

## Original Article

# Efficacy and risk factors of traditional denture restoration versus biofunctional complete denture restoration system

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**Abstract:** Objective: This study was designed to determine the efficacy of a traditional complete denture and a biofunctional prosthetic system of a complete denture, and risk factors affecting their efficacy. Methods: A retrospective analysis was performed on 95 patients with total dentition loss admitted to our hospital from January 2015 to June 2022. Among them, 45 patients who received traditional dentures were assigned to a control group, and the other 50 who received a biofunctional prosthetic system with complete dentures were assigned to an observation group. The clinical efficacy was compared between the two groups before and after treatment, and the masticatory function indexes and comfort scores of the two groups were also compared. Logistics regression analysis was conducted to analyze the risk factors affecting the efficacy of patients. Results: The observation group showed a higher total effective rate than the control group ( $P<0.05$ ). After treatment, the observation group showed notably higher masticatory efficiency and absorbance of masticatory substances than the control group ( $P<0.05$ ). In addition, the denture tenderness point in the observation group was notably lower than that in the control group ( $P<0.05$ ). After treatment, the observation group had notably higher scores in General Comfort Questionnaire than the control group ( $P<0.05$ ). Moreover, according to Logistics regression analysis, older age, dentition loss caused by tooth defect, smoking history and traditional denture restoration were independent risk factors for ineffective treatment. Conclusion: The biofunctional prosthetic system of complete dentures can better improve the masticatory function and enhance the comfort of patients with total dentition loss, and with good efficacy.

**Keywords:** Dentition loss, complete denture, biofunctional prosthetic system complete denture, masticatory function

## Introduction

As societal aging continues, the incidence of oral diseases is growing annually, which seriously compromises the quality of life and social mode of patients [1]. According to prior research, severe periodontitis afflicts 10.5-12% of the population, with the highest incidence in the population around the age of 35-40 years old [2]. The development of oral diseases will trigger total dentition loss in severe cases [3]. The main cause of the disease is improper oral cleaning habits and poor eating habits. Incorrect oral cleaning methods can easily result in the accumulation of food residues in the periodontium, and bacteria will

cause corrosion to the periodontal tissue and deepen the depth of the periodontal pocket, compromising oral health [4, 5]. Dentition loss will adversely affect the overall health, quality of life and well-being of individuals [6]. It also seriously compromises patients' masticatory function and brings patients increased aging of their facial features [7].

Clinically, the most frequently-adopted method for dentition loss is still complete denture. An effective complete denture restoration process can not only restore the patient's facial appearance, but also restore the patient's masticatory function [8]. Clinically, the traditional method is generally adopted to repair complete dentures.

## Biofunctional prosthetic system of complete dentures is highly effective

Although it can help repair missing dentition to a certain extent and improve the appearance of maxillofacial region; however, it cannot deliver ideal effect in restoring the masticatory function due to the relatively serious degree of alveolar bone absorption in patients and is likely to bring adverse reactions such as loosening and shedding of dentures [9]. As a novel complete denture restoration technology, the biofunctional prosthetic system can not only meet the aesthetic requirements of patients, but also their physiological and anatomical structural and functional needs, so it is of a high clinical application value [10]. The biofunctional restoration system consists of a series of steps, including mold taking, bite recording, tooth arrangement, polymerization, completion and delivery. Every step is carried out according to clear procedures, and a personalized denture can be carried out for each patient by supporting equipment and materials [11]. The biofunctional prosthetic system in the fabrication of the complete denture meets the esthetic demand of patients with its unique Ivoclar teeth, which replicate the anatomy of the natural tooth. Ivoclar teeth are made up of 3 layers of cross-linked acrylic resins that contribute to a life-like appearance and are resistant to wear [12]. Nekora-Azak et al. [13] have described the use of a biofunctional prosthetic system to repair and rehabilitate edentulous patients with maxillary defects, and found that it could provide patients with the best form, function and aesthetics of complete dentures.

In this study, the traditional and bio-functional complete dentures were adopted to for patients with total dentition loss, and a clinical research report was made to explore how to better use complete denture to restore the physiological function of patients with total dentition loss.

### Methods and data

#### *Patient information*

A retrospective analysis was carried out on 95 patients with total dentition loss from January 2015 to June 2022. Among them, 45 patients who received traditional dentures were assigned to a control group, and the other 50 who received the biofunctional prosthetic system complete dentures were assigned to an observation group. This study was performed with permission from the Medical Ethics Committee

of Zhongshan Affiliated Hospital of Dalian University.

#### *Inclusion and exclusion criteria*

**Inclusion criteria:** Patients who were confirmed with total dentition loss by oral examination and had low alveolar ridge and normal mucosal color and smoothness, patients with normal consciousness who could cooperate with the treatment plan, and patients with detailed clinical data.

**Exclusion criteria:** Patients with congenital double-jaw deformity, patients with temporomandibular joint disorders, patients who had received a complete denture, patients with low tolerance to prosthetics, patient with unfavorable compliance, patients who were allergic to narcotic drugs, patients with severe systemic infection, and those with coagulation dysfunction.

#### *Treatment modes*

The control group was treated by the traditional complete dentures. With the two-step impression technique, the initial impression was made by adding alginate to the finished tray, and plaster was poured. The tray was made of photosensitive resin. Then, alginate was added to make the final impression, and the mold was filled. The wax embankment was made on the model, and the vertical distance and median jaw position were determined by the rest jaw position method and checkbite method, respectively. The midline, high lip line, low lip line and mouth line were simply assembled. The teeth were arranged according to the conventional order, and the compression molding method was used for filling. The conventional water bath was used for heat treatment, and the edge of the base was polished. The parts with insufficient muscle function were polished to be shorter. Patients were given the first try-in of complete dentures, and then followed up a week later, and the dentures were adjusted according to the try-in.

The observation group was treated with biofunctional prosthetic system complete denture. The special (frame cut back) tray (Ivoclar Vivadent, Liechtenstein) for both upper and lower teeth was used. Alginate (DENTSPLY SIRONA Inc, Tianjin, China) was used to make

## Biofunctional prosthetic system of complete dentures is highly effective

the initial impression, and a special light-curing resin plate (Ivoclar Vivadent, Liechtenstein) was used to make individual trays, and then Gnathometer M device (Ivoclar Vivadent, Liechtenstein) was installed on individual pallets. A closed impression was made with Virtual silicone rubber (Ivoclar Vivadent, Liechtenstein), and the edges were shaped.

The rest jaw position method and face bow transfer method were adopted to determine the vertical distance and jaw position relationship. The teeth were arranged by special biological functional jaw frame, and the edge of the base was polished by computer-controlled thermal polymerizer. The part with insufficient muscle function was polished to be shorter. Patients were given the first try-in of complete dentures, and then followed up a week later, and the dentures were adjusted according to the try-in.

### *Evaluation criteria of efficacy*

Half a year after the treatment, the efficacy on the patients was evaluated according to the following criteria: Markedly effective: After treatment, the dentures had good appearance, good stability and good masticatory function, without alveolar bone absorption; effective: After treatment, the dentures had relatively good appearance, high stability, slight alveolar bone absorption and obvious improvement of masticatory function; ineffective: None of the above criteria was met after treatment. Total effective rate = (number of cases with markedly effective treatment + that of cases of effectively treatment) / total number of cases × 100.00%.

### *Evaluation criteria of masticatory function*

The masticatory function of patients was evaluated before treatment and half a year after treatment. The masticatory function indexes included masticatory efficiency and absorbance of masticatory substances. Masticatory efficiency was measured by the weighing method. Masticatory efficiency = (total weight of chewed food - weight of leftover food residue) / total weight of chewed food × 100%. Detection method of absorbance of masticatory substances: 5.0 g of peanuts were put into the patient's mouth at one time, and the patient was asked to chew it as quickly as possible,

and spit out all the tested substances, and denture, after 30 s. The denture was rinsed, and the rinse solution was also collected in the cup, diluted with distilled water to 1000 mL, stirred for 1 min, and let to stand for 2 min. The upper 1/3 of the suspension in the measuring cylinder was sucked into a cuvette with a 722 spectrophotometer, and tested at 590 nm wavelength with distilled water as the control.

### *Outcome measures*

(1) The treatment efficacy was compared between the two groups. (2) The masticatory function of the two groups after therapy was compared; (3) The number of denture tenderness points was recorded and compared between the two groups half a year after treatment, and the tenderness points were evaluated with the General Comfort Questionnaire (GCQ) [14]. The scale included 28 items, with the score of 1-4 points for each item and a total score of 28 to 112 points. A higher score indicates a better comfort level. (4) The independent risk factors of ineffective treatment in patients were analyzed using multivariate analysis.

### *Statistical analyses*

This study adopted SPSS 20.0 software package for statistical analyses on the collected data, and GraphPad Prism 7 for visualization of the data into figures. Counting data (%) were analyzed using the chi-square test, and presented by  $\chi^2$ . The measurement data were expressed by mean ± SD, and the inter-group comparison of normally distributed data was performed by the independent sample t test, which was expressed by t. Independent risk factors of ineffective treatment were analyzed by multiple logistics regression.  $P < 0.05$  suggested a significant difference.

## **Results**

### *Baseline data*

According to comparison of baseline data, no notable difference was found between the two groups in terms of sex, age, cause for dentition loss, dental cleaning methods, hypertension history, diabetes mellitus history, smoking history and alcoholism history ( $P > 0.05$ , **Table 1**).

# Biofunctional prosthetic system of complete dentures is highly effective

**Table 1.** Baseline data

	Observation group (n=50)	Control group (n=45)	t/X <sup>2</sup>	P
Sex			0.826	0.363
Male	22 (44.00)	24 (53.33)		
Female	28 (56.00)	21 (46.67)		
Age (years)	67.62±5.65	67.22±6.09	0.332	0.741
Cause for dentition loss			0.324	0.569
Periodontal disease	34 (68.00)	33 (73.33)		
Dentition loss	16 (32.00)	12 (26.67)		
Tooth cleaning method			0.179	0.672
Correct	43 (86.00)	40 (88.89)		
Incorrect	7 (14.00)	5 (11.11)		
Hypertension history			0.264	0.608
Yes	11 (22.00)	8 (17.78)		
No	39 (78.00)	37 (82.22)		
Diabetes mellitus history			1.665	0.197
Yes	9 (18.00)	4 (8.89)		
No	41 (82.00)	41 (91.11)		
Smoking history			0.001	0.982
Yes	19 (38.00)	17 (37.78)		
No	31 (62.00)	28 (62.22)		
Alcoholism history			0.552	0.458
Yes	12 (24.00)	8 (17.78)		
No	38 (76.00)	37 (82.22)		

**Table 2.** Efficacy comparison between the two groups

	Markedly effective	Effective	Ineffective	Total effective rate
Observation group (n=50)	25 (50.00)	21 (42.00)	4 (8.00)	46 (92.00)
Control group (n=45)	12 (26.67)	22 (48.89)	11 (24.44)	34 (75.56)
X <sup>2</sup>		4.817		
P		0.028		

### *Comparison of efficacy between the two groups*

According to comparison between the two groups in clinical efficacy, the observation group showed a notably higher total effective rate than the control group (92.00% vs. 75.56%,  $P < 0.05$ , **Table 2**).

### *Comparison of masticatory function between the two groups*

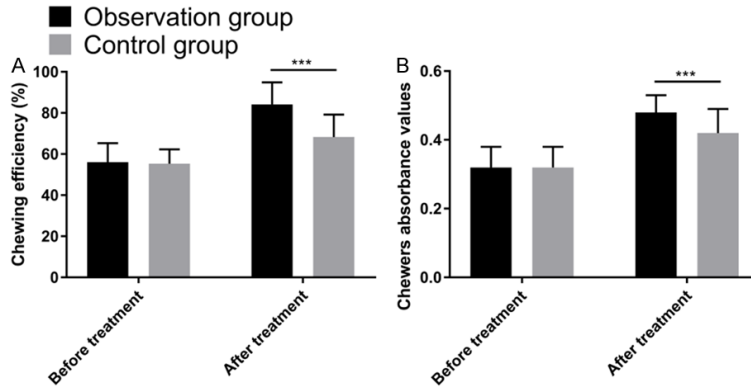
According to comparison of masticatory function between the two groups before and after therapy, the two groups were not significantly different in masticatory efficiency and absorbance of masticatory substances before therapy ( $P > 0.05$ ), while after therapy, the masticatory efficiency and absorbance of masticatory

substances in the two groups increased notably ( $P < 0.05$ ), with significantly higher masticatory efficiency and absorbance of masticatory substances in the observation group than those in the control group ( $P < 0.001$ , **Figure 1**).

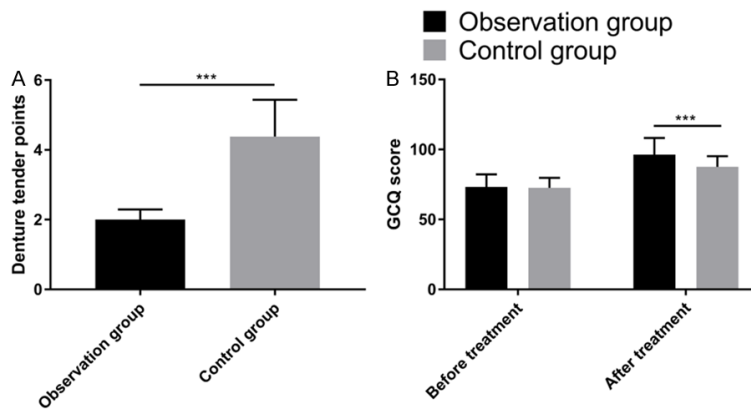
### *Comparison of comfort between the two groups*

According to the statistics about comfort in the two groups, the observation group showed significantly fewer denture tenderness points than the control group ( $P < 0.001$ ). Before therapy, the two groups were not significantly different in GCQ scores ( $P > 0.05$ ), while after therapy, the GCQ scores of both groups increased notably ( $P < 0.05$ ), with significantly higher scores in the observation group than those in the control group ( $P < 0.001$ , **Figure 2**).

## Biofunctional prosthetic system of complete dentures is highly effective



**Figure 1.** Comparison of masticatory function between the two groups. A. After therapy, the observation group showed a notably higher masticatory efficiency than the control group ( $P < 0.001$ ). B. After therapy, the observation group showed a notably higher absorbance of masticatory substances than the control group ( $P < 0.001$ ).



**Figure 2.** Comparison of comfort between the two groups. A. The observation group had notably fewer tenderness points than the control group ( $P < 0.001$ ). B. After treatment, the observation group got notably higher General Comfort Questionnaire (GCQ) score than the control group ( $P < 0.001$ ).

### Univariate analysis of risk factors for poor efficacy

The patients were grouped into an ineffective group and an effective group in the light of efficacy, including 15 cases in the former group and 80 cases in the latter group. According to comparison of clinical data, the two groups were greatly different in age, cause for dentition loss, dental cleaning method, smoking history and therapeutic regimen ( $P < 0.05$ , **Table 3**).

### Multivariate analysis of risk factors for poor efficacy

The indexes with difference in univariate analysis were assigned (**Table 4**), and were subjected to multivariate logistics regression analysis.

According to the results, older age, dentition loss caused by tooth defect, smoking and traditional denture were independent risk factors for ineffective treatment (**Table 5**).

### Discussion

Dentition loss is an oral disease with high prevalence among middle-aged and elderly population, and it is primarily manifested by tooth loss and defect [15]. It seriously compromises patients' oral pronunciation, masticatory and digestive functions, and dentition loss of the front teeth also seriously affects the facial appearance, and brings psychological impact to beauty lovers [16]. Whereas, the routine dentition restoration procedure is complicated, which needs preparation of a large number of teeth and reserve of a large restoration space, and brings some problems such as insufficient alveolar ridge height and poor denture retention, with unfavorable restoration effect [17]. The whole-mouth of teeth made by the biofunctional restoration system can effectively improve the height of the alveolar ridge, thus making up for the

shortcomings of the traditional denture, and it can also greatly increase the area of the alveolar ridge supporting denture and enhance the retention of the denture to ensure the stability of denture fixation [18].

Inter-group comparison of efficacy in this study revealed notably higher efficacy of the biofunctional prosthetic system complete denture than that of traditional complete denture. The possible reasons are as follows: the biofunctional prosthetic system can effectively simulate the biological functional state of human body to make impressions and determine the jaw position, and the use of the special jaw frame can also improve the effectiveness of denture adjustment and better guarantee the denture restoration effect [19]. In addition, the biofunc-

## Biofunctional prosthetic system of complete dentures is highly effective

**Table 3.** Univariate analysis

Factor	Ineffective group (n=15)	Effective group (n=80)	t/ $\chi^2$	P
Sex			0.506	0.477
Male	6 (40.00)	40 (50.00)		
Female	9 (60.00)	40 (50.00)		
Age (years)	73.00±3.27	66.39±5.62	4.405	<0.001
Cause for dentition loss			7.985	0.005
Periodontal disease	6 (40.00)	61 (76.25)		
Dentition loss	9 (60.00)	19 (23.75)		
Tooth cleaning method			6.917	0.009
Correct	10 (66.67)	73 (91.25)		
Incorrect	5 (33.33)	7 (8.75)		
Hypertension history			0.495	0.482
Yes	4 (26.67)	15 (18.75)		
No	11 (73.33)	65 (81.25)		
Diabetes mellitus history			0.602	0.438
Yes	3 (20.00)	10 (12.50)		
No	12 (80.00)	70 (87.50)		
Smoking history			6.265	0.012
Yes	10 (66.67)	26 (32.50)		
No	5 (33.33)	54 (67.50)		
History of alcoholism			1.036	0.309
Yes	5 (33.33)	17 (21.25)		
No	10 (66.67)	63 (78.75)		
Therapeutic regimen			4.817	0.028
Biofunctional complete denture	4 (8.00)	46 (92.00)		
Traditional prosthetic denture	11 (24.44)	34 (75.56)		

**Table 4.** Assignment

Factor	Assignment
Age	Data belonging to continuous variables were analyzed with their raw data.
Cause for dentition loss	Periodontal disease = 1, tooth defect = 2
Tooth cleaning method	Incorrect = 1, correct = 0
Smoking history	Yes = 1, no = 0
Therapeutic regimen	Functional complete denture = 1, traditional prosthetic denture = 2.
Efficacy	Ineffective = 1, effective = 0

tional prosthetic system is more procedural, standardized and refined in the process of making complete dentures, which reduces the blindness of traditional complete denture and improves the clinical success rate [20]. Study by Noh showed that bio functional prosthetic system complete denture was standardized and systematic at every stage, so even inexperienced clinicians can produce highly satisfactory dentures for patients and ensure a stable oral system [21]. Moreover, in this study, the

biofunctional prosthetic system complete denture contributed to better masticatory function after treatment, which confirmed that the application of bioremediation technology can effectively promote the restoration of complete dentition, thus improving the oral health of patients and their masticatory function. In the study by Deng et al. [22], the patients' satisfaction and clinical effect after the biofunctional complete denture were known through questionnaire survey, and the results showed that the biofunc-

## Biofunctional prosthetic system of complete dentures is highly effective

**Table 5.** Multivariate analysis

Factor	B	S.E.	Wald	Sig.	Exp (B)	95% C.I. of EXP(B)	
						Lower limit	Upper limit
Age	0.466	0.141	10.878	0.001	1.594	1.208	2.103
Causes for dentition loss	2.211	0.999	4.892	0.027	9.120	1.286	64.676
Tooth cleaning method	2.024	1.233	2.697	0.101	7.568	0.676	84.737
Smoking history	2.434	0.996	5.970	0.015	11.402	1.618	80.325
Therapeutic regimen	2.744	1.020	7.233	0.007	15.546	2.105	114.831

tional complete denture can provide good aesthetic satisfaction and good clinical effect, which is similar to the present research. In addition, in this study, the observation group had notably fewer postoperative denture tenderness points than the control group, and the comfort and treatment satisfaction of the observation group were greatly improved compared with those in the control group. This is mainly because the biofunctional prosthetic system can better simulate the biological functional state of human body to ensure that the manufactured denture model is more in line with the natural tooth shape, thus effectively increasing the area of alveolar ridge denture and the fixation stability of denture, and improving the masticatory function and comfort of patients [23]. Study by Deeksheetha et al. [21] compared the therapeutic effects of traditional complete dentures and biofunctional dentures. According to their study, patients with a biological functional denture were more satisfied with the aesthetics and fit of dentures, and had no pain or masticatory or speech problems during insertion, while patients with conventional complete dentures had pain, ulcers, masticatory and speech problems during insertion. In addition, there are fewer complications after the treatment of biofunctional denture system.

According to prior research, the final restoration effect of complete dentures is influenced by various factors, including the patient's own situation, the technical level and cooperation degree of doctors and technicians, and secondary factors such as the patient's adaptability and subjective feelings [25, 26]. At the end of the study, the factors impacting the efficacy in patients were analyzed. The results revealed that older age, dentition loss caused by tooth defect, smoking history and traditional denture restoration were independent risk factors for ineffective treatment. This also suggests that the biofunctional complete denture can contribute to better efficacy.

This study also has some limitations. Firstly, some indicators-associated information was collected from patients, which may be influenced by patients' own feelings or cause some bias. Secondly, the cost of the biofunctional complete dentures is relatively high, and the production time is relatively long, so further improvements are required in the future application process of it for the popularization of this technology.

To sum up, the biofunctional prosthetic system complete denture can better improve the masticatory function and enhance the comfort of patients with total dentition loss, with good efficacy.

### Disclosure of conflict of interest

None.

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## Biofunctional prosthetic system of complete dentures is highly effective

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