ORAFLOGO JUNIOR GEL USER SATISFACTION TESTING IN PATIENTS IN ORTHODONTIC THERAPY

Andrijana Kovačić M.Sc., DMD, spec.orthod.
Zdenka Nemec, mag. pharm.

Each area of dental medicine uses different means to achieve therapeutic results. Orthodontics is a branch of dental medicine that uses orthodontic appliances in its therapy, which can be divided into fixed and mobile (1).

Like any other medical intervention, orthodontic therapy can bring, aside from numerous benefits, some risks, complications and unwanted side effects.

The first few days after the patient receives the appliance, a feeling of discomfort and irritation occurs, and it takes some time for the patient to get used to the new foreign body in their mouth. Most patients experience their teeth becoming tender and painful, slightly movable, whereas irritations of the mucous membranes of the lips and cheeks are also common, caused by the device or its parts (brackets, wires, bands, hooks ...) in the first days of the therapy. It is possible to prevent or, at least, alleviate such irritations by coating parts of the appliance (brackets and wires) with a layer of wax (the so-called orthodontic silicone) or by applying various medicinal gels and coatings to the damaged mucosa.

For the past ten years, scientists have been working intensively on research into natural ingredients that could completely or partially replace synthetic preparations and thus alleviate mucosal irritations in patients undergoing orthodontic therapy (2,3,4,5,6).

The challenge the orthodontic medicine faces in the 21st century is the implementation of the best scientific knowledge in practice and it represents "golden standard" for the quality of medical care (7).

The **goal of** this study is to investigate the satisfaction of Oraflogo Junior gel users in patients undergoing orthodontic therapy

Keywords: orthodontic therapy, fixed orthodontic appliance, mobile orthodontic appliance, hyaluronic acid

DESCRIPTION OF ORAFLOGO JUNIOR GEL

The active ingredients of the gel are:

Hyaluronic acid - moisturizes the mucosa, accelerates tissue regeneration, reduces swelling and has an anti-inflammatory effect (8,9).

Aloe Vera (Aloe barbadensis) - a statistically significant proven improvement in wound healing, contributes to the reduction of scars, inflammation and moisturizes the mucosa (10,11).

Coenzyme Q10 *(ubiquinone)* **-** a powerful antioxidant, participates in the process of creating cellular energy, stabilizes the cell membrane, has a beneficial effect on periodontitis and reduces the index of bleeding and gingivitis (12,13,14,15,16).

Tea tree oil (Macadamia alternifolia) - statistically proven antibacterial, antifungal and antiviral activity, beneficial effect for healing canker sores and reducing mucosal swelling (17,18,19,20,21,22).

Thyme (Thymus vulgaris) - a beneficial effect in the oral cavity, strengthens the gums and protects against tooth decay.

Gotu kola (Centella asiatica) - contributes to the quality of collagen and prevents the formation of keloids.

Alantoin - has a beneficial effect on irritated skin by regenerating the epidermis.

Mediterranean cypress (Cupressus sempervirens) - has an astringent effect.

Australian walnut (Macadamia ternifolia) - contributes to the regeneration of the adipose tissue.

Fenugreek (Trigonella foenum graecum) - has an analgesic effect, softens skin and reduces scarring.

Horse chestnut (Aesculus hippocastanum) - has an anti-inflammatory effect and reduces swelling.

Anise (Pimpinella anisum) - disinfects the mucous membranes of the mouth and gums.

Tested sample - Oraflogo junior gel is intended for healing gums and oral mucosa: gum erosion, gingivitis, burns, canker sores, gum irritation, ulceration and mechanical damage to the oral mucosa (23,24,25,26).

SUMMARY

The study included patients enrolled in the orthodontic office of Andrijana Kovačić, an orthodontics specialist and a M.Sc. These patients undergo an orthodontic therapy with a fixed or mobile orthodontic appliance (mono-maxillary or bimaxillary aplliance). The survey of customer satisfaction with Oraflogo Junior gel included 100 respondents from the area of Zagreb and the surrounding settlements.

A sample of 100 respondents was used and the survey was conducted for each respondent on two occasions:

- after seven days of using the gel and
- after 14 days of use,

which enabled a comparison of their satisfaction.

The respondents provided data in questionnaires that had the following four groups of data, and since they respondents are underage, the parents or the guardians of patients filled out the questionnaires:

a) three general pieces of data concerning the subjects (sex, age and the orthodontic appliance type);

b) eight questions on satisfaction after seven days of use;

c) the same eight questions on satisfaction after 14 days of use;

d) user remarks and proposals (an open-ended question).

Sixteen questions about satisfaction on the gel use had answers on the scale of five

degrees, where 1 marked the least satisfactory level and 5 marked the greatest satisfaction level. Questions in the questionnaires were of a closed-ended type, with only one possible answer out of more options available, except for one open-ended question.

METHODS OF STATISTICAL ANALYSIS

After collecting the questionnaires, the data were entered into an excel file, from where they were converted into an SPSS file. Based on the SPSS file, certain types of statistical analyzes were performed (using IBM SPSS Statistics 25), while the graphical representation was created using Microsoft Excel 2010.

The statistical analysis methods used here are: descriptive methods (tabular and graphical representations, percentages, means, dispersion measures and Spearman rank correlation coefficient) and inferential methods (Kolmogorov-Smirnov distribution normality test, Wilcoxon sign test and Mann-Whitney U test). Conclusions regarding the differences and correlations between the variables were made taking into consideration the typical significance level of 0.05, with a confidence level of 95%. Since the tested sample included the exact number of 100 respondents, the percentages are not stated anywhere in the data analysis, since the absolute number also represents the percentage.

RESULTS

The sample of respondents consisted of 57 boys and 43 girls (57% and 43%) aged from 3 to 20 (13.7 years mean age). Of the 100 children surveyed, 48 used a fixed and 52 a mobile orthodontic appliance. The average age of users wearing the fixed appliance is 15.0 years, and the mobile appliance users 10.5 years.

The **evaluation rating of gel effectiveness** after 7 days of using the gel, for the first four questions (the reduction of pain, gingivitis, mucosal damage and bleeding gums), most commonly estimated to 4, while after 14 days of use, the most common score of the evaluation was 5. For the reduction of these symptoms, the gel worked favorably, as the scores were between 3 and 5, never estimating to 1 and 2 (see Table 1).

It is also visible from the arithmetic means, which are the highest in the first four questions (all above 4.00), and are always higher after 14 days of use compared to the averages after 7 days of use:

- pain reduction 4.09 <4.53
- the reduction of gingivitis 4.14 <4.55
- the reduction of mucosal damage 4.10 <4.56
- the reduction of gum bleeding 4.10 <4.48

The design / packaging evaluation did not change after 14 days of use compared to the rating after 7 days of use and is 3.49 and 3.48, respectively.

Table 1: The surveyed children, according to their use of *Oraflogo Junior* gel and their satisfaction with it (n= 100)

R b	Question	Testing time	1	2	3	4	5	Total
1.	Pain reduction	after 7 days of use	-	-	17	**57**	26	100
		after 14 days of use	-	-	1	45	**54**	100
2.	Reduction of gingivitis	after 7 days of use	-	-	17	**52**	31	100
		after 14 days of use	-	-	-	45	**55**	100
3.	The reduction of mucosal damage	after 7 days of use	-	-	16	**58**	26	100
		after 14 days of use	-	-	1	42	**53**	100
4.	The reduction of gum bleeding	after 7 days of use	-	-	17	**56**	27	100
		after 14 days of use	-	-	5	42	**53**	100
5.	Evaluation of product design / packaging	after 7 days of use	1	12	35	**41**	11	100
		after 14 days of use	1	14	**36**	34	15	100
6.	Gel flavor evaluation	after 7 days of use	5	22	**41**	28	4	100
		after 14 days of use	5	22	**40**	29	4	100
7.	The number of daily gel uses	after 7 days of use	6	**53**	27	12	2	100
		after 14 days of use	23	**35**	23	16	3	100
8.	General product evaluation	after 7 days of use	-	-	13	**60**	27	100
		after 14 days of use	-	-	2	**53**	45	100

The gel flavor evaluation has similar ratings and has the lowest average of 3.04 and 3.05, respectively, which means that this rating has stayed almost completely the same.

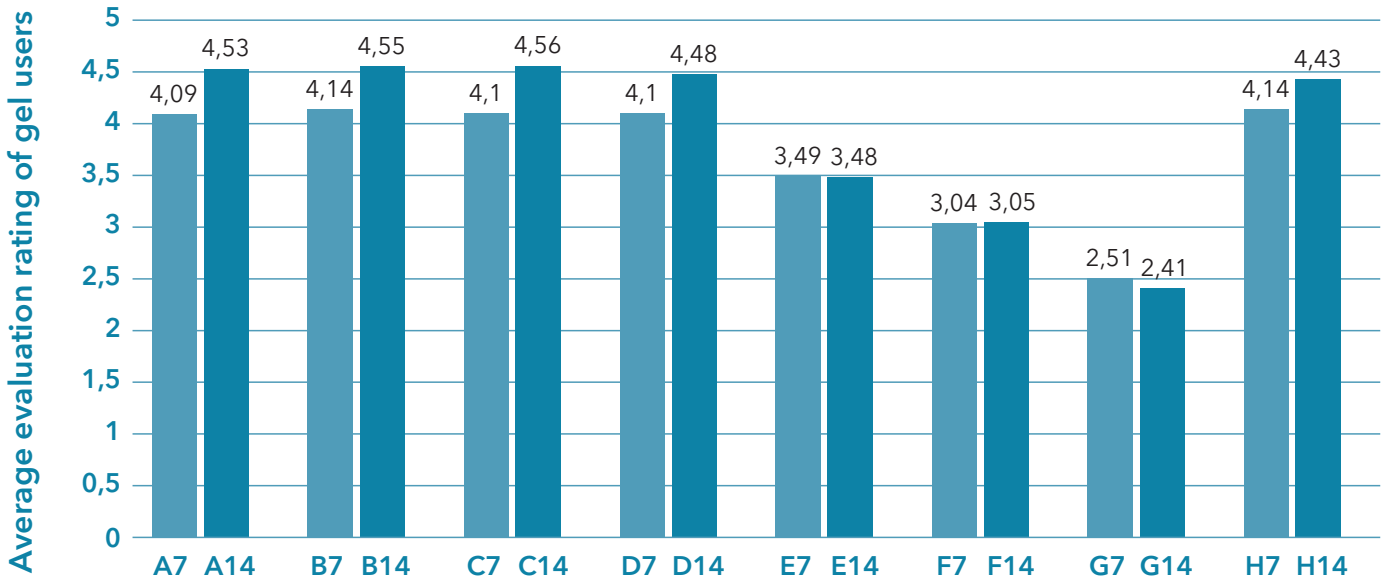
The number of the **daily usage** of the gel varies from 1 to 5 times a day (usually applied twice a day) and has a smaller average decline. Namely, for the use up to 7 days the gel was used 2.5 times a day on average, while after 7 days it was used 2.4 times a day on average.

The general product evaluation is most often 4 so the average is at relatively high 4.14 after 7 days of use and 4.43 after 14 days.

Table 2: Results of descriptive statistical analysis (arithmetic means, standard deviations and coefficients of variation) for n = 100

R. b.	Question	Testing time	Number of tested users	Arithmetic means	Standard deviation	Coefficient of variation
1.	Pain reduction	for at least 7 days	100	4.09	0.653	16
		for at least 14 days	100	4.53	0.521	12
2.	Reduction of gingivitis	for at least 7 days	100	4.14	0.682	16
		for at least 14 days	100	4.55	0.500	11
3.	The reduction of mucosal damage	for at least 7 days	100	4.10	0.644	16
		for at least 14 days	100	4.56	0.519	11
4.	The reduction of gum bleeding	for at least 7 days	100	4.10	0.659	16
		for at least 14 days	100	4.48	0.594	13
5.	Evaluation of product design / packaging	for at least 7 days	100	3.49	0.882	25
		for at least 14 days	100	3.48	0.948	27
6.	Gel flavor evaluation	for at least 7 days	100	3.04	0.931	31
		for at least 14 days	100	3.05	0.936	31
7.	The number of daily gel uses	for at least 7 days	100	2.51	0.859	34
		for at least 14 days	100	2.41	1.102	46
8.	General product evaluation	for at least 7 days	100	4.14	0.620	15
		for at least 14 days	100	4.43	0.537	12

Diagram 1: Comparison of average ratings of Oraflogo Junior gel after 7 days of use and after 14 days of use (n = 100)



Explanation of symbols:
A7 and A14 = Pain reduction after 7 and 14 days of use, respectively
B7 and B14 = Reduction of gingivitis after 7 and 14 days of use, respectively
C7 and C14 = Reduction of mucosal damage after 7 and 14 days of use, respectively
D7 and D14 = Reduction of gum bleeding after 7 and 14 days of use, respectively
E7 and E14 = Evaluation of product design / packaging after 7 and 14 days of use, respectively
F7 and F14 = Evaluation of gel taste after 7 and 14 days of use, respectively
G7 and G14 = Number of daily uses of the gel after 7 and 14 days of use, respectively
H7 and H14 = General product evaluation after 7 and 14 days, respectively

Differences in gel ratings of users of fixed and mobile appliances (Mann-Whitney U test). After 14 days of use, the ratings of users with **fixed** appliances are statistically **significantly higher** compared to the ones with the mobile appliances concerning:

- the reduction of gingivitis
- the reduction of mucosal damage

There was statistically no significant difference in the reduction of pain, gum bleeding, and overall product evaluation.

Differences in gel ratings in male children compared to female after 14 days of use:

the results (Mann-Whitney U test) show that the scores of female children are statistically significantly higher than the scores of male children ($p < 0.05$).

Comments and suggestions:

The majority of users (81%) had no objections, while 19% of users had the following suggestions:

- improve packaging and the applicator 6%
- increase density 3%
- improve flavor 6%
- increase the amount 1%
- add an applicator to apply the product easily 1%
- change the color of gel from yellow to white 5%
- no objections 81%

CONCLUSION

In the end, it can be briefly concluded that the ratings of Oraflogo Junior gel users who use the gel 2-3 times a day are significantly high, that after 14 days of use the ratings are even more favorable than after 7 days of use, that there is no need to improve the product's performance, but only its flavor, color, density and packaging. The obtained research results confirm the quality of action of Oraflogo Junior gel, but at the same time they represent a challenge for future work in order to improve the flavor, change the color of the product and the product packaging in the future.

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