

USE AND ADVERSE EFFECTS OF VACUUM-FORMED RETAINERS – COMPARISON OF THE EXPERIENCES OF ORTHODONTISTS IN CROATIA AND NORTH MACEDONIA

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ABSTRACT

Objective: To investigate experiences with vacuum-formed retainers (VFR), possible adverse effects and problems associated with their use among Croatian and Macedonian orthodontists.

Subjects and Methods: In 2023, a questionnaire on retention protocols was distributed by e-mail to 150 orthodontists in North Macedonia (78% of practicing orthodontists), with a response rate of 58%, and to 185 orthodontists in Croatia (85% of practicing orthodontists), with a response rate of 75%.

Results: VFR were the more frequently used retention appliance in Croatia than North Macedonia, both in maxilla (79 vs. 53%, $p < 0.001$) and mandible (66 vs. 44%, $p = 0.001$) mostly because of the availability of the appliance (66% in Croatia vs. 53% in North Macedonia; $p = 0.056$). The most used foil thickness for the VFRs was the 1 mm (71% in Croatia vs. 59% in North Macedonia; $p = 0.019$). The expected duration of the VFRs was 1-2 years (60% in Croatia vs. 47% in North Macedonia; $p = 0.015$), however, less than 25% of the patients agreed to make new VFRs in both countries. Clinicians had rarely observed adverse reactions to VFRs (3% in Croatia and none in North Macedonia). Reasons for changing the VFR material were more often costs in North Macedonia than in Croatia (62 vs. 2%; $p < 0.001$).

Conclusion: VFRs are preferred retention appliances among Croatian and North Macedonian orthodontists, mostly because of their availability. Patients tolerate them well, but failures mostly occur after 1-2 years and only ¼ of patients decide to make new retainers which can impose problems regarding relapse.

Keywords: adverse effects, orthodontics, retention, vacuum formed retainers

INTRODUCTION

Relapse occurs in about 70% of cases after orthodontic treatment [1, 2].

According to National Health Service in England, the orthodontist is responsible for a retention period of 12 months and patients were asked to sign a retention consent form. The approach suggesting that the retention should be at least 7 months is supported by histological studies that have demonstrated that supracrestal periodontal fibers remain stretched and relocated for more

than 7 months after the ending of orthodontic tooth movement [3].

Gingival and periodontal tissue reorganization, occlusal as well as growth related factors have impact on the tendency of the teeth to move back to their previous position prior to treatment, which makes the prevention of relapse after orthodontic treatment quite challenging [4,5].

Orthodontic corrections have to persist in a dynamic environment of sustained skeletal

changes, functional demands, and compensatory adaptations of the occlusion. Therefore retention is required in most cases to diminish both true relapse and maturational change [6,7].

Numerous clinical and meta-analyses have been conducted to analyze and compare different appliances, protocols, and retention durations, which still are pressing issues [8].

Angle and Case proposed a retention concept based on banded fixed appliances and Hawley suggested removable retainers. Kesling, in the 1940s, designed an elastoplastic positioner, and Nahoum, in late 1950s, developed the concept of vacuum-formed retainers (VFR) made of clear thermoplastic material [7].

The VFR is a custom-made, removable, comfortable, thin transparent thermoplastic bio-compatible retainer introduced by Ponitz in 1971 and further developed by Dr. John Sheridan in 1993 [9]. Nowadays, vacuum retainers are produced by many companies such as Essix®, Zendura® and Vivera® [10]. Materials used for the thermoplastic retainers are polypropylene polymer-based material (Invisacryl C, Essix C+), polyethylene copolymers (Essix ACE), and polyethylene terephthalate glycol copolymer—PETG (a hard sheet material) [11].

Numerous outcomes related to orthodontic retention with VFR were evaluated, like stability, oral health (plaque, calculus, inflammation, reces-sions, bleeding, attachment level), patient experience (speech, aesthetic, discomfort), survival and failure rates breakage, loss, detachment), duration, cost-effectiveness, frequency of follow-up, but most of the studies did not exceed one year of follow-up [12].

The objective of the research was to investigate experiences with vacuum-formed retainers (VFR), possible adverse effects and problems associated with their use among Croatian and Macedonian orthodontists.

SUBJECTS AND METHODS

In 2023, a questionnaire on retention protocols was distributed by e-mail to 150 orthodontists in North Macedonia (78% of practicing orthodontists), with a response rate of 58%, and to 185 orthodontists in Croatia (85% of practicing orthodontists), with a response rate of 75%.

The questionnaire used was modified from previous research [13, 14, 15].

It consisted of 12 questions, divided into several segments: (1) general information (gender, age, place of residency program, years of practicing orthodontics, main work location, days in working week) (2) most commonly used type of retainers and experiences about using VFR (3) main reason for choosing a VFR and factors for changes in protocols and registered adverse effects. The questionnaire allowed the responders to give multiple answers to many of the questions, which made the total exceed 100%.

The differences between practices and experience of orthodontists between the two countries were compared using the Mann-Whitney test, Fisher's exact test, and the χ^2 test. The commercial software IBM SPSS 22 (IBM, Armonk, USA) was used.

Table 1. Demographic characteristics of the sample and usage of VFR

Variable and country		Croatia	North Macedonia	p
Age	(median (IQR))	46 (42-51)	45 (38-54)	0.125
Gender	male (N; %)	40 (29%)	23 (24%)	0.456
	female (N; %)	98 (71%)	72 (76%)	
Specialist experience	(median (IQR))	14 (8-19)	12 (4-20)	0.068
Specialist experience	≤14 years (N; %)	70 (51%)	60 (63%)	0.081
	≥15 years (N; %)	68 (49%)	35 (37%)	
Maxilla VFR	most often used (N; %)	109 (79%)	50 (53%)	<0.001
	other appliance (N; %)	29 (21%)	45 (47%)	
Mandible VFR	most often used (N; %)	91 (66%)	42 (44%)	0.001
	other appliance (N; %)	47 (34%)	53 (56%)	

IQR – interquartile range; p-level of statistical significance.

RESULTS

The orthodontists in the sample in Croatia were aged 33-73 years (median 46; 71% female) and in North Macedonia 32-64 years (median 45; 76% female). There were no differences in age, gender distribution, or experience between orthodontists in the two countries (Table 1).

VFRs were the most commonly used retention appliances, more frequently in Croatia than in North Macedonia, both in the maxilla (79 vs. 53%, $p<0.001$) and mandible (66 vs. 44%, $p=0.001$) (Figure 1) mainly due to the availability of the appliance (66% in Croatia vs. 53% in North Macedonia; $p=0.056$).

The most commonly used foil thickness for VFRs was 1 mm (71% in Croatia vs. 59% in North Macedonia; $p=0.019$). The expected duration of VFRs was 1-2 years (60% in Croatia vs. 47% in North Macedonia; $p=0.015$), however, less than 25% of patients agreed to have new VFRs made in both countries (Table 2).

Reasons for changing VFR materials were more often cost-related in North Macedonia than in Croatia (62 vs. 2%; $p<0.001$) (Figure 2).

Clinicians rarely observed adverse effects with the use of VFRs (3% in Croatia and none in North Macedonia) (Figure 3).

DISCUSSION

The present survey showed that VFRs are the preferred retention appliances in both Croatia and North Macedonia and the side effects of using thermoplastic foil are rarely seen.

Age, years of specialist experience and gender distribution were similar in both countries implying that those parameters probably did not influence differences in practices with VFR between countries.

VFR were more frequently used as retention appliance in Croatia than North Macedonia, both in maxilla and mandible. The reasons may be in the different education and training of the residents or due to their greater availability in Croatia. Perhaps the way orthodontic practice is organized in terms of a state subsidy or privately, has an influence. Established traditional practices in North Macedonia may also play a role in these preferences. Our experiences are not much different from other countries.

VFR is the most commonly chosen retention appliance in both jaws in Ireland (53 and 33% respectively) [10] and Malaysia (47%) [16]. In the Netherlands, only in cases when extractions were performed or the upper arch was expanded during treatment, did the ortho-

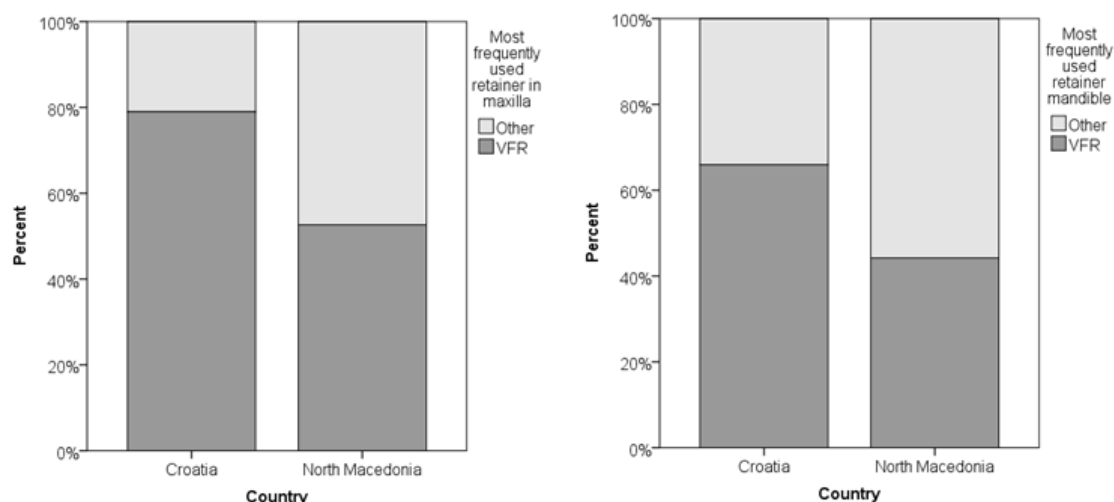


Figure 1. Comparison for most frequently used retainer in maxilla and mandible between countries

Table 2. Comparison of experiences with VFR between countries

		Croatia	North Macedonia	p
<u>VFR used because of:</u>				
availability	no (N; %)	47 (34%)	45 (47%)	0.056
	yes (N; %)	91 (66%)	50 (53%)	
costs	no (N; %)	107 (78%)	63 (66%)	0.072
	yes (N; %)	31 (23%)	32 (34%)	
quality	no (N; %)	84 (61%)	61 (64%)	0.680
	yes (N; %)	54 (39%)	34 (36%)	
recommendation	no (N; %)	124 (90%)	83 (87%)	0.673
	yes (N; %)	14 (10%)	12 (13%)	
<u>VFR thickness used</u>		0 (0%)	2 (2%)	0.019
	0,75 mm	12 (9%)	4 (4%)	
	1 mm	98 (71%)	56 (59%)	
	>1 mm	27 (20%)	29 (31%)	
	do not know	1 (1%)	4 (4%)	
<u>Change in VFR materials</u>		1 (1%)	3 (3%)	0.216
	yes (N; %)	15 (11%)	10 (11%)	
	no (N; %)	118 (86%)	79 (83%)	
	do not use VFR	0 (0%)	2 (2%)	
	do not know	4 (3%)	1 (1%)	0.577
<u>Reason for change of VFR material</u>		131 (95%)	88 (93%)	
availability	no (N; %)	7 (51%)	7 (7%)	<0.001
	yes (N; %)	135 (98%)	36 (38%)	
costs reason for change	no (N; %)	3 (2%)	59 (62%)	<0.001
	yes (N; %)	121 (88%)	95 (100%)	
quality reason for change	no (N; %)	17 (12%)	0 (0%)	0.647
	yes (N; %)	135 (98%)	94 (99%)	
recommendation reason for change	no (N; %)	3 (2%)	1 (1%)	0.015
	yes (N; %)	2 (1%)	2 (2%)	
duration of VFR	<1 year	21 (15%) ^a	29 (31%) ^b	0.018
	1-2 years	83 (60%)	45 (47%)	
	>2 years	31 (23%)	15 (16%)	
	do not know	1 (1%)	4 (4%)	
	percentage of patients that make new VFR	27 (20%) ^a	32 (34%) ^b	
percentage of patients that make new VFR	<10%	60 (44%)	33 (35%)	0.147
	10-25%	25 (18%)	9 (10%)	
	25-50%	19 (14%)	10 (11%)	
	>50%	7 (5%)	11 (12%)	
	do not know	4 (3%)	0 (0%)	
side effects	no (N; %)	134 (97%)	95 (100%)	0.081
	yes (N; %)	133 (96%)	95 (100%)	
side effects on mucosa	no (N; %)	5 (4%)	0 (0%)	0.515
	yes (N; %)	136 (99%)	95 (100%)	
side effects on lips	no (N; %)	2 (1%)	0 (0%)	
	yes (N; %)			

p-level of statistical significance

dontists place a removable retainer. In all other cases bonded retainers are used [13], the same is found in Switzerland [17]. VFR were the most commonly used type in hospital practice and the publicly funded healthcare systems of the United Kingdom, and, in community practice, Hawley retainers [18]. In a global study among participants from different demographics, thermoplastic retainers were the most popular retention regime for the maxillary arch for both adults (47%) and adolescents (42%) [19].

Only in the maxilla were VFR the most commonly chosen option in Australia and New Zealand [20, 21], Croatia (52%) [22] and Canada (51%) [23].

It should be kept in mind that the results of studies conducted 10 and 20 years ago are being compared with the data we collected in 2023/4. We are sure that trends are changing in other countries as well. It is also important that there are surveys with different percentages of responses and different methods of organizing the orthodontic health-care system.

Reasons against choosing the VFR may be breakage and poor wear resistance, a possible inability to maintain expanded arches and to maintain alignment of previously severely rotated and/or displaced teeth due to its lack of rigidity; inhibition of any desired vertical ‘settling-in’ of the occlusion subsequent to active orthodontic

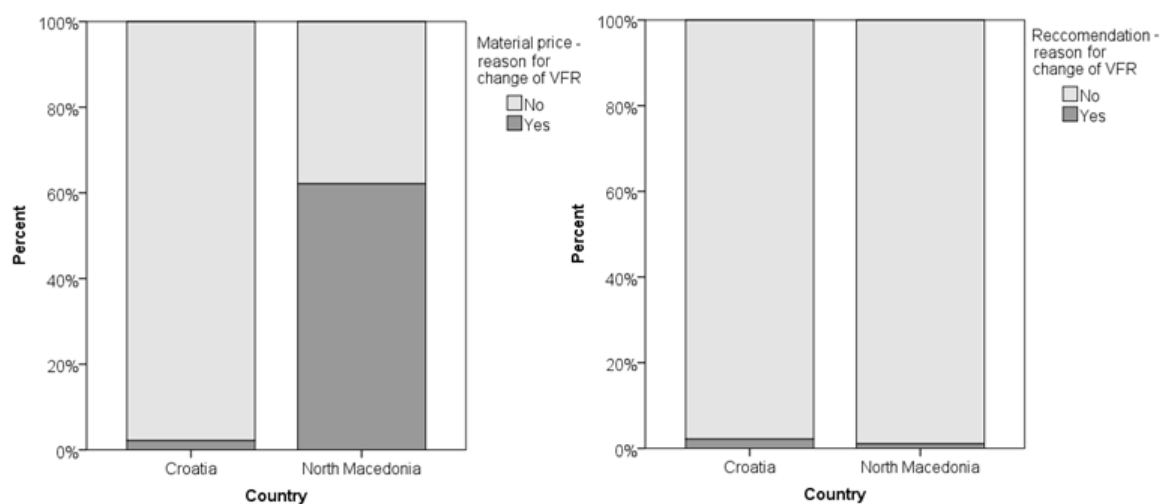


Figure 2. Comparison for material price and recommendation as reasons for change the VFR between countries

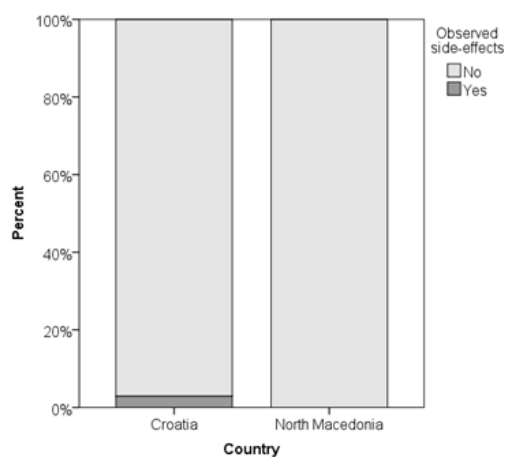


Figure 3. Comparison for side effects related to VFR wear between countries

treatment; the potential for demineralization, caries and poor gingival health if a careless dietary lifestyle with frequent carbonated beverages intake rich with sugar and is adopted while the VFR is being worn [9]; need for proper patient cooperation and shorter durability [11]. Furthermore, significantly higher plaque and calculus scores were found in clear retainers group than in Hawley retainers, with no significant difference for gingival inflammation and bleeding on probing at half-year follow-up [24].

The widespread use and popularity of VFR is certainly due to its numerous positive aspects: aesthetic appearance, patient comfort and acceptability, easy hygiene maintenance and speed, ease and low cost of fabrication. Also, changes in articulation, like sound distortion is less obvious than with the Hawley acrylic retainer [25].

In our research, VFRs are a retention choice in the mandible less often than in the maxilla (66% in Croatia vs. 53% in North Macedonia). Generally, protocols for the mandible are a little more unified, so bonded retainers are most often used alone [13, 15, 17, 19, 20, 21, 23, 26, 27, 28, 29] or in combination with VFR [18, 22, 30].

Orthodontists in current research choose VFR mostly because of availability (66% in Croatia vs. 53% in North Macedonia). Other less common reasons are quality, cost and least often recommendation. Other reasons for selection included, according to orthodontists, hygiene, esthetics, comfort, experience and the patient's wish. First availability, then quality were the main reasons for this choice among Scandinavian orthodontists [15]. According to the Dental Practice Board in the United Kingdom, the popularity of VFRs is probably due to their improved esthetics, lower cost and ease of fabrication [31]. Cost-effectiveness, breakages and patient satisfaction all contribute to the opinion that VFRs were better from all perspectives than Hawley retainers [9, 32, 33]. A factor that cannot be ignored is patient preference. A survey on computer-modified standardized photographs of each subject wearing the different retainers found social perceptions to be influenced by retainer design and appearance [34].

VFR sheet thicknesses of 1.0 mm and 0.75 mm were most commonly recommended by orthodontists, but 1.5 less often [10]. The most used foil thickness for the VFRs in our survey was the 1 mm (71% in Croatia vs. 59% in North Macedonia) and this thickness was most often

used in other studies [10, 21, 35]. A thicknesses of 0.75mm was associated with significantly higher breakage than 1 mm at one-year follow-up [36]. 0.75 mm thickness was associated with higher failure rates than Hawley retainers; with a statistically non-significant difference [37]. Moslemzadeh et al. found similar stability levels for clear retainers made from 1 mm and 1.5 mm and Hawley retainers [38].

An Australian study confirms that thermoformed retainers do not thin out consistently throughout the dentition, being the thinnest over the mid-labial surface of the lower incisors, so there is no clear benefit in using a specific type of thermoforming machine or material [39].

Two-thirds of the orthodontists were unaware of the thermoplastic material used, and 58% did not acquire knowledge of the materials [15]. Only 37% were aware of the type of material used to fabricate their vacuum formed retainers [35].

The expected duration of the VFRs was 1-2 years (more often reported in Croatia than in North Macedonia), however, less than 25% of the patients agreed to make new VFRs in both countries. In the literature the expected lifespan of VFRs is 1-3 years [40], but most orthodontists limit this to a period of up to 2 years [9, 37, 41].

Several factors influence how long particular retainer will serve effectively, like proper removal technique, consistent cleaning, exposure to heat and storage practices. Bruxism, bite force and retainer thickness are also listed as influential.

Many factors can shorten the lifetime of a clear retainer, for example wear and flexibility make it more prone to cracking, staining, and oral fluid absorption. Moreover, because it covers occlusal surfaces it tends to break from the stresses of both functional and parafunctional activities [42].

Part-time wearing of the VFR might also be related to the increased longevity of the material [43]. Staining, white calcium deposits or persistent bad smell are visual and odor changes often signal material breakdown [40].

Effective cleaning methods can increase the lifespan of retainers, maintaining its translucency, flexibility, color stability and promote overall better retainer-wear compliance. Chemical cleaning agents adversely affect each thermoplastic retainer polymer at various degrees. Knowing the polymer used in each clinical set-

ting is pertinent to allow a clinician to advise the best cleaning agent to the patients with the least adverse effects on the retainer properties [44].

The lifespan of the mandibular VFR is shorter than maxillary one, due to high lingual attachment, the increased buccal root torque in posterior segment and greater deformity of the retainer to overcome the mandibular undercut [33].

Reasons for changing the VFR material were more often associated with cost in North Macedonia than in Croatia, thus reflecting the differences in economic background.

Other aspects and concerns arising from the use of polymers and plastics are discussed in the literature, too. Micro plastic release by retainers has emerged as a significant human health and environmental concern. Studies indicate that minuscule non-biodegradable plastic particles can lead to adverse health effects upon ingestion or inhalation, potentially causing systemic inflammation and health risks [45]. In the harsh oral cavity environment, saliva, enzymes, pH, pressure and temperature fluctuations, biting force, etc., aggravate the ageing of material is even more. Water absorption followed by proteinaceous biofilm apposition that in areas with saliva stagnation is prone to calcification, affect the mechanical properties of the thermoplastic materials [46] and may result in leaching of unreacted components including bisphenol-A (BPA) [47]. Our surveyed clinicians had rarely observed adverse reactions to VFR sin both countries. 1% of Scandinavian orthodontists registered an adverse effect like clicking in the TMJ or allergic reactions of the gingiva, lips, and skin, but none of the responders recognized what kind of material caused the side effect [15].

This research is the first comprehensive and comparative survey to identify habits, practices and experiences of the use of VRF in North Macedonia and Croatia, as countries with geographical and social affinities, highlighting regional similarities and differences in clinical practices. This study provides valuable insights, and it can be helpful for in determining direction for improvement. It is also worth continuing the analysis of challenges with the use of VFR in the wider region. One limitation of the study was that participation was voluntary, so there may have been over- or under-reporting. Future studies could include more countries.

CONCLUSION

VFRs are the preferred retention appliances among Croatian and North Macedonian orthodontists, mainly due to their availability. They are well tolerated by patients, but failures usually occur after 1-2 years, and only ¼ of patients decide to have new retention appliances made, which can pose problems with relapse.

Author's contribution:

B.Dz. – conceptualization, data collection and writing; M.Z. – data collection, writing (review and editing); K.B. – data collection, writing; M.Dz. – data collection and writing; S.S. – conceptualization, project leading, data collection, statistical analysis, supervision, writing (review and editing).

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Резиме**УПОТРЕБА И НЕСАКАНИ ЕФЕКТИ
НА ВАКУУМ-ФОРМИРАНИТЕ РЕТЕЈНЕРИ – СПОРЕДБА НА ИСКУСТВАТА
НА ОРТОДОНТИТЕ ВО ХРВАТСКА И ВО СЕВЕРНА МАКЕДОНИЈА**

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Цел: Да се испитаат искуствата со вакуум-формирани ретејнери (ВФР), можните несакани ефекти и проблемите поврзани со нивната употреба кај хрватските и кај македонските ортодонти.

Материјал и методи: Во 2023 година беше дистрибуиран прашалник за протоколите за ретенција по е-пошта до 150 ортодонти во Северна Македонија (78 % од ортодонтите), со стапка на одговор од 58 %, и до 185 ортодонти во Хрватска (85 % од ортодонтите), со стапка на одговор од 75 %.

Резултати: ВФР се почесто користениот апарат за ретенција во Хрватска отколку во Северна Македонија, и во максилата (79 наспроти 53 %, $p < 0,001$) и во мандибулата (66 наспроти 44 %, $p = 0,001$), главно поради достапноста на апаратот (66 % во Хрватска наспроти 53 % во Северна Македонија; $p = 0,056$). Најчесто користената дебелина на фолијата за ВФР е 1 mm (71 % во Хрватска наспроти 59 % во Северна Македонија; $p = 0,019$). Очекуваното времетраење на ВФР е 1-2 години (60 % во Хрватска наспроти 47 % во Северна Македонија; $p = 0,015$), меѓутоа, помалку од 25 % од пациентите се согласни да направат нови ВФР во обете земји. Клиничарите ретко забележале несакани реакции на ВФР (3 % во Хрватска и ниту еднаш во Северна Македонија). Причините за промена на материјалот за ВФР почесто се трошоците во Северна Македонија отколку во Хрватска (62 наспроти 2 %; $p < 0,001$).

Заклучок: ВФР се претпочитани апарати за ретенција кај хрватските и кај македонските ортодонти, главно поради нивната достапност. Пациентите добро ги толерираат, но дефектите најчесто се јавуваат по 1-2 години и само ¼ од пациентите одлучуваат да направат нови ретејнери, што може да предизвика проблеми со релапс.

Клучни зборови: несакани ефекти, ортодонција, ретенција, вакуумски формирани ретејнери