stimulus in terms of the routinely injection of the local anesthetic in pediatric dentistry.
- using standardized acupuncture-needles, so-called press needles

- providing a statistically significant number of participant
- ensuring randomization

In addition, the format of this study is designed to meet the circumstances and requirements in the daily clinical practice which allows every practitioner, even without any previous knowledge about acupuncture, to easily implement it in private practice. Finally it has to be noted, that the aim of this study is not a further attempt to explain the mechanism of acupuncture. Instead it focuses solely on the question whether acupuncture works in reducing pain in pediatrics, or not. Therefore, this study does not exclude subjective expectations, psychological aspects or placebo effects as a possible part of the acupuncture effect, and hence does not require a uni- or double-blinded study design.

2 Background

2.1 Acupuncture

Acupuncture is an ancient mode of treatment which is used in various occasions. According to the traditional Chinese perception, our health correlates directly with the so-called „Qi“, which can be described as vital, immaterial energy which flows through our body along „Meridians“. These meridians form a network and channel the Qi while each is specialized in an organ or part of the body. If the flow of the Qi is interrupted or impaired it may lead to internal or external ailment. In order to recover health and therefore the flow, certain acupuncture points which are situated along the meridians, need to be stimulated [Rademacher, 2009; Stux et al., 2007; Greten, 2004; Pothman and Meng, 2002].

2.2 Acupuncture and western medicine

The practice of traditional Chinese acupuncture in western medicine was dramatically accelerated in 1971, when James Reston reported on an appendectomy following acupuncture as pain treatment in the New York Times. Henceforward, effort was made in researching this sector of medicine producing a multitude of hypotheses concerning the analgetic mechanism of acupuncture. Until now a consensus could not be reached concerning this topic. This led to a variety of studies with different

approaches in methodology. Hence seldom standardized, comparable and consecutive research was conducted which didn't allow clear findings in the adult - as well as in the pediatric sector [Ernst et al., 2011; Wu et al., 2009; Kundu and Berman, 2007]

Especially the analgesic effect of acupuncture was brought into focus. Great effort was made to explore whether its effectiveness is due to the actual acupuncture points or a psychological effect (or both). For instance, studies were conducted treating headache, migraine, osteoarthritis or backache, using sham acupuncture (wrong acupuncture points). Yet no clear conclusions could be drawn according to these studies, either supporting or denying verum acupuncture's superiority with regard to sham acupuncture [Linde et al., 2009; Haake et al., 2007; Witt et al., 2006; Linde et al., 2005].

However, this mode of therapy proved to be superior to the conservative one [Colagiuri and Smith, 2011; Park et al., 2008; Haake et al., 2007].

Both, acupuncture – and expectation-induced placebo effect, show similar neurobiological characteristics affecting the same neurochemical pathways. Therefore, it can be concluded that the analgesic effect of acupuncture involves both specific neurobiological mechanisms generated only by acupuncture and less specific mechanisms elicited by expectation-induced placebo effect [Musial et al., 2009].

2.3 Physiological explanations

Repeatedly, physiological reactions and responses of the body to acupuncture have been verified. Acupuncture analgesia is an integrative process which takes part at different stages of the CNS between afferent signals from the pain region and impulses from acupoints [Zhao ZQ, 2008]. Opioids or neurotransmitters (for example: enkephaline, dynorphine, GABA) were verifiably released during acupuncture treatment. This release of neurotransmitters could explain a possible effect on the pain-transmission and an associating analgesic effect.

A complex network of brain structures, mostly the limbic system and nuclei that are part of the endogenous descending inhibitory system of the CNS, is involved in generating a reduction in pain [Wang et al., 2008].

Another theory suggests a mediation of the autonomic nervous system through acupuncture. Specific to the site of stimulation, acupuncture may affect sympathetic

and parasympathetic nervous system activity. An effect on the parasympathetic nervous system could explain the soothing effect of acupuncture, for instance by reducing the sympathetic activity, which in turn might alter pain experience [Gold et al., 2008].

However, to what extent which component, physiologically and/or psychologically, participates in the functioning process of acupuncture is still to be investigated [Enck et al., 2010; Musial et al., 2009]

2.4 Pediatric pain treatment

Today, acupuncture has been increasingly used especially in pediatric pain treatment. Particularly parents welcome acupuncture as an alternative and safe treatment due to concerns about the myriad of side-effects of various medicaments [Adams et al., 2011; Wu et al., 2009; Gold et al., 2008]. According to Kundu and Berman children are open to acupuncture especially when carefully explained and demonstrated before the treatment. In addition to the analgesic effect children explained to feel better overall and parents even reported improved behavior in school, improved sleep patterns and children took part in extracurricular activities more often [Kundu and Berman, 2007].

2.5 Connection between anxiety and pain

Anxiety can cause an increase in pain. Studies about acupuncture and acupressure in the dental sector showed a soothing effect on patients during the treatment. Therefore, a reduction of anxiety represents a further possible explanation for the analgesic effect of acupuncture [Mamut, 2008; Wang et al., 2008; Karst, 2007].

2.6 Acute pain

Few studies exist about treating acute pain in children with acupuncture. Yet those are promising [Wu et al., 2009]. These results match with those studies conducted with adults concerning acute pain relief. For instance, there are various randomized, double-blinded, placebo-controlled acupuncture studies with adults, that show clear efficacy of acupuncture in patients suffering postoperative pain in which average pain medication consumption or the amount of local anesthesia was significantly less in the acupuncture group [Pfister et al., 2010; Yeh et al., 2010; Usichenko et al., 2005].

Yet still there are controversial debates about the effectiveness of acupuncture itself as well as the use of intraoperative acupuncture for anesthetic and analgesic requirements [Ernst, 2011; Kundu and Berman, 2007].

Though it is rather difficult to establish a one-to-one connection between research in adults and children it still may hold for a tendency of its outcome [Gold et al., 2008; Jindal et al., 2008; Suresh, 2004].

2.7 Options for studying acupuncture in dentistry

As the pain and anxiety-levels in the same child were to be compared, a cross-over design was feasible and no control group had to be recruited with acupuncture. This reduces any selection bias and it increases the credibility and accuracy of the results, since pain acceptance, response and perception, which are due to biologic, psychological and social factors, differ from person to person [Ranger and Campbell-Yeo, 2008].

To our knowledge, there is no randomized controlled trial (RCT) assessing effectiveness of acupuncture for complementary intraoperative analgesia in pediatric dentistry concerning the process of infiltration anesthesia. We tested whether the stimulation of a specific acupuncture point (Li 4) influences the intraoperative pain level during analgesic treatment in a large scale randomized study. Li 4 is said to reduce pain and stress levels when stimulated and was successfully used in several studies on pain [Lin et al., 2009; Kim et al., 2009; Shen and Goddard, 2009; Shen and Goddard, 2007; Chao et al., 2006]. We developed a simple complementary treatment design to relieve acute pain with acupuncture during the injection of the anesthetic agent. The results were then compared with the pain figures of the dental session without acupuncture of the same child.

3. Methods

3.1 Participants

For this cross-over study, participants were recruited from the regular patients at the University Dental Clinics in Greifswald/Germany (Department of Preventive and Paediatric Dentistry).

The inclusion criteria were children:

- who received dental treatment requiring local anaesthesia at least twice
- classified as ASA Physical Status (I-II)
- ranging between five and seventeen years

After approval by the Ethics Committee of the University of Greifswald, all children legible for the study as well as their parents were informed about the aim and the procedural course of the study. Consent was obtained and signed from all parents (Appendix A). All children agreed to participate and to comply with the study. Full dental care was granted during the period of the investigation.

Exclusion criteria were the presence of:

- local or systemic infections
- a history of psychiatric diseases
- intra-procedural complications (strong bleeding, allergic reactions etc.)

3.2 Materials and study design

The study was designed as cross-over trial with half of the children receiving acupuncture for the first session with local anaesthesia and the second session without acupuncture. The remaining children were assigned to the opposite sequence. After obtaining parental content, randomization was performed by tossing a coin.

According to the recommendation from CAMELOT Research Institute for clinical research, this study focused on acupuncture versus usual-care designs, keeping out sham acupuncture until physiologically fully understood [MacPherson et al., 2008].

The choice of the acupuncture point, which is said to reduce pain and stress levels, was based on various studies using the acupuncture point Li 4 (Figure 3.2.1) and the recommendation of Dr. T. Usichenko (anaesthesiologist and licensed acupuncturist with acupuncture experience of more than 10 years).



Figure 3.2.1.: Li. 4 (Hegu): at the highest point of the musculus adductor pollicis with thumb and index finger adducted

Each session was monitored with a percutaneous pulse oximetry (OxiPen®, Envitec, Germany) in order to control the child's heart rate (Figure 3.2.2). The heart rate figures were observed and documented:

- before acupuncture treatment
- during acupuncture treatment
- during injection of the local anaesthetic
- during dental treatment
- when removing the needles

In each case the highest rate was noted.

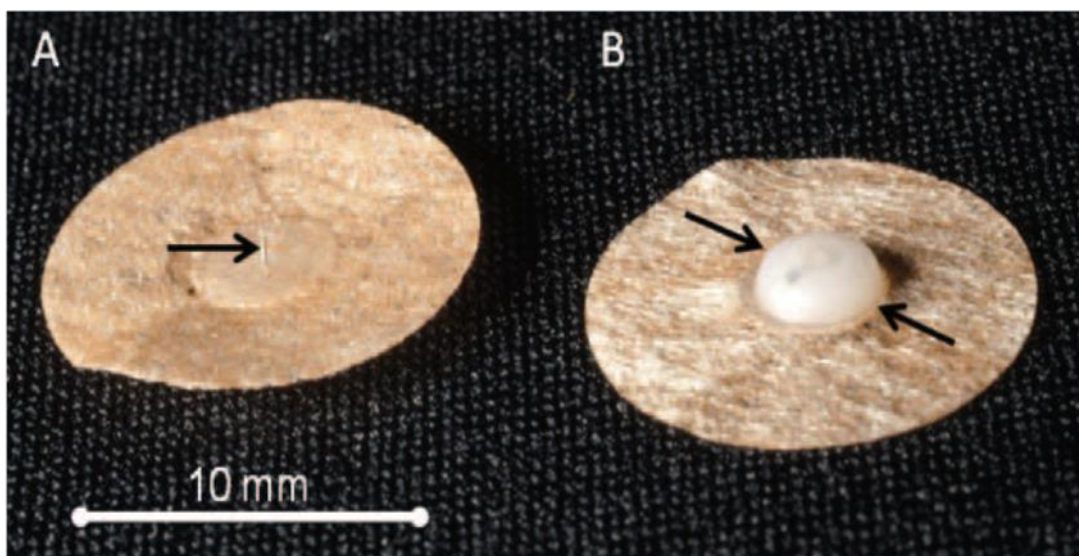


Figure 3.2.2.: Percutaneous pulse oximetry

3.3 Acupuncture

The indwelling permanent New Pyonex needles 1.5 mm length and 0.2 mm diameter, originally designed for auricular acupuncture by Seirin CORP., Japan, were used in this study for acupuncture procedure (Figure 3.3.1).

The relevant acupuncture parts of the skin were disinfected with alcohol swabs before the needles were applied and after being removed at the end of the dental treatment. The New Pyonex needles are standardized needles in a sterile plastic container which are fixed to a self-adhesive tape. This allows a standardized attachment to the skin as well as a standardized penetration of the skin. The needles were placed at the acupuncture point Li 4 (Hegu), approximately one to two minutes before the injection of the local anaesthetic, bilaterally (Fig. 4). Each acupuncture needle was manually manipulated throughout the treatment and kept in situ until the end of the dental treatment. The manipulation of the needles was either conducted by the acupuncturist or by third parties (parents etc. or the patient itself) which were instructed beforehand how to massage the acupuncture point.



Figures 3.3.1.: Seirin New Pyonex Needles



Fig. 4: Seirin New Pyonex Needle placed at Li 4 (Hegu) [Usichenko et al., 2012]

3.4 Anesthetic procedure

The anaesthetic procedure was started with a topical anaesthesia of the gingiva using lidocaine (Xylocain® Pumpspray, Astra Zeneca, Germany). A cotton pellet soaked in lidocaine was placed at the spot of the following anaesthetic injection and stayed there for at least 30 seconds.

The therapist then chose the appropriate technique of injection

1. Infiltration
2. Intraligamentary
3. Block anaesthesia

The cannulas used for the intraligamentary injection were 21 mm of length with a gauge of 0, 3 mm (Terumo®, Miraject, Hager & Werken GmbH & Co.KG, Germany). For infiltration we used cannulas of 12 mm length and gauge of 0.3 mm (SOPIRA® Carpule®, Heraeus Kulzer GmbH, Germany). Block anaesthesia cannulas were 40 mm of length with a gauge of 0.4 mm (Sterican®, B. Braun Melsungen AG, Germany). The local anaesthetic Ultracain® DS forte (Sanofi Aventis, France) with the active ingredient articaine was administered in ampullas of 1.7 ml. 1 ml equals 40 mg articaine hydrochloride and 0.012mg epinephrine hydrochloride which is included

as vasoconstrictor.

Individual age-and treatment-dependent dose limits were always been taken into account and the amount of local anaesthetic was documented.

The whole anaesthetic procedure was recorded and documented on video-tape.

3.5 Mode of pain assessment

After the dental treatment the child as well as the parent or caregiver of the child were interviewed independently by the physician who performed the study.

Both were asked to evaluate the pain:

1. before acupuncture treatment
2. during acupuncture treatment
3. during the injection of the local anaesthetic
4. during dental treatment
5. when removing the needles

The level of pain was assessed by using commercially available numeric rating scales 0 - 10 which also had equivalent pictograms for the children, respectively [Williamson A, Hoggart B, 2005] (Figures 3.5.1 and 3.5.2).



Figure 3.5.1.: Faces Pain Scale (VAS - 10: Visual Analogue Scale)



Figure 3.5.2.: Numeric Rating Scale (NRS – 10)

Furthermore, the child and the parent were asked to evaluate the treatment by giving grades:

- 1 = very good
- 2 = good
- 3 = satisfactory
- 4 = fair/pass
- 5 = poor

In the end, they were queried whether they would like to be treated in future with acupuncture as an additional analgesic tool in paediatric dentistry.

3.6 Pain and stress assessment by the dentist

All dental procedures were carried out by the 10 dentists working in the Department of Preventive and Paediatric Dentistry including 6 postgraduate students. The dentist, who performed the treatment, was also interviewed. Apart from the pain level of the child during these procedures, he/she also had to assess the stress level using again the numeric rating scale (NRS 0 - 10) described above.

3.7 Additional parameter on the questionnaire

The dentist was also asked about his/her level of concentration and physical effort during the treatment, rating from 1 = extremely easy to 7 = extremely challenging.

In addition the dentist had to document the following parameters in the data sheet (Appendix B):

1. Complications during dental treatment? (yes/no)
2. Complications during acupuncture treatment? (yes/no)
3. Gingival inflammation in area of anaesthetic injection? (yes/no)
4. Gauge of cannula (0.3/0.4 mm)
5. Amount and kind of local anaesthetic
6. Tooth and dental treatment
7. The type of anaesthesia (infiltration, block anaesthesia, intraligamentary)

3.8 Film footage evaluation and preparation

The film footage of the injection during dental treatment was separately assessed by the physician who conducted the study and by the student of psychology. A modified version of the FLACC scale (F=Face, L=Legs, A=Activity, C=Cry, C=Consolability), which is a reliable tool in assessing acute pain in children (Voepel-Lewis et al., 2010), was used to evaluate the pain of the child (Table 3.8.1). The results yielded by both evaluators were compared and analysed by means of differences and correlations using the statistic program SPSS – 11.5.

Table 3.8.1.: Modified FLACC-Scale (Pain assessment scale evaluating the face, activity, cry and consolability.)

Date/time	Results
Face 0 – No particular expression or smile 1.5 – Occasional grimace or frown, withdrawn, disinterested 2.5 – Frequent to constant quivering chin, clenched jaw	
Consolability 0 – Content, relaxed 1.5 – Reassured by occasional touching,	

hugging or being talked to, distractible 2.5 – Difficult to console or comfort	
Activity 0 – Lying quietly, normal position, moves easily 1.5 – Squirming, shifting back and forth, tense 2.5 – Arched, rigid or jerking	
Cry 0 – No cry (awake or asleep) 1.5 – Moans or whimpers; occasional complaint 2.5 – Crying steadily, screams or sobs, frequent complaints	
Total Score	

In order to blind the assessing person we removed the acupunctured hand from the film footage by using a video software (Video deluxe 17 Premium, Magix, Germany). This, however, often made it impossible to rate the legs. Therefore, we only could assess the child's face, activity, cry and consolability (FACC). In order to grant comparability as to the numeric scales (0 - 100), we changed the rating scale of the FLACC from 0 - 1 - 2 to 0 - 1, 5 - 2, 5, respectively (FACC).

The film footage of both dental treatments of the child (with or without acupuncture) was shown successively to the assessing person, in order to grant a direct comparison. Each film footage was coded beforehand by the physician who performed the study which allowed identifying each film-footage afterwards according to whether it showed a treatment with or without acupuncture.

In order to grant quality of the person evaluating the video, a test-run was assigned. Ten randomly selected film-footages were assessed according to the FACC scale and the results were documented. Two weeks later the aforesaid procedure was repeated.

The results were then taken and compared with the previous assessment in order to

detect possible deviations. In addition, these results were compared to those independently evaluated by the physician, who performed the study, in the same manner as seen above.

3.9 Statistic analysis

The primary outcome of this study was to assess a possible analgesic effect of acupuncture during local anaesthesia in paediatric treatment by comparing two dental sessions with the same child, with and without acupuncture.

The secondary outcome was a possible change of the intra-procedural stress level by using acupuncture and/or a possible positive effect on the therapist concerning his/her working conditions.

In order to calculate the appropriate sample size, we set the level for statistical significance to 0, 05 and for power to 85%. Based on the results of previous reports on acupuncture [Biella, G. et al., 2001; Yuan-Chi MD MPH* et al., 2009], the effect size for the difference of mean pain intensity to be at least 30%. We calculated the required number of patients to be 41. Taking into account the drop-out/withdrawal rate of 10-25% in clinical studies on acupuncture [Linde et al. 2005; Melchart et al. 2005; Leibing et al. 2002], the study size was predefined to a total of 50 patients.

All data were entered into Microsoft Office Excel 2003 and imported into SPSS - 11.5 for further statistical analysis. After an initial descriptive analysis of the variables for ranges, mean and median values as well as statistical variation, analytical statistics were performed for testing the primary and secondary outcomes (Student's *t*-test, Mann-Whitney-test).

In addition, associations between pain and stress levels and the kind of anaesthetic technique, the size of the needle, the kind of dental procedure, the use of acupuncture as well as the treating dentist were assessed with bi-variate correlations (Spearman) and finally in a regression analysis.

The main outcome variables, taken at defined stages of the study, were:

1. Pain and stress assessment of the child by the dentist as well as pulse-oximetry readings either with (Figure 3.9.1) or without acupuncture (Figure 3.9.2)
2. Pain assessment by the parent as well as the child's pain self-report with (Figure 3.9.1) and without acupuncture (Figure 3.9.2)
3. Pain assessment by author and F.Gutt via film-footage with (Figure

3.9.1) and without acupuncture (Figure 3.9.2)

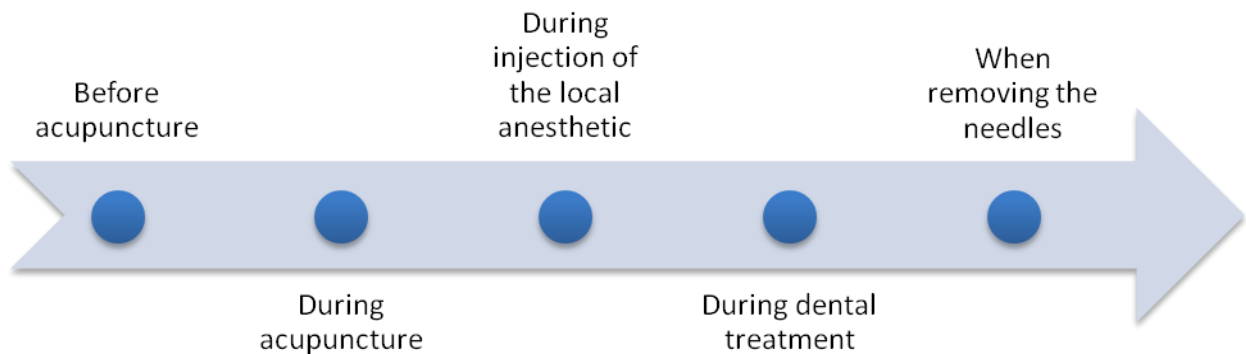


Figure 3.9.1.: Pain-level of the child assessed by the child, parent, and dentist as well as pain assessment by FG and the author of the study via film footage at different stages of the treatment with acupuncture - before and during acupuncture treatment, during injection and dental treatment and when removing the needles. In addition, stress-level assessment of the child by the dentist and pulse-oximetry readings.



Figure 3.9.2.: Pain-level of the child assessed by the child, parent, and dentist as well as pain assessment by FG and the author of the study via film footage at different stages during dental treatment – before dental treatment, during injection of

local anesthetic and dental treatment. In addition, stress-level assessment of the child by the dentist and pulse-oximetry readings.

4. Results

4.1. Baseline data

Of the 74 patients invited to participate 72 accepted and 2 declined. One of the two was afraid of plasters the other simply did not want to participate without giving any reasons. 49 of the participants completed the study and 23 did not. The data of those 23 children was withdrawn from the final assessment. The 49 children (22 female / 27 male) that completed the study were 4 to 18 years old (9.8 ± 4). Both groups were the same in terms of age, gender and pain intensity, since both contained the same patients. The study was well balanced concerning the size of cannula, the type of LA-injection and the therapist.

In 68 percent ($n = 33$) of all our patients we used the same size of cannula during both dental sessions. 32 percent ($n = 16$) were treated with different cannula. The proportion of those dental sessions using 0.4 mm cannula with acupuncture is almost equal to those without acupuncture (Table 4.1). There is not a statistically significant difference in the proportion of different cannula used during LA-injection with or without acupuncture ($p = 0.481$; Mc Nemar's test).

43 of all patients had a healthy gingiva during LA-injection without acupuncture in comparison to 35 patients with a healthy condition during LA-injection with acupuncture (Table 4.1). More children with inflamed gingiva were treated with acupuncture (14 vs. 6) (Table 4.1) However, this does not constitute a statistically significant difference in the proportion of either healthy or inflamed gingiva conditions during LA-injection with or without acupuncture ($p = 0.07$; Mc Nemar test). Thirty-three of all patients showed either healthy or inflamed gingiva conditions during both dental sessions. This, however, did not apply to the rest of the tested participants ($n = 16$) 12 of all participants had an inflamed gingiva when treated with acupuncture and a healthy one during the dental session without acupuncture whereas in the case of four children it was the other way around.

43 of all our patients were treated during both dental sessions with the same type of injection. Due to unpredictable dental circumstances, however, in some cases we

had to adapt and to change the type of injection at the second meeting. The statistical distribution of those dental sessions that did not match, as shown in Table 4.1, is evenly spread.

In 38 patients the same dentist conducted both treatment sessions. The remaining 11 children were treated by a different dentist during each dental session. That was due to unpredictable organizational circumstances

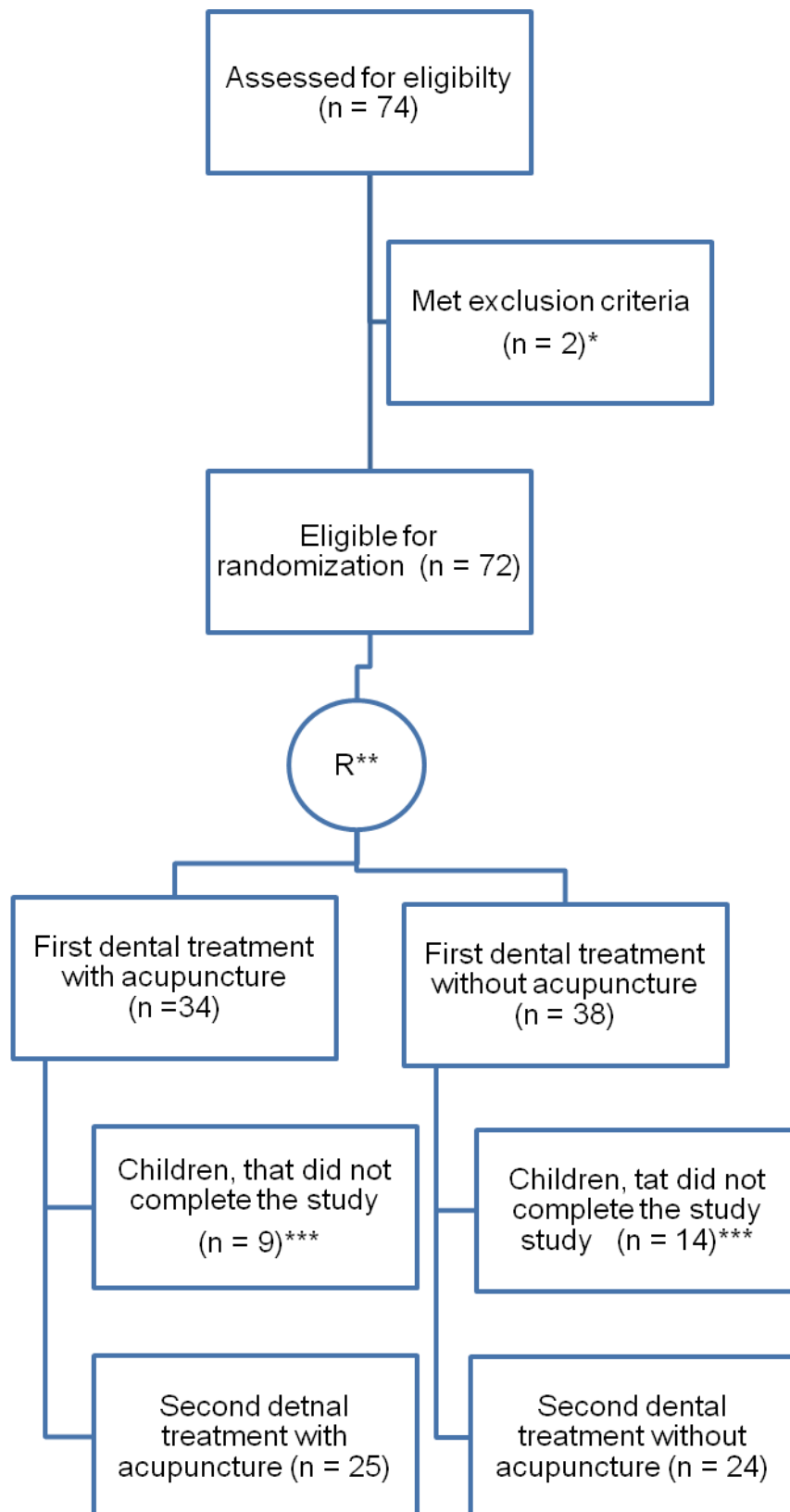
24 children started the study without acupuncture during their first dental treatment whereas 25 children were dentally treated with acupuncture (Table 4.1).

Table 4.1.: Baseline characteristics of pediatric patients undergoing dental LA- anesthesia

Characteristic	Control n = 49	Acupuncture n = 49
Size of injection cannula		
0.4 mm	14	18
0.3 mm	35	31
Gingival condition		
Inflamed	6	14
Healthy	43	35
Type of LA-injection		
Infiltration	43	44
Intraligamentary analgesia	2	2
Block analgesia	4	3
Number of children starting with or without acupuncture during the first dental session	24	25

Note: SD = Standard Deviation

*Except where indicated otherwise



*one child was afraid of plasters the other did not want to participate without giving any reasons

**randomization, whether the patient was treated with acupuncture during the first or second dental session, was assured by flipping a coin before the treatment

***these children did not show up for their second dental treatment (n=21) or suddenly changed their mind due to reasons stated beneath (n=2)

Figure 4.1.: Flow diagram of the study with 49 patients completing the study.

Reasons for not completing the study:

- the main reason was that the patient did not show up for the second dental session (n=21)
- one patient was ashamed to show her hands since she bit her nails and her hand (n=1)
- one was afraid of the needle when he discovered it beneath the plaster (n=1)

The data of the patients who did not complete the study was not taken into account and was excluded from the study.

All patients did not have any experience concerning acupuncture whatsoever. Forty-nine patients completed the study, 25 started with the acupuncture treatment and 24 with the non-acupuncture treatment (Table 4.1).

4.2 Self-reported pain reaction of the child

The children treated with acupuncture during anesthesia statistically reported less pain intensity (2.2 ± 2.5) in comparison to LA-injection without acupuncture during the control visit (3.9 ± 2.7 ; $p < 0.001$; Student's *t*-test). Thus, the mean difference in perceived pain added up to 1.7.

The children treated with acupuncture also reported a pain decrease for the tooth treatment session (2.9 ± 3.0 vs. 3.2 ± 3.1) However, the difference was statistically not significant ($p = 0.5$; Student's *t*-test) (Figure 4.2 and Table 4.2).

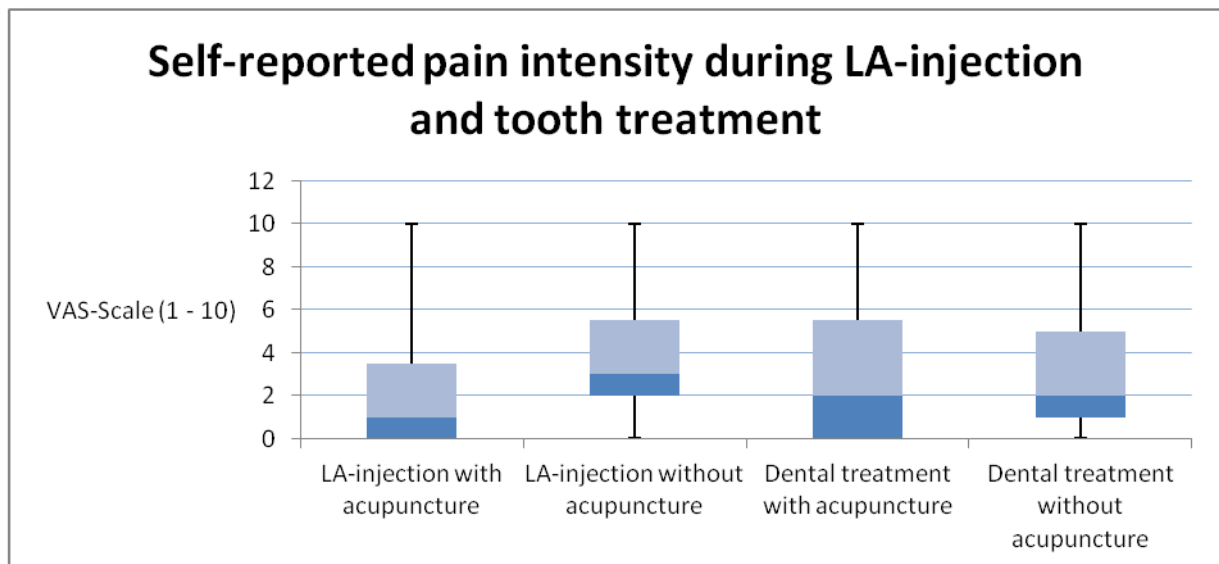


Figure 4.2.: Pain intensity (VAS – 10) in children (n = 49) during LA-injection and the following dental treatment with and without acupuncture

Table 4.2.: Self-reported pain intensity figures (VAS – 10) according to Figure 4.2

	LA-injection with acupuncture	LA-injection without acupuncture	Dental treatment with acupuncture	Dental treatment without acupuncture
max	10	10	10	10
min	0	0	0	0
per 25	0	2	0	1
per 50	1	1	2	1
per75	2,5	2,5	3,5	3

4.3 Heart rate

The heart rate showed statistically significant lower values during LA-injection with acupuncture (90.2 ± 14.4) in comparison to the control visit (99 ± 16 ; $p = 0.002$; Student's *t*-test). This did also apply to the following dental treatment (92 ± 13 vs. 98 ± 16 ; $p = 0.025$) (Figure 4.3 and Table 4.3).

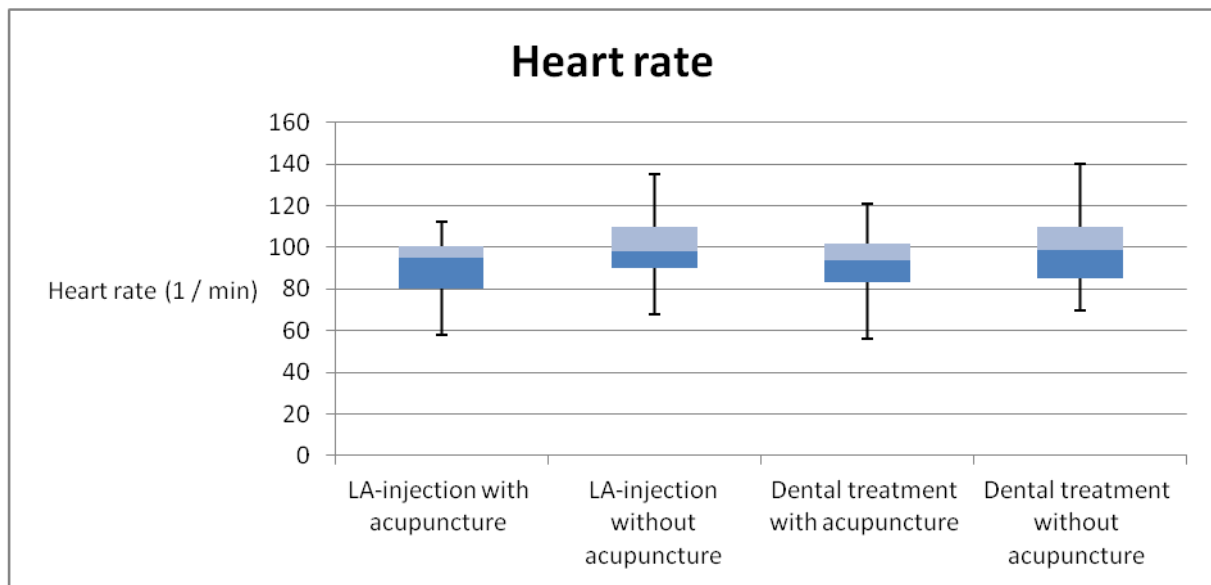


Figure 4.3.: Heart rate (1/min) in children (n = 47) during LA-injection and the dental treatment with and without acupuncture

Table 4.3.: Heart rate (1/min) in children (n=47) during LA-injection according to Figure 4.3

	LA-injection with acupuncture	LA-injection without acupuncture	Dental treatment with acupuncture	Dental treatment without acupuncture
max	112	135	121	140
min	58	68	56	70
per25	80	90	83,2	85
per50	95	98	94	99
per75	100	110	102	110

4.4 Pain assessment by parents, dentist and through video analysis

We observed no significant statistical difference between LA-injection with or without acupuncture according to the pain assessment of the child's parents (2.6 ± 2.4 vs. 3.3 ± 2.5 ; $p = 0.076$; Student's *t*-test). No improvement in terms of pain reduction due to acupuncture during LA-injection could be detected according to the assessment of the dentist (2.5 ± 2.1 vs. 3.0 ± 1.9 ; $p = 0.223$; Student's *t*-test). That also applied to the assessment of the dentist as well as the parent concerning the dental treatment. No relevant pain reduction could be found neither according to the dentist (2.1 ± 2.1 vs. 1.6 ± 2.0 ; $p = 0.209$; Student's *t*-test) nor the parent (3.0 ± 2.9 vs. 2.4 ± 2.8 ; $p =$

0.192; Student's *t*-test) during dental treatment (Figure 4.4.1 - 4.4.2 and Table 4.4.2). The pain intensity (FACC - 10) in children was also assessed by 2 evaluators during LA-injection with and without acupuncture on the basis of video clips (n = 44). One of the evaluators was an independent and uninvolved assessor in order to reduce a possible bias. The outcome of both assessors correlated highly with each other ($p < 0.0001$). However, in the video material only a minimal improvement in pain reduction during LA-injection could be found when the children were treated with acupuncture (Table 4.4 and Table 4.4.1).

Table 4.4.: Pain intensity assessed by FG and the author on the basis of video clips

	LA-injection (FG)	LA-injection (Author)
With acupuncture	1.6 ± 2.5	1.5 ± 2.4
Without acupuncture	1.7 ± 2.5	1.8 ± 2.5
p	0.783	0.286

Table 4.4.1.: Pain assessment through video analysis by 2 independent evaluators with FACC-Scale (1-10). No significant relevant figures could be found that would speak in favor of acupuncture for pain reduction in children

	LA-injection with acupuncture (FG)	LA-injection with acupuncture (Author)	LA-injection without acupuncture (FG)	LA-injection without acupuncture (Author)
max	9	7	7	7
min	0	0	0	0
per25	0	0	0	0
per50	0	0	0	0
per75	2.8	2	3	3

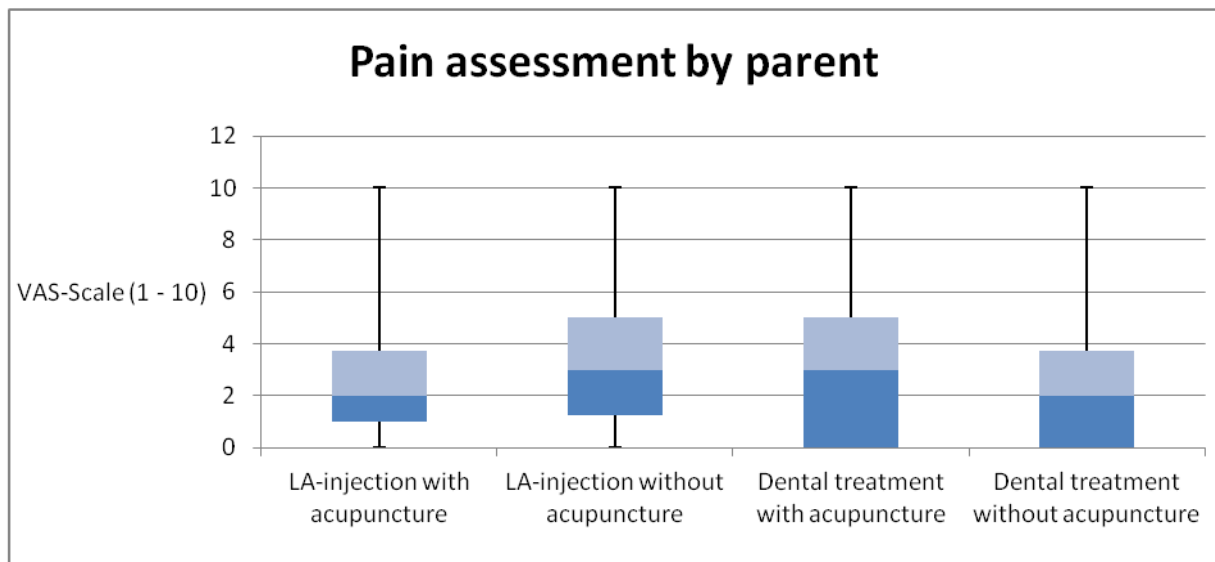


Figure 4.4.1.: Pain intensity (VAS – 10) in children assessed by parents (n = 48) during LA-injection and dental treatment with and without acupuncture. Generally the pain perception was lower during dental treatment in comparison to LA-injection. The parents assessed an increase in the child’s pain after LA-injection when treated with acupuncture. An improvement of pain reduction during LA-injection was noticed.

Table 4.4.2.: Pain assessment by parent according to Figure 4.4.1

	LA-injection with acupuncture	LA-injection without acupuncture	Dental treatment with acupuncture	Dental treatment without acupuncture
max	10	10	10	10
min	0	0	0	0
per25	1	1.25	0	0
per50	2	3	3	2
per75	3.8	5	5	3.8

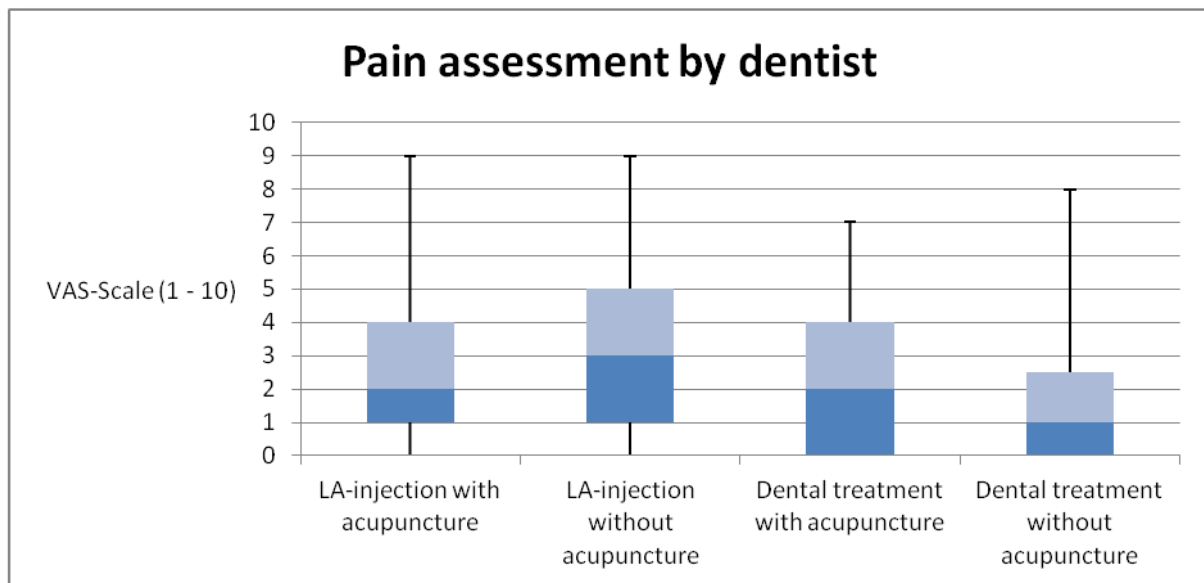


Figure 4.4.2.: Pain intensity (VAS – 10) in children assessed by dentist (n = 49) during LA-injection and dental treatment with and without acupuncture. A slight improvement in terms of pain reduction during LA-injection with acupuncture can be observed.

Table 4.4.3.: Pain assessment by dentist according to Figure 4.4.2

	LA-injection with acupuncture	LA-injection without acupuncture	Dental treatment with acupuncture	Dental treatment without acupuncture
max	9	9	7	8
min	0	0	0	0
per25	1	1	0	0
per50	2	3	2	1
per75	4	5	4	2.5

4.5 Differences in pain assessment between child, parent and dentist

When we compared the pain assessment of the child, parent and dentist for the different treatments, we found out, that the results were similar (Figure 4.5). Still there were relevant differences in pain assessment between:

- dentist and child during dental treatment with acupuncture (p = 0.028; Student's t-test)
- dentist and child during dental treatment without acupuncture (p = 0.003; Student's t-test)
- parent and dentist during dental treatment without acupuncture (p = 0.05;

Student's t-test)

- parent and dentist during dental treatment with acupuncture ($p = 0.01$; Student's t-test)

The parents' assessment was closer to the child's than the dentists' assessment. The dentists' assessment generally showed lower values compared with those by the child and the parent, except during LA-injection with acupuncture. Here, the child indicated the lowest figures (Figure 4.5).

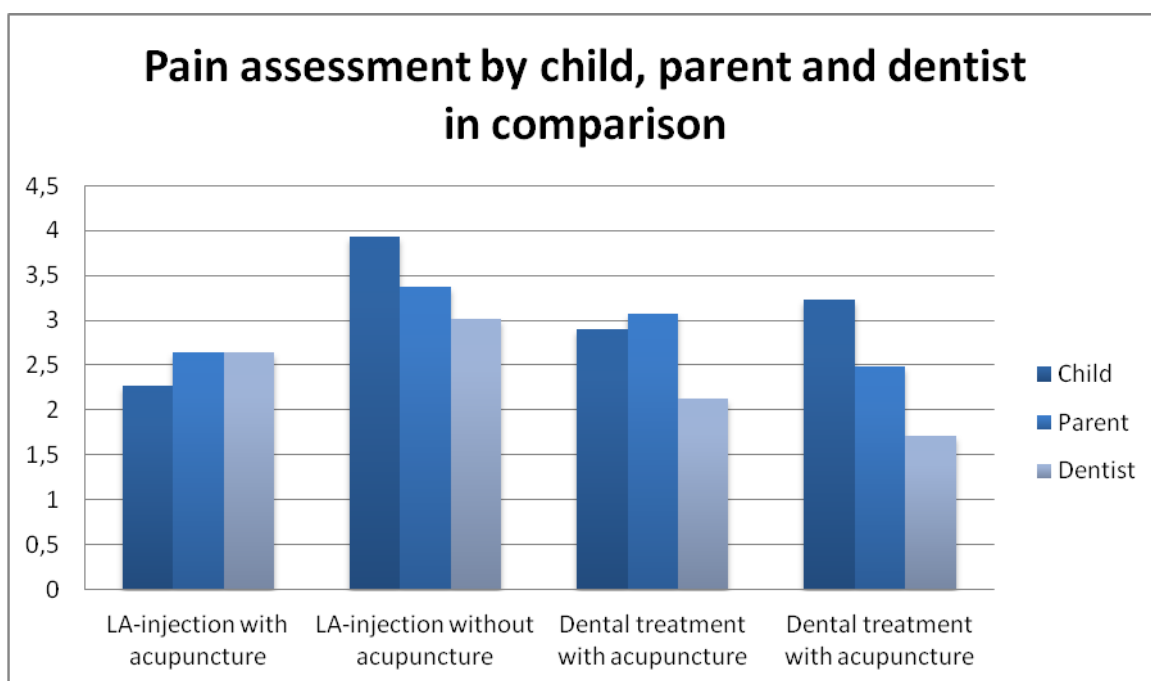


Figure 4.5.: Mean pain intensity values (VAS – 10) given by parent ($n = 48$), child ($n = 49$) and dentist ($n = 49$) for different treatments

4.6 Stress reaction assessed by dentist

We discovered no significant differences in the child's stress reaction when comparing LA-injection ($p = 0.591$) (Student's t-test) as well as dental treatment ($p = 0.341$) (Student's t-test) with and without acupuncture (Figure 4.6 and Table 4.6). The mean values were generally low.

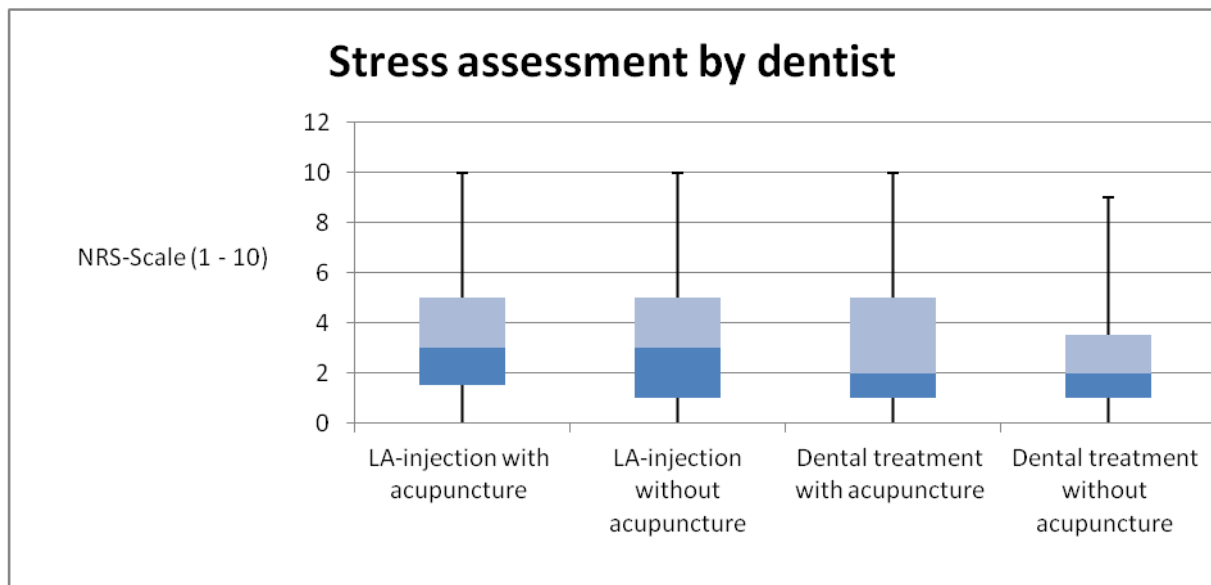


Figure 4.6.: Stress (NRS – Scale) in children assessed by dentist during LA-Injection and dental treatment with and without acupuncture. The mean difference of stress during LA-injection with and without acupuncture was 0.4 and during dental treatment only 0.2 on NRS-11.

Table 4.6.: Stress assessment by the dentist according to Figure 4.6

	LA-injection with acupuncture	LA-injection without acupuncture	Dental treatment with acupuncture	Dental treatment without acupuncture
max	10	10	10	9
min	0	0	0	0
per25	1.5	1	1	1
per50	3	3	2	2
per75	5	5	5	3.5

4.7 Relation between pain – size of cannula, type of injection and gingiva condition according to the child's self-report

In 67 percent (n = 66) of all LA-injections performed (n = 98) we used a 0.3 sized cannula and in 33 percent (n = 32) a 0.4 sized cannula.

We could not detect a statistically significant difference between the size of the cannula and pain reported by the child during LA-injection with or without acupuncture (Table 4.7, 4.7.1 and Figure 4.7).

As almost exclusively infiltration analgesia was used, this unevenly spread sample does not allow a conclusion concerning the painfulness of each type of injection

(Table 4.7.2).

The condition of the gingiva of the children during LA-injection, either healthy or inflamed, did not influence the outcome of the child's pain assessment (3.1 ± 2.8 vs. 3.1 ± 2.4 ; $n = 98$).

Table 4.7.: Self-reported pain for 0.3 and 0.4 cannula

		Cannula 0.3	Cannula 0.4	p (Student's t-test)
LA-injection with acupuncture		2.3 ± 2.7	2.0 ± 2.0	0.7
LA-injection (n = 49) without acupuncture (n = 49)		3.6 ± 2.7	4.0 ± 2.2	0.7
LA-injection with and without acupuncture (n = 98)		3.2 ± 3.0	2.7 ± 2.0	0.4

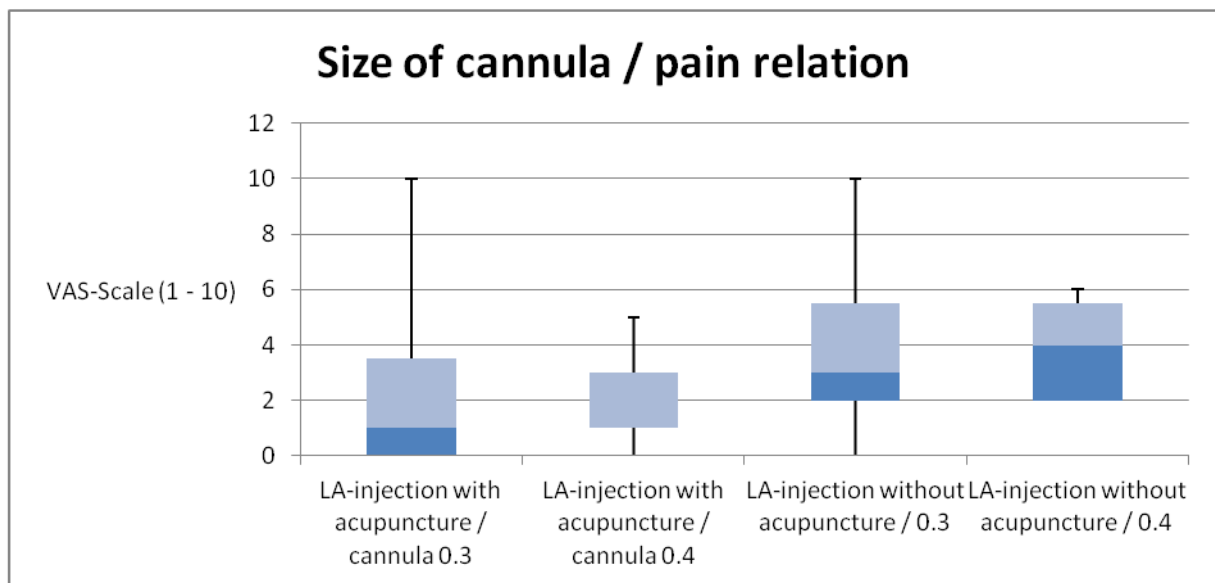


Figure 4.7.: Self-reported pain intensity (VAS - 10) / size of cannula (0.3 mm and 0.4 mm) relation during LA-Injection with acupuncture and without acupuncture ($n = 49$).

Table 4.7.1.: Size of cannula and pain relation according to Figure 4.7

	LA-injection with acupuncture / cannula 0.3	LA-injection with acupuncture / cannula 0.4	LA-injection without acupuncture / cannula 0.3	LA-injection without acupuncture / cannula 0.4
max	10	5	10	6
min	0	0	0	2
per25	0	1	2	2
per50	1	1	3	4
per75	3.5	3	5.5	5.5

Table 4.7.2.: Pain assessment for different types of LA-injection by the child with and without acupuncture

Type of injection	Sample size (n = 49) with acupuncture (Mean ± SD)	Sample size (n = 49) without acupuncture (Mean ± SD)	Sample size (n = 98) with / - without acupuncture (Mean ± SD)
Infiltration	44 (2.0 ± 2.6)	43 (4.0 ± 2.8)	87 (3.0 ± 2.8)
Intraligamentary analgesia	2 (4.5 ± 2.1)	2 (2.5 ± 2.1)	4 (3.5 ± 2.0)
Lower alveolar block	3 (3.0 ± 1.0)	4 (3.5 ± 1.2)	7 (3.2 ± 1.1)

4.8 Customer satisfaction

When we asked the parent and the child to evaluate both dental sessions, which had been performed with and without acupuncture, we observed a general tendency for the child as well as for the parent to prefer the dental treatment with acupuncture. In comparison to the parents' rating (1.1 ± 0.6 vs. 1.2 ± 0.4 ; $p = 0.2$), the children showed a statistically significant difference with better values for acupuncture (1.2 ± 0.5 vs. 1.5 ± 0.7 ; $p = 0.002$; Student's t-test) (Figure 4.8). When we asked the patient if he/she would like future dental sessions to be accompanied with acupuncture, ninety-four percent spoke in favor of acupuncture during dental treatment (Figure 4.8.1)

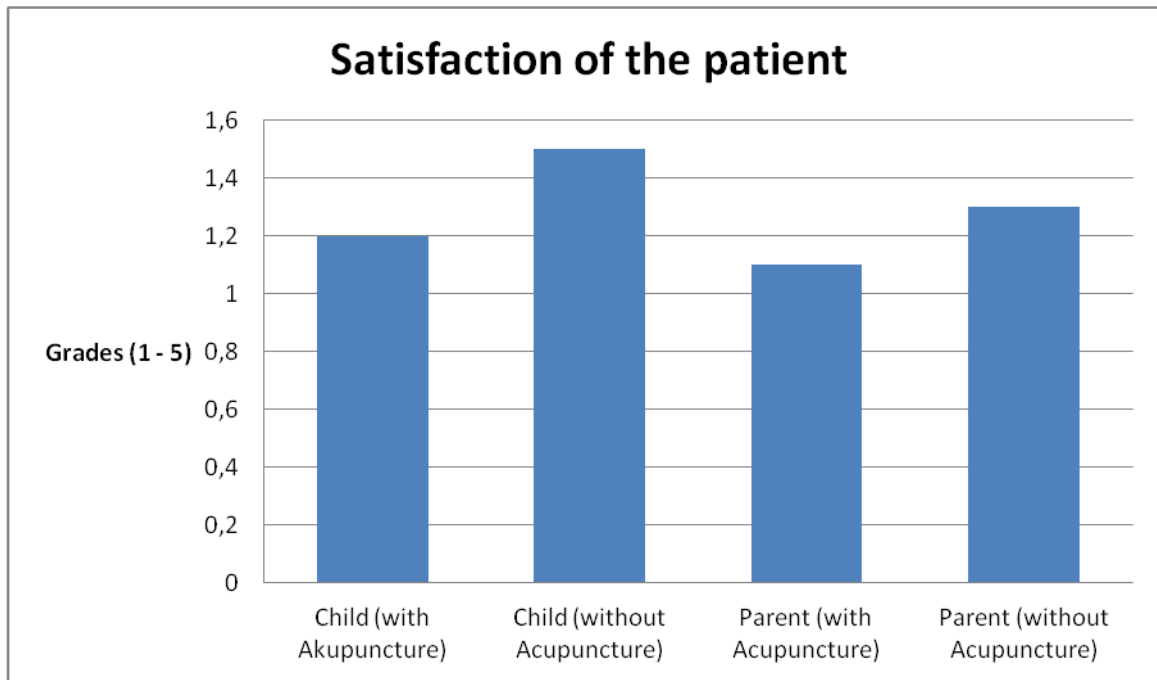


Figure 4.8.: Mean grades given by parent (n = 46) and child (n = 47) on a scale of one to five (NRS – 5) where “one” represents the best and “five” the worst grade.

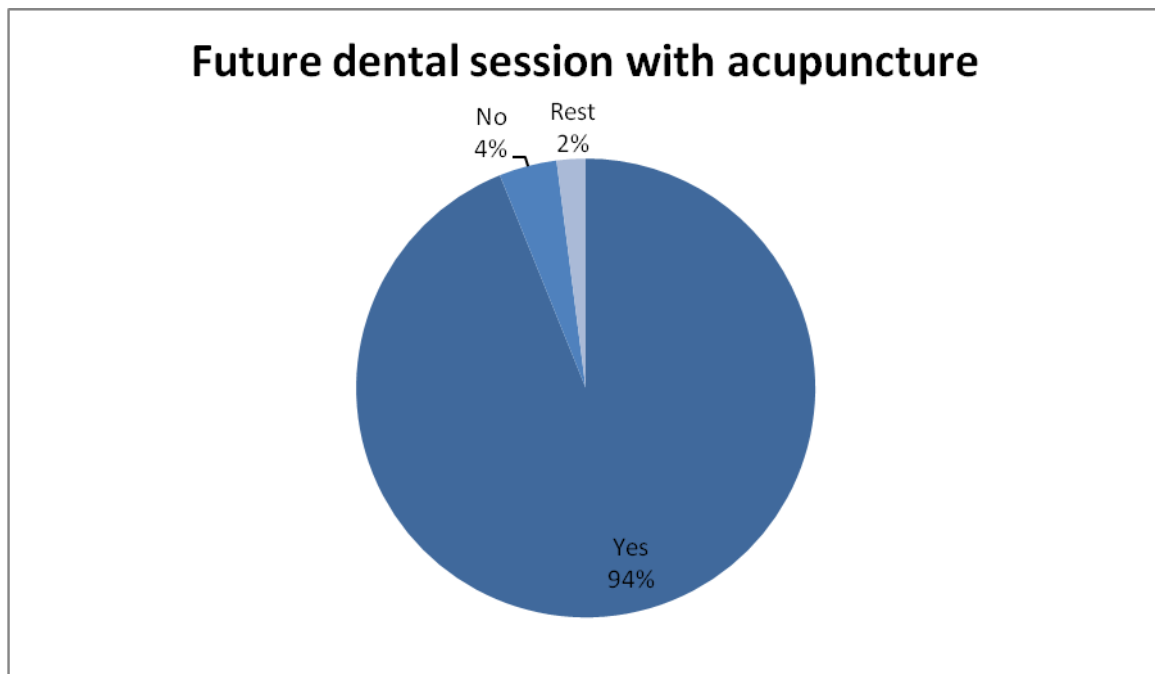


Figure 4.8.1.: Distribution for future treatment preference with acupuncture.

4.9 Pain assessment when applying acupuncture needles

More than half of all our patients did not recognize any pain concerning the application of acupuncture needles according to the child's self-report (57%; 1.2 ± 2.2), the parent (55%; 0.9 ± 1.3 ; Student's t-test) and the dentist (67%; 0.5 ± 0.9 ; Student's t-test) (Table 4.9)

Table 4.9.: Self-reported and assessed pain intensity (VAS – 10) by the dentist and the parent during the appliance of acupuncture needles

Column1	Child	Parent	Dentist
max	10	5	4
min	0	0	0
per25	0	0	0
per50	0	0	0
per75	2	1.8	1

4.10 Comparison between compliance of the child, physical effort and effort of concentration for the dentist with and without acupuncture

We found neither statistically significant difference concerning the compliance of the child, nor any changes for the better (or vice versa) with regard to the physical effort as well as the effort of concentration for the dentist, when comparing dental treatment with and without acupuncture (Table 4.10).

Table 4.10.: Child's compliance, physical effort and effort of concentration assessed by the dentist during dental treatment with and without acupuncture (NRS – 5 scale from 1=best to 5=worst and NRS – 7 scale from 1=extremely easy and 7=extremely difficult, resp.)

	With acupuncture	Without acupuncture	P (Student's t-test)
Compliance of the child (NRS – 5)	1.8 ± 0.9	1.9 ± 1.2	0.3
Effort of concentration (NRS – 7)	3.4 ± 1.0	3.4 ± 1.1	0.7
Physical effort (NRS – 7)	3.2 ± 1.0	3.3 ± 0.9	0.6

4.11 Comparison of the performing dentists according to the child's pain assessment

We found no relevant or statistically significant differences in self-reported pain during local anesthesia for the different dentists (mean 2.9 ± 2.7 , $p > 0.05$, the variation even within one dentist was considerable (Figure 4.11 and Table 4.11).

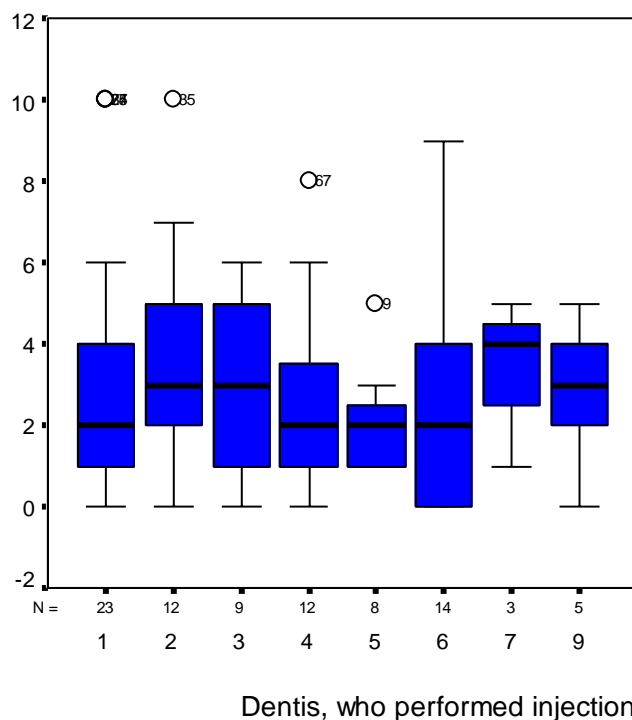


Figure 4.11.: Pain figures assessed by the child (VAS – 10) during LA-injection without acupuncture performed by different dentists

Table 4.11.: Pain assessment by the child according to Figure 4.11

	Dentist 1	Dentist 2	Dentist 3	Dentist 4	Dentist 5	Dentist 6	Dentist 7	Dentist 9
max	6	7	6	6	3	9	5	5
min	0	0	0	0	1	0	1	0
per25	1	2	1	1	1	0	3	2
per50	2	3	3	2	2	2	4	3
per75	4	5	5	3	2	4	5	4

5. Discussion

5.1 The decision to perform this study

The decision to perform this study in the dental sector was made due to the following positive characteristics:

I. Similarity in pain

The pain intensity of each injection is often similar. This was warranted through the following aspects:

1. Anesthetic injection is a standard procedure in the dental sector allowing an almost equal pain-stimulus.
2. All dentists participating in this study were experienced pediatric dentists, which were faced with mostly predictable injections, leaving little room for possible differences in the pain-perception.
3. Both sessions contained generally the same kind of analgesia (infiltration, block anesthesia, intraligamentary analgesia), since the injection pain can differ between the three analgesic types. For instance, the intraligamentary injection seems to be more uncomfortable for their patients than infiltration [Meechan and Ledvinka, 2002].

II. Little time span between each dental session

Both sessions with and without acupuncture were generally performed with little time span in between, thus reducing possible deviations concerning the assessment of pain and anxiety.

III. Desensibilization

In general, all children had been to the dental section before treatment. Therefore, they knew the surroundings, their dentist as well as their acupuncturist and how it feels like to be treated dentally. This kind of deliberate desensibilization of the children, with regard to possible lower anxiety levels, allowed a more or less equal and relaxed situation and atmosphere at the first dental session. Since anxiety can increase the pain level, as stated above, we hoped therewith to generate optimal conditions for

this study [Thompson, 2008].

IV. Better comparability of pain and anxiety-levels

As the pain and anxiety-levels in the same child were to be compared, a cross-over design was feasible and no control group had to be recruited with acupuncture. This reduces any selection bias and it increases the credibility and accuracy of the results, since pain acceptance, response and perception, which is due to biologic, psychological and social factors, differ from person to person [Ranger and Campbell-Yeo, 2008].

V. A statistically sufficient sample-size

Although research outcome could only demonstrate a partly reduction of pain, one may point out that the quality of pain differs in the present study. As those studies, for instance, concentrated on acute pain-reduction during or after surgical operation or tooth extraction, this study examines solely a needle penetration of the gingiva. Therefore, one may assume, that the effectiveness of acupuncture in a study, concerning a comparatively rather moderate and brief pain, will turn out relatively high.

5.2 Analgesic characteristics of pediatric acupuncture in dentistry

The study shows that acupuncture reduces acute pain in pediatric dentistry during the injection of anesthetics.

The mean figures of operative pain intensity during the control visit, according to the children's' self-report were 3.8 ± 2.6 mm based on a VAS – 10 scale and 2.2 ± 2.5 mm when treated with acupuncture ($P=0.0001$). Powell et al. [2001] found the minimum clinically relevant difference in visual analog pain score for children to be 1 mm. According to this, we could conclude, that our study with a mean difference of 1.5 mm is clinically relevant. However, Kelly [2001] raised that benchmark to 2.0 mm and recommended that “studies should be designed and reported relative to this benchmark rather than the minimum clinically significant difference in visual analogue scale pain score”. On that basis our study revealed no mean clinically significant difference in pain score. However, when we applied this benchmark to each patient separately, twenty-five out of forty-nine patients reported a minimum of 2 mm pain

reduction when treated with acupuncture.

It might be suggested that the minimum clinically significant difference (MCSD) in VAS pain score is not the same across the whole range of the scale, which would lead to difficulties when interpreting the results. This, however, is not the case according to Kelly [2001].

The dropout rate of the children participating in this study was 32%, which is slightly higher than the dropout rate of other acupuncture studies (13 - 28%) [Wu et al., 2009; Usichenko et al., 2006], but as the dropout was not associated to the acupuncture it can be considered as neutral dropout which does not create any selection bias.

According to various textbooks and basic science research about acupuncture the effect of acupuncture is supposed to be higher when applying it in an individualized and personal manner rather than a standardized and formalized one, as being conducted in the present study [Liu and Yu, 2011]. This study-design, however, was intended to meet western medicine standards and to encourage and convince dentists to adopt acupuncture as an adjunctive tool of pain alleviation if the outcome was persuasive.

5.3 Comparison with other studies

The results of our study support studies that proofed to be effective in pediatric pain management with acupuncture as an analgesic adjunctive tool [Wu et al., 2009; Yuan-Chi et al., 2009; Gold et al., 2008]. However, these studies concentrated on chronic pain or acute post-operative pain in children. To our knowledge, to this moment, there is no study that challenges the question whether acupuncture can be effective in children with acute intra-operative pain.

One might argue that this study does not proof the effectiveness of acupuncture itself since part of the positive analgesic outcome might have been rather due to a placebo effect than to acupuncture. That would have implied a third dental session with sham acupuncture at a non-acupuncture point (invasive or non-invasive). However, according to recent science research, acupuncture itself is described as an “enhanced placebo”. Three factors, sensory, cognitive and emotional, are identified to play an important role in activating endogenous opioids which cause the analgesic effect. Therefore, the orchestration of a “painful stimulus applied in an enhanced

cognitive (positive expectation for this pain stimulus) and emotional (fear and anxiety induced by the application of this stimulus) context” lead to placebo analgesia by releasing opioids [Liu and Yu, 2011]. Harris et al. [2009] found out that the opioid receptor mechanism of acupuncture and sham acupuncture is divergent - which might have been due to non-invasive sham acupuncture – however, the reduction in clinical pain in both groups was similar. In his review comparing the effect of acupuncture with sham acupuncture, Moffet [2009] found no difference with regard to a superior efficiency of acupuncture. Although the jury is still out and these results only include formalized clinical trials leaving out personal and individual aspects, - which might lead to different results yet difficult to simulate in a study -, these facts speak for themselves and led us to the conviction that sham acupuncture was not necessarily needed in our study.

5.4 Pain assessment results and comparison

The overall statistically significant analgesic effect as well as the clinically significant analgesic effect in more than half of all our patients according to the self-report of the child’s pain intensity goes along with the lower heart rate figures measured during the dental treatment. However, it stands in contrast with the assessment given by the parent, dentist and through video analysis that could not find a significant effect of acupuncture. This phenomenon will be discussed in more detail in the following sections.

5.4.1 Connection between heart rate, anxiety and pain

The significantly mean lower heart rate figures due to acupuncture during LA-injection and during dental treatment - 9 respectively 7 beats/min lower than during the control visit - fall into line with studies for instance by Lee et al. [2010], who proved acupuncture at specific acupuncture points, to be effective in enhancing parasympathetic function. It seems likely that this physiological response in terms of a “relaxing and harmonizing effect on the heart rhythm” also may have played an important role in this study in reducing the child’s stress and anxiety [Vickland et al., 2009]. This conclusion goes along with findings by Sakatani et al. [2010] who measured the activity of the prefrontal cortex, which is said to play an important role in human stress response, linking acupuncture with an increase in parasympathetic

functions and a decrease in mental stress.

According to van Wijk et al. [2009]; Mamut [2008]; Wang et al. [2008]; Karst [2007]; Schwartz et al. [1999], (dental) anxiety can cause an increase in pain perception. Therefore, our measurement of stress (heart rate) which revealed lower mean levels during LA-injection and during dental treatment could have played an important role in lowering pain levels in this study, linking stress and pain in a mode of dynamic interaction.

However, ratings given by the dentist concerning the child's stress level did not reveal any significant effect of acupuncture.

5.4.2 Pain assessment and explanation for low correlation between different assessors

We used a VAS pain scale since according to Cohen et al. [2008] ratings, given by the children correlated significantly with the parents' and with medical personnels' ratings.

However, pain level assessment correlated poorly between the patient and the observers. While the children stated a significant reduction in pain when treated with acupuncture, the pain figures of the observers only suggested a slight tendency of improvement. Generally, the dentists' pain ratings were lower than that of the parent, though statistically not significant. Parents' ratings were closer to that of their child's whose rating figures were generally higher than that of the dentist and the parent. Only during LA-injection with acupuncture both, parent and dentist, gave higher grades in contrast to the child.

This phenomenon can be explained either by the patients' tendency to over-rate their severity of pain, the observers' underestimation of the intensity of that pain, or both. Higher grades given by the parent in comparison to the dentist may be due to the intimate relationship between child and parent reflecting their subjective perception of the child's pain whereas the dentists' lower grades may be due to preoccupation, personal beliefs and clinical experience [Manne et al., 1990]. Versloot et al. [2004] also detected this phenomenon. In their study the dentists' pain assessment was the lowest when comparing assessments of the child, the dentist and an independent observer during dental injection.

An explanation for the contrary outcome of our study could be the small pain stimulus

in terms of the injection. Few children showed intense signs of distress during anesthesia and, therefore, made it difficult for the observer to assess the pain-level. One may also take into account that each child expresses its feelings and emotions differently, which can impair the judgment [Alaki, 2010].

These findings of poor correlation of pain assessment between the child on one hand and the parent or dentist on the other go along with the conclusion of the review by Zhou et al. [2008]. Thus, the observers' perception of children's' pain should only be considered as estimates rather than expressions of the child's pain due to the lack of correlation. The child's self-report can therefore be seen as the "gold standard" for pain assessment in children, if the child is not impaired in its ability to communicate [Alaki, 2010, Lord et al., 2003].

5.4.3 Video analysis

Apart from the self-report by the child, video observation is regarded as the most reliable and accurate method to assess pain [Versloot et al., 2004]. However, the pain assessment through video analysis by FG and the author did not correlate with that of the child in the present study. One might detect a slight tendency of improvement in favor of acupuncture as in the case of the parents' and dentists' assessment yet it was not statistically significant. Again, the poor outcome might be explained by the small pain stimulus and the individual way of expressing the pain of each child. Whereas some children were easy to assess according to the guidelines of the FACC scale, a high percentage of the children showed no or just small signs which were hard to read and hard to categorize. With the children of this study seldom showing intense signs of pain during the anesthetic injection the video assessor had, in the majority of cases, only the child's face to focus on, assessing its expression. Apart from the fact, that this led to no or only slight differences in the allocation of points according to the FACC scale parameters during both dental sessions, hence no statistically significant outcome, we also have to take into account, that the video clips itself had shortcomings. The facial expressions were not always clear to detect, hence to assess. In some cases that was due to the dentist or the assistant changing their position during analgesia partly blocking the cameras' view. Another reason was the adjustment of the cameras' zoom which was set in a way to catch not only the face but also the upper body in order to meet the FACC scale parameters. An exclusive focus on the face could have been utile in assessing the child's

expressions more accurately.

5.4.4 Type of injection, size of cannula and pain perception

We used three technique types of analgesic injections: infiltration, intraligamentary analgesia and block analgesia. We assumed that each technique might lead to different results in pain intensity although Yassen [2010] as well as Ram and Peretz [2001] comparing block analgesia and infiltration in children found almost no difference in pain intensity. Still, we tried to treat each child in both sessions with the same technique in order to be on the safe side. However, ten percent of our patients were treated with different techniques during both dental treatments possibly lowering comparability and significance and weakening the overall result. Yet in the end, those dental sessions that did not match the type of injection during both sessions were evenly distributed to both acupuncture and control visit, minimizing possible bias drastically. This also applies to the size of cannula, although the distribution of dental sessions with different sizes was thirty-two percent. One might suggest that the difference in size might lead to higher pain experiences. Our figures, however, do not support this hypothesis. This outcome tallies with the conclusion of the study by Flanagan et al. [2007] that the size of cannula does not set the tone concerning the magnitude of pain perception.

5.4.5 Inflamed gingiva and pain perception

The presence of inflammation decreases the efficiency of local anesthesia which can lead to higher pain perception not only during dental treatment but also during injection [Ueno et al., 2008]. A missing accordance concerning the gingival condition in the area of injection during both sessions (with and without acupuncture) could constitute a risk of bias. The accordance with regards of the gingival condition during both sessions was 67 %. In 33% of the cases the gingival tissue was inflamed either during the dental session with -or during the dental session without acupuncture. This could have led to false outcomes or tendencies with regard to the pain perception, if the gingiva was inflamed primarily during the control visit, weakening the positive results of acupuncture. This, however, was not the case. Three quarter of the patients that showed no accordance in gingival condition during both sessions (33%) had inflamed gingiva when treated with acupuncture. Hence, assuming that the pain

perception is elevated during LA-injection as well as during dental treatment when the patients' gingiva is inflamed these figures support the positive outcome of acupuncture treatment even more.

5.4.6 Different dentist operators

One might assume that different dentists with different techniques and different approaches might lead to incomparable outcomes with regard to the pain experienced by the children. That is why the study was intended that each patient was treated by the same therapist in both sessions. In thirty-eight out of forty-nine children that was the case. Though eleven children were treated during both sessions by different pediatric specialists, we found no statistically significant differences in treatment concerning the child's pain perception. This outcome goes along with Koyuturk et al. [2009] who found no difference in the child's pain perception with regard to the therapist when comparing two different injection techniques. A possible explanation for the absence of different outcomes concerning the child's pain perception might be the fact that all participating pediatric specialists had been trained by the same person and high standardization how topical anesthesia was supposed to be administered in one department.

5.4.7 Customer satisfaction and acceptance of acupuncture

We found out that the acceptance of acupuncture in pediatric dentistry was high. Ninety-four percent of all children spoke in favor of acupuncture when asked about dental treatment together with acupuncture in future. Apart from lower pain intensity during the dental session possibly also owing to the fact, that most of the children did not experience any pain when being acupunctured. Wu et al. [2009] and Gold et al. [2008] also found out that children tolerate acupuncture well and that they view it as a positive experience.

5.4.8 Compliance of the child during dental treatment

The figures concerning the child's compliance given by the dentist showed little changes for the better when comparing acupuncture and non-acupuncture treatment. When being asked to assess his/her physical effort and effort of concentration during the treatment we could not detect any statistically relevant variation for the dentist as

a result of acupuncture. Unfortunately, we could not find comparative clinical trials in order to make a conclusive statement.

In general, the results of this study show that acupuncture in pediatric dentistry can account for a reduction in pain perception during LA-injection in terms of an adjunctive anesthetic tool. Further well-designed randomized controlled trials are necessary in order to back up these findings.

5.5 Methodological aspects of the study and limitations

The study design was based on guidelines provided by CONSORT [Schulz et al., 2010], which stands for Consolidated Standards of Reporting Trials and adapted to special requirements for clinical trials of acupuncture according to STRICTA (Standards for Reporting Interventions in Clinical Trials of Acupuncture) [MacPherson et al., 2010].

In respect of the gender the sample was well-balanced. The mean age was ten years whereat the fragment of those children seven to nine years old constituted the greatest deal. The study design provided high trial standards through randomization of the patients, blinded video analysis and collection of subjective as well as objective data and treatment of each patient with and without acupuncture minimizing possible bias.

In general, we believe that the video analysis is a good way of additionally assessing the pain apart from the child. However, the pain stimulus of this study was apparently so low, that an accurate assessment of the child's pain perception by video analysis was difficult to give. Future studies with low pain stimuli could think about focusing the camera exclusively on the child's face, in order to catch even the smallest facial reactions. Cry, consolability and activity as assessment parameters of the FACC scale, still can be included.

This study did not include a sham treatment apart from an acupuncture treatment and a control visit. A sham treatment might have shed light on the actual effect of true acupuncture at acupuncture points excluding a possible placebo effect. However, this would have meant a draft of children which exhibit dental conditions that require at least three analgesic injections during three dental sessions. In general, this would

limit the study to participants which have to undertake a major dental treatment complex, but nonetheless could be of special interest. We, however, concentrated on acupuncture versus usual-care designs according to the recommendations of CAMELOT Research Institute [MacPherson et al., 2008].

Another limitation of this study was the small sample size. A greater quantity of children would have been favorable; possibly reducing bias and amplifying the significance of this study. However, these limitations do not prevent the conclusion that acupuncture in children is not effective.

5.6 Clinical conclusion and clinical utilization

We conclude that the use of acupuncture at the acupuncture point Li 4 did reduce the pain perception and anxiety in children during the dental anesthetic injection significantly. The use of press needles at the specific acupuncture point was easy to learn. Therefore, this technique can be adopted by a dentist even without acupuncture experience. It would be desirable to back up our results by further large-scaled clinically randomized studies.

6 Conclusions

Despite a plethora of therapeutic approaches, the injection of local anaesthetics itself remains one of the most painful and dreadful procedures among children. Stimulation of acupoint LI4 is associated with analgesic effects in dentistry.

Goal of the study

To investigate whether stimulation of LI4, added to standard therapy (ST), reduces pain and distress during injection of local anaesthetic (LA) in comparison with ST alone.

Materials and Methods

Children, scheduled for dental treatment in local anaesthesia on 2 separate days were enrolled in this trial, approved by local ethics commission. On one day each child received bilateral acupuncture of LI4 point, using indwelling fixed “New Pyonex” needles (0.2 x 1.5 mm; Seirin, Japan). The parents of the children were asked to stimulate the needles by massage. Standardized injection of LA was performed 5 min following acupuncture. The needles were withdrawn at the end of dental treatment.

On the other day of treatment children received LA injection without acupuncture. The order of treatment days (acupuncture first or vice versa) was randomised. Primary endpoint was the pain intensity during LA injection reported by children on Visual Rating Scale from 0=no pain to 10=maximal pain imaginable (VRS-11). Secondary endpoints were parent- and dentist-assessed pain intensity (measured on Numeric Rating Scale 1-10), patients' heart rate before and during dental treatment and satisfaction with received therapy (measured on Numerical Rating Scale 1-5.) Side effects of LI4 stimulation were also recorded.

Results and Discussion

The data of 49 children (22 females; age 10 ± 4 yrs; mean \pm SD), who completed both visits, were analysed. Children reported less pain with than without acupuncture: 2.2 ± 2.5 vs. 3.9 ± 2.7 ; mean \pm SD, $p < 0.001$. Heart rate decreased after LI4 stimulation compared to ST alone throughout the dental treatment ($p < 0.05$). LI4 stimulation was safe and raised better satisfaction with the treatment among children and parents, than ST alone ($p < 0.05$). Other secondary endpoints were comparable between both sessions.

Conclusion

Stimulation of acupuncture point LI4 reduces pain and autonomous stress during injection of local anaesthetics in paediatric dentistry.

7. References

Adams D, Cheng F, Jou H, Aung S, Yasui Y, Vohra S. The safety of pediatric acupuncture: a systematic review. *Pediatrics*. 2011 Dec;128(6):e1575-87.

Ahn CB, Jang KJ, Yoon HM, Kim CH, Min YK, Song CH, Lee JC. Sa-Ahm Five Element acupuncture. *J Acupunct Meridian Stud*. 2010 Sep;3(3):203-13.

Berry H, Fernandes L, Bloom, B Clark RJ, Hamilton EB. Clinical study comparing acupuncture, physiotherapy, injection and oral anti-inflammatory therapy in shoulder-cuff lesions. *Lancet*, 1980 Jan 26;1(8161):208-9.

Biella G, Sotgiu ML, Pellegata G, Paulesu E, Castiglioni I, Fazio. Acupuncture produces central activations in pain regions. *Neuroimage*, 2001 Jul;14(1 Pt 1):60-6.

Brinkhaus B, Witt CM, Jena S, Linde K, Streng A, Wagenpfeil S, Imich D, Walther HU, Melchart D, Willich SN. Acupuncture in patients with chronic low back pain: a randomized controlled trial. *Arch Intern Med*. 2006 Feb 27;166(4):450-7.

Chao AS, Chao A, Wang TH, Chang YC, Peng HH, Chang SD, Chao A, Chang CJ, Lai CH, Wong AM. Pain relief by applying transcutaneous electrical nerve stimulation (TENS) on acupuncture points during the first stage of labor: a randomized double-blind placebo-controlled trial. *Pain* 2007 Feb;127(3):214-20.

Colagiuri B, Smith CA. A systematic review of the effect of expectancy on treatment responses to acupuncture. *Evid Based Complement Alternat Med*. 2011 Nov 14;15(2):313-19.

Diener, H. C., Kronfeld, K., Boewing, G., Lungenhausen, M., Maier, C., Molsberger, A., Tegenthoff, M., Trampisch, H. J., Zenz, M., and Meinert, R; GERAC Migraine Study Group. Efficacy of acupuncture for the prophylaxis of migraine: a multicentre randomised controlled clinical trial. *Lancet Neurol.* 2006 Apr;5(4): 310-6.

Dufton LM, Konik B, Colletti R, Stanger C, Boyer M, Morrow S, Compas BE. Effects of stress on pain threshold and tolerance in children with recurrent abdominal pain. *Pain.* 2008 May;136(1-2):38-43. Epub 2007 Aug 22.

Enck P, Klosterhalfen S, Zipfel S. Acupuncture, psyche and the placebo response. *Auton Neurosci.* 2010 Oct 28;157(1-2):68-73.

Ernst E, Lee MS, Choi TY. Acupuncture: does it alleviate pain and are there serious risks? A review of reviews. *Pain.* 2011 Apr;152(4):755-64.

Ernst E, Pittler MH. The effectiveness of acupuncture in treating acute dental pain: a systematic review. *Br Dent J.* 1998 May 9;184(9):443-7.

Evans S, Tsao JC, Zeltzer LK. Complementary and alternative medicine for acute procedural pain in children. *Altern Ther Health Med.* 2008 Sep-Oct;14(5):52-6.

Fan GQ, Zhao Y, Fu ZH. Acupuncture analgesia and the direction, angle and depth of needle insertion. *Zhongguo Zhen Jiu.* 2010 Nov;30(11):965-8.

Flanagan T, Wahl MJ, Schmitt MM, Wahl JA. Size doesn't matter: needle gauge and injection pain. *Gen Dent*. 2007 May-Jun;55(3):216-7.

Gaw AC, Chang LW, Shaw L-C. Efficacy of acupuncture on osteoarthritic pain. A controlled, double-blind study. *N Engl J Med*. 1975 Aug 21;293(8):375-8.

Giraudeau B, Rozenberg S, Valat J-P. Assessment of the clinically relevant change in pain for patients with sciatica. *Ann Rheum Dis*. 2004 Sep;63(9):1180-1.

Godfrey CM, Morgan P. A controlled trial of the theory of acupuncture in musculoskeletal pain. *J Rheumatol*. 1978 Summer;5(2):121-4.

Gold JI, Nicolaou CD, Belmont KA, Katz AR, Benaron DM, Yu W. Pediatric acupuncture: a review of clinical research. *Evid Based Complement Alternat Med*. 2009 Dec;6(4):429-39.

Greten HJ. *Kursbuch Traditionelle Chinesische Medizin* 2. Auflage, Thieme, Stuttgart 2004

Haake M, Müller HH, Schade-Brittinger C, Basler HD, Schäfer H, Maier C, Endres HG, Trampisch HJ, Molsberger A. German Acupuncture Trials (GERAC) for chronic low back pain: randomized, multicenter, blinded, parallel-group trial with 3 groups. *Arch Intern Med*. 2007 Sep 24;167(17):1892-8.

Hui, K. K., Liu J., Makris N., Gollub R. L., Chen A. J., Moore C. I., Kennedy D. N., Rosen B.R. and Kwong K. K. Acupuncture modulates the limbic system and subcortical gray structures of the human brain: evidence from fMRI studies in normal

subjects. *Hum. Brain Mapp.* 2000; 9:(1)13-25.

Huang CS, Tsai YF. Somatosympathetic reflex and acupuncture-related analgesia. *Chin J Physiol.* 2009 Nov 30;52(5 Suppl):345-57.

Huntley AL, Coon JT, Ernst E. Complementary and alternative medicine for labor pain: a systematic review. *Am J Obstet Gynecol.* 2004 Jul;191(1):36-44.

Jennings Pa, Cameron P, Bernard S. Measuring acute pain in the prehospital setting. *Emerg Med J.* 2009 Aug;26(8):552-5.

Jindal V, Ge A, Mansky PJ. Safety and efficacy of acupuncture in children: a review of the evidence. *J Pediatr Hematol Oncol.* 2008 Jun;30(6):431-42.

Karst M, Winterhalter M, Münte S, Francki B, Hondronikos A, Eckardt A, Hoy L, Buhck H, Bernateck M, Fink M. Auricular acupuncture for dental anxiety: a randomized controlled trial. *Anesth Analg.* 2007 Feb;104(2):295-300.

Kelly AM. Setting the benchmark for research in the management of acute pain in emergency departments. 2001 Mar;13(1):57-60.

Kim KS, Kim KN, Hwang KG, Park CJ. Capsicum plaster at the Hegu point reduces postoperative analgesic requirement after orthognathic surgery. *Anesth Analg.* 2009 Mar;108(3):992-6.

Kim LW, Guo NN, Ma LX, Yang H, Liu WN, Zhu J. Review on clinical application of needling techniques in chapter Guan Zhen (Official Needling Techniques) of Ling Shu (Spiritual Pivot). *Zhen Ci Yan Jiu*. 2007 Oct;32(5):351-4.

Kleinhenz, J. Acupuncture mechanisms, indications and effectiveness according to recent western literature. *Am. J. Acupuncture* 1995 Mar; 23(3): 211-8.

Kundu A, Berman B. Acupuncture for pediatric pain and symptom management. *Pediatr Clin North Am*. 2007 Dec;54(6):885-9; x.

Lee PK, Anderson TW, Modell JH, Saga SA. Treatment of chronic pain with acupuncture. *J Amer Med Ass*. 1975 Apr; 23(2): 1133-5.

Lee S, Chae Y, Kim SN, Kim SY, Park JY, Kwark YR, Kang OS, Lee H, Yin CS, Park HJ. Short term effects by acupuncture to SP3 on the autonomic blood flow control. *Neurol Res*. 2010 Feb;32 Suppl 1:37-42.

Lee S, Lee MS, Choi JY, Lee SW, Jeong SY, Ernst E. Acupuncture and heart rate variability: a systematic review. *Auton Neurosci*. 2010 Jun 24;155(1-2):5-13.

Leibing E, Leonhardt U, Köster G, Goerlitz A, Rosenfeldt JA, Hilgers R, Ramadori G. Acupuncture treatment of chronic low-back pain -- a randomized, blinded, placebo-controlled trial with 9-month follow-up. *Pain*. 2002 Mar;96(1-2):189-96.

Li XM. Complementary and alternative medicine in pediatric allergic disorders. *Curr Opin Allergy Clin Immunol*. 2009 Apr;9(2):161-7.

Libonate J, Evans S, Tsao JC. Efficacy of acupuncture for health conditions in children: a review. *ScientificWorldJournal*. 2008 Jul 13;8:670-82.

Lin JG, Chen WL. Review: acupuncture analgesia in clinical trials. *Am J Chin Med*. 2009;37(1):1-18.

Lin YC et al. Acupuncture management of pain and emergence agitation in children after bilateral myringotomy and tympanostomy tube insertion. *Paediatr Anaesth*. 2009 Nov;19(11):1096-101.

Linde K, Streng A, Jürgens S, Hoppe A, Brinkhaus B, Witt C, Wagenpfeil S, Pfaffenrath V, Hammes MG, Weidenhammer W, Willich SN, Melchart D. Acupuncture for patients with migraine: a randomized controlled trial. *J Amer Med Ass*. 2005 May 4;293(17):2118-25.

Linde K, Allais G, Brinkhaus B, Manheimer E, Vickers A, White AR. Acupuncture for tension-type headache. *Cochrane Database Syst Rev*. 2009 Jan 21;(1):CD007587.

Liu T. Acupuncture: What Underlies Needle Administration? *Evid Based Complement Alternat Med*. 2009 Jun; 6(2):185-93.

Liu T, Yu CP Placebo analgesia, acupuncture and sham surgery. *Evid Based Complement Alternat Med*. 2011;2011:943147.

MacPherson H, Nahin R, Paterson C, Cassidy CM, Lewith GT, Hammerschlag R. Developments in acupuncture research: big-picture perspectives from the leading

edge. J Altern Complement Med. 2008 Sep;14(7):883-7.

Mamut I-R. Akupressur als Intervention gegen Angst vor zahnärztlichen Eingriffen. Eine prospektiv randomisierte Doppelblindstudie am Patientenkollektiv der Allgemeinen Ambulanz der Bernhard Gottlieb Universitätszahnklinik Wien 2008

Marques AH, Siverman MN, Sternberg EM. Evaluation of stress systems by applying noninvasive methodologies: measurements of neuroimmune biomarkers in the sweat, heart rate variability and salivary cortisol. Neuroimmunomodulation. 2010 Feb;17(3):205-8

Meechan JG, Ledvinka JI. Pulpal anaesthesia for mandibular central incisor teeth: a comparison of infiltration and intraligamentary injections. Int Endod J. 2002 Jul;35(7):629-34.

Melchart D, Streng A, Hoppe A, Brinkhaus B, Witt C, Wagenpfeil S, Pfaffenrath V, Hammes M, Hummelsberger J, Irnich D, Weidenhammer W, Willich SN, Linde K. Acupuncture in patients with tension-type headache: randomised controlled trial. BMJ. 2005 Aug 13;331(7513):376-82.

Musial F, Tao I, Dobos G. [Is the analgesic effect of acupuncture a placebo effect?] Schmerz. 2009 Aug;23(4):341-6.

Nilsson S, Finnström B, Kokinsky E. The FLACC behavioral scale for procedural pain assessment in children aged 5-16 years. Paediatr Anaesth. 2008 Aug;18(8):767-74.

Park J, Linde K, Manheimer E, Molsberger A, Sherman K, Smith C, Sung J, Vickers

A, Schnyer R. The status and future of acupuncture clinical research. J Altern Complement Med. 2008 Sep;14(7):871-81.

Pfister DG, Cassileth BR, Deng GE, Yeung KS, Lee JS, Garrity D, Cronin A, Lee N, Kraus D, Shaha AR, Shah J, Vickers AJ. Acupuncture for pain and dysfunction after neck dissection: results of a randomized controlled trial. J Clin. Oncol. 2010 May 20;28(15):2565-70.

Pothman R, Meng AC, Akupunktur in der Kinderheilkunde, 2. Auflage, Hippokrates Verlag, Stuttgart 2002

Powell CV, Kelly AM, Williams A. Determining the minimum clinically significant difference in visual analog pain score for children. Emerg Med (Fremantle). Ann Emerg Med. 2001 Jan;37(1):28-31.

Rademacher W. Shiatsu in der Praxis, Urban/Fischer, München 2009

Ranger M, Campbell-Yeo M. Pulpal anaesthesia for mandibular central incisor teeth: a comparison of infiltration and intraligamentary injections. Int Endod J. 2002 Jul;35(7):629-34.

Reis DG, Scopinho AA, Guimaraes FS, Correa FM, Resstel LB. Behavioral and Autonomic Responses to Acute Restraint Stress Are Segregated within the Lateral Septal Area of Rats. PLoS One.2011;6(8):e23171.

Richardson PH, Vincent C. Acupuncture for the treatment of pain: a review of evaluative research. Pain. 1986 Jan;24(1):15-40.

Sakatani K, Kitagawa T, Aoyama N, Sasaki M. Effects of acupuncture on autonomic nervous function and prefrontal cortex activity. *Adv Exp Med Biol.* 2010;662:455-60.

Sharma RK, Balhara YP, Sagar R, Deepak KK, Mehta M. Heart rate variability study of childhood anxiety disorders. *J Cardiovasc Dis Res.* 2011 Apr;2(2):115-22.

Shen YF, Goddard G. The short-term effects of acupuncture on myofascial pain patients after clenching. *Pain Pract.* 2007 Sep;7(3):256-64.

Smith L, Oldman A. Acupuncture and dental pain. *Br Dent J.* 1999 Feb 27;186(4 Spec No):158-9.

Sood A, Sood R, Bauer BA, Ebbert JO. Cochrane systematic reviews in acupuncture: methodological diversity in database searching. *J Altern Complement Med.* 2005 Aug;11(4):719-22.

Stux G, Stiller N, Berman B, Pomeranz B. *Akupunktur Lehrbuch und Atlas*, Springer Verlag, 2007

Thompson T, Keogh E, French CC, Davis R. Anxiety sensitivity and pain: generalisability across noxious stimuli. *Pain.* 2008 Jan;134(1-2):187-96.

Usichenko TI, Dinse M, Lysenyuk VP, Wendt M, Pavlovic D, Lehmann C. Auricular acupuncture reduces intraoperative fentanyl requirement during hip arthroplasty--a randomized double-blinded study. *Acupunct Electrother Res.* 2006;31(3-4):213-21.

Usichenko TI, Wolters P, Santamaria R, Leutzow B, Meissner K, Splieth Ch. Acupuncture reduces pain during injection of local anaesthetic in paediatric dentistry - a randomized crossover trial. *Eur J Anaesthesiol* 2012;29(Suppl. 50):159.

Vincent C, Lewith G. Placebo controls for acupuncture studies. *J R Soc Med.* 1995 Apr;88(4):199-202.

Voepel-Lewis T, Zanoliti J, Dammeyer JA, Merkel S. Reliability and validity of the face, legs, activity, cry, consolability behavioral tool in assessing acute pain in critically ill patients. *Am J Crit Care.* 2010 Jan;19(1):55-61; quiz 62.

Wang SM, Kain ZN, White P. Acupuncture analgesia: I. The scientific basis. *Anesth Analg.* 2008 Feb;106(2):602-10.

Wang SM, Escalera S, Lin EC, Maranets I, Kain ZN. Extra-1 Acupressure for Children Undergoing Anesthesia. *Anesth Analg.* 2008 Sep;107(3):811-6.

Wang SC, Shan WZ, Sun SF. [Needle sticking method]. *Zhongguo Zhen Jiu.* 2011 Mar;31(3):227-31.

Wetzel B, Pavlovic D, Kuse R, Gibb A, Merk H, Lehmann C, Wendt M, Usichenko TI. The effect of auricular acupuncture on fentanyl requirement during hip arthroplasty: a randomized controlled trial. *Clin J Pain.* 2011 Mar-Apr;27(3):262-7.

Williamson A, Hoggart B. Pain: a review of three commonly used pain rating scales. *J Clin Nurs.* 2005 Aug;14(7):798-804.

Witt C, Brinkhaus B, Jena S, Linde K, Streng A, Wagenpfeil S, Hummelsberger J, Walther HU, Melchart D, Willich SN. Acupuncture in patients with osteoarthritis of the knee: a randomised trial. *Lancet*. 2005 Jul 9-15;366(9480):136-43.

Wu MT, Hsieh JC, Xiong J, Yang CF, Pan HB, Chen YC, Tsai G, Rosen BR, Kwong KK. Central nervous pathway for acupuncture stimulation: localization of processing with functional MR imaging of the brain--preliminary experience. *Radiology*. 1999 Jul;212(1):133-41.

Wu S, Sapru A, Stewart MA, Milet MJ, Hudes M, Livermore LF, Flori HR. Using acupuncture for acute pain in hospitalized children. *Pediatr Crit Care Med*. 2009 May;10(3):291-6.

Yassen GH. Evaluation of mandibular infiltration versus mandibular block anaesthesia in treating primary canines in children. *Int J Paediatr Dent*. 2010 Jan;20(1):43-9.

Yeh ML, Chung YC, Chen KM, Tsou MY, Chenn HH. Acupoint electrical stimulation reduces acute postoperative pain in surgical patients with patient-controlled analgesia: a randomized controlled study. *Altern. Ther. Health Med*. 2010 Nov-Dec;16(6):10-8.

Yoshi F. Shen DDS and Greg Goddard DDS. The Short-Term Effects of Acupuncture on Myofascial Pain Patients After Clenching. *Pain Practice* Volume 7, Issue 3, pages 256–264, September 2007.

Yu F, Takahashi T, Moriva J, Kawaura K, Yamakawa J, Kusaka K, Itoh T, Morimoto S, Yamaguchi N, Kanda T. Traditional Chinese medicine and Kampo: a review from the distant past for the future. *J Int Med Res.* 2006 May-Jun;34(3):231-9.

Zhao ZQ. Neural mechanism underlying acupuncture analgesia. *Prog Neurobiol.* 2008 Aug;85(4):355-75.

8. APPENDICES

Appendix A. Einverständniserklärung für die Teilnahme an einer Klinischen Studie

Name, Vorname des
Patienten:

Geburtsdatum:

**Titel der Studie: Akupunktur zur komplementären Schmerzlinderung bei der
Terminalanästhesie in der Kinderzahnheilkunde**

Ich wurde von dem unterzeichnenden Arzt über Art, Ablauf und Ziel der Akupunktur sowie die zu erwartenden Wirkungen, Nebenwirkungen und Risiken des Verfahrens aufgeklärt. Die spezielle Patienteninformation („Reduktion des Schmerzes während der dentalen Behandlung mit Akupunktur“) habe ich gelesen und verstanden. Ich fühle mich umfangreich aufgeklärt. Momentan bestehen meinerseits keine weiteren Fragen bzw. Unklarheiten.

Meine Teilnahme an der Akupunktur-Studie ist freiwillig, und ich kann jederzeit, auch ohne Angabe von Gründen, die Mitwirkung beenden, ohne dass mir dadurch Nachteile entstehen.

Ich bin damit einverstanden, dass die im Rahmen der klinischen Beobachtung erhobenen Daten zur wissenschaftlichen Auswertung in anonymer Form verwendet werden. Weiterhin wurde ich darüber informiert, dass meine Personengebundenen Daten ausschließlich zur Qualitätssicherung der Studie in der Klinik für Anästhesie und Intensivmedizin der Ernst-Moritz-Arndt-Universität Greifswald erfasst werden und durch die zuständige Überwachungsbehörde des Qualitätsmanagements eingesehen werden dürfen.

Ich erkläre mich bereit, zu den obigen Bedingungen an dieser Behandlung teilzunehmen.

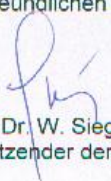
Greifswald, den

Unterschrift des Betreuers

Greifswald, den

Unterschrift des aufklärenden
Arztes

Appendix B. Ethics Vote

<div>ERNST MORITZ ARNDT UNIVERSITÄT GREIFSWALD</div> <div><div>Wissen lockt. Seit 1456</div></div>	
<div>Medizinische Fakultät Fleischmann Strasse 8 D-17475 Greifswald</div> <div>Herrn Prof. Dr. Ch. Splieth Universitätsklinikum Greifswald Zentrum für Zahn-, Mund- und Kieferheilkunde Abteilung für Präventive Zahnmedizin und Kinderzahnheilkunde Rotgerberstr. 8 D-17487 Greifswald</div>	<div>Ethikkommission</div> <div>GESCHÄFTSSTELLE Ernst-Moritz-Arndt-Universität Medizinische Fakultät Ethikkommission Institut für Pharmakologie Friedrich-Löffler Strasse 23 d D-17487 Greifswald</div> <div>BEARBEITER Frau Dr. K. Kindermann</div>
<div><u>Votum der Ethikkommission</u></div>	
<div>Titel der Studie: Treatment of pain and anxiety during injection of local anaesthetic for pediatric dentistry using acupuncture – a randomised controlled trial</div> <div>Antrag vom: 21.04.2010</div> <div>Eingegangen am: 24.04.2010</div> <div>Reg.-Nr.: BB 57/10</div>	<div>DATUM: 29.04.2010</div>
<div>Sehr geehrter Herr Prof. Dr. Splieth,</div> <div>die Ethikkommission der Medizinischen Fakultät an der Ernst-Moritz-Arndt-Universität Greifswald hat die zum o.g. Versuchsplan eingereichten Unterlagen in ihrer Sitzung am 27.04.2010 geprüft.</div> <div>Die Kommission stellte mehrheitlich fest, dass gegen die Durchführung der Studie keine ethischen und rechtlichen Bedenken bestehen und befürwortet deshalb das Vorhaben.</div> <div>Sie bittet aber darum, die Studenten und postgraduierten Zahnärzte aus der Prüfarztliste zu streichen.</div> <div>Am Ende der Elterninformation sollte bei der Nennung der Studienleiter die englische Phrase gestrichen bzw. übersetzt werden.</div> <div>Die Kommission empfiehlt weiterhin, die Patienteninformation für Kinder in mehreren Versionen altersdifferenziert zu gestalten.</div> <div>Die Mitglieder der Kommission wünschen Ihnen viel Erfolg bei der Durchführung des Vorhabens.</div>	
<div>Mit freundlichen Grüßen</div> <div></div> <div>Prof. Dr. W. Siegmund Vorsitzender der Ethikkommission</div>	<div>Telefon: 03834 – 86 5644</div> <div>Telefax: 03834 – 88 5631</div> <div>e-mail: ethik@uni-greifswald.de</div> <div>Internet: www.medizin.uni-greifswald.de</div> <div>Bankverbindung: Deutsche Bundesbank Rostock Konto-Nr. 130 015 30 BLZ 130 000 00</div> <div>USID: DE137584813</div>

Eidesstattliche Erklärung

Hiermit erkläre ich, dass ich die vorliegende Dissertation selbständig verfasst und keine anderen als die angegebenen Hilfsmittel benutzt habe.

Die Dissertation ist bisher keiner anderen Fakultät, keiner anderen wissenschaftlichen Einrichtung vorgelegt worden.

Ich erkläre, dass ich bisher kein Promotionsverfahren erfolglos beendet habe und dass eine Aberkennung eines bereits erworbenen Doktorgrades nicht vorliegt.

Datum

Unterschrift

Danksagung:

Meinen besonderen Dank gilt Hr. Prof. Splieth und Hr. Prof. Usichenko für die tatkräftige Unterstützung und Betreuung der Arbeit.

Auch möchte ich mich bei der gesamten Kinderabteilung, Dr. Alkilzy und allen Postgraduates (Katia Taxou, Ruth Santamaria Sanchez, Ourania Papageorgiu, Marina-Agathi Petrou und Basel Altarabulsi) bedanken für die Unterstützung die sie mir haben zukommen lassen, ohne die ich das Projekt nicht erfolgreich hätte beenden können!

Meinen Eltern und Geschwistern danke ich für ihre Geduld und Beistand.