MACEDONIAN DENTAL REVIEW

ISSN 2545-4757 | 4 46 2023

Macedonian Dental Review is publishing by the Faculty of Dentistry, University „Ss. Cyril and Methodius“, Skopje, Republic of North Macedonia and Macedonian Dental Society

http://stomfak.ukim.edu.mk/msp/

MACEDONIAN DENTAL REVIEW **Contents**

2023 ● Year **XXXXVI** ● Nummber 4 ● стр. 109-142

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Adress - Macedonian Dental Review, str. Majka Tereza br. 43 Skopje, Republic of North Macedonia, **http://stomfak.ukim.edu.mk/msp/**

МАКЕДОНСКИ СТОМАТОЛОШКИ ПРЕГЛЕД **Содржина**

2023 ● година **XXXXVI** ● Број 4 ● Страна 109-142

Македонски стоматолошки преглед го издава Стоматолошкиот факултет при Универзитетот „Св. Кирил и Методиј“ Скопје, Република Северна Македонија и Македонското стоматолошко друштво.

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UDK: 616.314.16-089.87

ASSESSMENT OF POSTOPERATIVE MORBIDITY AND ROOT MIGRATION IN APPLICATION OF THE METHOD OF CORONECTOMY

ПРОЦЕНКА НА ПОСТОПЕРАТИВЕН МОРБИДИТЕТ И КОРЕНСКА МИГРАЦИЈА ПРИ ПРИМЕНА НА МЕТОДОТ НА КОРОНЕКТОМИЈА

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Abstract

Background: Extraction of the impacted mandibular third molar represents a complicated surgical intervention due to the position of the inferior alveolar nerve and is often accompanied by postoperative neurosensory deficit. The risk of changing sensitivity is significantly lower when performing coronectomy, as a technique for conventional surgical extraction and prevention of potential neuropathy. **Aim:** The presented paper focuses on the importance of using coronectomy as an alternative surgical technique, due to its demonstrated efficacy in cases with high risk of nerve injury, in order to achieve good clinical results and minimize possible sudden complications. **Materials and methods:** The research sample includes a total of 30 patients who were diagnosed with presence of an impacted mandibular third molar in close relation to the mandibular canal, according to the clinical examination and radiological evaluation using cone beam computed tomography (CBCT) and conventional radiography. The sample is divided into two groups: control group (15 patients) in which a conventional operative extraction of an impacted lower third molar will be performed, and the other experimental group (15 patients) where the method of coronectomy was performed. **Results:** The mean follow-up time was 12 months for the experimental group of patients (where coronectomy was performed), and a mean root migration of 2.52±0.46 was observed. Regarding the postoperative complications, one patient with IAN injury and paresthesia was observed in the control group, which disappeared within one month, while in the group of coronectomy none of the patients have been diagnosed with this injury. For $p>0.05$, no significant differences were determined between two groups, regarding swelling. While for $p<0.05$, pain intensity in patients in control group was significantly higher compared to the patients in experimental group. **Conclusion:** Coronectomy can be considered a safe treatment alternative for patients who demonstrate elevated risk for injury to the inferior alveolar nerve with removal of the third molars. Coronectomy does not increase the incidence of damage to the inferior alveolar nerve and would be safer than complete extraction in situations in which the root of the mandibular third molar overlaps or is in close proximity to the mandibular canal. **Key words:** coronectomy, impaction, mandibular third molar, inferior alveolar nerve, CBCT.

Апстракт

Вовед: Екстракцијата на импактиран мандибуларен трет молар претставува комплицирана хируршка интервенција поради положбата на долниот алвеоларен нерв и често е придружена со постоперативен неуросензитивен дефицит. Ризикот од промена на чувствителноста на нервот е значително помал при изведување на коронектомија, како техника за конвенционална хируршка екстракција и спречување на потенцијална неуропатија.**Цел:** Презентираниот труд се фокусира на предноста на спроведување на коронектомија како алтернативна хируршка техника, поради нејзината покажана ефикасност во случаи со висок ризик од повреда на нервот, со цел да се постигнат добри клинички резултати и да се минимизираат можните ненадејни компликации.**Материјал и метод:** Истражувачкиот примерок вклучува вкупно 30 пациенти на кои им е дијагностицирано присуство на импактиран мандибуларен трет молар во блиска кореација со мандибуларниот канал, според клиничкиот преглед и радиолошката евалуација со помош на компјутерска томографија со конусен зрак (CBCT) и конвенционална радиографија. Примерокот е поделен во две групи: контролна група (15 пациенти) во која се реализира конвенционална оперативна екстракција на импактиран мандибуларен трет молар и другата експериментална група (15 пациенти) каде е спроведена методата на коронектомија. **Резултати:** Просечното време на следење беше 12 месеци за експерименталната група на пациенти (каде беше реализирана коронектомија), а беше регистрирана просечна вредност на миграција на коренот од 2,52±0,46. Во однос на постоперативните компликации, во контролната група е регистриран еден пациент со повреда на долен алвеоларен нерв и парестезија, која исчезнала во рок од еден месец, додека во групата на коронектомија на ниту еден од пациентите не им била дијагностицирана оваа повреда. За $p>0,05$ не беа утврдени значајни разлики помеѓу две групи за отокот. Додека за $p<0,05$, интензитетот на болката кај пациентите во контролната група беше значително повисок во споредба со пациентите во експерименталната група. **Заклучок:** Коронектомија може да се смета за безбедна алтернатива за третман за пациенти кои покажуваат зголемен ризик за повреда на долниот алвеоларен нерв при екстракција на третиот мандибуларен молар. Коронектомијата не ја зголеми инциденцата на оштетување на долниот алвеоларен нерв и би била побезбедна метода од целосната екстракција на забот, во ситуации во кои коренитe на третиот мандибуларен молар се во непосредна близина со мандибуларниот канал. **Клучни зборови:** коронектомија, импакција, мандибуларен трет молар, долен алвеоларен нерв, CBCT.

Introduction

Impacted teeth are fully formed in the jawbone but have not yet erupted in their place, or anywhere else on the dental arch, due to disruption of the eruptive process. The impaction of third mandibular molars is followed by the appearance of pathological conditions, with different degrees of severity. Therefore, this imposes the need for a radical therapeutic approach, i.e. their surgical extraction.

The most common and severe complications of third molar extraction surgery include dry socket, postoperative infection, alveolar bone fracture, damage of inferior alveolar nerve or lingual nerve and, in rare cases, mandibular fracture. Therefore, intentional coronectomy is a well-established technique where the root/roots of the wisdom tooth are left in situ and only the crown is sectioned and removed (odontectomy). This technique was proposed by Knuttson K.[1] in 1989, as an alternative method for preserving the inferior alveolar nerve (IAN). The method aims to remove only the crown of the tooth, leaving the root intact in the alveolus in situ, Leung Y. et al.[2] This procedure has been proven to be effective at reducing the risk of mandibular third molar surgery, but it has its own complications[3]. According to Rezai F. et al.[4] the disadvantages of this technique include: creation of deep periodontal pockets on the distal surface of the second molar, migration of the root with the eventual need for a second surgical procedure (reoperation), occurrence of alveolitis, local postoperative wound infection, postoperative pain, accidental removal of the root, which may increase the risk of injury to the contents of the mandibular canal.

By applying certain radiological modalities, the ratio of the root complex of the impacted tooth and the mandibular bone canal are precisely detected. CBCT is used in implantology, oral and maxillofacial surgery, orthodontics, endodontics. CBCT is an appropriate method in the case when the ratio of the roots of the impacted mandibular third molar with the contents of the mandibular canal, as well as other adjacent anatomical structures, needs to be visualized in a three-dimensional view[5,6].

Material and methods

The research sample in our study includes a total of 30 patients who were diagnosed with an impacted mandibular third molar in close proximity to the mandibular canal, according to the clinical examination and the radiological evaluation using cone beam computed tomography (CBCT) and conventional orthopantomography. Based on the American Society of Anesthesiologists criteria, our patients belong to the following group: ASA I (normal, healthy patients) and ASA II (patients with moderate systemic disease, such as: smokers, pregnant women, obesity (30<BMI (body mass index)<40), moderate lung disease)[7]. The sample was divided into two groups: one group (15 patients) where the method of coronectomy was applied, and the other control group (15 patients) in which a conventional operative extraction of an impacted lower third molar was performed. All the procedures were performed by the same surgeon using the same approach. For CBCT and conventional orthopantomogram imaging, CS 8100 3D was used, imaging was performed in the radiographic cabinet “Mintas", Tetovo. (Figure 1 and Figure 2).

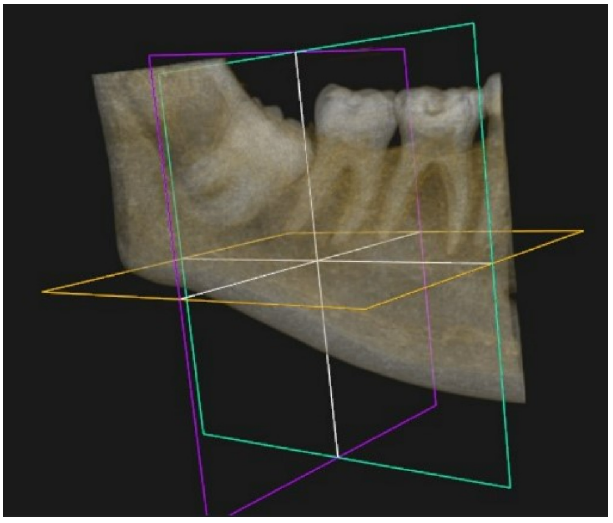


Figure 1. *CBCT of impacted molar 48*

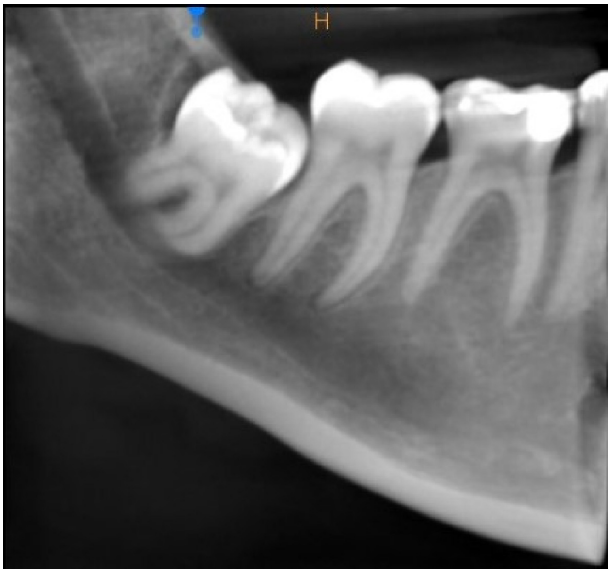


Figure 2. *CBCT of impacted molar 48*

The planned therapeutic procedure is implemented following the basic surgical principles in relation to the conventional surgical extraction and the coronectomy method, i.e. surgical principles for work in soft and bony tissue. Regarding the surgical technique of coronectomy we follow the steps below: to achieve a painless area, a local block anesthesia is applied for n.alveolaris inferior, n.lingualis and n.buccalis, with 2% mepivacaine hydrochloride with 1:20000 levonordefrin; then a full thickness mucoperiosteal incision is elevated with a buccal release; a conservative buccal trough is created using a round carbide bur on a surgical handpiece to allow access to the cementoenamel junction of the tooth; we take care to maintain as much crestal bone height as possible by minimising the width of the buccal trough; after exposing the teeth, a round carbide bur is used to make a 45^{o} cut through the tooth at the level of the cementoenamel junction; the crown is delicately fractured and separated from the residual roots of the tooth; the remaining enamel is typically reduced approximately 2 mm below the buccal crest of the alveolar bone; the surgical wound is closed primarily (Figure 3, Figure 4, Figure 5 and Figure 6). Patients were subject to clinical and radiological evaluation in an observation period of 6 and 12 months following the surgical intervention.

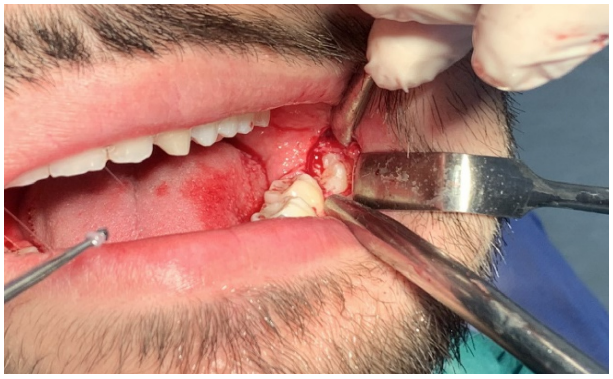


Figure 3. *Elevation of mucoperiostal lambo*

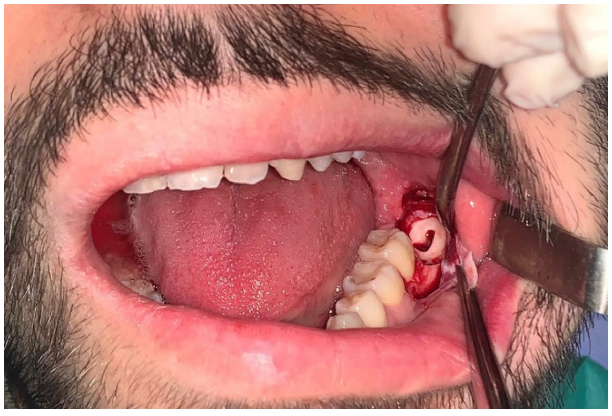


Figure 4. *Sectioning of the crown*

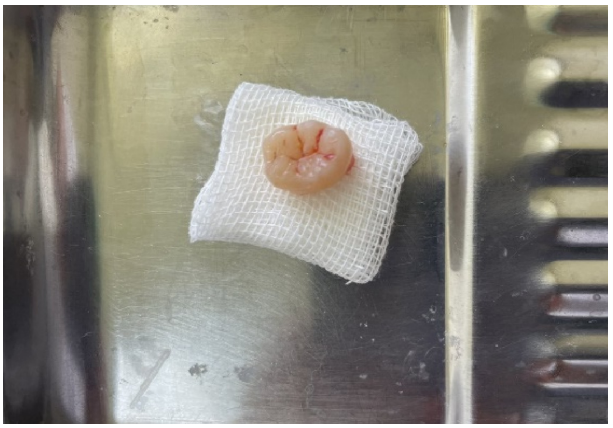


Figure 5. *Full crown removal*

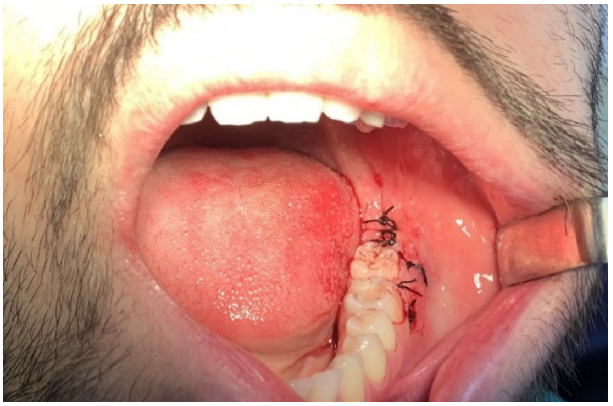


Figure 6. *Surgical wound closed primarly*

Exclusion criteria from the study:

- Horizontally placed impacted mandibular third molar (along the direction of extension of the mandibular canal) where there is a high risk of injury to the inferior alveolar nerve during tooth separation.
- Acute infection present in the oral cavity or in the close area of the tooth - subject to coronectomy.

Early postoperative observation of the patients includes a control examination on the first, third and seventh day after the surgical intervention. The subject of analysis is the clinical expression of postoperative morbidity, with special emphasis on the IAN injury, intensity of postoperative pain (VAS scale), and assessment of postoperative swelling (facial reference points).

Pain assessment – will be realized through a horizontal VAS scale to determine the intensity of pain from 1 to 10 by the patient on the first, third and seventh day postoperatively Kaczmarzyk T. et al.[8] (figure 7).

Assessment of swelling – measuring the distance of certain points in the face, tragus (point A), labial commissure (point C), pogonion (point D), lateral angle of

the eye (point B) and angle of the mandible (point E), with flexible splint on the first, third and seventh day postoperatively, Essam Ahmed Al-Moraissi et al.[9] (figure 8)

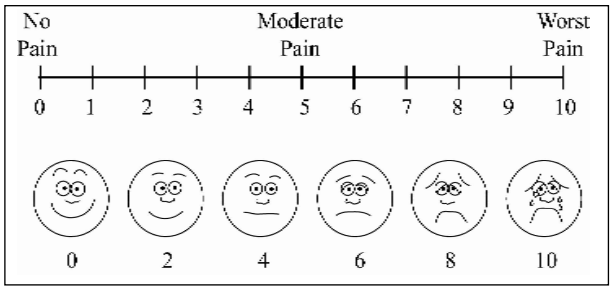


Figure 7. *VAS scale – intensity of pain*

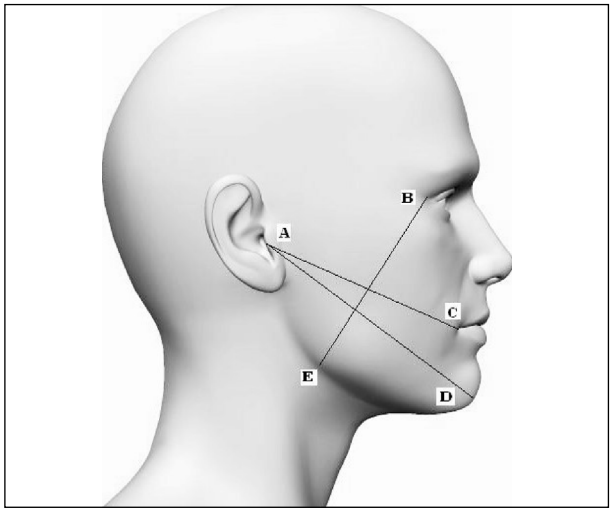


Figure 8. *Facial reference points for swelling measurement*

The radiographic analysis of root migration in patients who have undergone coronectomy was performed on the 6-th and 12-th month-period after the intervention (Figure 9 and Figure 10).

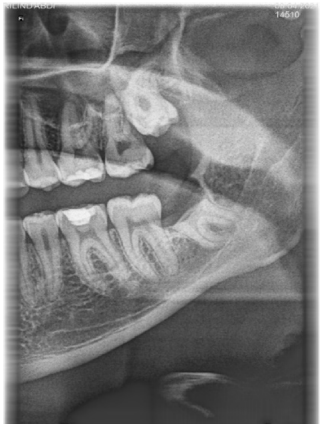


Figure 9. *Immediately after coronectomy*

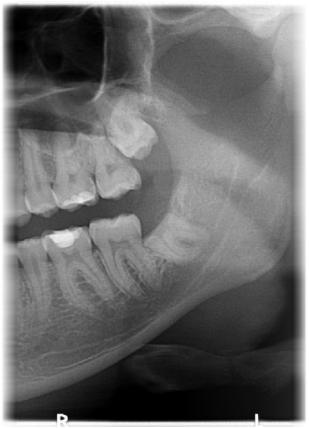


Figure 10. *Root migration after 12 months*

Statistical analysis

The data obtained during the research were statistically processed using the SPSS software package, version 22.0 for Windows (SPSS, Chicago, IL, USA). The analysis of the attributive (qualitative) series was done by determining the coefficient of relationships, proportions and ratios, and they were shown as absolute and relative numbers. Numerical (quantitative) series were analyzed using measures of central tendency (average, median, minimum values, maximum values), as well as measures of dispersion (standard deviation). Shapiro-Wilk W test was used to determine the normality of the frequency distribution of the studied variables. The Wilcoxon Signed Ranks Test was used to test the significance of the difference between two dependent parameters with irregular frequency distribution. The Mann-Whitney U Test was used to determine a statistically significant difference between two independent quantitative parameters with irregular frequency distribution. A two-tailed analysis with a significance level of $p<0.05$ was used to determine statistical significance.

Results

Data of post-operative complications of the group with conventional extraction of the third mandibular molar, and from a 12 month follow-up period of patients with impacted mandibular third molar treated with coronectomy technique were collected. The assessment and evaluation of all cases were done by the same surgeon who performed the operation. Each patient was reviewed, and information on postoperative complications, such as pain, swelling, IAN injury and migration of the root was collected.

The distribution of the Experimental Group (EG), from 15 (100%) patients, according to gender, indicated the presence of 5 (33.33%) males and 10 (66.67%) females with a

Table 1. Analysis of groups according to gender

Groups	Gender			1p
	EG	CG	Total	
Male	5 (33,33%)	8 (53,33%)	15 (50%)	X^2=1,221; df=1; p=0,2691
MaleFemale	10 (66,67%)	7 (46,67%)	15 (50%)	

EG=Experimental Group; CG=Control Group; [1]Pearson Chi-square test; *significant for p<0,05

Table 2. Analysis of groups by age (years)

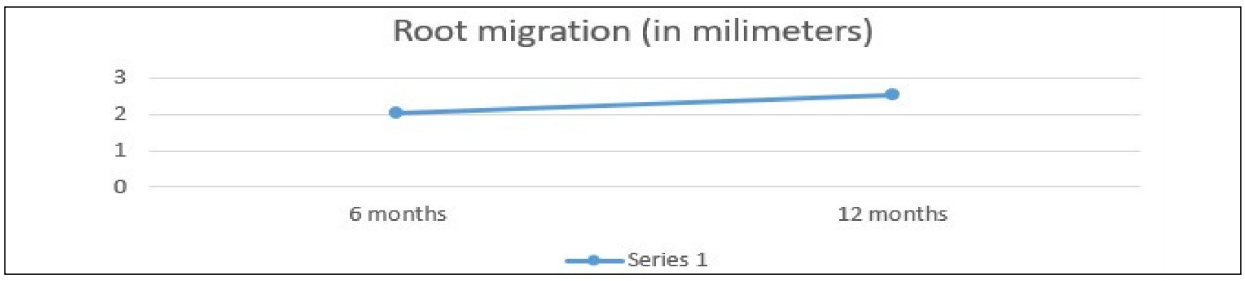
Age (years)		Statistic	Std. Error	95% Confidence Interval for Mean	
				Lower	Upper
Experimental Group (EG)	**Total**				
	Number (N)	15	1.32	24.17	29.83
	Mean ±SD	27,01±5,11			
	Min/ Max	19/36			
	Median (IQR)	28 (22-30)			
Control Group (CG)	**Total**				
	Number (N)	15	1.25	23.65	29.01
	Mean ±SD	26,33±4,83			
	Min/ Max	19/34			
	Median (IQR)	6 (22-31)			

EG/CG: Mann-Whitney U Test: Z=0,269; p=0,7875
*significant for p<0,05

gender ratio of 0.5:1. In the Control Group (CG), out of 15 (100%) male patients were 8 (53.33%), and 7 (46.67%) female patients with a gender ratio of 1.1:1. For p>0.05, no significant association was determined between gender and the group to which the respondents belong for the consequent Pearson Chi-square test: X2=1.221; df = 1; p=0.2691 (Table 1).

The mean age of EG patients was 27.01±5.11 [95% CI (24.2–29.3)] years with a min/max age of 19/36 years (Table 2). The analysis indicated that 50% of respondents in the EG were younger than 28 years for Median (IQR)=28 (22-30). Among CG subjects, the mean age was 26.33±4.83 [95% CI (23.6 – 29.0)] years, with a min/max age of 19/34, and 50% of subjects younger than 26 years for Median (IQR)=26 (22-31). The analysis indicated that for p>0.05, there was no significant difference between the patients of the two groups in terms of age (Mann-Whitney U Test Z=0.269; p=0.7875).

Root migration was evaluated by comparing the original root position with that after 6 and 12 months. The analysis of migration in the experimental group indicated that after 6 months its average value was 2.03±0.38mm, and after 12 months it was 2.52±0.46mm (Graph.1). For p<0.05, a significant difference was determined between the two points in time (6 and 12 months), regarding the migration in the EG, in addition to a significantly higher value after 12 months (Wilcoxon Matched Pairs Test: Z=3.407; p=0.0006)



Graph 1. *Average root migration in 6 months and 12 months after the surgery*

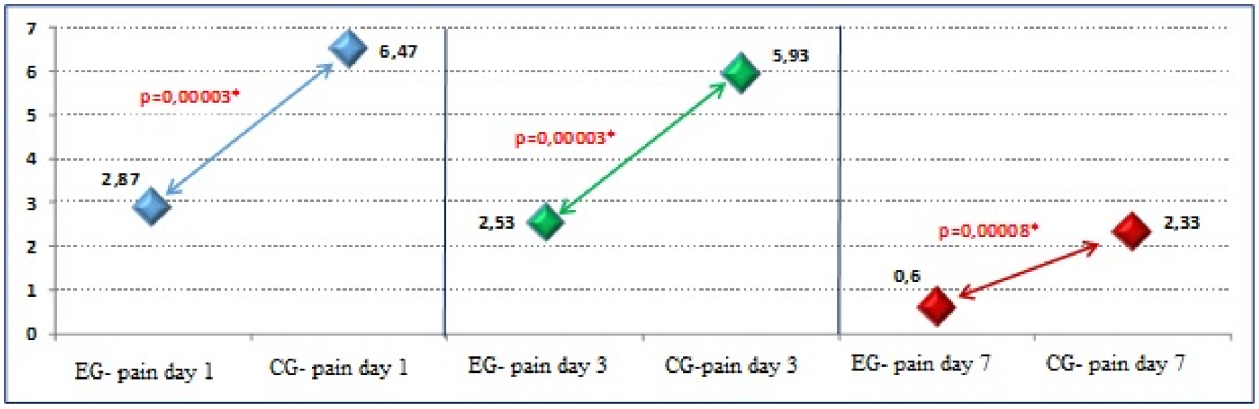
The average pain of the patients was evaluated on a scale from 1 to 10. The analysis indicated that for (Table 3 and Graph 2):

- **day 1** - the average pain intensity was as follows: a) EG -2.87±0.91 with a min/max intensity of ¼, and 50% of patients in whom the pain was greater than 3 for Median (IQR)= 3 (2-4); and in b) CG -6.47±1.3 with a min/max intensity of 5/9, and 50% of patients in whom the pain was greater than 6 for Median (IQR)=6 (5-8); For p<0.05, pain intensity in patients in CG was significantly higher compared to the same in patients in EG (Mann-Whitney U Test: Z=-4.655; p=0.00003).
- **day 3** - the average pain intensity was as follows: a) EG - 2.53±0.74 with a min/max intensity of ¼, and 50% of patients in whom the pain was less than 3 for Median (IQR)= 3 (2-4); and in b) CG – 5.93±1.0 with a min/max intensity of 5/8, and 50% of patients whose pain was less than 6 for Median (IQR)=6 (5-7); For p<0.05, pain intensity in patients in CG was significantly higher compared to the same in patients in EG (Mann-Whitney U Test: Z=-4.666; p=0.00003).
- **day 7** - the average pain intensity was as follows: a) EG – 0.60±0.51 with a min/max intensity of 0/1, and 50% of patients in whom the pain was less than 1 for Median (IQR)=1(0-1); and in, b) KG -2.33±1.0 with a min/max intensity of ¼, and 50% of patients whose pain was less than 2 for Median (IQR)=2 (1-3); For p<0.05, pain intensity in patients in CG was significantly higher compared to the same in patients in EG (Mann-Whitney U Test: Z=-3.919; p=0.00003).

Table 3. Comparison of groups according to pain for three periods

Pain	Number (N)	Mean	Standard Deviation (SD)	Min	Max	Median IQR	1p
Pain day 1							
EG	15	2.87	0.91	1	4	3 (2-4)	Z=-4.655; **p=0.00003***
CG	15	6.47	1.30	5	9	6 (5-8)	
Pain day 3							
EG	15	2.53	0.74	1	4	3(2-3)	Z=-4.666; **p=0.00003***
CG	15	5.93	1.03	5	8	6(5-7)	
Pain day 7							
EG	15	0.60	0.51	0	1	1(0-1)	Z=-3.919; **p=0.00008***
CG	15	2.33	1.04	1	4	2(1-3)	

EG=Experimental group; CG=Control group; [1]Z=Mann-Whitney U Test;
*significant for p<0,05

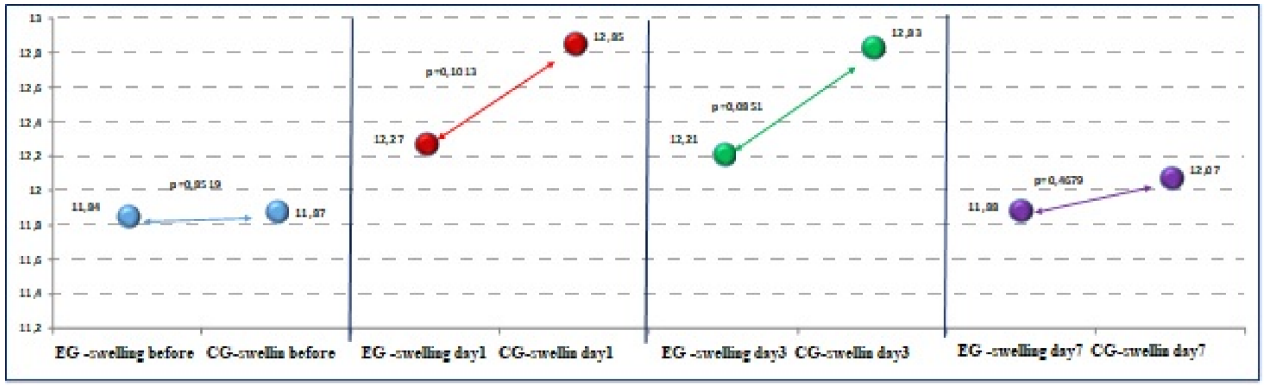


Graph 2. *Comparison of groups according to pain for three periods*

Table 4. Comparison of groups according to swelling for four periods

Swelling	Number (N)	Mean	Standard Deviation (SD)	Min	Max	Median IQR	1p
Swelling before operation (cm)							
EG	15	11.84	1.01	10.5	13.1	11.9 (10.7-12.9)	Z=-0.187; p=0.8519
CG	15	11.87	1.06	10.3	13.3	12.2 (10.8-12.9)	
Swelling day 1 (cm)							
EG	15	12.27	1.07	10.8	13.5	12.7 (11.1-13.3)	Z=-1.638; p=0.1013
CG	15	12.85	1.10	11.0	14.1	13.1 (11.9-13.9)	
Swelling day 3 (cm)							
EG	15	12.21	1.03	10.8	13.5	12.4 (11.1-13.2)	Z=-1.721; p=0.0851
CG	15	12.83	1.10	11.2	14.1	12.9 (11.9-13.9)	
Swelling day 7 (cm)							
EG	15	11.88	1.01	10.5	13.1	12.0 (10.8-12.9)	Z=-0.726; p=0.4679
CG	15	12.07	1.06	10.5	13.5	12.4 (11.0-13.1)	

EG=Experimental group; CG=Control group; [1]Z=Mann-Whitney U Test;
*significant for p<0,05



Graph 3. *Comparison of groups according to swelling for four periods*

The comparison of the size of the swelling between EG and CG indicated that in none of the four analysed periods (before surgery, on day 1, day 3, and day 7), for p>0.05, no significant difference was determined between the two groups. The analysis shows that in each of the three analysed periods after surgery (day 1, day 3, and day 7) the size of the swelling in the EG was insignificantly smaller compared to the one in CG (Table 4 and Graph 2).

Discussion

Coronectomy is a reasonable alternative procedure for reducing the risk of inferior alveolar nerve injury when the lower third molar roots are in close proximity to the IAN. Our finding is compatible with the conclusion of Geisler S.[10], Long H.[11], Monaco G.[12] and Quek Sl.[13] who consider coronectomy a safe treatment for patients who demonstrate an elevated risk of IAN injury with the removal of third molars.

Agbaje et al.[14] found out that the incidence of impacted mandibular third molar with close proximity to the IAN in this series was slightly higher in females, with a male to female ratio of 1:1.3. Similar to Agbaje, the result for the gender ratio in our study was 0.5:1 which shows a higher incidence of impacted third mandibular molars with close proximity to the IAN in females compared to males.

The reduction in the incidence of injury to the inferior alveolar nerve, found in our study, is in agreement with Renton et al.[14]. His results show that coronectomy preserves the damage of inferior alveolar nerve. The surgical skill of the operator has been indicated to be one of the main risk factors for developing permanent sensory dysfunction in the distribution of the IAN after coronectomy, Jerjes W. et al[15], Bataineh AB[16].

After coronectomy and complete mandibular third molar extraction, except IAN injury, morbidity includes pain. The comparison of pain between the experimental and the control group in the first, third and seventh day after surgery, based on VAS measurement, show significantly lower pain intensity in patients with performed coronectomy, the difference is 1:2. Leung Y. and Cheung L.[2] registered more patients with pain after complete removal of impacted third molar than after coronectomy. The studies are not homogeneous about pain, because some authors like Hatano Y.[21], Cilasun U.[22], reported increased pain in patients who underwent coronectomy versus complete extraction.

Our study aimed to determine the migration of the remaining roots after coronectomy. We obtained radiography analysis 6 and 12 months after the coronectomy, to observe whether root migration or inflammatory changes have occurred. In the studies of Gady J[17], Patel V.[18] migration of the roots has been reported as the most common situation for a long-term follow up of patients after coronectomy. This situation is confirmed by our findings too (Graph.1). We found out that analysis of root migration in experimental group indicated an average value of 2.03±0.38 mm after 6 months, and 2.52±0.46 mm after 12 months. We registered that the greatest migration occurred 6 months after coronectomy compared to the radiography analysis after 12 month follow-up. Our results are similar to Simons RN.[23] where the mean root migration was 2.53 mm 6 months after coronectomy .

We found out that the migration of the remaining roots was affected by the impaction depth and migration pattern, while it was not affected by gender, as mentioned above. Radiography analysis of our study showed that deeper impaction was associated with new bone forming above the cut surface, followed by less migration. Our finding correlates with Yan et al[24], Kouwenberg et al[25] who found that impaction depth affected root migration. Regarding migration pattern, an important moment, according to Hanisch M. et al.,[20] is that the migration mechanism is based on the removal of mechanical interferences along the eruption path.

According to these studies, our opinion is that a 12 month follow-up is sufficient for evaluating root migration and deciding whether a root removal is necessary in order to avoid extensive surgery.

Conclusions

The results indicate that coronectomy can be a safe treatment alternative for patients who show elevated risk for injury to the inferior alveolar nerve with removal of the mandibular third molar. Coronectomy, as a surgical technique, has fewer complications compared to complete extraction, in situations where the roots of the mandibular third molars are in close proximity to the mandibular canal.

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COMPREHENSIVE ORTHODONTIC TREATMENT IN GROWING PATIENT WITH EXTRACTED UPPER CENTRAL INCISOR

СОВРЕМЕН ОРТОДОНТСКИ ТРЕТМАН КАЈ ПАЦИЕНТИ ВО РАСТ СО ЕКСТРАХИРАН ГОРЕН ЦЕНТРАЛЕН ИНЦИЗИВ

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Abstract

In everyday orthodontic practice, patients with missing central upper incisor or the ones whose central upper incisor needs to be extracted are occasional. Having in mind that most of the orthodontic patients are children who are growing and by influencing the smile esthetics, the orthodontist is influencing general quality of life itself. Therefore, it is clear that these cases are as challenging as can be. Few treatment options are possible, but single osteointegration implant and orthodontic space closure with bringing the lateral incisor in the extracted area are the most popular. The aim of this case report is to present space closure in the upper front area as an evidence-based treatment option that should be considered as first alternative in growing patients as it reduces the invasiveness of the subsequent restorative treatment, offering long-term periodontal health and optimal aesthetic and functional results.

Апстракт

Во секојдневната ортодонтска пракса, чести се пациентите со хиподонцијана горен централен инцизив или ониекаде постои индикација за екстракција. Имајќи во предвид дека најголем дел од ортодонтските пациенти се деца во фаза на активен раст,со делувањето на естетиката на насмевката, ортодонтот влијае и на општиот квалитет на животот, па јасно е дека овие клинички случаи се најпредизвикувачки. Во вакви случаеви постајат повеќе опции за третман меѓу коикако најпопуларни се поставување на остеоинтегрирачки имплант и ортодонтско затворање на просторот со доведување на латералниот инцизив во екстакциониот простор. Целта на овој приказ на случај е да се презентира затворањето на простор во горниот антериорен сегмент како опција за третман базирана на докази која треба да се смета како прва алтернатива кај пациенти во раст бидејќи ја намалува инвазивноста на последователниот реставративен третман, нуди долгорочно пародонтално здравје и оптимални естетски и функционални резултати.

Introduction

Years ago, the goal of orthodontic treatment was to achieve "ideal" occlusal relationship. According to E. Angle and his followers, maintaining an intact dentition and ideal occlusion was the only way to achieve best aesthetic. Nowadays, the goals of orthodontic treatment have changed. Today, the focus is on facial proportion and the impact of dentition on facial appearance[1].

People with more attractive face are perceived to have higher athletic, social and leadership skills[2] and it has been found that the eyes and the mouth where the most important factors in a hierarchy of characteristics for determining facial beauty[3]. On the other hand, there are several studies who have demonstrated that maxillary central incisors can be the most important factor influencing the perception of smile aesthetic[4]. Consequently, when orthodontist is treating a patient whose maxillary central incisor is/or needs to be extracted, he is facing one of the biggest challenges.

Cases where maxillary central incisor is missing or needs to be extracted are occasional in orthodontic practice. When they are malformed, dilacerated, irreparably fractured or associated with local pathology, extraction

may be the logical and unavoidable step of the treatment[5]. Different factors, like number of missing teeth, existing occlusion, space conditions, soft tissue profile of the face, age of the patient, tooth morphology, growth pattern, the need of orthodontic treatment in general etc., can influence the decision on the treatment module to be chosen[6]. The treatment options for patients with missing or extracted central incisor are few, such as removable partial dentures, transplantation of developing premolars, maintenance of extraction space and placing a resin bonded bridge or single osseointegrated implant, or orthodontic space closure by substituting lateral incisor for central incisor[7]. Among all these treatment modalities, the last two are the most popular among clinicians. The question is: can lateral substitution be solution as good as single implant, or is it even better, especially if the patient is an individual still experiencing growth?

The **aim** of this article is to show the rationale for orthodontic space closure in cases when one central maxillary incisor was extracted due to poor prognosis and the results (dental and facial aesthetic and satisfactory occlusion) were obtained with lateral incisor substitution, which, from our professional and from the patients' perspective, was acceptable and satisfactory.

Case Report

A female patient, 16 years old, presented to our clinic with a main complaint of misaligned upper teeth, non-aesthetic "dark" upper central incisor, claiming that she felt that her upper right canine "sticks out". The patient had good general and oral health and presented history of trauma to her maxillary left central incisor when she was 13 years old. The tooth was fractured and endodontically treated by her general dentist at the time, with severe recession and unaesthetic look and bad (short-term) prognosis.

Extraoral clinical examination (Figure 1) showed that she had leptoprosopic and apparently symmetrical face. Convex profile and increased lower facial third height were present. The lips were protrusive and incompetent. There was inconsonant smile.

Intraoral examination (Figure 2) showed that she presented Angel's Class II molar relationship bilaterally, 1/2 Class II canine relationship bilaterally, right maxillary canine with vestibular ectopic infraposition and non-aesthetic appealing, changed color, left maxillary central incisor with mobile coronal fragment. Protrusion of the maxillary frontal teeth and moderate crowding in the mandibular anterior region was also present. Increased overjet of 1 mm and overbite of 4 mm were present. Radiographic examination (Figure 3) revealed periapical translucency, failed root canal treatment and metal intrapulpal post on the tooth 21. There was subgingival, in the gingival third of the root, fracture line on the tooth 21. All the permanent teeth were erupted and the germs of three wisdom teeth where present.

The treatment plan included:

- Extraction of 14 and 21;
- Fixed orthodontic appliance in upper and lower jaws;
- Use of trans palatal arch as reinforcement of upper posterior anchorage;
- Composite aesthetic buildup of 22 and aesthetic reshaping of 23.

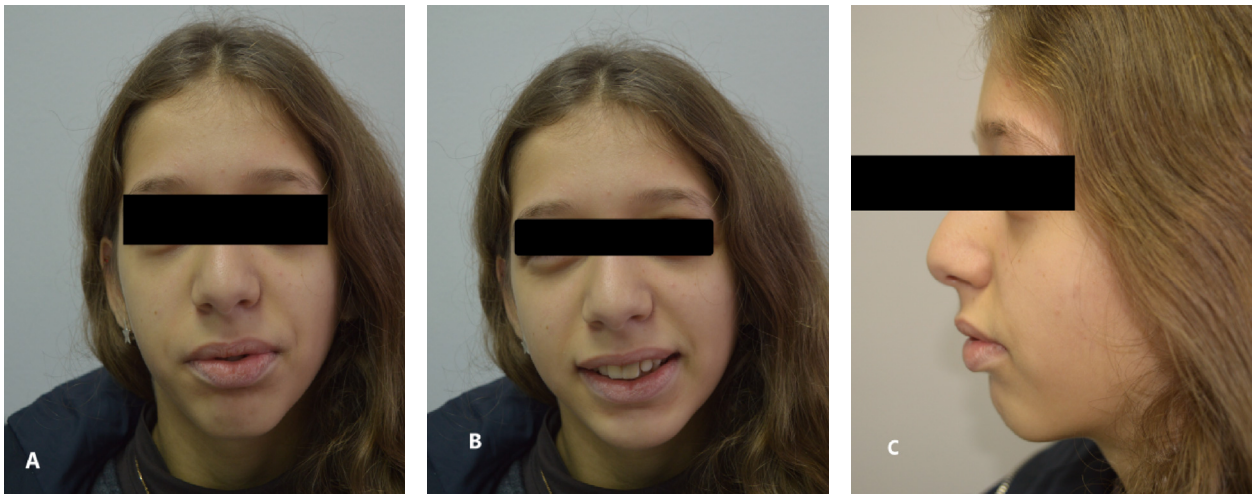


Figure 1. *Pretreatment facial photography:* ***A)*** *Front;* ***B)*** *Smiling;* ***C)*** *Profile*

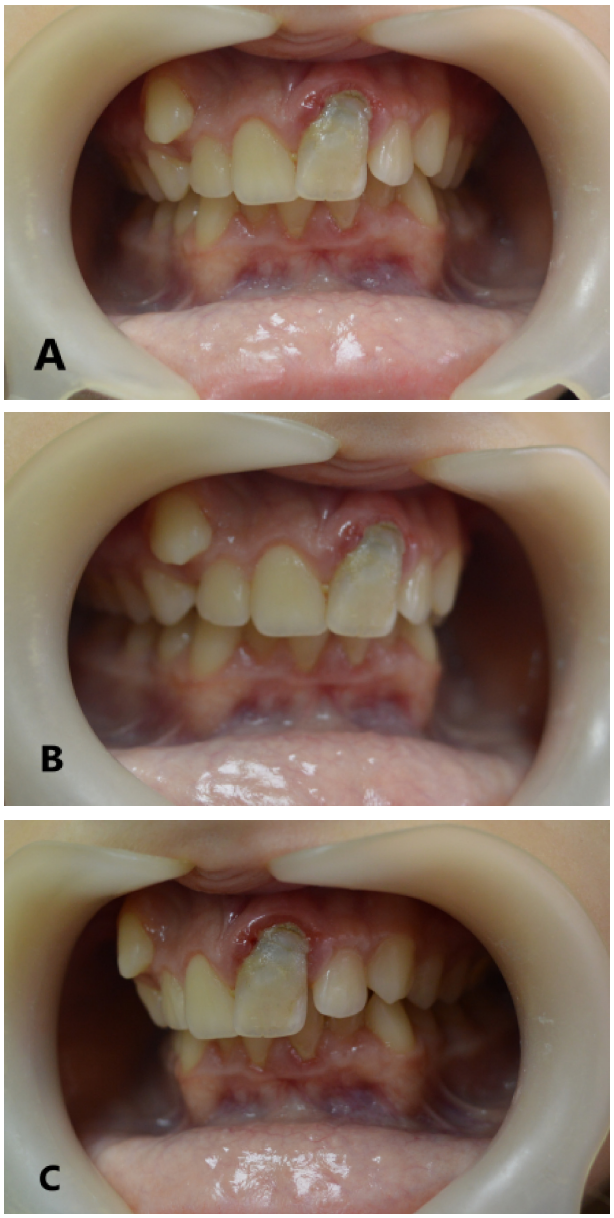


Figure 2. *Pretreatment intraoral photography:* ***A)*** *Front;* ***B)*** *Right side;* ***C)*** *Left side*

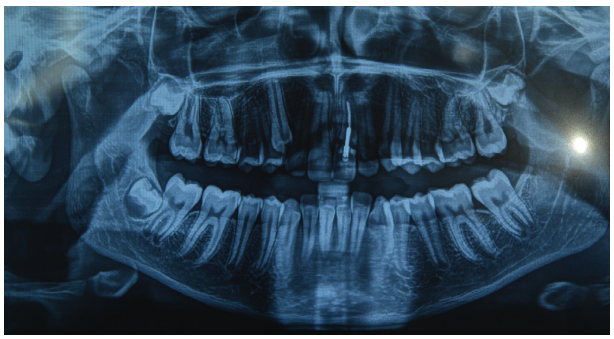


Figure 3. *Pretreatment panoramic radiograph*

The treatment objective included:

- Positioning of 22 on the place of 21, 23 on the place of 22, etc…
- Correction of crowding;
- Correction of distocclusion and protrusion of upper frontal teeth;
- Correction of the lip incompetence and providing better profile;
- Establishing a stable occlusion with normal overbite and overjet, and aesthetic smile;
- Achieving a pleasing aesthetic facial profile.

After assessment of all possible treatment alternatives, decision was made for extraction of the left maxillary central incisor, followed by mesialisation and aesthetic reshaping of the maxillary lateral incisor, mesialisation and anatomization of the maxillary canine and premolars into lateral incisor and canine space, respectively. Extraction of right maxillary first premolar was planned to create space for alignment of maxillary right canine and resolve the proclination of the upper frontal teeth.

The case was treated with convectional braces (using Roth 0.022" slot prescription) which were bonded on the upper and lower dental arches. Upper left lateral incisor was bonded with bracket for the upper left central incisor in order to maintain better mesiodistal angulation and normal inclination i.e.in order for the lateral left incisor to get three dimensional position of the central left incisor, while the upper left canine received a bracket for upper left lateral incisor for the same reason. Enameloplasty on the canine was performed before bonding, considering the flatter base of the lateral incisor bracket. The maxillary canine bracket was placed on the first premolar, so that there would be expressed minimum root torque on the first premolar.

Phase I (leveling and alignment phase) started with 0.013 inch round Coper nickel- titanium (Cu Ni-Ti) wire, followed by a round 0.016 Cu Ni-Ti wire. The anchorage was critical during the fixed mechanotherapy because of bilaterally asymmetrical extraction in the upper jaw and the existing increased overjet. Therefore, transpalatal arch was used and was later reinforced by bonding the second molars as well.

After three months into a fixed appliance therapy, the leveling phase was finished. Extraction of tooth 21 was requested (Figure 4). Round 0.016-inch stainless steel wire was installed. We moved onto phase II (working phase) which included mesialization of 22 and 23, and at the same time reducing the increased overjet (Figure 5). After mesialisation movement has finished, 0.014 x 0.025" Cu Ni-Ti archwires were placed for duration of two months followed by 0.016 x 0.025" Cu Ni-Ti arch-

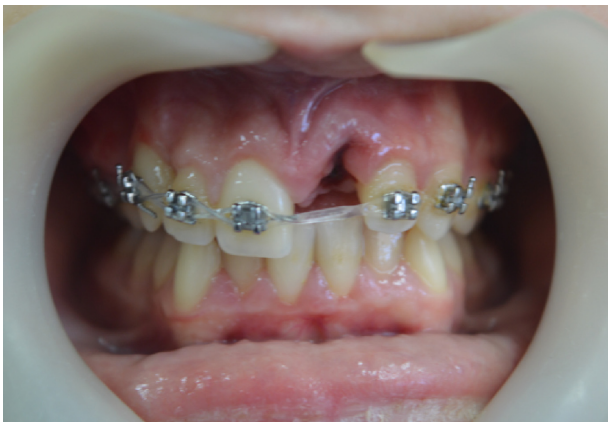


Figure 4. *Intraoral situation immediately after extraction of 21*

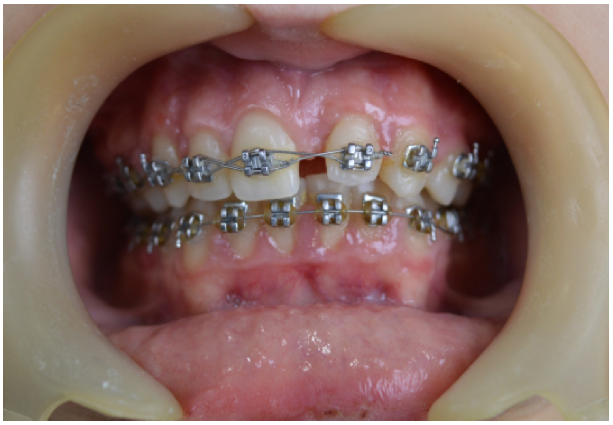
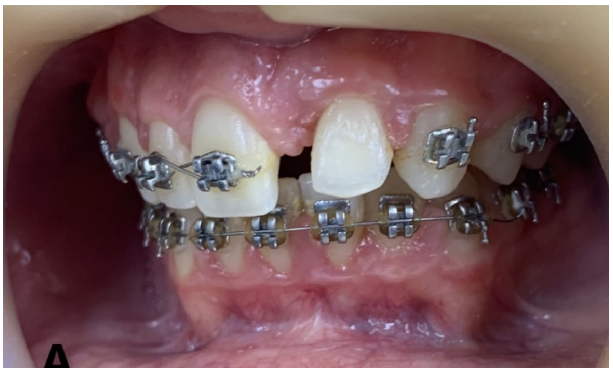


Figure 5. *Intraoral photography of treatment progress, working wires, mesialised 22 and decreaced OJ*

wire placed in the upper and lower dental arches for a period of three months. For that time, intermaxillary elastics were placed according to the current situation of force delivery and occlusal situation. The working phase lasted 12 months.

In phase III (finishing phase), rectangular 0,016x0.025 inch SS arch wire was placed in the upper and the lower jaws and the intercuspation procedure was started. At the end of the occlusal settling procedure and the occlusal adjustment, which lasted for three mounts, the fixed orthodontic appliance was debonded. Aesthetic composite buildup was made on the tooth 22, and aesthetic reshaping was performed on the left canine (Figure 6). Its length was reduced by flattening the canine's corner. The tip of the palatal cusp of the first premolar was also reduced to be less prominent while speaking and smiling. Fixed retainers in the lower and the upper frontal teeth (canine to canine) were installed, made of 0.0175 inches co-axial wire. (Figure 7)



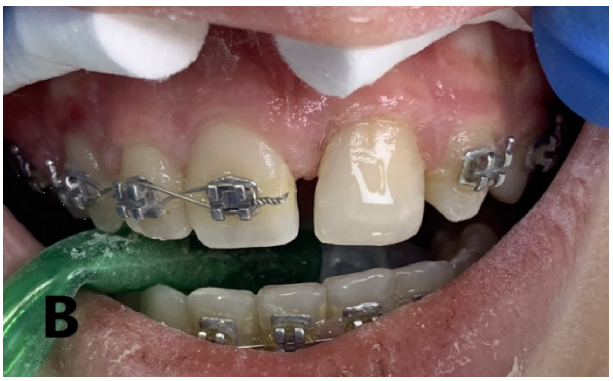
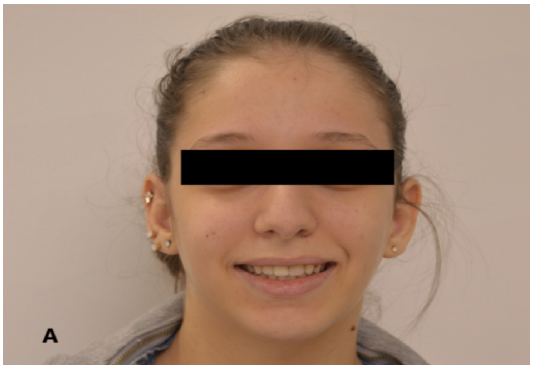


Figure 6. *Intraoral photography of tooth 22:*
A) *Debonded bracket before composite bild-up;*
B) *After the composite bild-up*



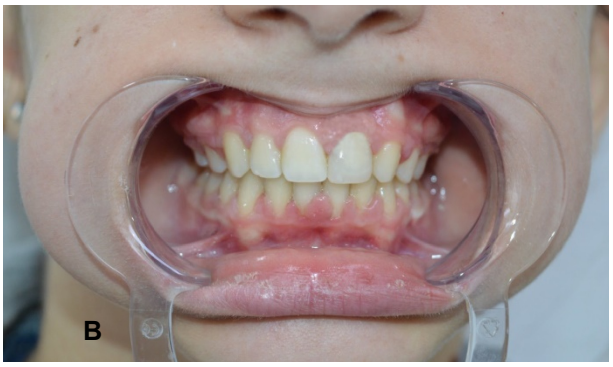


Figure 7. *Posttreatment photography:*
A) *Extraoral;* ***B)*** *Intraoral*

After removing the appliance, the patient was instructed to have orthodontic check-up every three months during the first year in retention, two check-ups the second year, and one check-up in the following three years.

Discussion

Cases when maxillary central incisor is missing or need to be extracted are relatively rare in everyday orthodontic practice. Facing this kind of problem, there are few considerations that need to be taken in mind when deciding between two of the most popular treatment modalities: implant or natural tooth.

Majority of the orthodontic patients are children still experiencing growth. Orthodontic treatment is usually carried out in the early permanent dentition, with duration between 18 and 30 months and conclusion at age 14 or 15[8]. At that age, bone maturity is not at the necessary level for osseointegrated implant to be installed. Placing an osseointegrated implant in individuals with pubertal growth spurt is considered to be contraindication[9]. Meaning, the patient needs to be treated with temporary replacement of the missing tooth if single implant is planned as final restoration.

The anterior maxilla is considered to be the riskiest site for early implantation due to growth unpredictability in the area, especially if natural teeth are present. The vertical growth in this area exceeded the growth in the other dimensions and continues at a later age[10].

Because of the intimate bone apposition (osseointegration), which resembles ankylosis, single osseointegrated implants do act like ankylosed teeth and do not follow the spontaneous and continuous eruption of natural dentition and facial growth, respectively. Such implants may even disturb a normal development of the jawbones. However, bone growth resembles the other areas next to the implant which often results in infraocclusion in implant patients. Five years after treatment, Jamilian and al. and Rossie and al. found 1mm infraocclusion in all examined implant patients[11,12]. Dental aesthetic is not just the teeth, but maintaining a reasonably even gingival margins in the maxillary incisor area is particularly important as well, especially if patients show the gingiva when they smile. A lot of researchers report that even if the implant is inserted after 19 years of age, the adjacent teeth and surrounding alveolar bone may continue to develop vertically and may continue to erupt, resulting in a discrepancy between the gingival margin of the implant restoration, and the gingival margin of the adjacent natural teeth a few years after treatment of the the implant becomes submerged[13,14].

Among the implant disadvantages, there were some periodontal problems, such as increased periimplantitis, gingivitis, increased probing depth, bleeding on probing, and progressive loss of marginal bone support at the buccal aspect of the implant [15,16,17]. It has also been shown that most implant crowns show some lack of interdental papillary fill, particularly, blue coloring of the labial gingiva on the distal papilla has been reported in above more than 50% of single-implant crowns at 4-year follow-ups[18].

Aesthetic result for single implants in the aesthetic zone can sometimes be suboptimal, even in adults and elderly patients, and especially in patients with unfinished skeletal growth[19].

Contrary to everything listed above, when orthodontic space closure, using natural tooth, is chosen as a treatment plan, the advantages are as follows:

The treatment is finished as soon as the orthodontic treatment is finished. This is crucial when treating adolescent patient.

To achieve satisfying aesthetic, aesthetic reshaping of the canine and the first premolar often needs to be performed. It is found that it is possible to perform extensive interproximal, facial and cuspal grinding of young teeth without significant discomfort to the patient and with none, or minimal pulp reaction. If proper grinding technique is used, the risk for introducing iatrogenic damage is negligible[20].

Better periodontal condition is found when orthodontic space closure is performed. When the lateral incisor is mesialised as part of the treatment plan, a new alveolar processes will be established with attached gingiva and intact interdental papillae adjusted to the mesialised tooth. These features will be preserved during the continued growth of the dentofacial complex. Accordingly, the appearance of the soft tissue surrounding the tooth ("red aesthetic") can be maintained, which can be difficult to obtain compared with prosthodontics replacement or implant[21].

Space closure provides patients with better long-term aesthetic outcome in the transition area, due to lack of bone loss and fewer periodontal problems[22].

Using composite build-up to alter tooth morphology to resemble the contralateral maxillary central incisor is minimally invasive treatment plan. The need for tooth preparation is minimal and the patient has open options to have further restorative dentistry performed, if desired.

It is a cost-effective treatment option in the short and long run. There are no initial implant/bridge costs for placement and no costs associated with implant/bridge management and future replacement[23].

Any present malocclusion or malalignment of the teeth can be corrected simultaneously if there is an need for overall orthodontic treatment.

Conclusion

Recently, there have been a rising number of adults seeking orthodontic treatment. Around 20 to 25 percent of orthodontic patients are reported to be adults. This trend is likely to rise in the near future because the society is becoming more conscious concerning dental health and aesthetic, which directly affects facial aesthetic[24]. However, most of the orthodontic patients are still children, and it appears that if proper selection of the cases is made, and if the practitioner shows high level of professional skills and attention to detail during all stages of treatment, satisfactory and natural-looking results can be achieved, provided orthodontic space closure is chosen as a method of treatment. Patients treated this way will have their natural teeth in the frontal area and only small aesthetic correction will be necessary for overall attractive smile.

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UDK: 616.31-085.45/.47:614.253.8(497.7)

KNOWLEDGE, EXPERIENCE AND ATTITUTE OF PATIENTS REGARDING MATERIOVIGILANCE SYSTEM IN THE REPUBLIC OF NORTH MACEDONIA

ЗНАЕЊАТА, ИСКУСТВАТА И СТАВОВИТЕ НА ПАЦИЕНТИТЕ ЗА СИСТЕМОТ ЗА МАТЕРИОВИГИЛАНЦА ВО РЕПУБЛИКА СЕВЕРНА МАКЕДОНИЈА

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Abstract

Introduction. Materiovigilance is a structured approach aimed at detecting, collecting, monitoring, evaluating, and ensuring the appropriateness of new safety data concerning medical devices and potential incidents of use. **This paper aims** to explore patients' knowledge, experiences, and attitudes regarding the established materiovigilance system in the Republic of North Macedonia, considering that patients may also report adverse reactions to medical devices. **Material and Method.** To achieve this aim, we conducted a cross-sectional study utilizing a survey questionnaire among 200 patients seeking dental services at the PHI University Dental Clinical Center Ss. Panteleimon in Skopje. The collected data underwent statistical analysis. **Results.** The majority of patients demonstrated limited awareness of medical devices, lacked knowledge about the national materiovigilance system, and were unfamiliar with its purpose. None of the patients reported experiencing adverse reactions to medical devices, nor had they observed such events in others. Most patients indicated they would inform their prescribing or dispensing healthcare provider if they encountered an adverse reaction. Furthermore, 94% of patients expressed the belief that they should not necessarily be aware of their ability to report adverse reactions to medical devices. **Conclusion.** Our study reveals that patients exhibited minimal understanding of the materiovigilance system and displayed a notably negative inclination toward reporting adverse events associated with medical device use. We assume that greater implementation of the materiovigilance system and cooperation between universities, healthcare professionals, patients, manufacturers, government and national agencies, media, civil society and international organizations working on medical device safety is needed.. **Key words:** materiovigilance, patients, medical devices.

Апстракт

Вовед. Материовигиланца претставува систем кој се применува за откривање, собирање, следење, процена и обезбедување на соодветност на новите податоци за безбедноста на медицинското средство поврзано со можните инциденти од употребата. Имајќи предвид дека и пациентите можат да пријавуваат несакани реакции (ефекти) од медицинските средства, целта на трудот е да ги прикаже знаењата, искуствата и ставовите на пациентите за воспоставениот систем за материовигиланца во Република Северна Македонија. **Материјал и метод.** За да одговориме на поставената цел, спроведовме студија на пресек, со користење на анкетен прашалник кај 200 пациенти кои дошле за добивање на стоматолошка услуга во ЈЗУ Универзитетски стоматолошки клинички центар ,,Св. Пантелејмон" во Скопје. Добиените податоци беа статистички обработени. **Резултати.** Мнозинството од пациентите не знаат што претставува медицинско средство, немаат познавања за воспоставениот национален систем на материовигиланца и не ја знаат целта на овој систем. Ниту еден пациент не смета дека му се случила несакана реакција (ефект) /настан предизвикана од употреба на медицинско средство, ниту пак виделе ваква појава кај некој друг. Мнозинството пациенти ќе го известат лекарот/фармацевтот кој им го препишал/издал медицинското средство во случај на забележана несакана реакција. 94% од пациентите сметаат дека не треба да знаат дека можат да ги пријават несаканите реакции (ефекти) /настани од медицинското средство. **Заклучок:** Пациентите во нашето истражување имаа минимални познавања за системот за материовигиланца и загрижува нивниот негативен став за пријавување на несаканите настани предизвикани од употреба на медицинско средство. Сметаме дека е потребна поголема имплементација на системот на материовигиланца и соработка помеѓу универзитетите, здравствените работници, пациентите, производителите, владата и националните агенции, медиумите, граѓанските здруженија и меѓународните организации кои работат во областа на безбедноста на медицинските средства. **Клучни зборови:** материовигиланца, пациенти, медицински средства.

Introduction

The realm of medical devices encompasses a diverse array of products, ranging from single-use disposables to long-term implantables, and from monitoring to diagnostic or therapeutic tools, with delivery mechanisms spanning electronic, mechanical, or chemical means. Moreover, these products involve both users and patients, often overlapping, and are utilized across various settings, from hospitals to home care[1]. Therefore, stakeholders such as practitioners, policymakers, regulators, and patients must continually assess aspects like safety, effectiveness, and quality assurance with each new product entering the market. Long-term pharmacovigilance efforts address these parameters. A parallel concept and approach, termed materiovigilance, has been adapted for medical devices[2].

The term materiovigilance was first introduced in Macedonian legislation through the enactment of the Law on Medicines and Medical Devices in 2007[3]. In the preceding law[4] incidents resulting from the use of medical devices were referenced. The current law defines materiovigilance as a system designed to detect, collect, monitor, evaluate, and ensure the appropriateness of new safety data concerning medical devices and potential incidents of use[3]. Alongside this law, the Agency for Medicines and Medical devices of Republic of North Macedonia (MALMED) was mandated to establish and maintain a materiovigilance system. The governing sublegislative document overseeing the materiovigilance system in the Republic of North Macedonia was adopted in 2016. With the recent Rulebook are regulated the methods of reporting side effects during the use of the medical device, the types of reactions they cause, the actions of health professionals and suppliers, as well as the way of organizing the system for monitoring side effects and reactions from medical device[5].

The objective of materiovigilance is to improve protection of health and safety of patients, users, and others by reducing the likelihood of reoccurrence of incidents related to medical devices elsewhere. This can be achieved by evaluating adverse event reports and dissemination of information that may reduce the likelihood of adverse events, prevent repetition of adverse events, or alleviate consequences of such repetition[6]. Accumulation of risk-benefit information about devices continues beyond the point of regulatory decision-making for market approval into the post-approval period. Various tools have been developed to specifically evaluate device performance in the post-approval setting[7]. Organizing a program and raising awareness about reporting of medical device side effects could help improve spontaneous reporting with patient and caregivers' safety[8].

The national regulatory agency, MALMED, facilitates the submission of adverse reactions to medical devices by: 1) manufacturers or holders of product registration, 2) users of medical devices (including health facilities, professionals, and patients), and 3) third parties (e.g., distributors or wholesalers)[9]. The listed entities are required to submit a report on an adverse reaction to the medical device, and based on the collected data on the adverse reactions of the medical device and identifying new knowledge related to its safety, MALMED can take measures to ensure the safety of the medical device.

Considering patients' ability to report adverse reactions and actively participate in the materiovigilance system through spontaneous reporting, our paper **aims** to assess patients' knowledge, experiences, and attitudes regarding the established materiovigilance system in the Republic of North Macedonia.

Material and method

To achieve our research aim, we conducted a cross-sectional study involving 200 patients seeking dental services at the PHI University Dental Clinical Center Ss. Panteleimon in Skopje. The study included patients aged 18-65 with at least a secondary education.

A survey questionnaire comprising 15 questions was utilized to assess patients' knowledge, experiences, and attitudes toward the materiovigilance system in our country. The collected data were statistically processed using SPSS Statistica v23 for Windows, with tests adequate to the sample characteristics. Results of the study are presented with total numbers and percentages. Chi-square test was used to find the association between two attributes at $p<0.05$ significance.

Results

Of the 200 patients included in our study, 44.5% were male and 55.5% were female. The average age of all respondents was 46.1±13.1 years. Regarding education level, 45.5% had secondary education, while 54.5% had higher education. The majority of surveyed patients, 88.5%, resided in urban areas, with only 11.5% in rural areas. In terms of ethnicity, Macedonians comprised 61.5%, Albanians 20.0%, Roma 8.5%, and others (including Turks, Serbs, Vlachs, and others) accounted for 10.0%.

Considering the purpose of our paper and the nature of the questions posed to patients, we organized the results into three parts. The first part, focusing on patients' knowledge of the materiovigilance system, is presented through two tables. The second part pertains to patients' experiences with the materiovigilance system, while the third part addresses their attitudes toward the system.

1. Patients' knowledge regarding materiovigilance system

Table 1. Summary of patient's knowledge regarding materiovigilance

Question	Affirmative answer		Negative answer		Answer not provided	
	number	%	number	%	number	%
Q1. Have you ever heard of the term materiovigilance?	6	3.0	158	79.0	36	18.0
Q2. Do you know that medical devices can cause side effects/events?	22	11.0	104	52.0	74	37.0
Q3. Has medical devices adverse event reporting system been established in the Republic of North Macedonia?	4	2.0	74	37.0	122	61.0

Table 2. Correct and incorrect answers of patient's regarding medical devices and materiovigilance

Question	Correct answer		Incorrect answer	
	number	%	number	%
Q4. Which of the following is a medical device?	34	17.0	166	83.0
Q5. Is the term medical device and medical instrument the same term?	4	2.0	196	98.0
Q6. If you consider that the system of materiovigilance is in place, which regulatory body is responsible for monitoring adverse reactions (effects) / events from a medical device?	2	1.0	198	99.0
Q7. Who do you think can report an adverse reaction (effect)/event from a medical device?	50	25.0	150	75
Q8. What is the purpose of reporting adverse reactions (effects)/events caused by the use of a medical device?	26	13.0	174	87.0

The percentage difference between confirmed and negative responses of patients, on questions shown in table no. 1, which refer to the knowledge of the materiovigilance system, is statistically significant for $p<0.05$ (Difference test, p=.0000).

In Table 2, on Question 4, 17.0% of the surveyed patients provided the accurate response acknowledging medical instruments, implantation tools, plasters, gauzes, medical technology devices, and their corresponding software as constituting medical devices. Conversely, merely 2.0% of respondents correctly identified "medical device" and "medical instrument" as synonymous terms, as indicated in Question 5. Notably, only 1.0% of participants were aware that the MALMED serves as the regulatory body responsible for monitoring adverse reactions/events stemming from medical devices, as highlighted in Question 6, indicating a concerning lack of awareness. Regarding Question 7, 25.0% of respondents correctly recognized that patients, beyond healthcare professionals, can report adverse reactions/events associated with medical device usage. However, only 13.0% of respondents correctly identified the purpose of reporting adverse reactions/events as enhancing patient safety, as presented in Question 8. There is a statistically significant percentage difference between respondents providing correct versus incorrect answers (Difference test, $p < 0.05$, $p = 0.0000$

2. Patients' experience regarding materiovigilance system

Table 3. Summary of patient's experience regarding an adverse reaction (effect) / event caused by the use of a medical device

Question	Affirmative answer		Negative answer		Answer not provided	
	number	%	number	%	number	%
Q9. Have you ever had an adverse reaction (effect)/event caused by the use of a medical device?	0	0	118	59.0	82	41.0
Q10. Have you ever seen an adverse reaction (effect)/event from a medication that happened to someone else?	0	0	80	40.0	120	60.0
Q11. Have you ever reported an adverse reaction (effect)/event caused by the use of a medical device?Q8. What is the purpose of reporting adverse reactions (effects)/events caused by the use of a medical device?	0	0	200	100.0	0	0

The percentage difference between those who gave an affirmative answer versus those who gave a negative answer of the questions presented in table 3 is statistically significant for $p<0.05$ (Difference test, p=.0000).

3. Summary of patient's attitudes regarding materiovigilance

Table 4. Summary of patient's attitudes regarding materiovigilance

Question	Affirmative answer		Negative answer		Answer not provided	
	number	%	number	%	number	%
Q12. Do you think it is necessary to report adverse reactions (effects)/events from the use of medical devices?	98	49.0	58	29.0	44	22.0
Q13. Do you think that establishing a system for reporting adverse reactions (effects)/events from medical devices is useful for the public?	82	41.0	80	40.0	38	19.0
Q14. Do you think that patients should know that they can report adverse reactions (effects)/events from the medical device?	4	2.0	188	94.0	8	4.0

Regarding Question 12, a statistically significant percentage difference was observed between respondents who affirmed versus those who negated, with a p-value less than 0.05 (Difference test, $p = 0.0207$), underscoring the importance of the findings. For the Question 13, the percentage difference between respondents exhibiting positive versus negative attitudes was statistically insignificant, with a p-value greater than 0.05, indicating no significant association (Difference test, $p > 0.05$). No significant associations were found between gender, age (above and below 40 years), level of education, place of residence, and ethnicity, and the responses to Question 13. Regarding Question 14, a statistically significant percentage difference was observed between respondents who

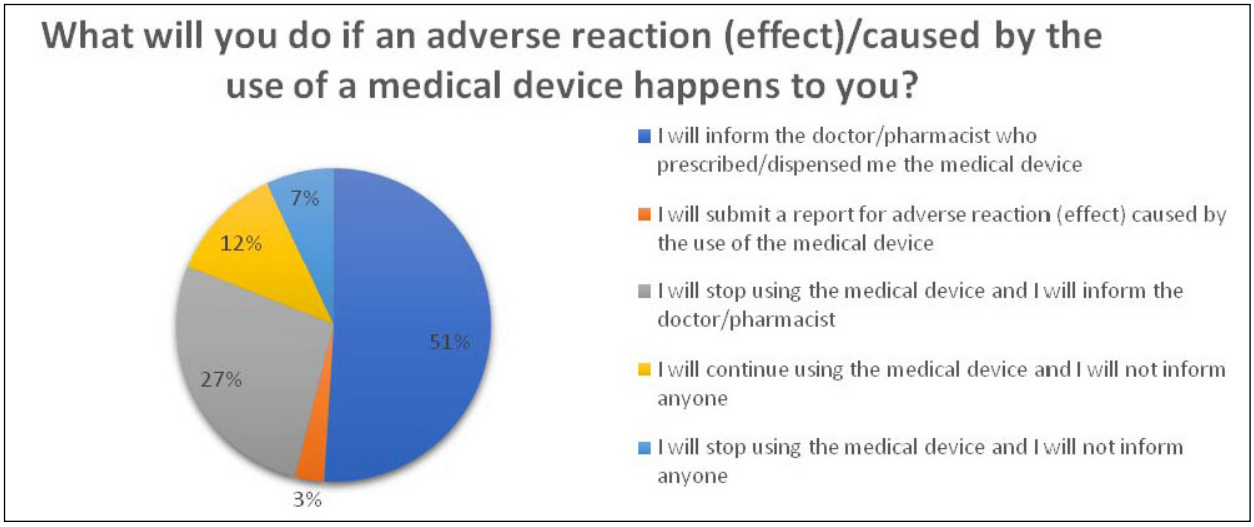

Chart 1. *Responses of patients in their behavior if an adverse reaction (effect) / event caused by the use of a medical device occurs*

answered affirmatively versus those who did not, with a p-value less than 0.05 (Difference test, p=0.0000), highlighting the significance of the response pattern.

The percentage difference between those who give an answer that they will inform the doctor/pharmacist who prescribed/issued the medical device versus those who give other answers is statistically significant for p<0.05 (Difference test, p=.0000).

Discussion

Adverse medical device events, particularly those among higher risk devices with serious negative implications for patient outcomes, have garnered widespread attention through media reports and even litigation, and calls to action for implementing measures that balance access to innovative medical devices with strategies that minimise associated risk and enhance patient safety[10]. The best evidence suggests that medical devices can also cause substantial harm. Errors that underlie device-related injuries are often categorised into three groups: manufacturer-related errors, user errors and use or design errors[11]. In the United State of America (USA), more than 1 million adverse medical device events occur annually, at a rate of 6.3 events per 1000 patient days[12]. Studies conducted by World Health Organization (WHO) suggest that adverse medical device events might be particularly problematic in developing countries, where medical equipment is often improperly maintained or replaced, placing patients at great risk[13,14]. One study from a transitional nation found that the rates of infection from medical devices alone were 34.2 per 1000 patient days in the hospital[14].

Within the available literature, only one study has examined patients' knowledge and attitudes regarding the materiovigilance system. The sole paper addressing this topic, authored by Aslani P. et al., explored the knowledge and attitudes of 29 patients/users in Sydney, Australia, concerning medical devices and the reporting of adverse events stemming from their usage. Consequently, our research aims to juxtapose the findings of our study with those obtained in this aforementioned investigation[15].

In our survey, we aimed to evaluate patients' knowledge regarding medical devices by prompting them to identify what constitutes a medical device. However, only 17.0% of respondents provided a correct answer, while 83.0% provided incorrect responses. The statistically significant percentage difference between those who provided correct versus incorrect answers underscores the need for improved awareness (Difference test, p = 0.0000). Similarly, when asked if the term "medical device" is synonymous with "medical instrument," only 2.0% of respondents answered correctly. Again, a statistically significant percentage difference was noted between correct and incorrect responses (Difference test, p = 0.0000). Contrary to our findings, the study conducted by Aslani P. et al.[15]. revealed that patients exhibited a robust understanding of medical devices. Through enumerating various types of medical devices, the authors concluded that respondents possessed familiarity with the term "medical device." Compared to our respondents, those in the aforementioned study demonstrated superior knowledge regarding medical devices.

When queried about their awareness of the potential for medical devices to cause unwanted reactions or

effects, only 11.0% of respondents acknowledged this possibility. In contrast, the study by Aslani P. et al.[15] revealed that all respondents were familiar with adverse events and their association with medical device usage.

In our study, respondents were asked if they had ever experienced or witnessed adverse reactions or events resulting from medical device use, to which none responded affirmatively. Conversely, in a study conducted in Australia, several patients reported experiencing adverse reactions caused by medical device usage[15]. This discrepancy suggests that our patients may have insufficient awareness of potential adverse events or may consider them to be normal occurrences. This perception could stem from inadequate health education. This perspective is corroborated by the findings of Tong V. et al.[16], which highlight how patients comprehend information about side effects. However, it's essential to note that the disparity between our results and those of the Sydney study could be attributed to differences in sample size and methodological approaches. Our study included 200 respondents and utilized a survey questionnaire, while Aslani P. et al.[15] employed focus groups and direct interaction with 29 respondents to ascertain their knowledge and attitudes regarding medical devices and adverse event reporting.

In our survey, questions were incorporated to gauge patients' knowledge about the materiovigilance system. Our findings indicate a lack of awareness among patients regarding the existence of the materiovigilance system in our country, the regulatory body responsible for monitoring adverse reactions/events from medical devices, and the purpose of reporting such events. Remarkably, 96.0% of respondents had not even heard of the term "materiovigilance." Similarly, insufficient knowledge about reporting adverse events was noted in the study conducted by Aslani P. et al.[15]. The majority of respondents in their study were unaware of the regulatory body responsible for monitoring adverse drug events and the purpose of reporting. We hypothesize that our respondents' lack of awareness may stem from their limited prior experience with adverse events resulting from medical device usage. Notably, none of our respondents reported experiencing adverse reactions/events caused by medical devices, thereby obviating the need for knowledge about reporting channels.

In contrast, respondents in the study by Aslani P. et al.[15] expressed support for reporting adverse reactions/events through national platforms, indicating a divergence in attitudes between our respondents and theirs.

When queried about their course of action in the event of experiencing an adverse reaction/event from the use of a medical device, our survey revealed various responses among respondents. Fifty-one percent indicated they would inform the doctor/pharmacist who prescribed/dispensed the medical device, while 3.0% stated they would file a report for adverse reaction to the medical device. Additionally, 27.0% expressed they would cease using the medical device and inform the doctor/pharmacist, whereas 12.0% would continue usage without informing anyone. Seven percent declared they would discontinue usage without informing anyone. In a study conducted in Australia[15], respondents exhibited a preference for reporting adverse events caused by medical device usage to their doctor. The authors attributed this preference to the nature of medical devices, including the potential for implantation, and the challenges in distinguishing whether adverse effects are related to usage or integral to treatment. However, depending on the severity of the side effect, a substantial number of respondents indicated they would report the event to the manufacturer. This inclination may facilitate the promotion of spontaneous reporting, as manufacturers are obligated to report adverse events to regulatory bodies. Patients have the option to report adverse events directly to regulatory bodies or through manufacturers, who can provide additional data on adverse effects of medical device usage. Pharmaceutical companies play a pivotal role in both medical device and drug vigilance systems[17].

Manufacturers, government agencies, medical practitioners, and patients/caregivers must cooperate closely for a materiovigilance program to be successful[18]. Social media, like LinkedIn, Facebook, Twitter, YouTube, help to provide users with rapid and up-to-date information on rational selection and undesired events and promote health- and science-related developments and issues[19]. This will ultimately make the users and practitioners aware of the latest regulatory actions or provisions related to the device[2].

Consumers in the USA are somewhat aware of reporting MDAEs like quality issues and administration errors experienced with devices and filling the Form FDA 3500B and reporting via MedWatch voluntary reporting system[20]. In Australia, the Therapeutic Goods Administration (TGA) has developed a website to empower the users' reporting practice[21]. Similarly, in New Zealand, the MedSafe system developed a form for the consumers to be filled in the Word document format and send via email on its website[22]. The reporting by the consumers helps practitioners, pharmacists, and policymakers to know the users' perspectives and concerns on devices in strengthening the reporting systems and ultimately in focusing on the quality products[2].

In order to maintain patient safety and the materiovigilance program, it is imperative that any adverse

events associated to devices are appropriately reported. A benefit-risk ratio will be established as a result of the ongoing collection of adverse reactions and the signal detection procedure, which will assist provide data about the dangers and advantages of the devices. Since materiovigilance is a continuous process, the information gathered over time will assist patients and healthcare providers in making more educated decisions[18].

Conclusions

The patients in our study had minimal knowledge of the materiovigilance system and their negative attitude towards reporting adverse events caused by the use of a medical device is worrying. We assume that greater implementation of the materiovigilance system and cooperation between universities, healthcare professionals, patients, manufacturers, government and national agencies, media, civil society and international organizations working on medical device safety is needed.

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UDK: 616.311.2-085.849.19

NUTRITIONAL RECOMMENDATION FOR PERINATAL, MOTHER AND INFANT ORAL HEALTH - LITERATURE REVIEW

ПРЕПОРАКИ ЗА ИСХРАНАТА СО ЦЕЛ ДОБРО ПЕРИНАТАЛНО, МАЈЧИНО И ИНФАНТИЛНО ОРАЛНО ЗДРАВЈЕ - ЛИТЕРАТУРЕН ПРЕГЛЕД

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Abstract

The diet affects the health of the mother, the pregnancy, and the development of the baby from the moment of conception. The availability of appropriate nutrients is crucial for the growth, development, maintenance and repair of oral and dental tissues. Pregnancy is a specific period of a woman's life, when the probability of changing certain habits and behaviors related to her health and the health of the unborn baby are high. Therefore, all health professionals who contact women who are planning pregnancy or pregnant women, as well as mothers of children, need to be provided with appropriate and unified information and education to preserve and optimize oral health as an integrated part of general health. These interventions can significantly change the trajectory of oral health for both the mother and her future child. For this purpose, nutritional protocols and guides for nutrition and perinatal oral health are essential, in which creating nutritionist should be included. **Key words:** guidance, perinatal oral health, early childhood caries.

Апстракт

Исхраната влијае на мајчиното здравје, на бременоста и развојот на бебето од моментот на зачнување. Достапноста на соодветни хранливи материи е од клучно значење за растот, развојот, одржувањето и репарација на оралните и денталните ткива. Бременоста е специфичен период од животот на жената, кога веројатноста за менувањето на одредени навики и однесувања поврзани со нејзиното здравје и здравјето на неродената бебе се големи. Затоа потребно е сите здравствени професионалци со кои стапуваат во контакт жените кои планираат бременост или бремените жени, како и мајките на деца да им обезбедат соодветна и унифицирана информација и едукација за зачувување и оптимизирање на оралното здравје како интегрален дел од општото здравје. Овие интервенции може значително да ја променат траекторијата на оралното здравје и за жената и за нејзиното идно дете. За оваа цел потребни се протоколи и водичи наменети за сите здравствени професионалци, во чија изработка ќе бидат вклучени диететичари и нитриционисти. **Клучни зборови:** guidance, perinatal oral health, early childhood caries.

Introduction

The United Nations with the Global Strategy for the Health of Mothers, Children and Adolescents has a vision by 2030, for a world in which every woman, child, adolescent in every sense will realize their rights to physical and mental health and well-being, has social and economic opportunities and is able to participate fully in shaping prosperous and sustainable societies.1 The Global Strategy has adopted an integrated and multi-sector approach, recognizing the factors that improve health, including nutrition, education, water, clean air, sanitation, hygiene and infrastructure, as essential to achieving the Sustainable Development Goals by 2030[1]. The U.S. government (U.S.) has been involved in supporting global Maternal and Child Health (MCH) efforts for more than 50 years and is the largest donor government to (MCH) activities in the world, to nutrition-related activities globally, projecting $1.38 trillion for fiscal 2020. Therefore, in our search of PubMed and Google scholar literature, most of the guidelines and guides for oral health, nutrition, and perinatal period originated from the United States.

According to the WHO definition, maternal health is the health of the mother during pregnancy, childbirth and the postpartum period, child health means health from birth to adolescence with a focus on the period up to five

years of age, and newborn health is the period from birth to the 28th day of life. Maternal and child health care also means oral health care as an essential component of the overall health status of pregnant women, women of childbearing age[2] and children. Paglie L. in 2019 defines the perinatal period as the period from the beginning of pregnancy to two months after birth[3]. An old adage "one pregnancy - one tooth less" indicates that the connection between pregnancy and oral health has long been known. Science says the impact is in two directions. There are several scientific studies and hypotheses that there is a correlation between periodontal disease and adverse pregnancy outcomes such as preterm delivery, low birth weight babies and preeclampsia. Physiological changes that occur in the mouth during pregnancy, as well as lifestyle changes may lead to an increased risk of some dental conditions such as gingivitis gravidarum, with an increased risk of periodontal disease[4,5,6], benign gingival lesions (pyogenic granuloma, granuloma gravidarum or pregnancy epulis), tooth mobility, as well as an increased risk of erosion and caries[7].

According to the WHO Regional Office for Europe, dental caries is the most common non-communicable disease (NCDs) disease on European soil. Because dental caries is a progressive cumulative long-term disease, the low level of caries in early childhood is something we need to aim for[9]. Early childhood caries is oral disease with the highest prevalence globally. It is defined as the presence of one or more carious, extracted (due to caries) or sealed deciduous tooth surfaces in a child aged 71 months or less[10]. Dental caries, despite its high prevalence, has a great potential for prevention because the whole pathogenetic process for the occurrence of this disease is well known. Four factors are involved: the host tooth, cariogenic bacteria, carbohydrates from the diet and time. Therefore, prevention programs include activities and interventions that are aimed at socio-behavioral risk factors, by changing nutrition and hygiene habits, by raising awareness of the importance of oral health in the individual. Practicing good oral hygiene, proper nutrition with adequate nutritional intake of micro and macronutrients, availability of occupational health care are essential to ensure that mother, child and adolescent achieve and maintain oral health at optimum[11]. Prevention, diagnostics and restorations treatments are safe during pregnancy and are effective in improving and maintaining oral health[6]. The perinatal period is a critical time when the determinants of health and oral health are set, and thus an important time for intervention[12].

Having in mind that pregnancy is a specific period of a woman's life, when the likelihood of changing certain habits and behaviors related to her health and the health of the unborn baby, it is an ideal time to promote good oral health and proper nutrition and hygiene as a factor. It is therefore necessary for all health professionals contacted by women planning a pregnancy or pregnant women as well as mothers of children to provide appropriate and unified information and education for the preservation and optimization of oral health[13]. These interventions can significantly change the trajectory of oral health for both the woman and her future child[14]. Oral health counseling can prevent or reduce the transmission of cariogenic bacteria from the mother to the child, thereby preventing or delaying the onset of early childhood caries (ECC), helping the mother to improve her own oral health[4].

Important steps for a healthy pregnancy are a balanced diet, regular physical activity, taking vitamin and mineral supplements if recommended by a doctor, and avoiding alcohol, cigarettes, and other harmful substances[3]. Diet affects maternal health, pregnancy, and the development of the baby from the moment of conception, with a possible influence on the future growth of the newborn[15]. The availability of adequate nutrients is crucial for the growth, development, maintenance and repair of oral and dental tissues[16]. During gestation and lactation, and even during the pre-conception period, tooth development may be affected by deficiency of vitamins and minerals in the mother.

Folic acid reduces the likelihood of DNA damage during mitosis, a particularly important function during embryogenesis. Inadequate folic acid intake can therefore interfere with normal embryonic growth, causing neural tube defects. Maternal intake of folic acid and vitamin A during pregnancy implies the occurrence of unilateral cleft lip with or without cleft palate. One month before conception, during pregnancy and during lactation, the recommended daily intake of folic acid is 600 mcg.

Vitamin A, D and C deficiency affects embryonic development and mineralization of deciduous and permanent teeth. Children with vitamin D deficiency are at risk of developing hypomineralized enamel, with an increased chance of caries. Calcium deficiency is very common and often goes hand in hand with vitamin D and phosphate deficiency. According to the American Dietary Guidelines 2105-2020 (2015-2020 Dietary Guidelines for Americans), children aged 1-3 years should receive 700 mg of Calcium as a recommended dietary supplement (RDA), and children aged 4-8 years should take 1000 mg daily[17]. Vitamin C deficiency can trigger gingival inflammation and is a risk factor for periodontal disease if combined with poor oral hygiene.

Deficiency of ***proteins*** in pregnancy can lead to formation of smaller sublingual glands, which will result in reduced salivary secretion, and easier dental plaque adhesion. Decreased secretion of the parotid gland is triggered by a lack of vitamins A, D, zinc and iron.

Consumption of foods with a high percentage of sugars, sticky foods, leads to prevalence of the demineralization process, which if not treated, can progress to caries. It occurs in people with frequent sugar consumption. It takes approximately 30 minutes to lower the pH of saliva after sugar intake, so extra sugar intake in those 30 minutes is less harmful than the sugar intake again after more than half an hour[18].

One of the determinants of the occurrence of EEC is mother's dietary habits, and food choices for her baby. Frequent daily bottle-feeding, night-prolonged bottle-feeding or breastfeeding after the 12th month, as well as consumption of dried fruit or fruit juices between meals, have been linked to EEC[19,20,21,22]. In the UK, the "5 per day" campaign for the daily intake of fruits and vegetables, was misunderstood by the public that frequent consumption of dried fruits and fruit juices is a healthy habit, says Morgan MZ in 2011[23].

Between 2006 and 2016, guidelines and recommendations for oral health during pregnancy were developed by several organizations[24]. Over the past three decades, federal US agencies and organizations have launched programs, advanced policies, produced resources, and provided education and training for health care workers and pregnant women aimed to raise awareness of the importance and safety of obtaining oral health care during pregnancy. Although the National Health Service (NHS) in the UK has promoted a strong campaign for healthy eating; however, the new food labels do not inform consumers about the impact of the food on teeth[25].

Material and method

The research was conducted at the Faculty of Dentistry, University Ss Cyril and Methodius in Skopje, in the period January-June 2020, by two independent researchers. The following keywords were entered on PubMed/Medline and Google Scholar: Guide, Recommendations, Nutrition, Infantile Oral Health, Perinatal Oral Health, Early Childhood Caries, Pregnancy. For the requirements of this paper, papers and guides for infantile oral health and oral health during pregnancy were analyzed, as well as nutritional recommendations for the same period, which were published after 2002.

Results

The United States, Canada, Australia, the United Kingdom, Scotland and the WHO are unique in their guidelines and recommendations for nutrition and good oral health:

1. Drink plenty of water. If you prefer bottled water, choose water that contains fluoride, packaged in a glass bottle[26]. Optimal concentration of fluoride in water is 0.07 ppm[27]. According to the data obtained from the fluorine map of the Republic of Macedonia prepared by the Institute of Public Health and the Faculty of Dentistry, the concentration of fluoride in drinking water in our country is below 0.3 mg Fluoride per liter of water, which from a preventive point of view are insignificant amounts[28];
2. Eat a well-balanced diet that includes plenty of fresh vegetables and fruits, wholegrain bread preferably with sprouts, meat, fish, eggs, and other protein sources, low-fat dairy products, potatoes, rice, and limit the intake of sugar, salt and saturated fats; divide the plate into three parts - half of it should belong to fresh fruits and vegetables, 25 percent protein and 25 percent whole grains[3,26];
3. If you have problems with nausea and vomiting, try to eat small amounts of healthy food divided into several meals. Do not brush your teeth immediately after vomiting; take a glass of water in which a tablespoon of baking soda has been dissolved[26];
4. To reduce the risk of birth defects, take 600 micrograms of folic acid every day during your pregnancy. Naturally found in: asparagus, broccoli and green leafy vegetables, such as lettuce and spinach, legumes (beans, peas, lentils), papaya, oranges, strawberries, and bananas; grain products enriched with folic acid (bread, cereals, corn, flour, pasta, white rice)[3,6,13,26];
5. Have three healthy main meals a day, and if you opt for a dessert, consume it immediately after the main meal. Then, brush your teeth, or if you are not able to, take sugar-free chewing gum and chew for a few minutes to continue the secretion of saliva that will help in the physiological cleaning of the teeth[6,13,29];
6. For healthy teeth, the choice of your snacks is important. If you have snacks, try to take healthy food with low sugar, i.e. vegetables, fruits, nuts, soup, smoothies, dairy products, seeds. It takes half an hour to an hour to return the neutral pH of the saliva after consuming something light and if we often consume sugars, the pH of the saliva is acidic for a long time which gives the possibility for demineralization of enamel and caries. Avoid hard and soft candies, chewing gum with sugar, cakes, chocolates, croissants, hazelnut and chocolate cream, chips and other sticky foods[3,6,13,29,30];
7. Avoid sugary foods or drinks before bedtime. During the night, the secretion of saliva is

reduced, which normally washes the teeth, increases the acidity in the mouth and creates an optimal environment for the enamel to erode. Whatever your meal, never go to bed with unbrushed teeth. Brushing your teeth at night is more important than in the morning;

8. Medicines sometimes contain added sugars, like some syrups. Consult your doctor and ask for a sugar-free syrup[26];
9. Drink unsweetened juices, tea, coffee[3,26,29]. Carbonated juices, energy drinks, conserved juices, contain a high percentage of sugars, which would lead to tooth erosion[26,29];
10. Naturally squeezed juices also have an erosive effect, but the benefits of their consumption for the overall health are great. To reduce the erosive effect, drink them during the main meal or as a main meal if it is a smoothie. Drink them very cold, they should not be drunk slowly, and if you drink them with a straw, put it behind the front teeth, closer to the back of the mouth, in order to reduce the contact with the tooth surfaces. After drinking these juices, the teeth must not be washed in the next hour[26,29];
11. Whenever you buy products, look at the nutrition chart of the product to see if there is a high, medium or low sugar level in the product. High sugar level is more than 15 grams per 100 grams of food, medium sugar level is 5-15 grams per 100 grams of food and low sugar level is below 5 grams per 100 grams of food[26,29]. Choose a low level-sugar product[31]; Public health in England calculated that less than 5% for children aged 4-6 means no more than 19 grams per day of free carbohydrates[32];
12. Pay attention to micronutrients, i.e. the intake of vitamins and minerals. Iron deficiency during pregnancy and lactation is the most common nutritional deficiency[3];
13. There are many components of food that have a protective effect on the teeth. These are the fluorides that we ingest through fluoridated water, calcium, phosphorus and casein ingested through milk, xylitol has antibacterial action and initiates the production of saliva, fresh raw fruits and vegetables through vitamin C, phosphates and phytates that each it takes longer to chew acts protectively through increased saliva secretion[26,29,31];
14. Postpartum breastfeeding is the most natural and best way to feed a newborn. Exclusive breastfeeding without addition of water is recommended in the first 6 months, because breast milk provides all the fluids and nutrients necessary for proper growth and development of the infant[26]. Only those drugs or vitamins and minerals recommended by a pediatrician are added. There is evidence that breastfeeding has a positive effect on both the baby and the mother. Breastfed babies are less prone to abdominal, respiratory, urinary and ear infections, are less prone to allergies (eczema, asthma), type 2 diabetes and less prone to obesity later in life. Mothers, on the other hand, have lower risk of breast and ovarian cancer, and by consuming more calories for breastfeeding, they can easily regain their weight from before the pregnancy[29]. The available evidence indicates that breastfeeding up to 12 months of age is associated with a decreased risk of dental caries and may offer protection when compared with infant formula feeding. However, some limited observational evidence suggests that once the primary teeth erupt, factors such as breastfeeding ad libitum, and nocturnal feeding may be associated with an increased risk of dental caries[33]. American Academy for Pediatric Dentistry-AAPD (2021) in their manual for perinatal and infant oral health says that breastfeeding and baby bottle beyond 12 months, especially if frequent and/or nocturnal, are associated with ECC[34]. The evidence on breastfeeding after one year is not straightforward because much of the research is observational and does not adjust for confounders such as dietary factors, oral hygiene practices and use of fluoride containing products. Further well-designed research is needed[35], especially meta-analyses[36]. Differing from this attitude, according to WHO (2019) recommendations for ending childhood caries, the child should be breastfed until the end of the second year, but also longer, if the mother and child feel that way[37]. At the end of the 6th month, solid foods and fluids are introduced, because there is not enough iron in breast milk[38]. Solid food is in the form of porridge, it is introduced in a certain order, taking care to introduce one type of food at a time. At this age - the period when the first baby teeth sprout, the baby already shows interest in food and putting it in the mouth and chewing.
15. Formula fed infants are given water between meals for the first 6 months[26,38]. The milk formula diet is with a bottle with a pacifier which is recommended to be used until the 12th month at the most, with the recommendation that after the 6th month the parents should start giving the milk in a cup[34]. Breastfeeding or giving milk formula at night is not recommended, after 12 months

because milk lactose sticks to baby's teeth and in case of poor and improper oral hygiene and due to reduced saliva secretion at night, demineralization of enamel can easily occur.

Conclusion

Protocols, guidelines to proper nutrition are necessary to unify the information and education of mothers and children, by family doctors, gynecologists and dentists. It is extremely important in each country to have guidelines for health professionals that will be developed in collaboration with dietitians and nutritionists. A good and quality prevention program requires multi-sectoral cooperation and above all confidence in the power of prevention. In our country, since 2008, the National Strategy for Prevention of Oral Diseases in children aged 0-14 years has been implemented, which aims to reduce the DMFT index and eradicate caries as a highly preventable disease through several measures. One of the measures is education for proper nutrition. After ten years of implementation of the strategy, there is a significant decrease in the DMFT index among the young population. However, it is necessary to start preventive activities earlier, in the perinatal period, in order to achieve even better and faster results. Creating guidelines for nutrition and oral health and their distribution and availability to all primary health workers is one of the activities that could help eradication of ECC.

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UDK: 616.314-77:615.28

HORIZONTAL DIMENSIONAL DEVIATIONS IN PLASTER CASTS TAKEN WITH ALGINATE WITH DIFFERENT CHEMICAL COMPOSITION

ХОРИЗОНТАЛНИ ОТСТАПУВАЊА ВО ДИМЕНЗИИТЕ НА ГИПСЕНИ МОДЕЛИ ЗЕМЕНИ СО АЛГИНАТИ СО РАЗЛИЧЕН ХЕМИСКИ СОСТАВ

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Abstract

Introduction: The dimensional stability of impression materials and plaster has the highest impact on working models precision and stability. **The Aim** of this article was to measure and compare linear dimensional changes of three alginate materials after immersion in disinfectant for a certain period of time. **Materials and Method:** To achieve the purpose of the examination, we included a physical standard, from which impression were taken and plaster casts were made. Depending on the alginate type, three groups were made: group I – standard type alginate, group II – alginate enriched with phosphate particles, group III – alginate with disinfectant. Within these three groups, three subgroups were formed: subgroup I (control) – non disinfected impressions, cast with hard plaster 30 minutes after taking the impression; subgroup II – impressions immersed 15 minutes in 0.5% sodium hypochlorite; subgroup III – impressions immersed 30 minutes in 0.5% sodium hypochlorite. After the completed disinfection, the impressions were cast with plaster and the linear distances between the defined points on the models were measured using a digital micrometer with measurement capacity up to the second decimal. The obtained values and determined linear variations were statistically analyzed in further research. **The Results** of the tests showed that the method of immersing three different alginate impression materials for 15 and 30 minutes, do not cause significant linear dimensional changes, and clinically negligible. **Conclusion:** Short term immersion in a disinfectant, from 15 to 30 minutes, is an acceptable method for disinfecting alginate impressions without significant dimensional changes occurring. **Key words:** alginate, disinfection, dimensional changes.

Апстракт

Вовед: Димензионалната стабилност на масите за отпечатување и на гипсот имаат најголемо влијание на прецизноста и стабилноста на работниот модел. **Целта** на овој труд беше да се измерат и споредат линеарните димензионални промени на три алгинати со различен состав по потопување во дезифициенс во одреден временски интервал. **Материјал и метод:** За реализација на целите во испитувањето вклучивме изработка на физички еталон од кој се земени отпечатоците и излеани гипсени модели. Според видот на алгинатот конципиравме три групи: I група – алгинат, стандарден по состав, II група - алгинат збогатен со фосфатни честички и III група - алгинат со дезинфициенс. Во рамките на секоја од овие три групи формирани се три подгрупи: подгрупа 1 (контролна група) недизинфицирани отпечатоци излеани со тврд гипс 30 минути по земање на отпечатокот, втора подгрупа отпечатоци потопени 15 минути во 0,5% натриум хипохлорит и трета подгрупа отпечатоци потопени 30 минути во 0,5% натриум хипохлорит. По завршената дезинфекција отпечатоците се излеани со гипс и на моделите извршивме мерења на линеарните растојанија помеѓу дефинирани точки со дигитален микрометар со капацитет на мерност до втората децимала. Добиените вредности и детерминираните линеарни варијации во натамошното истражување беа стастистички анализирани. **Резултатите** од испитувањата покажаа дека методот на потопување на отпечатоците земени со трите вида алгинат во времетраење од 15 и 30 минути не предизвика значајни линеарни димензионални промени, односно се занемарливи од клинички аспект. **Заклучок:** Краткотрајното потопување во дезинфекционо средство од 15 до 30 минути е прифатлив метод за дезинфекција на отпечатоците земени со алгинат без да се појават значајни димензионални промени. **Клучни зборови:** алгинат, дезинфекција, димензионални промени.

Introduction

Dental impressions are potential sources for bacterial contamination. At the same time the possibility of contamination with pathogenic microorganisms is high, and the impression materials that are exposed to infected saliva or blood can become the main source of infection[1,2,3]. Various chemicals have been used to disinfect dental impressions, such as: sodium hypochlorite, glutaraldehyde, chlorhexidine, iodophor, peracetic acid and mixed disinfectants[4].

Sodium hypochlorite and glutaraldehyde are the most commonly used disinfectants[2,5,6]. Several authors have used sodium hypochlorite in a 2% concentration to disinfect alginate, including Badrian et al.[7], Porrelli et al.[8], Rentzia et al.[9] and Lorson et al.[10]. The basic requirement is that the disinfection lasts as short as possible and to not affect the dimensional stability of the impression. However, there might be side effects associated with the disinfection process due to chemical or physicochemical interaction between the impression material and the disinfection solution[11]. Ghasemi et al.[12] examined the effect of disinfection on the dimensional changes of alginate impression materials using the spray method with 0.5% sodium hypochlorite as disinfectant for a period of 10 minutes and concluded that this method had no significant impact on the dimensions on plaster cast models. The effect of different disinfection systems on the dimensional stability of alginate and addition silicone impressions was compared by Samra and Bhide[13]. They recommend disinfection of these materials with sodium hypochlorite and an ultraviolet chamber. In their study, Babiker et al.[5] investigated the effect of 1% and 5.25% sodium hypochlorite, as spray and immersion solutions, on the dimensional accuracy of alginate impression material. In their study, Ulgey and Yesilyurt[14] determined the best approach to reduce adverse changes on alginate impressions in three different dimensions with disinfection duration of 15 and 30 minutes. They concluded that a 15-minute disinfection can provide favorable results to obtain all prints with minimal distortion. In their research, Altaf et al.[15], in 2020, compared the linear dimensional changes of alginate impressions disinfected by immersion in 0.525% sodium hypochlorite solution for 10 minutes. The authors concluded that disinfection by immersion in a 0.525% sodium hypochlorite solution had no significant effect on dimensional stability. Adding a disinfectant to alginate impression materials can eliminate the disinfection procedure, to avoid dimensional changes. The aim of the study by Amalan et al.[16] was to evaluate the effect of the alginate material containing disinfectant chlorhexidine (0.1 and 0.2%) and sodium hypochlorite (0.1 and 0.5%) on the dimensional stability. From the obtained results, we can conclude that the dimensional changes were below the limit of the material specification.

Aim

As a current problem, the protection of the dental team, as well as the proper production of prosthetic restorations, were the motive for setting the goal of this paper:

To measure and compare the linear dimensional changes of three different irreversible hydrocolloid materials (alginates) after immersion in disinfectant for different time intervals.

Material and method

In the research, we used alginate with standard composition, alginate with phosphate particles in the composition, and alginate with disinfectant. We used 0.5% sodium hypochlorite for disinfection.

To achieve the set goals, we used an acrylate master model for taking impressions and making plaster casts, for measurements and comparative analyses. Linear measurements were performed between precisely defined points on the palatal surface of the maxillary central incisors in the region of the cingulum. The master model was placed on a milling machine and with the help of a metal milling cutter, a cylindrical recess was made with an angle of 60 degrees with a point bottom and constant depth. The points are marked as point A and B. On the occlusal surfaces of the two first maxillary molars of the master model, the same cylindrical recesses were made in the middle of the central fissure. These points are marked as point C and D.

The horizontal linear distances between the points: A and B, A and C, C and D, D and B were measured. To

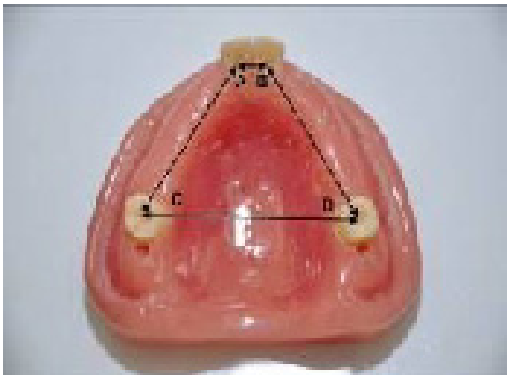

Figure 1. *Defined points for measuring horizontal distance*

Figure 2. *Measurement of horizontal distance*

realize and prove the goals of the research, three groups were defined: group I – standard irreversible hydrocolloid, group II – modified irreversible hydrocolloid enriched with phosphate particles, group III – irreversible hydrocolloid with disinfectant.

Within each of these three groups, three subgroups were formed. First subgroup – impressions were taken and rinsed with running water and cast with hard plaster 30 minutes after taking the impression (control group). Second subgroup – impressions kept in 0.5% sodium hypochlorite for 15 minutes and cast after 30 minutes. Third subgroup – impressions kept in 0.5% sodium hypochlorite for 30 minutes and cast with hard plaster 60 minutes after taking the impression. These three procedures were repeated for all three groups with different alginates, and for the realization of the tests, a total of 90 plaster casts were made (30 casts of each group). Measurements were performed with digital micrometer with measurement capacity up to the second decimal. The obtained values and determined linear variations in further research were statistically analyzed through: maximum value of measured distance, minimum value of measured distance, mean and average value of measured distance, standard deviation Kruskal Wallis, ANOVA test, Mann – Whitney test, t – test for independent samples, variance analysis, and Post hoc analysis Tukey HSD test.

Results

This part of the research shows the results obtained by processing and statistical analysis of data, obtained by measuring and comparing the linear dimensions (AB, AC, CD, DB) of the three different types of alginate impressions, and one reference model. The values of the descriptive measures for the length of the horizontal distances AB and AC on impressions from all three groups, and the reference model are shown in figures 3 and 4.

The values of descriptive measures for length of horizontal distances CD and DB in impressions from all

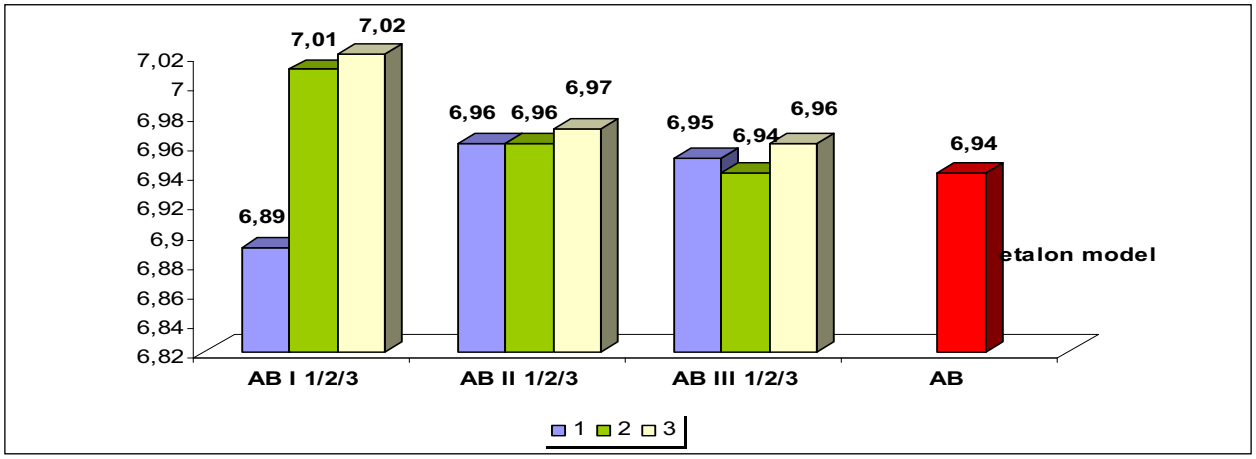

Figure 3. *Longitudinal horizontal distance AB*

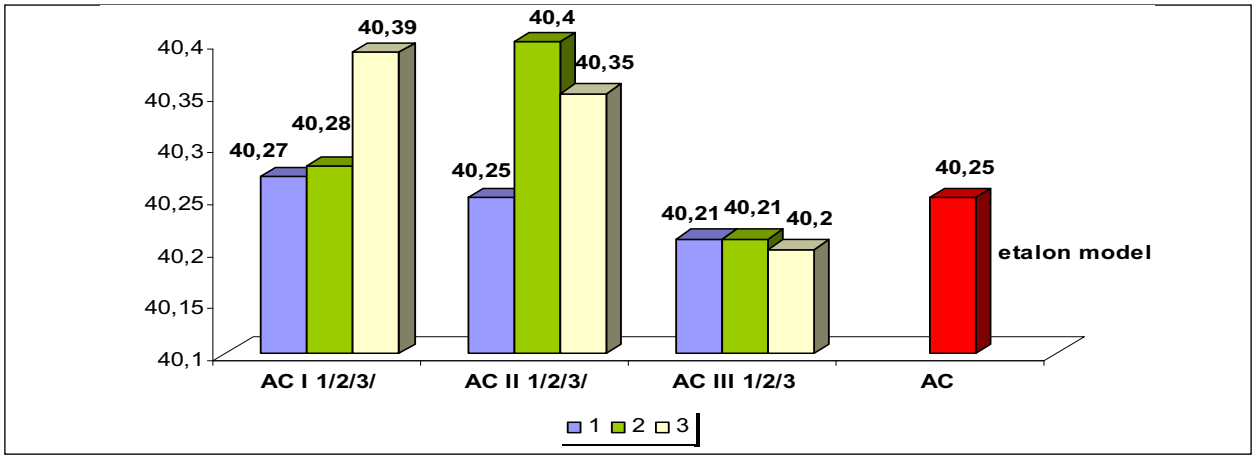

Figure 4. *Longitudinal horizontal distance AC*

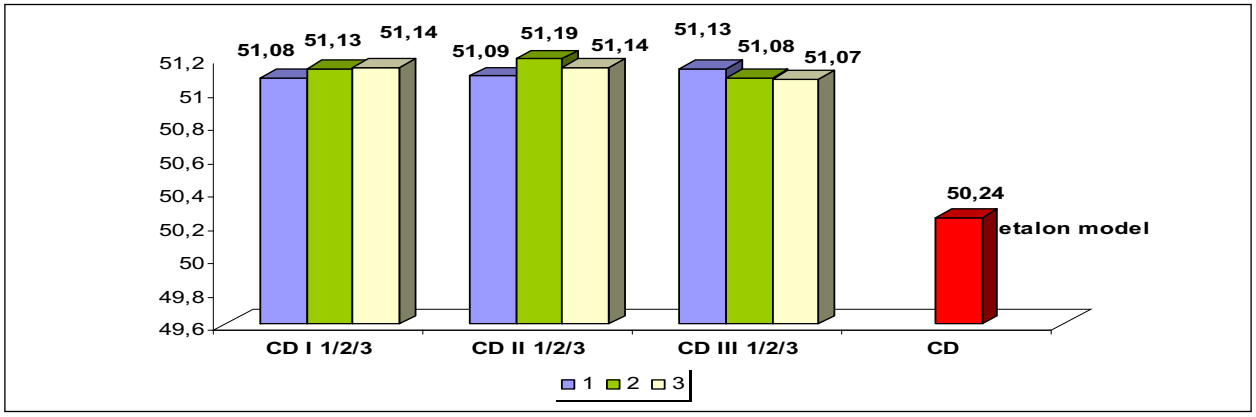

Figure 5. *Longitudinal horizontal distance CD*

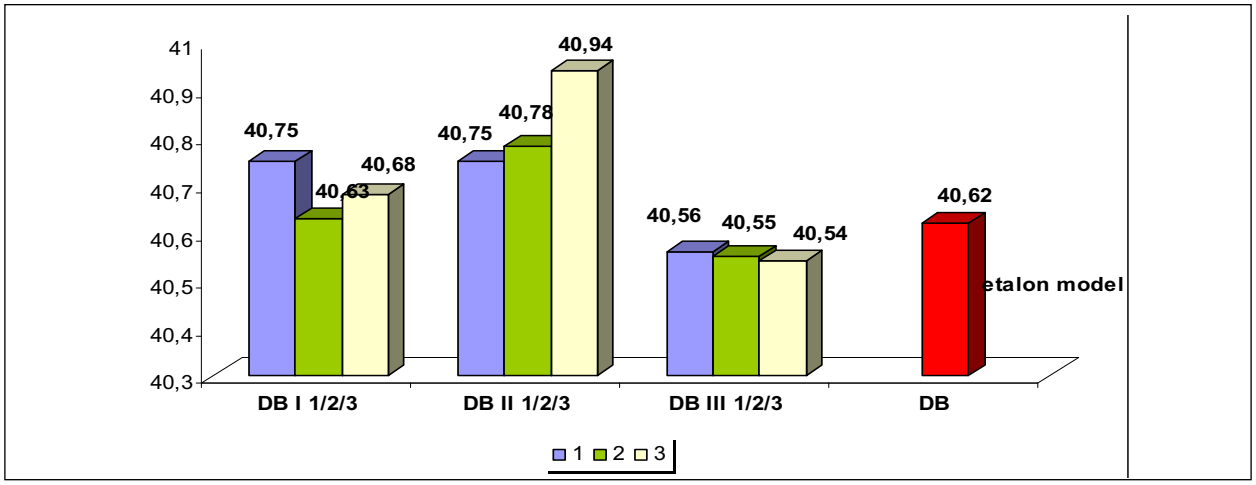

Figure 6. *Longitudinal horizontal distance DB*

Table 1. Results of tested differences between the analyzed groups of impressions.

Разлики меѓу групи	Mann-Whitney U					
	Rank Sum	Rank Sum	U	Z	p	Sig./N.Sig.
I/II	58596.0	56843.0	27923.5	0.58	0.56	N.Sig.
I/III	59624.0	55816.0	26896.0	1.25	0.21	N.Sig.
II/III	58822.0	56617.5	27697.5	0.73	0.47	N.Sig.

three groups, and the reference model are shown in figures 5 and 6.

The results of the tested differences between the analyzed groups of prints through the Mann – Whitney U test are shown in Table 1.

Discussion

The obtained results, by testing the differences in the average lengths AB, AC, CD and DB in the impressions taken with standard alginate that are not kept in solution

(control group), show smaller lengths of these distances compared to the impressions from the disinfected groups. The obtained values confirm the fact that disinfection by the immersion method has a significant influence on the linear changes of the alginate impression material. The immersion time plays an insignificant role in the water imbibitions process, in the appearance of the dimensional changes, after disinfection for a period of 15 and 30 minutes. This indicates that the optimal disinfection time is up to 15 minutes, a time during which the impression material is dimensionally stable. Our results correlate with the results of Ulgej et al.[14]. By examining the effect of immersion in a solution of sodium hypochlorite for a duration of 15 minutes, impressions with minimal dimensional changes are obtained. Similar results are presented by Wu HM et al.[17]. Babiker et al.[5]. In their study they investigated the effect of 1% and 5,25% sodium hypochlorite (NaOCl), as a spray and as an immersion solution, on the dimensional accuracy of alginate impression material. They indicate that it would be more appropriate to disinfect the impressions by spraying NaOCl solution rather than by immersion. Hiragushi et al.[18] investigated the dimensional changes of plaster casts, using the method of immersing alginate impressions in 0.5% sodium hypochlorite solution for 15 minutes. The differences in dimensional changes between casts from disinfected impression and non-disinfected ones were less than 15μm. Samra and Bhide[13] analyzed and compared the effect of different disinfection systems on the dimensional stability of commonly used alginate and addition silicone impression materials. They concluded that the tested materials could be safely disinfected with sodium hypochlorite for 10 minutes. Ismail et al.[19] examined the dimensional stability of alginate impressions by immersion in two different solutions (1% sodium hypochlorite and 2% glutaraldehide) for 10 and 60 minutes. They found that immersion in disinfectant for 10 minutes did not affect the dimensional stability. In their study, Ghasemi et al.[12], examined the effect of three disinfectants on the dimensional changes of alginate and additive silicone impression materials. Impressions are disinfected by the spray method for 10 minutes not including the control group. We can conclude that disinfection of alginate and addition silicone impressions with 0.5% sodium hypochlorite has no significant effect on the dimensions of the plaster casts. Altaf et al.[15] compared the changes in linear dimension of alginate impression by immersion in 0.525% sodium hypochlorite solution for 10 minutes, and determined that this immersion period did not cause significant changes on the dimensional stability of the impression. The stability of alginate impressions deteriorates over time due to water evaporation. Casting impressions immediately after taking provides the highest accuracy[20,21]. Alginate impressions have tendency to absorb water due to the differential osmotic pressure between the impression and the disinfecting solution[22,18]. Among the three subgroups of impressions taken with alginate with phosphate particles, the tested differences in the largest horizontal dimension (CD) were statistically insignificant ($p<0.05$). This means that in the impressions of modified alginate enriched with phosphate particles, we obtained the smallest and insignificant dimensional changes in relation to the measured horizontal distances. The largest part of alginate is water, therefore, any change in the amount of water has a significant impact on the properties of the materials or the accuracy of the impression. Guiraldo et al. and Hamedi et al.[4,22] indicate that disinfection does not significantly affect the dimensional integrity. Some researchers used self-disinfecting alginates and added solutions of chemical disinfectants when mixing the alginate. Benakatti et al.[23], investigated the effect of four commercially available alginate impression materials, that were mixed with disinfectant liquid containing chlorhexidine and sodium hypochlorite, on the properties. Alginate impression materials mixed with chlorhexidine expressed varying degrees of antibacterial activity without affecting dimensional stability. The values we obtained when determining the parameters in a linear direction, in correlation with the exposure time to disinfection in some conditions showed a statistical and in some insignificant difference, which gives us the right to conclude that 15 to 30 minutes is the time necessary for disinfection of impression materials that do not affect the precision and quality of the cast, and consequently the prosthetic restoration. In this paper we used three different alginates which, compared and statistically analyzed, did not show a statistically significant difference in relation to the linear deformation. Variations in subgroups generally do not affect different impression materials. With these values, we can safely say that conventional alginate is an impression material that can be used daily with a disinfection procedure.

Conclusion

Based on the measured values and parameters and their statistical analysis we can summarize the following: during the disinfection procedure, alginate impression materials show linear dimensional changes when immersed in a hypochlorite solution. Regardless of the time of exposure to the disinfectant solution, 15 or 30 minutes, conventional alginates do not demonstrate statistically significant differences in all dimensions. Short-term immersion in a disinfectant for 15 minutes is an acceptable method for disinfecting alginate impressions without significant dimensional changes and is clinically acceptable.

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