The Pharma Innovation Journal 2017; 6(4): 166-171

www.ThePharmaJournal.com

The Pharma Innovation

ISSN (E): 2277- 7695
ISSN (P): 2349-8242
NAAS Rating 2017: 5.03
TPI 2017; 6(4): 166-171

www.thepharmajournal.com
Received: 28-02-2017
Accepted: 30-03-2017

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Clinical analysis of the efficiency of hydrogel use on the basis of adhesive active polymer with antiseptic in the composition of temporary removable laminar denture

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Abstract
The results of study of laboratory and technical combination of hydrogel adhesive – active polymer enriched with chlorhexidine bigluconate with basis of removable acrylic denture and application of modified denture in the clinic are presented in paper. It is established that the use of worked out construction contributes to the improvement of the process of epithelialization of damaged tissues through the direct influence of a therapeutic drug for tissue prosthetic bed, allows for the admission of a strictly controlled amount of preparation into affected area, prevents the spread of the medication throughout the oral cavity. The improving of efficiency of treatment is associated with the decrease of clinical manifestations of the negative effect of the removable denture that allows to loos and absorb the peaks of the chewing pressure, creating favorable conditions for further prosthetics.

Keywords: Removable prosthetics, hydrogel adhesive – active polymer, chlorhexidine bigluconate, generalized periodontitis, medicamental drug of prolonged local action

Introduction
For the patients with generalized periodontitis at the multiple extractions in the frontal area of jaws especially there is a question of temporary prosthetics for providing of both function and aesthetics and ensure of quality of the postoperative wound healing and reducing the time from an operation to permanent prosthetics. There are similar requirements at two-stage implantation with application four and more implants, particularly in the frontal area of jaws, when for the regeneration of aesthetics is possible use of only temporary removable denture.
Through the necessity of prevent complications after dental interventions, associated with the violation of integrity of the mucous membrane of the oral cavity, there is a need to develop better technology of the support of appropriate concentration of active medicinal substances still need of temporary prosthetics [1, 2].
The use of drugs according to traditional schemes often does not allow purposefully delivering medications to wound surfaces. For an effective action the medicament must penetrate to all problem area and its concentration must be supported during long period of time. The observance of such requirements in the oral cavity complicate through permanent moisturing of mucosa, regularity of eating, difficult relief of elements of the oral cavity, presence of prosthetic constructions.
Providing of local delivery of pharmaceutical ingredients acquires popularity as a result of prolonged medicamental action and greater concentration of preparation in the necessary area, applying low doses of total exposure with the corresponding decrease of side effects compared with their systemic entering. The considerable pharmaceutical activity is provided with the pronounced oral mucosa expressed capillary net, bypassing the internal organs, which in its turn leads to high bioavailability. The drugs local delivery enables the pharmaceutical ingredients using which are not suitable for systemic administration [3, 4, 5, 6].
The purpose of the study was to learn laboratory and technical combination of the system of local delivery of pharmaceutical ingredients of the hydrogel adhesive − active polymer, enriched with chlorhexidine bigluconate with basis of temporary removable denture and application of modified denture in the clinic.

Materials and methods
Offered by nonreactive hydrogel − adhesive active polymer based on a copolymer hydroxyethyl methacrylate with polyvinylpyrrolidone molecular weight of 12 thousand

obtained by the method of block copolymerization with participation of peroxide initiator with subsequent stepwise hydration in hot water, solution of sodium bicarbonate and 3% hydrogen peroxide, worked out on the department of chemical technology of plastics processing of the National University „Lviv Polytechnic". The hydrogel lining composed of temporary removable denture is attractive from the position of good bio tolerance, high sorption capacity of water-soluble and alcohol-soluble substances, resistance to high temperatures (110 – 120 °C) and typical highly elastic condition [7, 8].

As a medicamental excipient chlorhexidine bigluconate was used in research, that owns property to contact with the surfaces of soft and (or) hard tissues of the oral cavity, creating the „depot of medications" thus. The connective preparation is gradually secreted in a bioactive form that prolongs the period of its half-life. This property is known as substantively and first described in dentistry relatively to chlorhexidine. This property is known as substantively and described for the first time in dentistry relatively to chlorhexidine [9]. The mechanism of preparation action is that the positively charged molecules of chlorhexidine contact with the negatively charged components of membrane of bacteria and proteins of saliva. Chlorhexidine is adsorbed on the surface of cellular membrane of sensitive to it microorganisms with strong adsorption to the certain components containing phosphate. In turn, that violates the integrity of the membrane and increases its penetration. The preparation is gradually secreted from connection with proteins of saliva and acts as an antiseptic during 8−12 hours.

For creation of method and confirmation of its efficiency were performed laboratory studies in vitro with the use of hydrogel with chlorhexidine bigluconate composed of temporary removable denture. A test tube was poured with the solution (5 ml) of 0.05% chlorhexidine bigluconate and sample (10 × 10 × 2 mm) of the hydrogel for adsorption of preparation was placed in this solution. At the same time in 3 cases (chart 1, samples 1, 2, 3) sorption was during 30 min, in 3 more cases (chart 2, samples 4, 5, 6) sorption was 60 min and for samples 7, 8, 9 (chart 3) sorption was carried out during 90 min.

Then in a clean test tube poured 5 ml of water, placed the corresponding sample of saturated polymer and performed measuring of the optical density of water solution at stated intervals. The charts of corresponding experiments are given below (from the calculation of concentration mcg in 5 ml on 1 g of polymer): chart 1 − for time of sorption 30 min, chart 2 − for 60 min and chart 3 − for 90 min, relatively.

The desorption process occurred in two stages. The first stage included the rapid secretion of preparation, which depend on the time of the polymer saturation in chlorhexidine bigluconate solution. In samples with 30 min sorption (chart 1) the first stage was protracted 110−130 min with the solutions concentrations in the range of 180−220 mcg/ml. At the second stage the deceleration of secretion in the conditions of poise.

In samples with 60 min sorption the first stage was protracted 280 min (chart 2) with the solutions concentrations in range of 170−240 mcg/ml.

In samples with 90 min solution of chlorhexidine bigluconate (chart 3) the first stage was protracted 230 min with solutions concentrations of 560 mcg/ml, that testify to possibility of slow secretion of medicinal preparation.

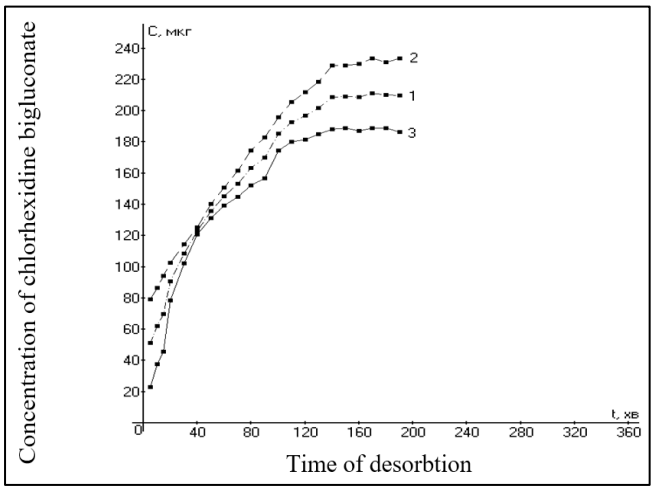

Chart 1: Desorption of samples with sorption time 30 min in 0.05% solution of chlorhexidine bigluconate (numbers indicate the number of sample of copolymer)

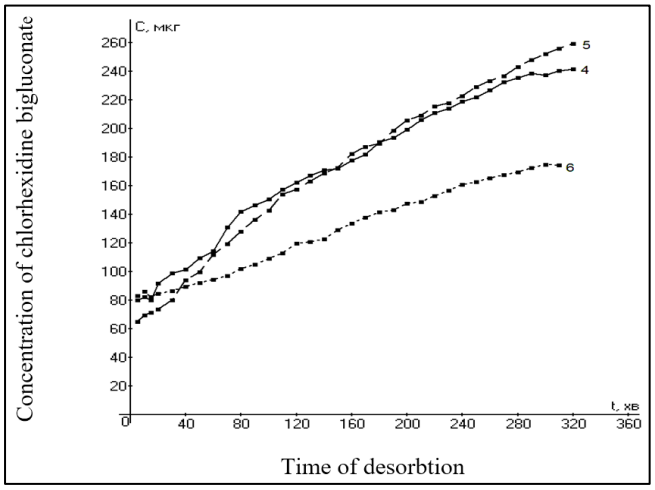

Chart 2: Desorption of samples with sorption time 60 min in 0.05% solution of chlorhexidine bigluconate (numbers indicate the number of sample of copolymer)

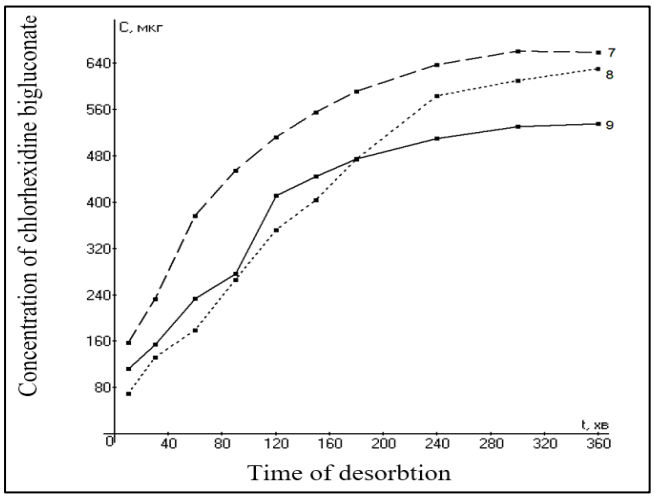

Chart 3: Desorption of samples with sorption time 90 min in 0.05% solution of chlorhexidine bigluconate (numbers indicate the number of sample of copolymer)

On the basis of conducted studies it was established that the most of medicinal preparations desorb samples obtained in sorption for 90 min. The time of offensive of poise processes sorption-desorption comes through 300−320 min saturation

(sorption) of the polymer by medicinal preparation means 60 and 90 min. For the saturation (sorption) of the polymer by chlorhexidine bigluconate for 30 min poise is achieved after 140−160 min.

The secretion of medicinal preparation in all cases has been happening for a long time. When second stage of desorption offensive medicinal preparation is not secreted completely and can preparative act from the surface in the state of established poise for a long time.

A possibility of the use of hydrogel lining as cover layer of the bases of removable dentures with determination of strength of its connection with the base of acrylic denture compared to elastic plastics of Villacryl Soft and Latacryl-L also studied. The samples investigated on adhesion strength, change and tear away. The studies of adhesion strength of hydrogel lining with acrylic plate carried out on bursting machine brands 050/RT-601U of the company „Kimura Machinery" at the speed of moving of crosshead a 25 mm/min.

The obtained results justified that the proposed polyvinylpyrrolidone−methacrylate hydrogel composition is characterized by high adhesion to acrylic materials. In comparing to the elastic plastics of Villacryl Soft and Latacryl-L indicators of adhesion a strength of the connection of hydrogel composition with the denture basis on acrylic base are higher and allow use it as cover layer of basis of removable dentures in practice of the dentistry [10].

For study the local effect of hydrogel with a therapeutic agent consisting of a temporary removable denture was conducted clinical study. The control and main group consisted of 40 patients with generalized periodontitis who needed to remove 2 or more teeth on the stage of complex periodontal treatment, including removable prosthetics. All of randomized patients were divided into two groups comparable by age and sex on main group (20 persons) and comparison group (20 persons).

The comparison group received the traditional complex of treatment with included surgical removal of teeth with next local treatment of postoperative wound. In one hour after removal of teeth temporary removable laminar denture was laid on patients with local medicamental therapy, which included irrigation with chlorhexidine bigluconate of the mucous membrane of oral cavity triple during 10 days.

In the main group on temporary denture in the projection of areas of remote teeth carried out individualized modeling and attached to the internal surface of denture hydrogel on the basis of adhesive active polymer [11, 12] enriched with chlorhexidine bigluconate. In addition to general recommendations patients were recommended after the hygienic cleaning of the denture appliance at first it in 3% solution of hydrogen peroxide during 10−15 minutes every day for cleaning hydrogel, with next immersion in 0.05% solution of chlorhexidine bigluconate during 1.5−2 hours [13].

At the local examination accented attention on the next signs of inflammation: swelling of soft tissues, pain at palpation, exposure of zones of irritation and hyperemia.

The dynamics of wound healing estimated on the next parameters: cleaning of wound, presence of granulation, epithelialization and getting used to denture.

The estimation of clinical signs was carried out after the point system:

A − presence of symptom;

B − depletion of symptom;

C − absence of the symptom.

The term of clinical observation started on the second day after operation and conducted during 10 days.

Results of the research and their discussion.

The studied hydrogel on the basis of adhesive active polymer saturated with chlorhexidine bigluconate combined with the basis of removable denture was used in 20 patients of the main group. The obtained results were compared with results of the study of 20 patients in the control group. The general state of patients in both groups during the observation period was noted as satisfactory.

The comparative analysis of clinical parameters of the control and main groups showed next (table 1, 2). The signs of inflammation in the control group of patients started to deplete from 3−4 days and in patients of the main group starting in 2 days.

Patients of the control group had an active process of reduction of inflammation for 5−7 days against 3−5 days in patients of the main group.

At a comparative analysis in percent equivalent the decrease of inflammatory process was found on the 4th day in 40% in the main group was revealed in the contrast to 10% in the control group and 83% in the main group against 55% in the control group on 6th day respectively.

The results of dynamics of wound healing in patients of the control and main group are given in table 3, 4.

Table 1: Clinical parameters of the control group

Clinical signs	Terms of observation (day)																																			
	1		2		3				4				5				6				7				8				9				10	
	A		A		A		B		A		B		A		B		A		B		B		C		B		C		B		C		C	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Edema	20	100,0	20	100,0	18	90,0	2	10,0	17	85,0	3	15,0	14	70,0	6	30,0	10	50,0	10	50,0	7	35,0	13	65,0	4	20,0	16	80,0	1	5,0	19	95,0	20	100,0
Pain at palpation	20	100,0	20	100,0	18	90,0	2	10,0	17	85.0	3	15,0	15	75,0	5	25,0	9	45,0	11	55,0	7	35,0	13	65,0	5	25,0	15	75,0	2	10,0	18	90,0	20	100,0
Zones of irritation	20	100,0	20	100,0	19	95,0	1	5,0	18	90,0	2	10,0	14	70,0	6	30,0	10	50,0	10	50,0	8	40,0	12	60,0	4	20,0	16	80,0	2	10,0	18	90,0	20	100,0
Hyperemia	20	100,0	20	100,0	19	95,0	1	5,0	18	90,0	2	10,0	12	60,0	8	40,0	7	35,0	13	65,0	5	25,0	15	75,0	3	15,0	17	85,0	1	5,0	19	95,0	20	100,0

Table 2: Clinical parameters of the main group

Clinical signs	Terms of observation (day)																															
	1	2					3				4				5				6				7				8		9		10	
	A	A		B			A		B		A		B		B		C		B		C		B		C		C		C		C	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Edema	20	100,0	18	90,0	2	10,0	14	70,0	6	30,0	9	45,0	11	55,0	4	20,0	16	80,0	3	15,0	17	85,0	1	5,0	19	95,0	20	100,0	20	100,0	20	100,0
Pain at palpation	20	100,0	19	95,0	1	5,0	15	75,0	5	25,0	10	50,0	10	50,0	4	20,0	16	80,0	2	10,0	18	90,0	1	5,0	19	95,0	20	100,0	20	100,0	20	100,0
Zones of irritation	20	100,0	20	100,0	-	-	18	90,0	2	10,0	15	75,0	5	25,0	9	45,0	11	55,0	5	25,0	15	75,0	3	15,0	17	85,0	20	100,0	20	100,0	20	100,0
Hypere-mia	20	100,0	20	100,0	-	-	18	90,0	2	10,0	14	70,0	6	30,0	7	35,0	13	65,0	4	20,0	16	80,0	2	10,0	18	90,0	20	100,0	20	100,0	20	100,0

Table 3: Dynamics of wound healing in the control group

Clinical signs	Terms of observation (day)																															
	1	2	3				4		5		6		7		8		9		10	
	C	C	C		B		C		B		C		B		B		B		B		B		B		B		A		A	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Cleaning of wound	20	100,0	20	100,0	15	75,0	5	25,0	9	45,0	11	55.0	4	20,0	16	80,0	3	15,0	17	85,0			20	100,0			20	100,0			20	100.0	20	100,0
Granulation	20	100,0	20	100,0	19	95,0	1	5,0	16	80,0	4	20,0	14	70,0	6	30,0	10	50,0	10	50,0	4	20,0	16	80,0	1	5,0	19	95,0			20	100.0	20	100,0
Epitheli-zation	20	100,0	20	100,0	20	100,0	-	-	18	90,0	2	10,0	15	75,0	5	25,0	9	45,0	11	55,0	7	35,0	13	65,0	5	25,0	15	75,0	2	10,0	18	90.0	20	100,0

Table 4: Dynamics of wound healing in the main group

Linical signs	Terms of observation (day)																															
	1	2				3			4		5		6		7			8				9		10	
	C	C		B		C		B		C		B		C		B		A		B		A		B		A		A		A	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Cleaning of wound	20	100,0	15	75,0	5	25,0	11	55,0	9	45,0	7	35,0	13	65,0	4	20,0	16	80,0			20	100,0			20	100,0			20	100,0	20	100,0	20	100,0
Granulation	20	100,0	18	90,0	2	10,0	15	75,0	5	25,0	10	50,0	10	50,0	3	15,0	17	85,0	1	5,0	19	95,0	1	5,0	19	95,0			20	100,0	20	100,0	20	100,0
Epitheli-zation	20	100,0	20	100,0			17	85,0	3	15,0	11	55,0	9	45,0	5	25,0	15	75,0	3	15,0	17	85,0	2	10,0	18	90,0	1	5,0	19	95,0	20	100,0	20	100,0

It was found that cleaning of the wound in patients of the control group took place on 3−4 days when in patients of the main group was on 2−3 days. The process of active granulation and epithelialization of wound in the control group observed on 4−5 day when in patients of the main group was on 3−4 day.

It was found in percent equivalent that for example on 3 day the healing process in the control group was 10% against 28% in the main group respectively and 45% in the control group against 80% in the main group on 5 day respectively.

When comparing clinical indicators of inflammatory process and dynamics of wound healing in patients of the control and main groups was found a positive dynamics, but in patients of the main group observed a reduction of healing time on 1−2 days.

On the example of clinical observation of patient shown stages of making of transitional removable laminar denture from acrylic plastic in combination with hydrogel on the basis of adhesive active polymer with chlorhexidine bigluconate.

Clinical observation

Patient K., 54 years old, appealed to the Dental Medical center of Danylo Galytsky Lviv National Medical University. Complaints about problems with chewing, aesthetic defect, bad breath. The clinical examination revealed the root of 11 tooth. Artificial crowns 13, 12, 21, 22, 23 with the roots of teeth, patient was taken out and laid in the holes of teeth like a removable construction together with clasp denture with the lock fixing (Fig.1). The local areas of atrophy of gums, distortion of the mucosa of alveolar process, excrescence of granulation were clinically revealed. The soft tissues are inflamed, on separate areas is bleeding at mechanical influence (Fig. 2). Pantomography snapshot showed the reduction of height of the alveolar process and loss of its cortical plate. After the stage of anti-inflammatory therapy the root of 11 tooth removed. After removal of the root (Fig. 3) making of full removable denture on the upper jaw took place by the traditional methodology.

On the prepared acrylic denture, its internal surface, in the projection of area of distorted mucous membrane a milling cutter is create a niche for placing of the hydrogel, in depth immersion to 2 mm. After a functional imprint is got model from silicone. By the next stage external part of acrylic denture fixed in a gypsum, giving to the slope for even distribution of the hydrogel and providing denture from deformation during the repeated polymerization. Niches on the internal surface of denture are filled by the preliminary calculated amount of the hydrogel. In further denture cover

with a model from silicone for providing of individual configuration of internal surface of denture. Polymerization was carried out by the worked out technical stages (Fig. 4).
In the clinic a saturation of the hydrogel on the basis of adhesive active polymer by a therapeutic agent (in the case of chlorhexidine bigluconate) according to the conducted studies in vitro by immersion of the temporary denture with the hydrogel in treatment solution during a half hour, after which removable denture fitted in the oral cavity. After general recommendations patients were recommended after the hygienic cleaning of the denture appliance at first it in 3% solution of hydrogen peroxide during 10−15 minutes every day for cleaning hydrogel.

Results and their discussion

The estimation of efficiency of modified denture with a therapeutic agent carried out on results of clinical picture before and after treatment. Already on 2−3 day there is reduction of edema, pain, mucous membrane of oral cavity turned pale pink color, pain sensitivity during wear of denture from the first day of the use reduced.
In connection with the volume deformations and excrescence of granulation tissue the fixation denture was broken approximately after 1.5 months. On the basis of clinical examination made decision to carry out the plastics of soft tissues (Fig. 5) with the next relocation of denture using hydrogel on the basis of adhesive denture polymer with chlorhexidine bigluconate (Fig. 6). All recommendations in relation to exploitation of removable construction remained the same as the previous one.

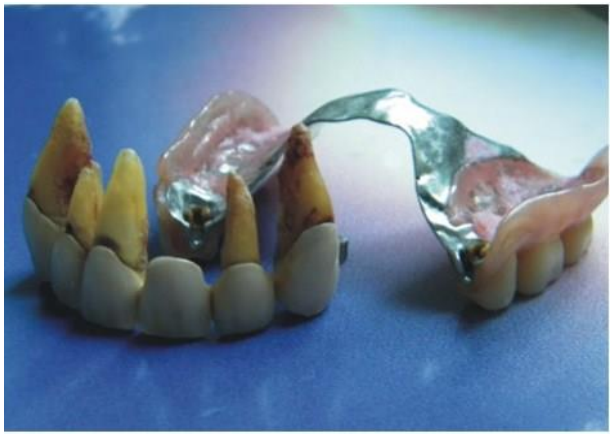

Fig 1: Artificial crowns with roots of teeth and clasp denture with the lock fixing

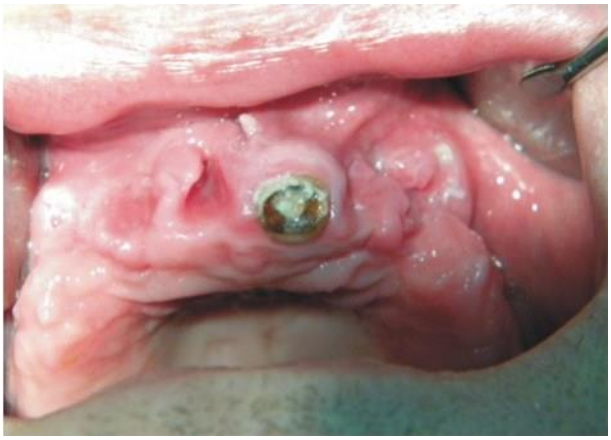

Fig 2: The initial clinical situation

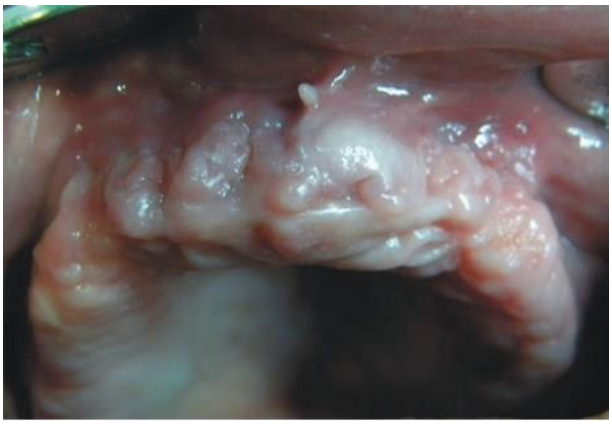

Fig 3; Mucosa three days after removing the root of 11 tooth

Fig 4: Hydrogel on the basis of adhesive active polymer with chlorhexidine bigluconate composed complete temporary removable denture

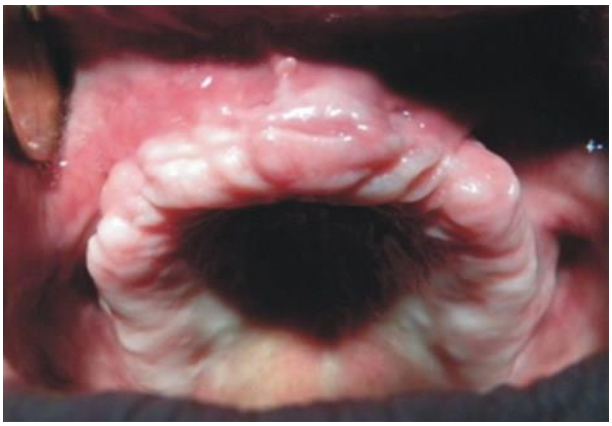

Fig 5: Mucosa 1 month after the plastics of soft tissues

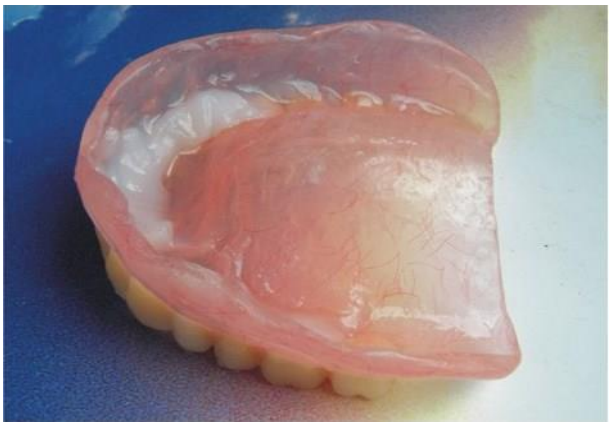

Fig 6: Transitional complete denture

The clinical picture of postoperative healing was satisfactory, there was a positive dynamics that visually showed up in the reduction of areas of inflammation and pain sensitivity during exploitation of modified removable denture with therapeutic agent. After 7, 14, 30 days and 1.5 months of observation the complication in the mucous area was not observed.

Conclusions

The use of modified temporary denture with hydrogel on the basis of adhesive active polymer with medicamental preparation allows not only to restore the chewing and aesthetic function after multiple tooth extractions, but also reduce inflammatory response of the mucosa of prosthetic bed due to direct influence of medical drug on the tissues of prosthetic bad, to ensure a strictly controlled amount of preparation in the affected area, preventing the spread of the medication throughout the oral cavity, thus, eliminating the uncontrolled influence on a mucous membrane and its medicinal means in the gastrointestinal tract. Also hydrogel prevents to penetration of nutria microflora, including potentially dangerous types of microorganisms in the area of wound, performing the barrier function to the same.

The clinical use of modified denture contributes to the reduction of clinical manifestations of negative action of removable denture, allows to weaken and amortizes the peaks of chewing pressure, that contributes to the slow process of resorption and atrophy of the alveolar process and alveolar part of jaw, creating favorable conditions for further prosthetics.

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