

Short-term Clinical Effect Evaluation of Trausim Implants

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[Abstract] Objective: To observe the short-term clinical effect of Trausim implants used and provide reference basis for its clinical application. **Methods:** A total of 24 subjects (46 implants) who received Trausim implants during June, 2016 to December, 2017 at the Implant Department, Stomatology Hospital of Guangzhou Medical University were selected. The success rate, the survival rate, marginal bone loss of dental implants, and dental implant-related complication were followed up. The relevant clinical data were analyzed. **Results:** All implants were clinically osseointegrated and restored, which were followed up 0.5-1.5 years. There was one case of peri-implantitis, the survival rate was 100% and the success rate was 97.83%. Mesial marginal bone height was (0.15 ± 0.43) mm, and the distal marginal bone height was (0.30 ± 0.47) mm after 0.5-1.5 years follow-up. The mean peri-implant bone resorption was (0.23 ± 0.33) mm. **Conclusion:** Trausim implants had satisfactory clinical effects in the case of strict control of indications and skilled operation, and its long-term efficacy needs further follow-up.

[Key words] Trausim implants Success rate Survival rate Marginal bone loss
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Brief introduction of author: WANG Liping (1969-), female, born in Zhejiang, master, chief doctor, dedicated in research on dental implantation.

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Good bone union is the premise of functional loading of the implant, and also an important indicator for evaluating successful implantation^[1]. With the rapid development of dental implantation technology, implant repair has become the first choice of dental defect repair method for patients because of its good function and aesthetic effect^[2]. For the single type and the design concept to be improved for the domestic implantation system, the international mainstream implantation system is applied in the domestic market. Jiangsu Trausim Medical Instrument Co., Ltd. has independently developed Trausim implant processed by surface treatment technique of MPS. The Trausim implant has good bone-implant contact percentage, and makes up for the deficiency of dental implant field in China^[3]. This study conducted a retrospective study with this system to evaluate its clinical application.

1. Materials and methods

1.1 Study subjects: 24 patients with dentition defect were selected, who received Trausim implant implantation in Stomatology/Affiliated Stomatology Hospital of Guangzhou Medical University from June 2016 to December 2017, including 11 males and 13 females, 27-84 (55.30±15.86) years old. Totally 46 implants were implanted, and the subjects were observed for 6-18 months. All patients signed the information consent form for this study, and were qualified for ethic review in the hospital.

1.2 Inclusion and exclusion criteria: inclusion criteria: single or multiple tooth loss; OHI-s<3, with good oral hygiene or controlled periodontitis, remaining adjacent teeth showed no active inflammation; preoperative CBCT showed class II and III alveolar bones in defect region; occlusion showed stable relationship; data of patients and reexamination were complete. Exclusion criteria: poor oral hygiene, OHI-s =3; history of bone implantation or guided bone regeneration (GBR) in the surgical region; combined with diabetes, hypertension, endocrine disorders, bone metabolism disorders, rheumatism; combined with myocardial infarction or installed pacemaker; history of tumor or radiotherapy in the surgical region; combined with oral mucosal diseases; combined with persistent intraoral infection; severe bruxism or clenching; rhinitis or maxillary sinusitis; smoking >10 cigarette/day; alcohol or drug abuse; pregnant women.

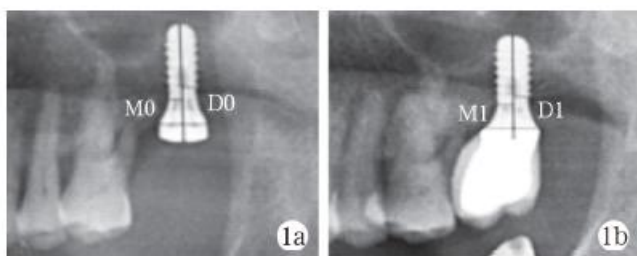
1.3 Trial materials and equipment: Trausim implantation system (Jiangsu Trausim Medical Instrument Co., Ltd., China), planter (NOU-VAG, Switzerland); CBCT (NewTom VG, Italy).

1.4 Clinical procedure: before the operation, detailed medical history was recorded, general oral examination was performed, CBCT showed position of maxillary sinus floor and the distribution of mandibular nerve canal, available height and width were measured, alveolar bone was observed in surgical region, and intraoral conditions of the patients were combined to determine the surgical plan and repair regimen. All patients agreed and signed the informed consent form. Oral antibiotics were taken before and after operation routinely. The operation was performed strictly as per the standard implantation manual of Trausim, routine disinfection, drape arrangement and local anesthesia were performed routinely, implantation pit was prepared for implantation. According to initial stability of implant, open/closed healing was chosen, then healing abutment/covering screw was placed, the incision was strictly aligned and sutured. Suture thread was removed 10 days after operation. X-ray film was taken 3-6 months after the first phase operation, tooth die was routinely taken, overdenture restorations supported by implant single crown, continuous crown or implant denture was performed according to actual conditions of the patient.

1.5 Observation parameters: survival rate of implant: implant will not be retained for those loosened by 1mm and x-ray film of root tip showed that the loss of alveolar bone reached root tip. Survival rate of implant = survived number of implant/total case numberX100%. Success rate of implant: by referring to the assessment criteria of implantation proposed by Al-brektsson, et al in 1986^[4], clinical examination showed implant was not loosened, without

inflammation; the patient showed no persistent infection, pain, paresthesia, etc. after implantation; X-ray film showed no continuous transmission shadow around implants; bone absorption at implant neck <2 mm within 1 year after operation, then <0.2mm each year in average subsequently; the prosthesis was good, the patient was satisfactory. Biological and mechanical complications: biological complications included severe pain, swelling, peri-implant inflammation, uncomfortable occlusion or neurological dysfunction, etc. after implantation; mechanical complications included implant breakage, abutment breakage, central screw loosening or breakage, porcelain crown collapse, prosthesis loss, etc.

Marginal bone loss (MBL) [5]: Image J program (Wayne Rasband, National Institutes of Health, MD, USA) software was used to measure reexamination X-ray films after implantation and implant prosthesis, to measure length of implant to correct the error of X-ray measurement, and the result was accurate to 0.01mm. Changes of distance from near central and distal implant-shoulder to bone were respectively recorded to compare the MBL. Implant MBL = implant MBL in X-ray film \times actual implant length \div implant length in X-ray film. All measurements were performed by the same person to respectively measure near central and distal central MBL, 3 times for each measurement to calculate the mean. Positive value of MBL indicated bone absorption, negative value of MBL indicated new bone formed. See results in figure 1.



1a: Immediately after operation; 1b: Follow up after restoration. Make horizontal lines of cervical plateau and marginal bone vertical to the long axis of implant, the difference between vertical distances between two lines at different follow up visits was recorded as the bone absorption degree, which was recorded as M1-M0 for near central bone absorption, D1-D0 for distal central bone absorption.

Fig. 1 Schematic diagram of implant marginal bone loss measurement.

1.6 Statistical treatment: all data were processed by using SPSS 22.0 software, and measurement data were expressed in $\bar{x} \pm s$. Life table method was used to calculate the accumulated successful rate and survival rate. $P < 0.05$ was adopted as the statistical significance level.

2. Results

2.1 Implantation of implant: among 24 patients, totally 46 Trausim implants were implanted, pattern numbers and implantation sites were listed in table 1.

Table 1 Information of implants

Items	Number of implants/piece
Implant length/mm	
8.0	10
10.0	36
Implant diameter/mm	
3.3	2
4.1	42
4.8	2
Implantation site	
Lateral incisor	1
Canine teeth	1
Premolar	14
Molar	30

2.2 Success and survival rates of implants: Before the second phase operation, none of 46 implants showed abnormal low density shadow, but good bone union. Six months after restoration, 1 implant showed peri-implant inflammation, X-ray film showed bone absorbed reached 1/2 of full implant length, and the patient had poor oral hygiene. X-ray films of other implants showed no transmission shadow around the implant, good plasticity of soft tissues, no clinical motility, no obvious discomfort in patient, and the survival rate of implant within the follow up period was 100%. See results in table 2.

Table 2 The success rate of implants

Observation parameters	Case number	Number of implants	Failed pieces	Success rate/%
Age/yrs				
≥60	11	20	1	95.00
<60	13	26	0	100.00
Sex				
Male	11	20	0	100.00
Female	13	26	1	96.15
Site				
Upper jaw	6	14	1	92.86
Lower jaw	19	32	0	100.00

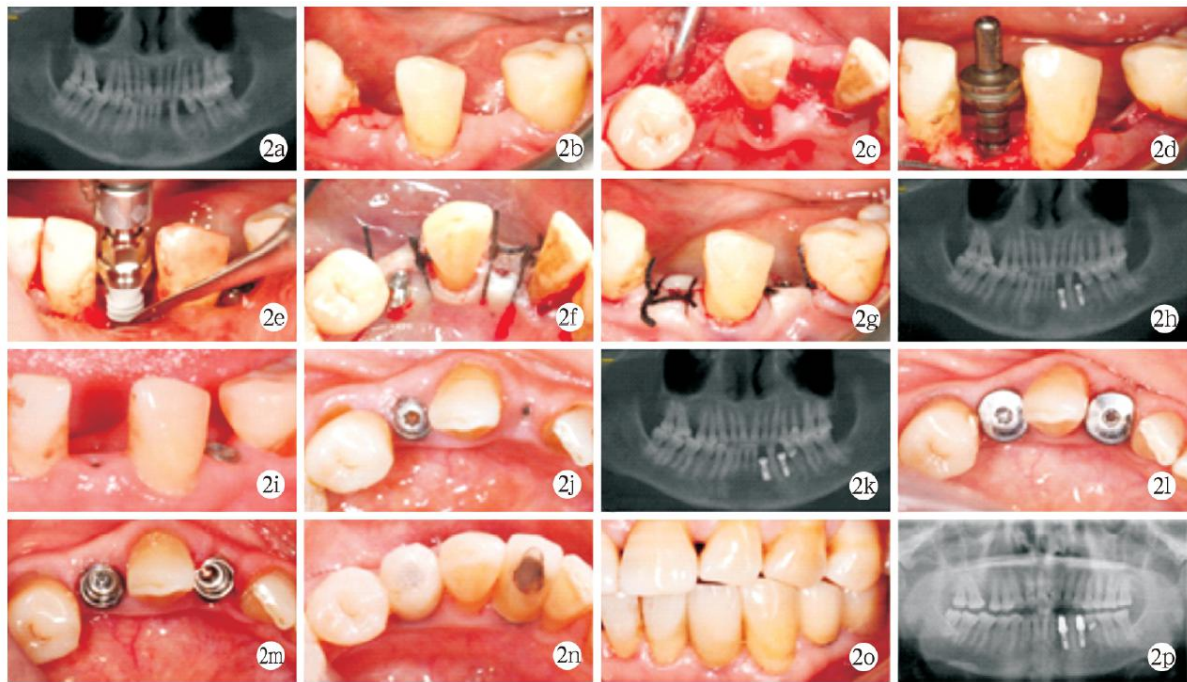
2.2 MBL of implant: totally 46 Trausim implants were implanted. In the follow up period of 6-18 months, near central MBL was (0.15 ± 0.43) mm, -0.65 mm as the minimal value and 0.80mm as the maximal value; distal central MBL was (0.30 ± 0.47) mm, -0.42mm as the minimal value and 1.13mm as the maximal value; the mean MBL was (0.23 ± 0.33) mm.

2.3 Typical cases Patient , female, 60 years old. Main complaint: the patient asked to repair the missed mandibular teeth. Examination: 34 and 36 missed, the remaining bone height was about 14mm, the alveolar bone level of the remaining teeth was absorbed to 1/3 of root length. Diagnosis: mandibular dentition defect; chronic periodontitis. Treatment: routinely disinfect face and arrange drapes, perform local anesthesia with articaine. Trausim 3.3mm×10mm implants were respectively implanted in 34 and 36, initial stability was 35N·cm, covering screw was loaded for embedded healing. Phase II surgery was performed 3 months after the operation, CBCT showed good bone union around the implant, no continuous transmission shadow. Porcelain-fused-to-metal crown restoration was performed at 34 and 36 one month after the phase II surgery. The patient was reexamined after restoration, the prosthesis showed good shape, tightly sealed margins, stable bone tissues around the implant, no bone absorption. See results in figure 2.

3. Discussion

MBL around the implant is an important indicator to assess survival rate and success rate of implant [6]. It is indicated in a study that, in 1 year after superior structure restoration, marginal bone tissues around the implant can be absorbed by (0.55 ± 0.45) mm [7]. Single factor or combined factors, including surface roughness, surface treatment technology, structural design and fretting between implant and superstructure, etc. can affect the degree of marginal bone absorption [8]. MBL around the implant also directly affects the stability and appearance of the implant, thus affecting the assessment of clinical success rate and survival rate.

The structural design and surface treatment technology of the implant are closely related with initial stability of implant and implant-bone contact percentage. Niu et al. have demonstrated that micro screw design of implant neck can obviously reduce MBL level [9]. Di Stefano et al. [10] have also indicated that, micro screw design and surface treatment can effectively protect the bone tissues around the implant, and reduce MBL. Trausim implant selected in this study adopts MPS for surface treatment similar to SLA surface treatment, promotes adhesion and growth of osteoblasts by changing surface structure and element distribution of the implant, and can provide good guarantee for bone-implant union rate and initial stability [3]. Trausim implant adopts the design of 15° bionic biological thread to effectively guarantee the initial stability of implant, meanwhile disperses the loading stress into tooth socket after the superior structure is restored using the implant, thus effectively reduce marginal bone loss. Trausim implant abutment adopts Moire taper design to provide high strength mechanical locking force, which can effectively reduce the implant-abutment gap and final motion, thus obviously reduce marginal bone loss [11]. In this study, there is no statistical difference in MBL between near and distal central parts. In the follow up period of 0.5-1.5 years, the near central MBL was (0.15 ± 0.43) mm, distal central MBL was (0.30 ± 0.47) mm, with a mean value of (0.23 ± 0.33) mm. According to the assessment criteria of implant proposed by Albrektsson et al., the bone absorption within 1 year after implantation should be less than 1.0mm. This study indicates that, the success rate is 100% for all 46 Trausim implants in the follow up period, similar to 97.6%, the short term success rate of implants treated by using surface etching reported by Oliva et al. [12]



2a: Preoperative CT; 2b-2g: During implantation; 2f: Postoperative CT; 2i-2j: before phase II surgery; 2k: Preoperative CT of phase II surgery; 2l: Postoperative CT of phase II surgery; 2m-2o: Final prosthesis loaded; 2p: Teeth wearing completed

Fig. 2 The implantation in the mandible

Good oral hygiene has important influences on the changes of soft and hard tissues around implants, their success rate and survival rate of implants. Plaque accumulation may cause the loss of attached gingiva, and the decline of attached gingiva level will further promote plaque accumulation, thus affecting the retraction of soft tissue around the implant [13]. In the follow-up period of this study involving 46 Trausim implants, some patients had plaque accumulation on the surface of the prosthesis, only 1 patient had peri-implant inflammation due to inadequate cleanliness of the adjacent surfaces. After washing with normal saline, palio was placed, and symptoms were alleviated in the patient after oral hygiene education, suggesting that good stability can be maintained for the soft tissues around the Trausim implant, and scientific and effective oral hygiene education has positive significance for preserving of soft and hard tissues around the implant.

In this study, the author has strictly grasped the indications of dental implantation and reasonably selected implants. The results of this study show that, Trausim implant has high survival rate and success rate, satisfactory repairing effect and good clinical efficacy. However, this study has not set control group, the long-term effect still needs to be observed in longer follow up period, and more study institutions are needed for comparing the results.

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