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Original Article

Application of Soft Relining Materials in Dental Medicine - Clinical Results

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Abstract

Aim: The objective of this study was to carry out an in vivo investigation of patients wearing dentures relined with soft materials, assuming their positive and negative alterations in time.

Materials and methods: A direct survey method was used to gather data from 23 patients included in this study (11 male and 12 female patients). Twenty-seven dentures were made (12 partial and 15 total dentures) 9 of which in chairside procedures, 11 - in a laboratory, and 7 were made using the direct-indirect method. Patients were included in regular follow-ups at one month and six months, and at one, two, and three years after dentures delivery. The study started in 2014 and continued till 2017.

The materials we used in the study were quite appropriate to this type of investigation, following the proper clinical and laboratory protocols. The two most commonly used groups of relining materials on the dental market nowadays were tested.

Results and discussion: All participants completed questionnaires which included questions related to changes in retention and stability of the relined dentures, changes in color and softness, in bond strength, and inflammation.

The majority of patients were satisfied with the new dentures, but they also reported some problems concerning the staining and hardness of some of the investigated materials.

Conclusion: There were no significant differences in the behavior of the different groups of materials at six months. After six months we observed decline in the bond strength of the vinyl-polysiloxane (VPS) materials, as well as increased staining and hardness in the poly-methyl-methacrylate (PMMA).

Keywords:

soft relining materials, questionnaire, stability

INTRODUCTION

British Standard Glossary of Dental Terms[1] defines soft relining materials (SRM) as resilient, elastic materials, covering the whole or part of the prosthetic field. They have usually a cushioning effect between the hard denture base and underlying mucosa, distributing the masticatory forces from the denture towards the soft tissues and alveolar bones. Six major groups of SRM (according to their chemical composition) are recognized: Indian rubber, acrylic, silicone, polyvinylchloride, polyurethane, fluoro rubber. According to their method of elastification, the SRM can be divided to: cold, hot and light-curing materials.

Despite the tremendous advance of modern dental medicine, treating completely edentulous patients still presents certain challenges. The encountered difficulties are even

greater in cases of atrophic alveolar ridges, presence of exostoses and undercut zones, expressed tuberosities and torus palatinus.[2,3] The use of soft relining materials (SRM) allows dental specialists to overcome these oral cavity conditions that appear to be adverse with regard to prosthetics. Furthermore, the 'two-layer dentures' are widely considered to be a reasonable alternative in resolving these issues.[4-7]

Nevertheless, SRM have a number of shortcomings, which is the reason why many clinicians refrain from using them.[8] Among these we can cite unreliable bonding with the denture basis[9-12], fast hardening[13-15] and tinting in the conditions of the oral cavity[16-18], as well as the presence of specific flavor and odor. Despite that the Dental Estimates Board Digest of Statistics for England and Wales states that dental laboratories there were able to make in the course of just one year 24000 'two-layer dentures' and reline with SRM 11000 'old' dentures. Besides that in this statistics the relined dentures using the so called 'chairside method' were not included.

The hypothesis of this study was to find out the patients' opinion about their new 'two-layer dentures', despite some of their undeniable shortcomings.

MATERIALS AND METHODS

The aim of the present study was to conduct an in vivo study of patients reporting their opinion of dentures relined with SRM. Specifically for this purpose, a patient questionnaire (Appendix A; Application A1) was developed and provided to the respondents. Recording of changes was scheduled for 1, 3, 6, 12, 24, and 36 months in follow-up examinations. The selection of patients was done by the SRM application criteria (retentive tuberosities, expressed torus palatinus, atrophic alveolar ridges lined with thin mucosa, presence of exostoses, etc.).

In this study 23 subjects were included, divided in two groups by gender (11 males, 12 females), and a total of 27 dentures were made (11 mandibular and 16 maxillary), of which 12 partial and 15 total dentures. Of these 9 dentures were fabricated using the direct method, 11 - the laboratory method, and 7 - the so called direct-indirect method.

The classical clinical and laboratory protocol was observed, i.e. taking an alginate impression with a standard metal impression tray and Ypeen (Spofa). The final impression was taken with Impregum Soft (3M - ESPE) and custom trays fabricated from photo polymerizing material (Megatray – Megadenta). We proceeded with identifying the central position of the lower jaw and then the denture wax try-in. The specifics in this type of prosthesis are the preliminary fabrication of a spacer to guarantee uniform thickness of the relining layer. We used, in particular, a 2-mm thermo-vacuum plate shaped in a vacuum forming device.

Indirect method

Indirect method for PMMA-based SRM

Using the indirect method, after the denture wax try-in and after the wax was rinsed off, the resin (Meliodent – Kulzer) was pressed in a flask, using a polyethylene (PE) foil between the acrylic resin and the spacer. The flask was placed in cold water and gradually heated up to 100°C, holding it for half an hour and then slowly cooling it down to ambient temperature (PMMA remains in pre-polymerized state). The thermo-vacuum plate and the PE-foil were removed and replaced with the SRM. The material we used with this method was Vertex Soft (Vertex), because this SRM is PMMA-based there is a chemical bond with the denture basis and no primer is required.

Indirect method for VPS-based SRM

We used a special primer to ensure bonding with the denture basis, when the relining material is VPS-based (Molloplast B - Detax). The Primo adhesive developed by the same manufacturer was applied twice and left for 60-90 min to dry (according to the instructions for use). To avoid the risk of deformity, the acrylic basis should demonstrate sufficient stiffness when opening the flask.

Molloplast B did not need any preliminary mixing, since it is a ready-to-use material of pasty consistency. It replaced the spacer and with the PE-foil back to place, the flask was closed and pressed. Releasing the pressure, the flask was opened, the PE-foil removed, as well as the excessive relining material.

The flask was re-closed, clamped and then placed in water for final polymerization. The water was gradually heated up to 100°C, maintaining this temperature for two hours, and then slowly cooled down to ambient temperature. We have to point out that there is an alternative way of polymerization for this material, using microwaves. To avoid overheating, we cut and trimmed the relining material at 15000-20000 rpm using the cutting tools and discs specially designed by the manufacturing company.

Direct method

With the materials Mollosil - Detax (VPS-based material) and Tissue Conditioner - GC (PMMA-based material), we applied the method of direct relining. The denture edges were trimmed and the spots traumatizing the mucosa were eliminated. The best precision for this is achieved by using the Pressure indicating pastes specifically intended for this procedure.

On the clean and dry denture, the manufacture branded adhesive was applied, and those areas that need to be protected were treated with coconut oil. The relining material

was mixed (for 30-60 sec., base and catalyst ratio 1:1 for the silicone-based materials or 1:2 powder and liquid for the PMMA-based materials). The mixture was applied to the denture, which in this case was used as a custom tray, and placed into the patient's oral cavity, and then the peripheral edges were functionally shaped. It was left in place for 5 min., after that the denture was taken out, the excessive material removed (with a sharp tool as scissors or a blade), the denture was washed and dried. On the relined surface, a coating agent was then applied for 5 min., paying special attention to the bordering area between the two materials.

Direct-indirect method

For the direct-indirect relining we used Villacryl soft (Zhermack). Mixing was done in a ratio of 2.2 g powder to 1.6 ml liquid. The preliminary contact zones were removed from the denture, providing sufficient space for the relining material (about 2 mm), then the denture was washed with water, dried and coated with monomer. The mixture was spread over the denture and placed into the patient's oral cavity. The patient was instructed to pass his tongue over his lips wetting them with saliva (that would prevent the material from adhering to the soft tissues). Following the functional impression tests and the preliminary polymerization (for about 3-4 min.), the process completion was done in hot water (65°C) and pressure (2 bar) applied for 30 min. in a special device.

Statistical analysis

The data we obtained were analysed using descriptive, correlation, and prognostic analyses and hypotheses verification. The statistical analysis was performed by SPSS statistical package, version 19 (SPSS Inc., IBM Company, Chicago, IL, USA). The data were summarized by frequencies and percentages for variables and by mean values and standard deviation. The independence of categorical data was evaluated with the help of the chi-square test. The results were considered to be statistically significant at p-values <0.05.

RESULTS

In the current study, a total of 23 subjects (12 females and 11 males) were included, some joined the study in 2014 as participants in the University project DP-06/2013. The Ethics Committee at the Medical University – Plovdiv approved the study. It was conducted in accordance with the ethical standards, laid down in the 1964 Declaration of Helsinki and its later amendments, guidelines for good clinical practices, local legislation and regulations on conducting clinical and scientific studies involving human subjects (Appendix A; Application A2). Being comprehensively informed about the aims, objectives and expected outcomes of the study, all the participants completed an informed consent statement (Appendix A; Application A3).

The materials used in this study were divided into two major groups: acrylic and silicone, since these are the most commonly applied soft relining materials, according to the specialized publications in the field. Tissue conditioner (TC) was used in the fabrication of 11 dentures, Vertex Soft (VrS) – 5 dentures, Molloplast B (MB) – 4 dentures, Mollosil (MS) – 5 dentures and Villacryl soft (VlS) – 2 dentures.

Color alterations after consumption of tea, coffee, red wine or tobacco

The following figures present the color alterations of the acrylic and silicone materials as a result of consuming tea, coffee, red wine or tobacco products (**Figs 1, 2**).

The $\chi 2$ independence criterion was applied for verification of the null hypothesis (H_0: Color alterations of the material as a result of consuming tea, coffee, red wine or tobacco products are not time related), versus the alternative hypothesis (H_1). The frequency distribution analysis with IBM SPSS Statistics 19 gave as a result $\chi^2_{emp.} = 47.478$, $p<0.0001$. Therefore the main hypothesis was rejected, accepting that color alterations of the material as a result of consuming tea, coffee, red wine or tobacco products are time related.

In comparison of color stability between acrylic and silicone materials as a result of consuming tea, coffee, red wine or tobacco products, the frequency distributions p-values of the acrylic materials and that of the silicone materials were used separately. The results proved that the p-values in both groups are insignificantly small. For the acrylic materials $p<0.0001$. We therefore adopted the hypothesis of greater stability of color in the silicone materials compared to the acrylic ones, though not so definitely expressed as a tendency.

Hardness changes

The frequency distributions of hardness changes in acrylic and silicone SRM are presented in **Figs 3, 4**.

Considering the difference in the chemical composition of the acrylic and silicone materials, they were subjected to separate analysis. The following two working hypotheses were formulated: H0: the elastic properties of the acrylic materials are not time related, versus the alternative hypothesis: (H_1).

The result was $\chi^2_{emp.} = 36.3733$ and $p<0.0001$. The H_0 was therefore rejected, and the alternative one confirmed. The frequency distributions of the silicone materials (**Fig. 4**) showed that all inquired subjects (100% of the inquired), irrespective of the period of use, reported absence of notable changes in the material hardness. Time, therefore, affects the elastic properties of the acrylic materials, but has almost no effect on silicone materials.

Data showed that during the first 6 months of the study, just a very small number of the inquired subjects noticed

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any changes in the relining material hardness. That gave us grounds to study the results on the materials' hardness in shorter periods of time. The following hypothesis was verified:

H_0: by six months no considerable changes in the hardness of the materials were observed, versus the alternative hypothesis (H_1).

For verification with IBM SPSS Statistics 19, only the data of: 1 week, 1 month and 6 months were used. The result was $\chi^2_{emp.}$=5.891 and the respective p=0.0526. It presented that with confidence factor of 0.05 there was no ground to reject H_0 and it was due to be considered confirmed. This allowed the conclusion that by the sixth month, no significant changes in the hardness of neither the acrylic nor the silicone relining materials were observed.

Bond failure and disintegration

Problems with the bonding and disintegration of the acrylic and silicone SRM are presented in **Figs 5, 6.**

The χ^2- independence criterion was applied for verification of the following hypothesis (H_0): stability in terms of detachment or disintegration of the acrylic materials is not time related, versus its alternative (H_1).

In the analysis of the frequency distribution performed with IBM SPSS Statistics 19, the result for the empirical quantity was $\chi^2_{emp.}$= 5.417 and p=0.862, which gave no grounds for rejecting H0 and it was thus confirmed. It is considered that in the course of time the acrylic materials remain stable in terms of detachment or disintegration.

Applying the χ^2- independence criterion to the frequency of only the "Yes" and "No" answers, the following hypothesis was verified (H_0): stability in terms of detachment or disintegration of the silicone materials is not time related, versus its alternative (H_1). The obtained result with IBM SPSS Statistics 19 was $\chi^2_{emp.}$=16.145, p=0.006443, which was the reason H_0 was rejected and the alternative one confirmed.

The inquiry results showed that the silicone materials stability in terms of detachment or disintegration decreases in time.

DISCUSSION

This study is the first to evaluate the majority of the positive and negative features of the SRM in Bulgaria. There is an enormous variety of materials nowadays on the market and our results could be of great help to the general practitioners in their everyday work.

Having a positive or negative feedback is very important from a practical point of view. It helps the practitioner to overcome even the most difficult obstacles, thus solving patients' problems. The results from the inquiry show that despite some undeniable disadvantages, patients declare their overall satisfaction from the new dentures. Moreover, they were invited to have regular follow-ups for a three-year period of time. This period is long enough to achieve some basic conclusions about investigated materials and their behavior in time.

Most of the in vivo results confirm the findings from our previous in vitro experiments with the same materials.[19-21] All patients included in this study stated that the retention and the stability of their dentures improved and no signs of soreness or redness were noticed. This is due to the cushioning effect of the SRM. This fact is reported by other authors.[5,22] Obviously the alterations in color are one of the most frequently mentioned shortcomings, from an esthetic point of view and that they are time related. The statistical analysis confirmed the hypothesis of greater stability of col-

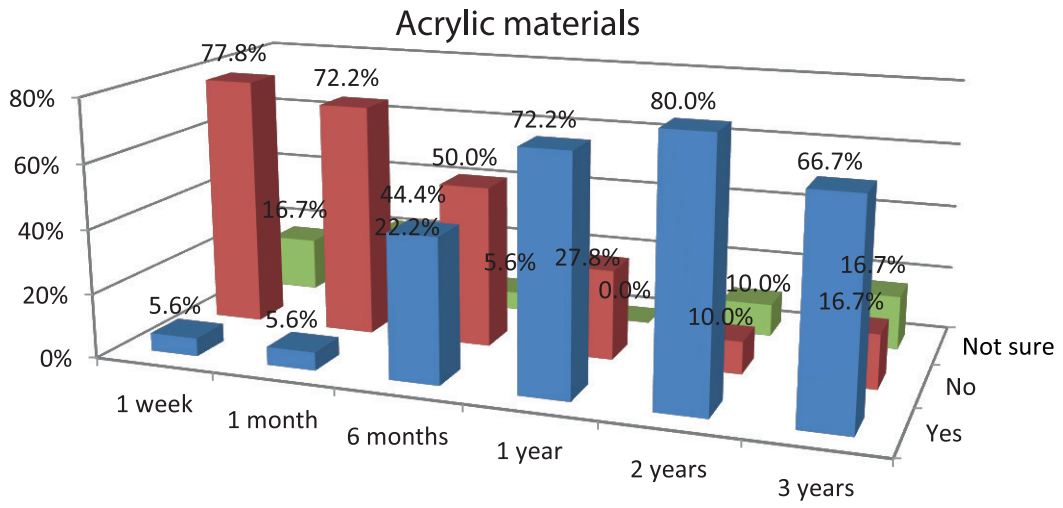

Figure 1. Alterations in color regarding a 3-year follow-up period (for acrylic SRM).

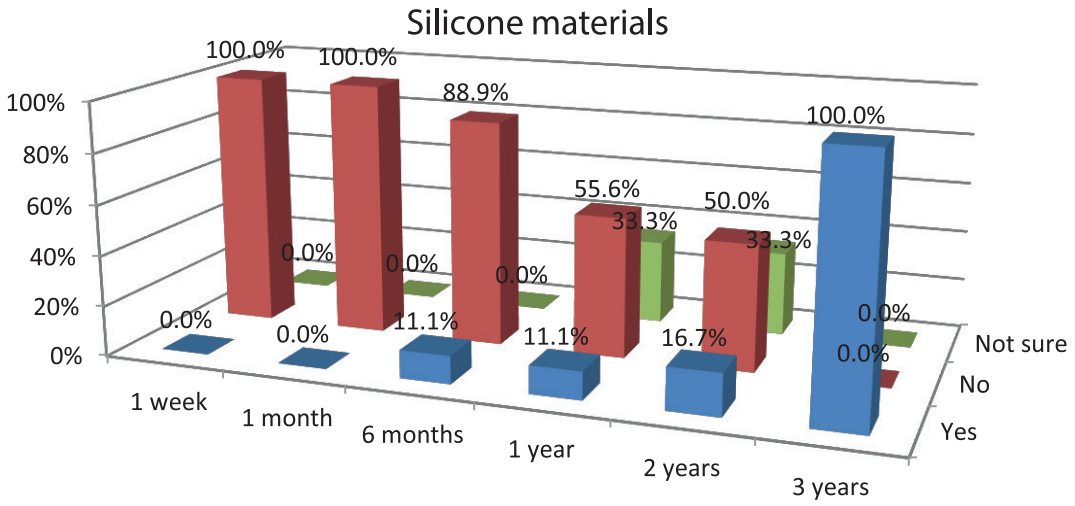

Figure 2. Alterations in color regarding a 3-year follow-up period (for silicone SRM).

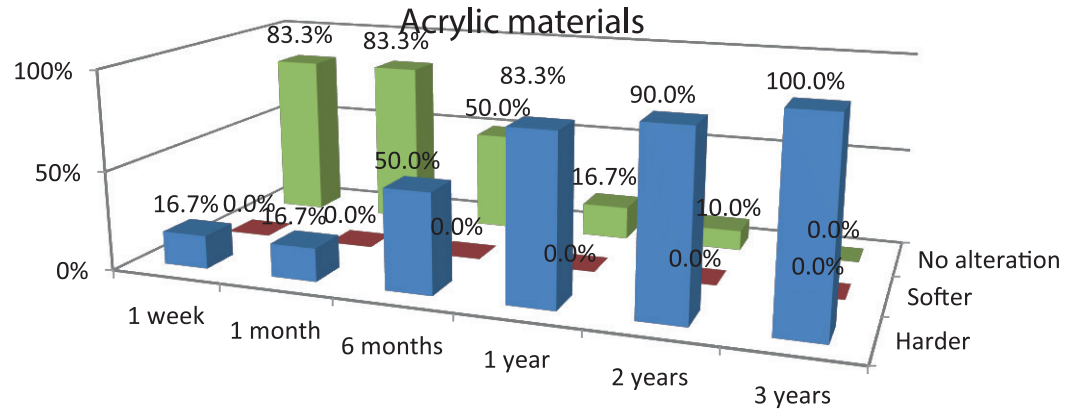

Figure 3. Alterations in hardness for a 3-year follow-up period (for acrylic SRM).

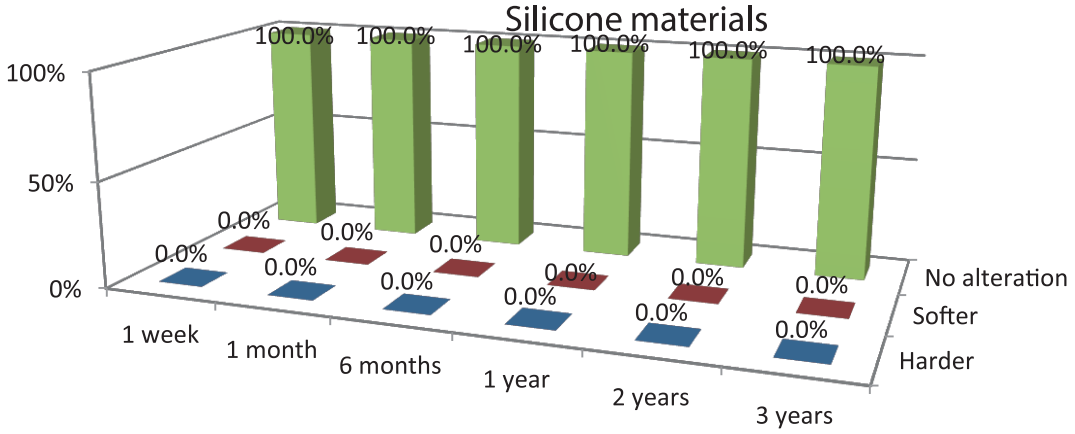

Figure 4. Alterations in hardness for a 3-year follow-up period (for silicone SRM).

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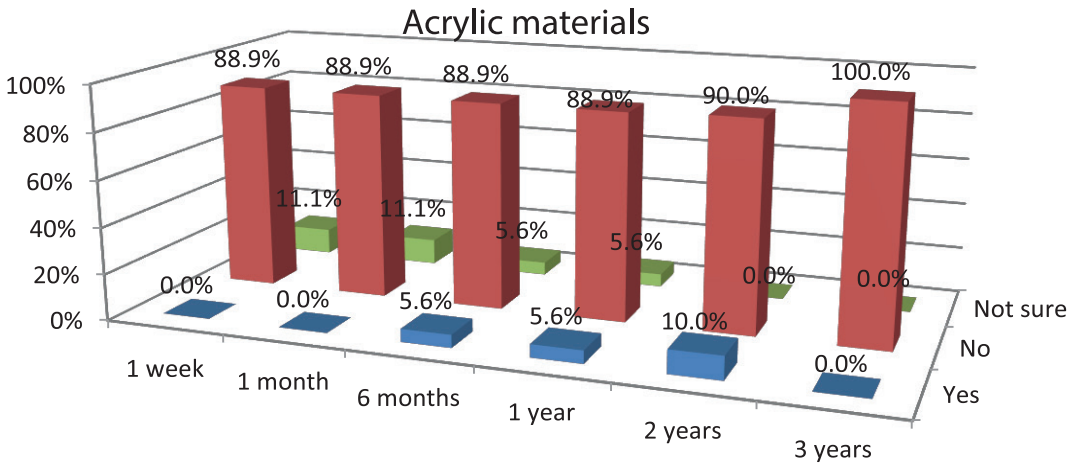

Figure 5. Detachment or disintegration of the acrylic SRM.

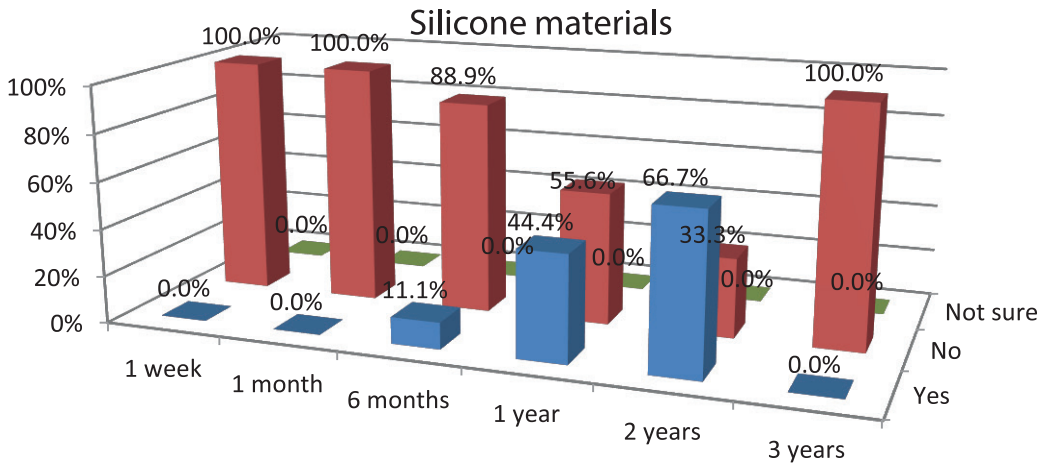

Figure 6. Detachment or disintegration of the silicone SRM.

or for the silicone materials compared to the acrylic ones, though not so definitely expressed as a tendency. The presence of plasticizers increases the polymer chains stretching thus ensuring pigments penetration inside the material. On the other hand plasticizers and alcohol leaching opens some extra space into the PMMA molecule, which is easily occupied by the colorants. PMMA molecules, besides, are hydrophilic and that leads to further attraction of the aqueous molecules and water absorption. Color stability depends on the quantity of the residual monomer as well. Its behavior is similar to that of the plasticizers. It increases the porosity of the SRM, allowing the pigments to penetrate deep into the material.[23,24]

The fluids have no adverse effect on the silicone materials. Being hydrophobic they do not allow any water penetration. That is why they are considered to be more stable as far as staining is concerned. Higher levels of absorption and solubility are connected with changes in color, odor, growth of pathogenic microorganisms etc. These two processes can be used as a landmark of the durability of the SRM. All VPS materials contain silica particles in different concentration. These modified fillers are hydrophobic by nature and repel the water molecules. That statement is in agreement with other researchers.[4,25,26]

Surface irregularities also play a crucial role in denture staining. The rougher the surface is the easier the pigments will be gripped to it. That is why it is very important for the dentures to be clean and very well polished.[27-29] Using specially designed soft brushes is recommendable.

Alteration in hardness is another shortcoming of the SRM. While the VPS materials remain relatively soft for a very long period, the PMMA group, because of plasticizer

leaching after the 6-th month becomes hard. That was confirmed by the statistical results of our investigation and is with agreement with the findings of Yano et al.[30] The softness can be preserved by adding of a superficial layer of coating agent called sealer. The alcohol has a deteriorating effect on SRM. That is why the patients should be advised to be very careful when using different disinfectant solutions, because some of them could be inappropriate for this purpose or in case they drink too much liquor. Some of the in vivo results differ from the in vitro tests and this is due to the diet, enzymes, microorganisms, drugs, changes in pH, temperature etc.

Type of polymerization is of primary importance as well. The SRM treated by heat, pressure or microwaves in the dental laboratories have higher degree of polymerization, in comparison to the materials used for direct relining.[31,32]

To improve the bond strength a lot of authors suggest various methods, including laser treatment, sandblasting, use of monomer, maleic acid etc. There are several types of tests for estimating the bond strength between two materials including: tensile bond strength, sheer bond strength and peel bond strength.[33-35]

From the statistical analysis it becomes evident that with the course of time the acrylic SRM remain stable in terms of detachment or disintegration. This can be explained with their similar chemical composition with the denture base material. The chemical bond is very strong and reliable.

On the other hand the inquiry results show that the silicone SRM stability in terms of detachment or disintegration decreases with time. The problem is that VPS and PMMA are very different from chemical point of view.

The findings of our study may differ from others, because of differences in study designs, tested materials, duration or applied statistical methods.

Study limitations

1. The number of patients included in this study is not representative for all denture wearing patients in Bulgaria.
2. Some major advantages and disadvantages of SRM were analyzed, but other criteria may be included in future investigations.
3. To have a better clinical perspective for these materials, the follow-up period can be increased.

CONCLUSION

1. The use of SRM leads to considerable improvement of retention and stability of the dentures, which is a reason for higher self-confidence and contentment of the patients.
2. Staining is one of the SRM shortcomings having adverse effect to esthetics.
3. Because of the plasticizers' leaching from SRM (PMMA-type), they become hard after 6 months.
4. The bond strength between the SRM (PMMA-type) and the denture base is more reliable due to their chemical similarity.
5. The relining materials for direct use are easy and convenient to work with, however with a comparatively short term of duration in the oral cavity, and therefore recommended for temporary application.
6. The dentures fabricated in dental laboratories (indirect method) demonstrate better physical and medico-biological properties, and are functionally operational for years.
7. The collected data reveals the fact that nowadays there is no single relining material to cover the entire set of physical, chemical and medico-biological criteria.

ABBREVIATIONS USED IN THIS ARTICLE

SRM: soft relining materials; CAD-CAM: computer-aided design, Computer-aided manufacturing; PMMA: poly-methyl-methacrylate; VPS: vinyl-polysiloxane; PE: polyethylene

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Addendum 1

PATIENT ASSESSMENT FORM

Name: …… Date: ……
Address: …… Phone: ……
Diagnosis: ……
Relining material: ……
Relining technique: ……

1. Has denture retention (at rest) improved after being relined with the soft relining material?

	At 1 wk	At 1 mo	At 6 mos	At 1 yr	At 2 yrs	At 3 yrs
Yes						
No						
I cannot assess						

2. Has the stability of the denture improved (while in action) after being relined with the soft relining material?

	At 1 wk	At 1 mo	At 6 mos	At 1 yr	At 2 yrs	At 3 yrs
Yes						
No						
I cannot assess						

3. Have you noticed any changes in the colouration of the denture after it was cleansed with disinfectant agents ?

	At 1 wk	At 1 mo	At 6 mos	At 1 yr	At 2 yrs	At 3 yrs
Yes						
No						
I cannot assess						

4. Have you noticed any change in the colouration of the denture after you have tea, coffee, red wine, or a cigarette?

	At 1 wk	At 1 mo	At 6 mos	At 1 yr	At 2 yrs	At 3 yrs
Yes						
No						
I cannot assess						

5. Have you noticed any changes in the hardness of the relining material with time?

	At 1 wk	At 1 mo	At 6 mos	At 1 yr	At 2 yrs	At 3 yrs
It became harder						
It became less hard						
I noticed no change						

Folia Medica

6. Have you noticed any evidence of changes in the bond strength or disintegration of the relining material?

	At 1 wk	At 1 mo	At 6 mos	At 1 yr	At 2 yrs	At 3 yrs
Yes						
No						
I cannot assess						

7. Have your overall comfort and confidence improved with your new dentures?

	At 1 wk	At 1 mo	At 6 mos	At 1 yr	At 2 yrs	At 3 yrs
Yes, they have definitely improved						
No, it is rather the opposite						
I noticed no change in them						

8. Do you notice redness or decubitus ulcers to the mucous membrane (to be completed by the attending dentists?)

	At 1 wk	At 1 mo	At 6 mos	At 1 yr	At 2 yrs	At 3 yrs
Yes, there are some						
No, there aren't any						
There is no change						

Date: ……..... Signature:….....

Addendum 2

MEDICAL UNIVERSITY - PLOVDIV
RESEARCH ETHICS COMMITTEE

Rector's Office
15A Vassil Aprilov Blvd.,
4002 Plovdiv

Phone: + 359 32 /602-588;
fax: +35932 /602-534

Medical University
Entry No 13-1544/13.03.2014

RESOLUTION

OF THE RESEARCH ETHICS COMMITTEE
AT THE MEDICAL UNIVERSITY PLOVDIV

Ref Entry No P-708/28.01.2014: Interuniversity research project (DP-06/2013) on the following topic: "Investigation of the strength of the bond between the prosthetic base and different types of relining materials and of the factors causing the destruction of the bond" with professor Hristo Kissov DDSc (Department of Prosthetic Dentistry, Faculty of Dental Medicine, Medical University, Plovdiv) as academic supervisor and Senior

Assistant Professor Ilian Hristov DD (Department of Prosthetic Dentistry, Faculty of Dental Medicine, Medical University, Plovdiv) as leading researcher.

After considering and discussing in detail the submitted documents related to the research project (the set of documents included The Research Summary, The Research Plan and Design; the Informed Consent Form, the Patients information, Clinical Card – Samples, and the Declaration of the leading researcher), the Research Ethics Committee at its meeting No. 1/06.02.2014, considers that

The proposed study is in complete accord with the criteria of scholarly and ethical standards

and complies fully with the Helsinki Declaration of Ethics in Science, the Principles of Good Clinical Practice, and the Bulgarian laws and regulations for conducting clinical and scientific research involving human subjects.

Date: 20.02.2014

Chairwoman: …..(Signature)
Professor M. Stoycheva, DMSc

Addendum 3

INFORMED CONSENT FORM

Participants's full name and age:……

……..
(address and phone of an individual for contact)

After I have been informed in detail about the ideas, aims and expected results of the study and after I have had the opportunity to ask questions to the leading researchers I hereby certify with my signature that I have given my consent to the following

- I voluntarily agree to participate in this research
- I shall collaborate with the attending physicians and strictly follow their instructions and recommendations.
- I shall come at the appointed days for control examinations.
- I am aware that the materials used in the research are not experimental and have no adverse effects on the human body.
- I acknowledge that the treatment plan may be changed during the course of treatment according to the requirements of the clinical protocol.
- I understand that I am free to withdraw from the research at any time without the act affecting the quality of my treatment.
- I have read and understand that my anonymity is guaranteed and my personal data will not be disclosed without my explicit consent.

Date: ……

Plovdiv……..….....……..(Patient)…….....……(Signature)

Применение мягких подкладочных материалов в стоматологии - клинические результаты

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Абстракт

Цель: Цель настоящей работы состояла в том, чтобы провести исследование in vivo пациентов, носящих протезы, с подкладкой из мягких материалов, учитывая их преимущества и недостатки с течением времени.

Материалы и методы: Метод прямого исследования использовался для сбора данных по 23 пациентам, включенным в это исследование (11 мужчин и 12 женщин). Было изготовлено 27 протезов (12 частичных и 15 полных), 9 из которых во время процедур в стоматологическом кресле, 11 в лаборатории и 7 были изготовлены с использованием прямого-косвенного метода. Пациенты были обследованы в первый и шестой месяцы, а затем в течение первого, второго и третьего года после установки протеза. Исследование началось в 2014 году. и продолжалось до 2017 года.

Материалы, использованные в исследовании, были вполне подходящими для этого типа исследования и следовали правильным клиническим и лабораторным протоколам. В наши дни были протестированы две наиболее часто используемые группы материалов для подкладок на стоматологическом рынке.

Результаты и обсуждение: Все участники заполнили анкету, включающую вопросы, касающиеся изменений в сохранении и стабильности подкладочных материалов, изменения цвета и мягкости, силы связывания и воспаления.

Большинство пациентов были довольны новыми зубными протезами, но они также сообщили о проблемах по поводу появления пятен и жёсткостью некоторых из исследованных материалов.

Выводы: В случаях с кистозными поражениями молочной железы из эндемичных районов мы рекомендуем применение любого метода диагностики, кроме маммографии и / или ультразвука. КТ и МРТ являются более точными, но дорогостоящими методами без возможности изменения хирургической практики. В отличие от других мест локализации КЭ, тотальное удаление кист является лучшим диагностическим и терапевтическим подходом.

Ключевые слова

Мягкие подкладочные материалы, анкета, стабильность