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What influences the success of pulpectomy treatment of primary molars in a specialized dental setting?

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List of abbreviations

Table 1: List of abbreviations

Abbreviation	Definition
GA	General Anesthesia
LA	Local Anesthesia
N ₂ O	Nitrous Oxide
OHRQoL	Oral Health-related Quality of Life
SSC	Stainless steel crown

1. Summary

Aim: to retrospectively investigate the success rate of pulpectomy treatments of primary molars (with the use of calcium-hydroxide/iodoform paste) over 4 years together with the possible influence of different factors on the outcome. In addition, the possible influence of the treatment setting (general anesthesia, nitrous oxide sedation and local anesthesia) on the outcome was also analyzed.

Materials and methods: patients' digital records who underwent a pulpectomy treatment were retrospectively analyzed. The impact of various patient-related, tooth-related and treatment-related factors were analyzed. The influence of the treatment setting (treatments performed under general anesthesia, nitrous oxide sedation or local anesthesia alone) on the success of the pulpectomy treatment was additionally analyzed as it can affect patient's compliance and thus the outcome. Multivariate and bivariate analyses were performed.

Results: pulpectomy treatments performed under general anesthesia had the highest success rate (78.6%) 4 years posttreatment. Followed by nitrous oxide sedation (57.1%) and then local anesthesia alone (43.8%). Furthermore, the arch type was also found to be clinically and statistically significant. The failure rate of the pulpectomized primary molars in the upper arch was more than that in the lower arch four years posttreatment (61.5% vs 29.2%).

Conclusion: preserving primary molars for as long as possible through pulpectomy treatment should always be included in the treatment planning of young children as it offers high success rates many years following the treatment, especially true for lower primary molars and cases performed under general anesthesia.

Keywords: primary molars, pulpectomy, success rate, nitrous oxide sedation, general anesthesia

2. Zusammenfassung

Ziel: Klinische Erfolgsrate von Pulpektomie-Behandlungen bei Milchmolaren unter Verwendung von Calciumhydroxid/Iodoform-Paste über 4 Jahre in einer spezialisierten Kinderzahnarztpraxis und Betrachtung möglicher Einflussfaktoren wie der Einfluss der Behandlungsart (Vollnarkose, Lachgassedierung oder nur Lokalanästhesie) auf den Behandlungserfolg.

Material und Methoden: Die Behandlungsakten der Patienten, die eine Pulpektomie am Milchmolaren in der spezialisierten Abteilung für Kinderzahnheilkunde der Universitätszahnklinik Greifswald im Zeitraum xx -xx erhielten, wurden retrospektiv ausgewertet. Der Einfluss verschiedener patientenbezogener, zahnbezogenen und behandlungsbezogenen Faktoren wurde zu den verschiedenen Follow-Up-Zeitpunkten ermittelt. Zusätzlich wurden bivariate und multivariate Analysen durchgeführt.

Ergebnisse: Pulpektomien, die unter Vollnarkose durchgeführt wurden, hatten nach vier Jahren deutlich die höchste Erfolgsrate (78,6 %), gefolgt von Lachgassedierung (57,1 %) und Lokalanästhesie (43,8 %). Die Misserfolgsrate der pulpektomierten Milchmolaren im Oberkiefer war vier Jahre nach der Behandlung klinisch relevant und statistisch signifikant höher als im Unterkiefer (61,5 % vs. 29,2 %).

Schlussfolgerung: Der Zahnerhalt von Milchmolaren mittels Pulpektomie sollte bei den zahnärztlichen Behandlungsplänen von kleinen Kindern als Alternative zur frühzeitigen Zahnextraktion berücksichtigt werden. Die klinischen Erfolgswahrscheinlichkeiten sind auch viele Jahre nach der Pulpektomie insbesondere bei unteren Milchmolaren und Narkosesanierungen hoch.

Schlüsselwörter: Milchzähne, Pulpektomie, Erfolgsrate, Lachgassedierung, Vollnarkose

3. Publications

This work is based on two international peer-review articles published in the journal Quintessence international (journal impact factor 2021: 1.677) (see Annex 1 and Annex 2).

3.1 Paper 1: One year clinical success of pulpectomy in primary molars with iodoform-calcium hydroxide paste

Al-Attiya H, Mourad S, Splieth C H, Schmoeckel J: One year clinical success of pulpectomy in primary molars with iodoform-calcium hydroxide paste. Quintessence Int 2021;52:528–537; doi: 10.3290/j.qi.b1244443.

3.2 Paper 2: Influence of treatment setting on success of pulpectomy in primary molars: a retrospective analysis up to 4 years

Al-Attiya H, Mourad S, Splieth C H, Schmoeckel J: Influence of treatment setting on success of pulpectomy in primary molars: a retrospective analysis up to 4 years. Quintessence Int 2022;53:2–11.

4. Introduction

Retaining primary teeth until their natural exfoliation has many obvious benefits such as maintaining proper occlusion, phonation, esthetics, mastication and guiding the erupting permanent successors into their proper location [Ahmed 2014]. Prematurely losing primary teeth especially primary molars mainly due to progression of caries has many detrimental consequences including but not limited to changes in the arch length [Kher 2020], negatively impacting the quality of life of young children and their guardians [Tinanoff 2019; Monte-Santo 2018], along with increasing the need for more complex orthodontic treatments later in life [Wagner 2020]. Although the prevalence of dental caries especially among young children remains a significant health problem [Chen 2019], every attempt should be aimed at trying to keep every primary tooth in a pain free status for as long as possible ideally until they are physiologically replaced by their permanent counterparts. Since the progression of caries in primary teeth occurs at a much higher pace than that in the permanent ones attributed to the thin enamel layer, pulp treatments such as pulpectomy are often needed to conserve these teeth. But unfortunately extracting pulpally involved primary teeth such as those with irreversible pulpitis or periapical/periradicular pathology is still commonly practiced despite all of the well-known negative sequelae [Rewal 2014]. Perhaps as a result of the uncertainty about the success rate of pulpectomy in primary molars as multiple factors play an important role on the outcome such as the unpredictable anatomy of primary molars canal system with the presence of multiple accessory canals and also the absence of an ideal root canal filling material that is able to ideally seal the entire root canal system and at the same time resorb at a rate similar to that of the physiologic root resorption of the primary tooth [Chen 2017] and its effect on the tooth bud lying underneath [Lokade 2019]. Moreover, the need for special skills in dealing with non-cooperative young children is also required [Rewal 2014]. In addition to the above mentioned reasons, the inconsistent and somewhat short term success rates that are reported in the literature might also have an effect on the choice of treatment of pulpally involved and necrotic primary teeth.

Consequently, the aim of the first paper was to retrospectively analyze the one year success rate of pulpectomy of primary molars (using calcium-hydroxide/iodoform paste) along with the possible impact of various factors on the outcome. Whereas in the second paper, a more comprehensive analysis was carried out to retrospectively

investigate the success of primary molars pulpectomy for up to four years posttreatment with the focus on the influence of the treatment setting (general anesthesia, nitrous oxide sedation and local anesthesia) on the treatment outcome.

5. Materials and Methods

This cumulative dissertation is based on two published papers (see Annex 1 and Annex 3), which are both retrospective analyses using patients' records of the Department of Preventive and Pediatric Dentistry at the University of Greifswald with ethical approval number (Internal RegNo BB 028/16). In both papers patients' digital records were searched and screened using specific key words from the time of the department foundation in 2012 up until the end of 2018 for the first paper. An expanded search was carried out for the second paper extending to the end of 2020 to increase the observation period and follow-up time. The inclusion and exclusion criteria in both papers were identical, namely;

5.1 Inclusion and exclusion criteria

Inclusion criteria:

- 1) pulpectomized primary molars during the appropriate time period completed by both the general and pediatric dentists working in the department, together with the cases carried out by the master students completing the pediatric master program offered by the department.
- 2) with calcium-hydroxide/iodoform paste as root canal filling material.
- 3) a minimum of one year follow-up period posttreatment.

Exclusion criteria:

- 1) anterior teeth.
- 2) pulpectomized primary molars with less than one year follow-up period.

Since radiographic evaluation succeeding pulp therapy is not the standard of care at the department to reduce children's exposure to radiation, success of the pulpectomy treatment was determined clinically.

5.2 Criteria for clinical success and failure

Accordingly, criteria for clinical success were:

- 1) lack of clinical signs of abscess and/or fistula.
- 2) lack of pain and complaints by the patients.
- 3) no further treatments were necessary following the pulpectomy treatment.
- 4) tooth exfoliated naturally at the average chronological age.
- 5) tooth was extracted because of severe mobility associated with normal physiological exfoliation at the appropriate chronological age with the absence of pathology.

Criteria for clinical failure were:

- 1) evidence of clinical and/or radiological signs and symptoms of pathology.
- 2) tooth was extracted due to the presence of abscess or sinus tract.
- 3) tooth was extracted because of extreme mobility related to non-physiologic root resorption at an age earlier than the appropriate chronological age.

The Department of Preventive and Pediatric Dentistry at the University of Greifswald has standardized all the procedures carried out in the department to ensure that all patients treated in the department receive the same quality of care whether carried out by master students or the dentists working there (general and pediatric dentists). The standard operative protocol for all pulpectomy treatments; after careful case selection through clinical and mostly also radiological examination considering the indications and contraindications and obtaining patients consent; is as follows: after administering local anesthesia (infiltration or intraligamentary) and isolation of the operative field using rubber dam; caries is excavated and the occlusal surface is reduced by about 1.5 mm for the preparation of the tooth to receive a stainless steel crown. After that an access cavity is achieved through the removal of the coronal pulp and the root canal orifices are identified. Followed by extirpation of the infected pulp tissue, using Hedstrom files to a length of 12 mm and to a minimum size of ISO35, along with the

use of sodium hypochlorite (0.6%) as an irrigant. After cleaning and shaping, the root canals are dried using sterile paper points. After that a calcium-hydroxide/iodoform paste is injected into the canals and the pulp chamber is sealed with zinc phosphate cement. As a final step, the stainless steel crown is adapted and cemented into place as a definitive restoration. Post operative evaluation and instructions are given to the patient/parent before dismissal.

5.3 Statistical analysis

After screening all patients records along with the application of the various inclusion and exclusion criteria, 62 primary molars in the first study and 105 primary molars in the second study satisfied all the inclusion and exclusion criteria and were included in the final analyses of the corresponding study. In both papers the influence of multiple factors related to the patients, teeth and treatments were analyzed as follows:

- 1) patient-related factors: a) sex; b) age at day of treatment; c) caries experience (dmft) at day of treatment; d) general health status; e) travel distance to clinic (in km).
- 2) tooth-related factors: a) tooth type; b) arch; c) pulpal and periapical condition prior to treatment.
- 3) treatment-related factors: a) treatment indication; b) academic qualification of the operator; c) number of visits; d) posttreatment restoration.

Furthermore, the pulpal and periapical condition of the tooth prior to the treatment was further divided into six categories; as the different pretreatment condition of the tooth might have to a greater extent an impact on the outcome into:

- 1) primary molars with a history of spontaneous pain or deep caries with/without pulpal involvement or primary molars with pulpal necrosis without signs of apical radiolucency.
- 2) necrotic primary molars with signs of apical radiolucency without clinical signs of abscess or fistula.
- 3) primary molars with clinical signs of fistula.
- 4) primary molars with clinical signs of an abscess.
- 5) previously pulpotomized primary molars with clinical and/or radiographic signs of failure.
- 6) primary molars with unknown diagnosis due to insufficient documentation and absence of a radiograph.

Along to the above mentioned factors that were analyzed in both papers, in the second paper the treatment setting (treatments carried out under GA, nitrous oxide sedation, local anesthesia alone) was additionally analyzed since increasing patients compliance by means of behavior management shaping using different pharmacological and non-pharmacological techniques can be a major determining factor in the performance and consequently in the success of the treatment.

To verify the quality and preciseness of the collected data, a native speaker pediatric specialist was consulted to clarify any uncertain documentation or doubts.

With the help of a Microsoft Excel (Microsoft® Excel® für Microsoft 365 MSO (Version 2208 Build 16.0.15601.20204) 64 Bit) Data Sheet; and after coding and transferring the collected data; Chi-squared test was conducted to evaluate the potential effect of the previously mentioned factors on the success of the pulpectomy treatment in primary molars. Additionally, ranges, distributions, mean values for numerical data with a normal distribution (age, caries prevalence) and standard deviations were conducted as part of the descriptive analyses in both papers.

Nine of the parents of some of the patients at baseline who failed to show up for the subsequent follow-up examination were contacted via the telephone and were asked about the condition of the treated teeth in an effort to enhance the follow-up numbers. These, however, were only brought up for additional informative purposes.

In addition, a multivariate analysis was carried out to assess the positive effect of secondary factors. A statistical Excel plugin was used for the multivariate analyses. In order to avoid overfitting of the regression due to the multitude of different variables, the adjusted squared multiple R was used.

6. Results

The study sample in both papers was composed mainly of young children about 5 years old (± 1.4 years) with high caries experience in the primary dentition (up to 8 ± 3.8 dmft) and no relevant medical history. The male : female ratio is almost equally presented in both papers. As a result of drop-out, the male : female ratio has changed in favor of females 4 years posttreatment, as more female patients complied to the follow-up visits than male patients. The majority of the patients had to travel no less than 11 km to reach the Department of Preventive and Pediatric Dentistry at the University of Greifswald.

In both papers the majority of the pulpectomized primary molars had proximal dentinal caries involving two or three surfaces and were second primary molars especially in the lower arch.

Nearly half of the pulpectomy treatments in the second paper were completed under general anesthesia (42.9%), while 20% of the treatments were carried out using nitrous oxide sedation.

6.1 Outcome of primary molar pulpectomy

Paper 1: one year clinical success of pulpectomy in primary molars with iodoform-calcium hydroxide paste

The overall one year success rate was 93.5%. The only variable that had an impact on the outcome of the treatment was the arch type. Pulpectomized primary molars in the lower arch were more successful than those in the upper arch (100% vs 83.3%) (see Table 2).

Detailed results of this paper can be viewed in the publication (see Annex).

Table 2: Retrospective outcome of pulpectomy in primary molars at 1-year follow-up in relation to different variables (data based on number of primary molars)

Variable		Success N (percent)	1-y follow-up	Failure N (percent)
Total, n (%)		58 (93.5)		4 (6.5)
Age	<i>P</i> (chi-squared test)		.00	
	3 y, n (%)	5 (100.0)		0 (0.0)
	4 y, n (%)	20 (100.0)		0 (0.0)
	5 y, n (%)	12 (92.3)		1 (7.7)
	6 y, n (%)	14 (100.0)		0 (0.0)
	7 y, n (%)	2 (40.0)		3 (60.0)
	8 y, n (%)	5 (100.0)		0 (0.0)
Treatment indication	<i>P</i> (chi-squared test)		.62	
	Irreversible pulpitis/ necrosis, n (%)	38 (92.7)		3 (7.3)
	Apical radiolucency, n (%)	11 (100.0)		0 (0.0)
	Fistula, n (%)	3 (100.0)		0 (0.0)
	Abscess, n (%)	1 (100.0)		0 (0.0)
	Failed pulpotomy, n (%)	3 (75.0)		1 (25.0)
	Unknown, n (%), n (%)	2 (100.0)		0 (0.0)
Operator	<i>P</i> (chi-squared test)		.80	
	Master student, n (%)	24 (92.3)		2 (7.7)
	Pedodontist/Professor, n (%)	10 (90.9)		1 (9.1)
	General dental practitioner working in a pediatric dental clinic, n (%)	24 (96.0)		1 (4.0)
Number of visits	<i>P</i> (chi-squared test)		.54	
	One visit, n (%)	53 (93.0)		4 (7.0)
	Two visits, n (%)	5 (100.0)		0 (0.0)
Posttreatment restoration	<i>P</i> (chi-squared test)		.79	
	SSC, n (%)	57 (93.4)		4 (6.6)
	Class II filling, n (%)	1 (100.0)		0 (0.0)
Tooth type	<i>P</i> (chi-squared test)		.14	
	1st primary molar, n (%)	11 (84.6)		2 (15.4)
	2nd primary molar, n (%)	47 (95.9)		2 (4.1)
Arch	<i>P</i> (chi-squared test)		.01	
	Maxillary, n (%)	20 (83.3)		4 (16.7)
	Mandibular, n (%)	38 (100.0)		0 (0.0)
Baseline radiograph	<i>P</i> (chi-squared test)		.5	
	Yes, n (%)	52 (94.5)		3 (5.5)
	No, n (%)	1 (100.0)		0 (0.0)
	Radiograph older than 6 months, n (%)	5 (83.3)		1 (16.7)
Type of radiograph	<i>P</i> (chi-squared test)		.06	
	Periapical radiograph, n (%)	21 (91.3)		2 (8.7)
	Panoramic radiograph, n (%)	35 (97.2)		1 (2.8)
	Panoramic radiograph half side, n (%)	1 (50.0)		1 (50.0)
	N/A, n (%)	1 (100.0)		0 (0.0)
Coronal lesion	<i>P</i> (chi-squared test)		.6	
	Occlusal, n (%)	8 (100.0)		0 (0.0)
	Approximal, n (%)	47 (92.2)		4 (7.8)
	3 surfaces or more, n (%)	3 (100.0)		0 (0.0)

SSC = Stainless steel crown

Paper 2: Influence of treatment setting on success of pulpectomy in primary molars: A retrospective analysis up to 4 years

The follow-up periods in this paper were extended to up to four years posttreatment in order to obtain a more thorough understanding of the long-term effect of the different variables on the outcome. For the 65 pulpectomized primary molars with a minimum follow-up period of one year, the success rate four years posttreatment was 59.5% with an average of 3.2 years follow-up time.

The factor that has the greatest impact on the outcome was the setting in which the treatment took place i.e. whether the treatment was carried out under general anesthesia or nitrous oxide sedation along with local anesthesia or local anesthesia alone. Pulpectomy treatments carried out under general anesthesia had the lowest failure rates four years posttreatment (21.4%). Whereas the failure rate is almost twice as high (43.8%) for cases that were carried out with local anesthesia alone.

The impact of the arch type on the outcome remained clinically and statistically significant as the success was higher in mandibular primary molars than in maxillary primary molars (see Table 3, alike outcome in paper 1 in the 1 y follow-up)

The rest of the variables that failed to reach a statistical significant effect can be viewed in the publication (see Annex 2).

Table 3: Retrospective outcome of pulpectomy in primary molars in relation to different variables (data based on number of primary molars) up to 4 years in bivariate analysis

Variable	1 y follow-up				2 y follow-up				3 y follow-up				4 y follow-up			
	Success		Failure		Success		Failure		Success		Failure		Success		Failure	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	N	%
Treatment modality	Ch ² = 0.02				Ch ² = 0.06				Ch ² = 0.02				Ch ² = 0.15			
LA	19	82.6%	4	17.4%	15	71.4%	6	28.6%	11	57.9%	8	42.1%	7	43.8%	9	56.3%
N ₂ O	14	100.0%	0	0.0%	10	90.9%	1	9.1%	9	81.8%	2	18.2%	4	57.1%	3	42.9%
GA	28	100.0%	0	0.0%	23	95.8%	1	4.2%	18	94.7%	1	5.3%	11	78.6%	3	21.4%
Arch	Ch ² = 0.01				Ch ² = 0.01				Ch ² = 0.12				Ch ² = 0.00			
Upper	22	84.6%	4	15.4%	14	70.0%	6	30.0%	11	64.7%	6	35.3%	5	38.5%	8	61.5%
Lower	39	100.0%	0	0.0%	34	94.4%	2	5.6%	27	84.4%	5	15.6%	17	70.8%	7	29.2%
Age (years)	Ch ² = 0.00				Ch ² = 0.00				Ch ² = 0.07				Ch ² = 0.07			
3	5	100.0%	0	0.0%	3	100.0%	0	0.0%	3	100.0%	0	0.0%	3	100.0%	0	0.0%
4	20	100.0%	0	0.0%	18	94.7%	1	5.3%	15	93.8%	1	6.3%	9	81.8%	2	18.2%
5	12	92.3%	1	7.7%	11	91.7%	1	8.3%	10	83.3%	2	16.7%	4	50.0%	4	50.0%
6	15	100.0%	0	0.0%	10	83.3%	2	16.7%	5	55.6%	4	44.4%	1	16.7%	5	83.3%
7	4	57.1%	3	42.9%	2	40.0%	3	60.0%	2	40.0%	3	60.0%	2	40.0%	3	60.0%
8	5	100.0%	0	0.0%	4	80.0%	1	20.0%	3	75.0%	1	25.0%	3	75.0%	1	25.0%

Variable	1 y follow-up				2 y follow-up				3 y follow-up				4 y follow-up			
	Success		Failure		Success		Failure		Success		Failure		Success		Failure	
Treatment indication	Ch ² = 0.61				Ch ² = 0.16				Ch ² = 0.19				Ch ² = 0.18			
Irreversible pulpitis/ necrosis	41	93.2%	3	6.8%	32	86.5%	5	13.5%	25	83.3%	5	16.7%	16	69.6%	7	30.4%
Apical radiolucency	11	100.0%	0	0.0%	9	90.0%	1	10.0%	6	60.0%	4	40.0%	4	44.4%	5	55.6%
Fistula	3	100.0%	0	0.0%	3	100.0%	0	0.0%	3	100.0%	0	0.0%	1	100.0%	0	0.0%
Abscess	1	100.0%	0	0.0%	1	100.0%	0	0.0%	1	100.0%	0	0.0%	0	0.0%	1	100.0%
Failed pulpotomy	3	75.0%	1	25.0%	1	33.3%	2	66.7%	1	33.3%	2	66.7%	0	0.0%	2	100.0%
Unknown	2	100.0%	0	0.0%	2	100.0%	0	0.0%	2	100.0%	0	0.0%	1	100.0%	0	0.0%
Operator	Ch ² = 0.74				Ch ² = 0.47				Ch ² = 0.97				Ch ² = 0.33			
Master student	24	92.3%	2	7.7%	19	79.2%	5	20.8%	17	77.3%	5	22.7%	10	58.8%	7	41.2%
Paedodontist/ professor	10	90.9%	1	9.1%	8	88.9%	1	11.1%	6	75.0%	2	25.0%	2	40.0%	3	60.0%
General dentist working in a paediatric dental clinic	27	96.4%	1	3.6%	21	91.3%	2	8.7%	15	78.9%	4	21.1%	10	66.7%	5	33.3%
Number of visits	Ch ² = 0.55				Ch ² = 0.40				Ch ² = 0.34				Ch ² = 0.22			
One visit	56	93.3%	4	6.7%	44	84.6%	8	15.4%	35	76.1%	11	23.9%	22	61.1%	14	38.9%
Two visits	5	100.0%	0	0.0%	4	100.0%	0	0.0%	3	100.0%	0	0.0%	0	0.0%	1	100.0%
Posttreatment restoration	Ch ² = 1.00				Ch ² = 1.00				Ch ² = 0.99				Ch ² = 0.95			
SSC	60	93.8%	4	6.3%	47	85.5%	8	14.5%	37	77.1%	11	22.9%	21	58.3%	15	41.7%
Filling	1	100.0%	0	0.0%	1	100.0%	0	0.0%	1	100.0%	0	0.0%	1	100.0%	0	0.0%

Variable	1 y follow-up				2 y follow-up				3 y follow-up				4 y follow-up			
	Success		Failure		Success		Failure		Success		Failure		Success		Failure	
Tooth type	Ch ² = 0.12				Ch ² = 0.68				Ch ² = 0.66				Ch ² = 0.54			
2nd primary molar	50	96.2%	2	3.8%	39	86.7%	6	13.3%	30	78.9%	8	21.1%	18	62.1%	11	37.9%
1st primary molar	11	84.6%	2	15.4%	9	81.8%	2	18.2%	8	72.7%	3	27.3%	4	50.0%	4	50.0%
Radiograph	Ch ² = 0.62				Chi ² = 0.91				Chi ² = 0.80				Ch ² = 0.97			
Yes	54	94.7%	3	5.3%	42	85.7%	7	14.3%	32	76.2%	10	23.8%	20	58.8%	14	41.2%
No	1	100.0%	0	0.0%	1	100.0%	0	0.0%	1	100.0%	0	0.0%	0	0.0%	0	0.0%
X-ray older than 6 months	6	85.7%	1	14.3%	5	83.3%	1	16.7%	5	83.3%	1	16.7%	2	66.7%	1	33.3%
Type of radiograph	Ch ² = 0.05				Ch ² = 0.51				Ch ² = 0.70				Ch ² = 0.99			
Periapical x-ray	23	92.0%	2	8.0%	18	85.7%	3	14.3%	14	82.4%	3	17.6%	7	58.3%	5	41.7%
Panoramic x-ray	36	97.3%	1	2.7%	28	87.5%	4	12.5%	22	75.9%	7	24.1%	14	60.9%	9	39.1%
Panoramic x-ray half side	1	50.0%	1	50.0%	1	50.0%	1	50.0%	1	50.0%	1	50.0%	1	50.0%	1	50.0%
N/A	1	100.0%	0	0.0%	1	100.0%	0	0.0%	1	100.0%	0	0.0%	0	0.0%	0	0.0%
Coronal lesion	Ch ² = 0.95				Ch ² = 0.82				Ch ² = 0.60				Ch ² = 0.38			
Occlusal	9	100.0%	0	0.0%	8	100.0%	0	0.0%	8	100.0%	0	0.0%	7	87.5%	1	12.5%
Approximal two or three surfaces)	52	92.9%	4	7.1%	40	83.3%	8	16.7%	30	73.2%	11	26.8%	15	51.7%	14	48.3%

LA = Local Anesthesia
N₂O = Nitrous Oxide
GA = General Anesthesia
SSC = Stainless steel crowns
N/A = Not Assessed

6.2 Multivariate regression analysis

As an output of the multivariate regression analysis, low squared multiple R (0.22) and low adjusted squared multiple R (0.09) were calculated. Based on low squared multiple R and adjusted squared multiple R, the regression analyses showed no good fit. No statistical significance besides the variable “dmft” (0.017), “number of visits” (0.020) and coronal lesion (0.026) could be found (all above 0.05) (see Table 4).

Table 4: Results of the multivariate regression analysis of the outcome after 4 years

	Coefficients	Standard deviation	t-Statistic value	P-value
Intersection	-0.1059	1.6181	-0.0654	0.9480
Gender	-0.1041	0.2369	-0.4395	0.6614
Overall health condition of the patient	-0.9017	0.5246	-1.7188	0.0891
Treatment modality	0.0384	0.1785	0.2152	0.8301
Arch type	-0.1941	0.2644	-0.7342	0.4647
Age at day of treatment	0.0192	0.0996	0.1931	0.8473
dmft at day of treatment	0.0910	0.0375	2.4252	0.0173
Indication of treatment	-0.0497	0.1089	-0.4565	0.6491
Operator	0.2148	0.1446	1.4860	0.1408
Number of visits	1.2852	0.5423	2.3699	0.0199
Posttreatment restoration	-0.1163	0.4368	-0.2663	0.7906
Tooth type	-0.0864	0.3242	-0.2664	0.7905
x-ray available	0.0529	0.2239	0.2362	0.8138
Type of x-ray	0.1741	0.2402	0.7248	0.4705
Coronal lesion	0.8694	0.3852	2.2570	0.0264

7. Discussion

The study samples of both papers mirror the majority of patients to be expected in a specialized pediatric dental clinic like the Department of Preventive and Pediatric Dentistry at the University of Greifswald. This is also reflected by the distance most of these patients had to travel to get to the facility that ranged between 11-70 km for the vast majority of patients. Moreover, the addition of data obtained through telephone interviews to the descriptive analysis that displayed comparable success rates reduces the risk of selection bias as a result of loss of follow-up.

Age of the child at pulpectomy performed was found to have a statistically significant correlation one and two years posttreatment but not afterwards probably due to low sample size due to loss in follow-up. This finding, however, was in contrast to one study in the literature that failed to show an effect of age on the outcome at the one year follow-up period [Brustolin 2016].

Literature search reveals a general lack of studies looking into the potential impact of various treatment settings on the outcome of pulpectomy treatment in primary teeth; as to the best of our knowledge; only few other studies could be found in the literature regarding this topic.

One of the fastest and most efficient ways to achieve long term sustainable outcomes in young non-compliant children requiring extensive oral rehabilitation is under general anesthesia which significantly enhances the overall OHRQoL of those children [Boukhobza 2021; Jiang 2020] .

Pulpectomy treatments performed under general anesthesia were found to have the highest success rate among all other treatment settings at all subsequent follow-up periods as it was markedly high (78.6%) four years posttreatment. Due to the fact that treatments under general anesthesia require careful and comprehensive planning with more strict indications, usually only maintaining teeth with expected good prognosis to avoid potential postoperative complications that might necessitate further interventions. For the same reason, teeth with unpredictable prognosis such as those showing clinical and/or radiological signs of abscess or fistula are usually extracted during general anesthesia. Likewise, patients' cooperation is not required during treatments under general anesthesia enhancing the quality of the delivered treatment. In contrast, pulpectomy treatments delivered with the use of local anesthesia alone

showed the highest failure rates (65.3%) four years posttreatment; probably as a sequela of trying to retain each primary molar until their physiologic exfoliation considering that in the event of failure especially in cooperative children only a second dental intervention would be required such as extraction and not a second general anesthesia.

Slightly lower success rates were achieved with the use of nitrous oxide sedation combined with local anesthesia as opposed to general anesthesia indicating that nitrous oxide sedation can be an effective method in controlling a child's fear and anxiety by elevating the child's pain reaction threshold and reducing fatigue [Wright 2014]. Nitrous oxide sedation is helpful in making the child relax, eliminating sudden unwanted movements during treatments, making lengthy appointments more tolerable by the child ensuring optimum procedures [Wright 2014].

The treatment setting showed a statistical significance even three years posttreatment in the bivariate analysis; but at four years posttreatment; treatment setting failed to reach a statistical significant value. It is, however, still clinically relevant. One explanation could be the relatively small remaining sample size. The low sample size might have also influenced the fit of the treatment setting variable in the multivariate analysis resulting in the statistical non-significant correlation.

Another explanation for the clinical significance of the treatment setting is perhaps a combined reflection of general anesthesia and other expected prognosis. Whilst the risk of failure of pulpectomy treatments carried out with local anesthesia alone are well thought of, but are not considered as an absolute contraindication as the child can handle a second intervention like extraction in case of failure.

A recent study in the literature; as opposed to this study; failed to find a significant difference in the survival rate of primary teeth pulpectomy performed under general anesthesia and local anesthesia five years following treatment [Songvejkasem 2021]. Although this study is also retrospective in nature, but both anterior and posterior teeth were included in the analysis exclusively those with irreversible pulpitis or pulp necrosis with or without apical/ interradicular radiolucency, excluding those with signs of abscess or fistula. Unlike our study, all pulpectomized primary molars were included irrespective of the pretreatment condition of the pulp and/or periapical/radicular area. In the literature, it is believed that the main source of failure of the severely infected

teeth is the incapability to completely eradicate all pathogens from the dental pulp and root canal system [Cancio 2017; Chen Y, 2020]. Another difference is the diversity of the root canal filling materials used in the studies. Consequently, the above mentioned differences could have altered the outcome by acting as a cofounder making the results of the two analyses none comparable.

The impact of dental arch remained statistically significant even four years posttreatment in the bivariate analysis corresponding with the previous study likely as a result of the straightforward access and the ability to utilize direct vision of the operative field, making it easier to perform the required treatment. Also, maxillary primary molars exhibit an array of anatomical irregularities as having a double canal system especially in the mesiobuccal root [Fumes 2014] and the extreme divergence of the distobuccal root [Gaurav 2013]. As the distribution of the treatment setting among the upper and lower arch remains somewhat constant, a confounding of the factor arch on the treatment setting can most probably be ruled out.

Preventing postoperative leakage of the oral fluids into the shaped, cleaned and filled root canals in order to prevent reinfection and in turn failure of the pulpectomy treatment is of utmost importance. Thus, the choice of the posttreatment restoration plays a role in the success of the treatment. Stainless steel crowns are the ideal choice after pulp therapy [Lin 2021; Aksoy 2022], as they have long term clinical success, are very durable and easy to use [Dimitrov 2017]. Additionally, they are capable of reducing the risk of major failures more than fillings [Innes 2015] and show a very high survival probability of 98% four years after placement on second primary molars under general anesthesia [Azadani 2020]. Since almost all teeth except one were restored with a stainless steel crown following the pulpectomy treatment, these teeth reflect the overall success rate of the treatment and show that standard protocol in the department is really generally considered .

Tooth type failed to show a statistical significant effect on the outcome of the procedure, even though nearly all of the pulpectomized primary molars in this study were second primary molars. Similarly, this finding was consistent with another study in which tooth type did not show an effect on the outcome 18 months following treatment [Mendoza-Mendoza 2017]. But, the important role of second primary molars in guiding the eruption of the first permanent molars and preventing their mesial shift that leads to arch length loss and ultimately crowding is well recognized [Law 2013]. In

case of the early loss of second primary molar before the eruption of the first permanent molar, a fixed space maintainer with distal shoe can be used as an alternative in maintaining the arch length as an alternative. However, a study on the survival rate of fixed space maintainers carried out in the same department of this study showed unsatisfactory results, especially true for fixed appliances with distal shoe and was ~60% [Abdin 2021]. Consequently, maintaining second primary molars to act as natural space maintainers is crucial for preserving arch integrity preferably until their natural exfoliation.

Maintaining primary molars in young children through pulpectomy treatment must always be considered before extraction even with a moderate four years success of the procedure. With the eruption of the first permanent molars it will be feasible to place a space maintainer after extraction or even not necessary at all as the space will be preserved naturally if the opposing first permanent molars are locked in a balanced occlusion [Albati 2018].

7.1 Strengths

One of the important strengths of this study is the inclusion of all pulpectomized primary molars that were carried out in the department to not influence the outcome, unlike other studies in the literature that applied a much more strict inclusion criteria and excluded all teeth showing clinical signs of abscess or fistula [Pramila 2016; Al-Ostwani 2016].

The pulpectomy treatments in this study that were carried out by dentists with varying levels of academic qualifications along with master students, showed comparable success rates with no statistical significance among them, perhaps influenced by the use of calcium-hydroxide/iodoform paste as a root canal filling material with its antimicrobial property and ease of application. Nevertheless, this excludes an allocation bias of the more complex cases to the more experienced and specialized operators. This factor adds to the strengths of this study as in dental practices general dentists often treat children and not only specialized pediatric dentists.

7.2 Limitations

The type of this study being retrospective in nature should not be ignored as it has some limitations such as the inability to control external factors. Moreover the limited sample size especially in the long-term follow-up period is a draw-back. Larger number of patients are generally necessary in retrospective studies looking into the correlation between multiple factors and their possible impact on the outcome of specific procedure. Also, incomplete documentation is sometimes encountered leading to loss of important data that might affect the outcome.

Furthermore, success of pulpectomy treatment in this study was interpreted based on clinical assessment alone, while in the literature it is based on both clinical and radiological assessment [Boutsiouki 2021].

8. Conclusion

In the light of the importance of primary molars in maintaining the integrity of dental arches, pulpectomy treatments of primary teeth rather than extraction should always be the first choice.

Planning complex oral rehabilitation of young children under general anesthesia should also include pulpectomy treatments as a mean of preserving those teeth for as long as possible as it had shown high success rate even several years following treatment.

Even with the somewhat complicated anatomy of primary molars, especially those in the maxilla, pulpectomy treatments should be applicable even in general practice to avoid space loss in the molar region with the subsequent need for complex orthodontic treatments in the future.

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References

- Abdin M. Survival and failure of fixed space maintainers placed in different clinical settings: A 5 year retrospective analysis: Masterthesis. Greifswald, 2021.
- Ahmed HMA. Pulpectomy procedures in primary molar teeth. *European Journal of General Dentistry* 2014;(3)(1):3–10.
- Aksoy B, Güngör HC, Uysal S, Gonzales CD, Ölmez S. Ferric sulfate pulpotomy in primary teeth with different base materials: a 2-year randomized controlled trial. *Quintessence international* (Berlin, Germany 1985) 2022;0(0):2–9.
- Al-Attiya H, Mourad S, Splieth C H, Schmoeckel J: One year clinical success of pulpectomy in primary molars with iodoform-calcium hydroxide paste. *Quintessence Int* 2021;52:528–537; doi: 10.3290/j.qi.b1244443.
- Al-Attiya H, Mourad S, Splieth C H, Schmoeckel J: Influence of treatment setting on success of pulpectomy in primary molars: a retrospective analysis up to 4 years. *Quintessence Int* 2022;53:2–11.
- Albati M, Showlag R, Akili A, Hanafiyyah H, AlNashri H, Aladwani W et al. Space maintainers application, indication and complications. *Int J Community Med Public Health* 2018;5(11):4970.
- Al-Ostwani AO, Al-Monaqel BM, Al-Tinawi MK. A clinical and radiographic study of four different root canal fillings in primary molars. *Journal of the Indian Society of Pedodontics and Preventive*
- Azadani EN, Peng J, Kumar A, Casamassimo PS, Griffen A, Amini H et al. A survival analysis of primary second molars in children treated under general anesthesia. *Journal of the American Dental Association* (1939) 2020;151(8):568–575.
- Boukhobza S, Stamm T, Glatthor J, Meißner N, Bekes K. Changes in oral health-related quality of life among Austrian preschool children following dental treatment under general anaesthesia. *Clinical oral investigations* 2021;25(5):2821–2826.
- Boutsiouki C, Frankenberger R, Krämer N. Clinical and radiographic success of (partial) pulpotomy and pulpectomy in primary teeth: A systematic review. *European journal of paediatric dentistry* 2021;22(4):273– 285.

Brustolin JP, Mariath AA, Ardenghi TM, Casagrande L. Survival and Factors Associated with Failure of Pulpectomies Performed in Primary Teeth by Dental Students. *Braz Dent J*. 2017 Jan-Feb;28(1):121-128. doi: 10.1590/0103-6440201601009. Epub 2016 Dec 12. PMID: 28301009.

Cancio V, Carvalho Ferreira Dd, Cavalcante FS, Rosado AS, Teixeira LM, Braga Oliveira Q et al. Can the *Enterococcus faecalis* identified in the root canals of primary teeth be a cause of failure of endodontic treatment? *Acta odontologica Scandinavica* 2017;75(6):423–428.

Chen KJ, Gao SS, Duangthip D, Lo ECM, Chu CH. Prevalence of early childhood caries among 5-year-old children: A systematic review. *Journal of investigative and clinical dentistry* 2019;10(1):e12376.

Chen X, Liu X, Zhong J. Clinical and radiographic evaluation of pulpectomy in primary teeth: an 18-months clinical randomized controlled trial. *Head Face Med* 2017;13:12.

Chen Y, Li H, Li M, Yang L, Sun Q, Chen K. Analysis of survival and factors associated with failure of primary tooth pulpectomies performed under general anaesthesia in children from South China. *International journal of paediatric dentistry* 2020;30(2):225–233.

Dimitrov E, Georgieva M, Dimova-Gabrovska M, Andreeva R, Belcheva-Krivorova A. Preformed metal crowns as a prosthetic restorations in pediatric dentistry. *JofIMAB* 2017;23(3):1627–1632.

Fumes AC, Sousa-Neto MD, Leoni GB, Versiani MA, da Silva LAB, da Silva RAB et al. Root canal morphology of primary molars: a micro-computed tomography study. *European archives of paediatric dentistry official journal of the European Academy of Paediatric Dentistry* 2014;15(5):317–326.

Gaurav V, Srivastava N, Rana V, Adlakha VK. A study of root canal morphology of human primary incisors and molars using cone beam computerized tomography: an in vitro study. *Journal of the Indian Society of Pedodontics and Preventive Dentistry* 2013;31(4):254–259.

Innes NPT, Ricketts D, Chong LY, Keightley AJ, Lamont T, Santamaria RM. Preformed crowns for decayed primary molar teeth. *The Cochrane database of systematic reviews* 2015(12):CD005512.

Jiang H-F, Qin D, He S-L, Wang J-H. OHRQoL changes among Chinese preschool children following dental treatment under general anesthesia. *Clinical oral investigations* 2020;24(6):1997–2004.

Kher MS, Rao A. Pulp therapy in primary teeth. *Clin Dent Rev* 2020;4(1):340.

Law CS. Management of premature primary tooth loss in the child patient. *Journal of the California Dental Association* 2013;41(8):612–618.

Lin GSS, Hisham ARB, Ch Er CIY, Cheah KK, Ghani NRNA, Noorani TY. Success rates of coronal and partial pulpotomies in mature permanent molars: a systematic review and single-arm meta-analysis. *Quintessence international (Berlin, Germany 1985)* 2021;0(0):0.

Lokade A, Thakur S, Singhal P, Chauhan D, Jayam C. Comparative evaluation of clinical and radiographic success of three different lesion sterilization and tissue repair techniques as treatment options in primary molars requiring pulpectomy: An in vivo study. *Journal of the Indian Society of Pedodontics and Preventive Dentistry* 2019;37(2):185–191.

Mendoza-Mendoza A, Caleza-Jiménez C, Solano-Mendoza B, Iglesias-Linares A. Are there any differences between first and second primary molar pulpectomy prognoses? A retrospective clinical study. *European journal of paediatric dentistry* 2017;18(1):41–44.

Monte-Santo AS, Viana SVC, Moreira KMS, Imparato JCP, Mendes FM, Bonini GAVC. Prevalence of early loss of primary molar and its impact in schoolchildren's quality of life. *International journal of paediatric dentistry* 2018;28(6):595–601.

Pramila R, Muthu MS, Deepa G, Farzan JM, Rodrigues SJL. Pulpectomies in primary mandibular molars: a comparison of outcomes using three root filling materials. *International endodontic journal* 2016;49(5):413–421.

Rewal N, Thakur AS, Sachdev V, Mahajan N. Comparison of endoflas and zinc oxide eugenol as root canal filling materials in primary dentition. *Journal of the Indian Society of Pedodontics and Preventive Dentistry* 2014;32(4):317–321.

Songvejkasem M, Auychai P, Chankanka O, Songsiripradubboon S. Survival rate and associated factors affecting pulpectomy treatment outcome in primary teeth. *Clinical and experimental dental research* 2021;7(6):978–986.

Tinanoff N, Baez RJ, Diaz Guillory C, Donly KJ, Feldens CA, McGrath C et al. Early childhood caries epidemiology, aetiology, risk assessment, societal burden, management, education, and policy: Global perspective. *International journal of paediatric dentistry* 2019;29(3):238–248.

Wagner Y, Knaup I, Knaup TJ, Jacobs C, Wolf M. Influence of a programme for prevention of early childhood caries on early orthodontic treatment needs. *Clinical oral investigations* 2020.

Wright GZ. *Behavior management in dentistry for children*. Ames, Iowa: John Wiley & Sons Inc, 2014.