METHODOLOGICAL APPROACHES AND LASER THERAPY EFFECTIVENESS UNDER THE TECHNOLOGY B-CURE LASER DENTAL PRO DURING DENTAL IMPLANTATION

RELEVANCE

In recent years dental implantation (DI) confidently maintains the status of the leading trend in modern dentistry [1], being a grave alternative to traditional methods of removable and non-removable prosthesis for dentition defects (DD), providing good aesthetic and functional results and improving patients' quality of life with respect to the dental sphere [2-8]. At the same time, even if DI is carried out in accordance with established protocol and in the presence of appropriate preoperative preparation and anesthesia care, probability of occurrence of early and late postoperative complications, ultimately reducing implant treatment efficiency, and therefore requiring appropriate prophylaxis, timely detection and correction [9-16] cannot be excluded completely.

Various physical factors, including low-intensity laser radiation (LILR), having multifactorial local and systemic effect on the organism [17-22], are widely used for the prevention and treatment of inflammatory, sensory and paresthetic complications associated with DI. In general, numerous experimental and clinical studies substantiate the feasibility of using LILR in the complex of measures for DI from the standpoint of its anti-inflammatory action, possibilities of harmonization of reparative regeneration processes of all structures of peri-implant tissue complex, due to the complete osseointegration and formation of the optimal peri-implant gingival attachment [23-32], at the same time, it is pointed out that assessment of LILR effect on the DI postoperative course should be conducted on the ground of modern principles of evidence-based medicine [33].

Development of new laser therapy technologies for dental diseases and modernization of existing technologies are relevant objective and promising direction in modern dentistry, physiotherapy and rehabilitation. Laser therapy technologies improvement in the area of dentistry follows the path of development of so-called "optimized" laser effects, assuming the possibility of variation of modes, wavelength, power and spatial distribution of laser radiation, as well as its combination with other physical factors. New aspects of the optimization of laser therapy method in dentistry are associated with the improvement of the apparatus design, its adaptation to ergonomics and its specificity within the professional use by the physician during dental appointment and by the patient using it as home physiotherapy device. Possibilities of application of the new portable diode laser apparatus based on the Ga-Al-As with infrared radiation range of defocused beam (wavelength - 808 nm, capacity - 250 mW) B-Cure Laser Dental Pro (Good Energies ®, Israel) in dental procedures...
practice have not been virtually investigated. The pilot data on the effectiveness of its clinical use in cases of temporomandibular joint (TMJ) [34] diseases was presented; the bactericidal effect of defocused laser beam on dental plaque biofilm's microorganisms [35] was demonstrated in vitro.

Methodological approaches and laser therapy effectiveness under the technology B-Cure Laser Dental Pro in complex of dental implantation have not been investigated yet and require substantiation and comprehensive study.

THE PURPOSE

The purpose of the study is to substantiate and develop methods and assess laser therapy effectiveness under the technology B-Cure Laser Dental Pro in complex of preventive, therapeutic and rehabilitation activities for patients with partial absence of teeth during prosthetic treatment using dental implants.

MATERIALS AND METHODS OF INVESTIGATION

Simple, blind, randomized, single-center, prospective, comparative, placebo-controlled clinical study on the effectiveness of low-intensity laser radiation of B-Cure Laser Dental Pro apparatus’s defocused beam in complex of preventive, therapeutic and rehabilitation activities on the surgical stage of dental implantation during prosthetic treatment of patients with partial absence of teeth was conducted within the period from June to October 2016 at the State Budgetary Health Care Institution of Perm Krai “City Dental Polyclinic No. 2” and the chair of therapeutic dentistry and propedetics of dental diseases Federal State Budgetary Educational Institution of Higher Education “Perm State Medical University named after academician E. A. Wagner” of Ministry of Health of The Russian Federation (city of Perm).

Patients inclusion criteria: included dentition defects (partially missing teeth; K.08.1 under International Classification of Diseases-10); aged 25 to 60; sanitized oral cavity and satisfactory oral hygiene; the absence of contraindications to the DI and laser therapy; availability of informed consent for prosthetic treatment using DI and laser therapy and also for involvement in the study.

Patients exclusion criteria: systemic, local or other contraindications to DI and laser therapy; under the age of 25 and above 60; the absence of consent for prosthesis for dentition defects using implants and for involvement in the study.

Subject of the study is laser therapy effectiveness under the technology B-Cure Laser Dental Pro in complex of DI activities for patients with partial absence of teeth.
Observation unit is a patient with partial absence of teeth (partial secondary edentia) planning to restore them using the DI method.

Objects of the study: 30 patients (13 men and 17 women aged 28 to 57) with included dentition defects of various localization and extent, having indications and intentions for prosthetic treatment with the use of structures, fixed on dental implants. Study groups for comparative placebo-controlled investigation were formed by the limited randomization method: experimental group (7 men and 8 women aged 31 to 54 years), patients of which received laser therapy in complex of DI activities from the “active” B-Cure Laser Dental Pro apparatus, generating a corresponding laser beam, and control group (6 men and 9 women aged 28 to 57 years), patients of which randomly received for treatment «inactive» B-Cure Laser Dental Pro placebo-apparatus with the identical external design and handling characteristics, simulating the generation of laser radiation and having a special encoding comprehensible merely to the dentist (Fig. 1).

Fig. 1. B-Cure Laser Dental Pro portable dental laser therapeutic apparatuses: «active» - generating laser radiation, and placebo apparatus simulating laser beam generation.

B-Cure Laser Dental Pro (Good Energies®, Israel) portable laser therapy dental apparatus of the 5-th generation with matrices consisting of pulsed semiconductor (Ga Al As) laser diodes generating infrared laser radiation (wavelength of 808 nm, capacity of 250 mW, pulse frequency of 14 kHz) by the defocused beam of 4.5 cm x 1.0 cm with an energy flux density of 14.4 J/m at the peak (3.2 J/cm² per min) were used among the patients of the experimental group. The apparatus has passed technical toxicological and clinical trials, it has the required international certificates (CE 0120 - Medical Device), and is admitted to application in health care sphere of the Russian Federation as medical device No. RZN 2014/2167 by the order No. 914 of Federal Service for the Oversight of Public Health and Social Development dated March 10th, 2015.
DI operation of patients of the study group was conducted by the standard two-stage procedure consisting of the endosseous threaded implant installation stage [36], and, 3 months later (in case of lower jaw) or 4-6 months later (in case of upper jaw) – implant uncovering stage and healing abutment installation. Upon the successful completion of the DI surgical stages patient was referred to implant-supported prosthesis. In total, 30 patients with 65 dentition defects (36 – in the experimental group, 29 – in the control group) were installed with 136 AlphaBio implants (79 - in the experimental group, 57 - in the control group ) with NanoTec™ surface (Alpha-Bio Tech, Israel) with a diameter of 3.5 - 5.0 mm and a length of 10.0 – 13.0 mm. DI operation was conducted using multifunctional implant-center Implant Center™ 2 (Acteon, France) (Fig. 2).

**Fig. 2. Multifunctional implant-center Implant Center™ 2 (Acteon, France)**

When planning DI, jointly conducted by dental surgeon and orthopedist, standard clinical and functional examination techniques were used. Systemic health state with definition of indications and contraindications for DI and laser therapy was determined according to the conclusions of general practitioner and the results of laboratory studies. Dental status assessment of patients in the study group included the calculation of the following indicators: caries intensity (CFE Index), gingival inflammation (PMA Index, %), and oral hygiene index OHI-S (Green J., Vermillion J., 1969). Based on the results of comprehensive dental examination, partial absence of teeth was diagnosed according to the ICD – 10, dentition defects were classified according to Kennedy E. (1923); masticatory efficiency was defined according to Oksman I. M. On the basis of radial diagnostic techniques (orthopantomography – OPTG, Orthopantomograph O/100-2-1-2; Instrumentarium Corp. Imaging Division, Finland; cone beam computed tomography, Planmeca ProMax 3D, PLANMECA, Finland) the quality (architectonic, density) and the degree of atrophy of the jaws bone tissue were defined according to Lekholm U. and Zarb G. (1985), Misch C. E. and Judy K. W. M. (1987).
Dynamic clinical and laboratory observation included a comparative analysis of the following indicators: masticatory efficiency (initially – before DI operation, and at the second stage – after prosthetics); range of mouth opening (value of the maximum distance between the incisors, MDBI, in mm), initially -T₀, on the 2nd-3rd day (T₂-₃), on the 5th-7th day (T₅-₇) and on the 10th-14th day (T₁₀-₁₄) after implants installation; primary and secondary implant stability (PIS and SIS) by frequency resonance method (apparatus Osstell Mentor ™, Gothenburg, Sweden; ISQ U) – at the first DI surgical stage (immediately following the implant installation) and at the second DI surgical stage (after the lower jaw implants uncovering, 3 months later); jaws bone tissue state was assessed according to radial diagnostics’ data - initially, before the operation (T₀) and 3 months later (T₉₀) - after lower jaw implants uncovering, before DI orthopedic stage.

Patients of the compared groups initially -T₀, on the 2nd-3rd day (T₂-₃), on the 5th-7th day (T₅-₇), on the 10th-14th day (T₁₀-₁₄) and 3 months later (T₉₀) after DI operation) were compared by the structure, frequency, intensity / severity and duration of complications within the early and late postoperative period: pain (algic) symptom, also combined with edema and inflammation (edema and pain symptom); general (temperature rise, increase of regional lymph nodes, etc.) and / or local inflammatory reaction of oral mucosa (OM) in the region of implantation and its perifocal zones (edema, hyperemia, presence of plaque), “peri-implant mucositis”; fascial edema; postoperative hematomas; abscesses; dehiscence and / or bleeding surgical wound; neurological disorders (hyper-, hypo- or paresthesias, neuralgic pain) in the maxillofacial region (MFR), taste disorders; halitosis, as well as the mobility of the implant with the development of "early" peri-implantitis.

The identified algic symptom was characterized according to its detection frequency, pattern of manifestation (intensity, duration, and localization), its impact on the "pain behavior", including the need of reduction using analgesics. In order to objectify the subjective sensations of pain symptom's intensity and interactively involve the patient in the diagnostic process, the author's pain symptoms assessment technique was used, which was modified by color and numeric scale ((Efficiency Suggestion No. 2706 dated June 6th, 2016), based on the principle of combining the numeric and the corresponding color "codes" of pain: 0 ≤ VAS <3 ("cold" violet-blue color codes) - a weak pain symptom, 3 ≤ VAS <7 (green-yellow color codes) - moderate pain symptom; 7 ≤ VAS <10 ("warm" orange and "hot" red color code) - strong pain symptom; VAS = 10 ("hot" red-maroon color code) - unbearable pain (Figure 3a, 3b).
Fig. 3. (a) Questionnaire for the dynamic assessment of pain symptoms during dental implantation; (b) Patient’s assessment of the pain symptoms on the modified color-numeric pain scale.

For dynamic assessment of patients’ life quality (LQ) with respect to the dental sphere validated Russian version of the questionnaire “Dental Health Impact profile” OHIP-49-RU (Gileva O. S. and coauthors, 2009; RP №2435 as of February 22nd 2008) was used among patients of compared groups; integral (ΣOHIP-49-RU) and on-the-scale index indicators were calculated before T₀, on the 2nd-3rd day (T₂₋₃), on the 5th-7th day (T₅₋₇), on the 10th-14th day (T₁₀₋₁₄) and 3 months later (T₉₀) after DI operation (before the lower jaw implant uncovering stage).

In general, according to the results of initial examination, patients of compared groups were comparable in age and sex characteristics, systematic and dental health preservation levels; dentition defects’ structure, clinical and topographical characteristics; quality of jaws bone tissue (I-II bone type, according to Lekholm U. and Zarb G., D2-D3 by Misch C.E. et al.) and level of reducing of the life quality dental indicators, resulting in a comparable approaches to the selection of DI technique and reconstructive plastic surgeries, as well as laser therapy modes carried out.

During the observation dynamic process in compliance with the required ethical standards the photographs were made, with the help of retractors and mirrors using a Canon EOS 600D camera (Japan).

Patients participating in the study pre-acquainted with the conditions (design) of its carrying out, and confirmed their consent for participation in written form. Plan, structure and methodological approaches used in the study were approved by Local Ethics Committee of the Federal State Budgetary Educational Institution of Higher Education “Perm State Medical University named after academician E. A. Wagner” of Ministry of Health of the Russian Federation.

The validity of differences between the compared values was assessed by parametric
methods (Student's t-test, using N. A. Plokhinsky's table in case of small sample) and by nonparametric methods (Fisher's F-test exact calculation), using “STATISTICA 10” software.

**Laser therapy methods and modes in complex of DI activities under B-Cure Laser Dental Pro technology.** During the traditional preoperative preparation for DI patients acquainted with the nature of the forthcoming comprehensive treatment, the advantages of space saving hardware laser therapy under B-Cure Laser Dental Pro technology, modes and methods of its professional and home application (**Fig. 4**), were instructed via specially prepared video materials.

![Figure 4](image)

**Fig. 4.** Patient involved in the study being instructed about the home application technique of the apparatus B-Cure Laser Dental Pro during the postoperative period of dental implantation.

In the complex of DI activities under B-Cure Laser Dental Pro technology laser therapy was carried out in "prophylactic" (preparatory, preoperative stage) and in “therapeutic and rehabilitative” modes.

Laser therapy procedures in "prophylactic mode" were conducted by the trained dentist in a dental reception environment 2-3 days prior to the forthcoming dental implants installation operation. The patient took a comfortable position sitting in the dental chair, with good head support fixation. The apparatus B-Cure Laser Dental Pro was prepared for work by setting the required duration of the procedure pressing the corresponding button. Segment of the facial skin that had to be irradiated, was wiped with gauze wad soaked in normal saline and then dried. Before the appointment for laser therapy the patient was recommended to avoid putting medical and cosmetic facials, creams, ointments and gels on the facial skin. Laser therapy was not carried out in the presence of acute inflammatory and neoplastic skin diseases, taking into account general contraindications for laser therapy with the use of infrared radiation. After the pre-antisepctic process contact sensor of the device was applied to the skin in the corresponding region (one of the six) of root segment (**Fig. 5**) with moderate compression along a particular section of the upper or lower jaw. The device was held on the skin surface during the whole session, and the focus was on the
sounds and green indicator light.

![Figure 5](image_url)

**Fig. 5.** Scheme-topogram of six (I-VI) root segments specifying the absent teeth (2.5, 2.6, 2.7), presumed regions of implantation and the corresponding radiation zone by the defocused laser beam (III, maxillary left lateral segment).

We used principle of sextant segmentation of root segments (6) and categorized them into front maxillary and mandibular, left (right) lateral maxillary and mandibular radiation zones for the topography following DI. We took into account planimetric characteristics of a wide coherent laser beam generated by B-Cure Laser Dental Pro (area of 4.5 cm², 4.5 cm long and 1 cm wide, corresponding to the implantation region, with small and extended dentition defects, up to 3-4 of absent teeth).

Scheme-topogram (Fig. 5) specifying the time limits and laser therapy mode (prophylactic / therapeutic and rehabilitative, data on the conducted doctor's instructions on post-operative home application of B-Cure Laser Dental Pro apparatus was attached to the medical card of dental patient receiving treatment with DI.

Laser therapy in "prophylactic mode" was held according to the contact, stable technique, with radiation capacity of 250 mW, a pulse frequency of 14 kHz, defocused beam with area of 4.5 cm², transcutaneously in the projection of the jaw segment corresponding to implant(s) placement; treatment course included 2-3 daily procedures, with duration of 8 minutes (Fig. 6).
Fig. 6. The dentist conducts laser therapy under B-Cure Laser Dental Pro technology in "prophylactic mode": the device sensor is installed in the region of VI root segment (planning of dental implantation in the region of absent 4.5, 4.6 teeth)

On the next day after surgical intervention the trained patient carried out laser therapy in "therapeutic and rehabilitative mode" domiciliary, using B-Cure Laser Dental Pro apparatus (Fig. 7). Postoperative laser therapy technique was: contact, stable, with similar wavelength parameters (808 nm), with radiation capacity of 250 mW, a pulse frequency of 14 kHz, radiation area of 4.5 cm² of facial skin in the projection of the jaw segment(s) where the DI was carried out. After the surgery laser therapy sessions were conducted 2 times daily, with duration of 8 minutes (total exposure – 16 minutes), treatment course lasted 7-10 days.

Fig. 7. The patient conducts laser therapy in postoperative period ("therapeutic and rehabilitative mode") domiciliary, using B-Cure Laser Dental Pro apparatus.

Additional hardware defocused laser beam laser therapy was carried out by the patient during installation of healing abutment(s) according to contact, stable technique, transcutaneously in the projection of installed healing abutment treatment course included 3-5 daily procedures, with duration of 8 minutes.
CLINICAL AND FUNCTIONAL RESULTS AND DISCUSSION

According to the results of initial examination, 65 dentition defects were revealed among the patients of compared groups with indications for recovery by using DI: most of defects (72.3%) were included (III-IV c.), and in most cases (57.0%) located on the maxilla. The share of free-end edentulous space accounted to 27.7% of the number of dentition defects (29.8% - in experimental group participants, 27.6% - in control group participants). Unilateral defects dominated within the structure of free-end edentulous space (88.9%) and were revealed in the maxilla and mandible with practically equal frequency. In most cases, the patient was presented with a combination of different included defects or (less often) - a combination thereof with free-end defects of the jaws. More often (63.8%) dentition defects derived from the absence of 2-3 teeth, in 29.8% of cases they were related to the loss of a single tooth. Extended dentition defects (> 3 absent teeth) were found in 7.7% of cases. Most patients (73.3%) had optimal quality of alveolar bone (I-II bone type, according to Lekholm U. and Zarb G., D2-D3 by Misch C.E. et al.) and did not require pre-reconstructive surgical intervention.

Clinical efficiency of laser therapy use under B-Cure Laser Dental Pro technology in DI complex was analyzed in comparative aspect (DI + LR, DI + LR-placebo) from the standpoint of prophylaxis and reduction of early and late postoperative complications, as well as providing a full osseointegration of implants with the formation of the optimal peri-implant gingival attachment. The intensity (magnitude), structure and duration of pain symptoms preservation among the patients of compared groups in postoperative period is presented in Fig. 8.

![Fig. 8](image.png)

*Fig. 8. The magnitude of pain (VAS, scores) and the restructuring of pain symptoms among the patients of compared groups during postoperative dental implantation stages (T2-3 — T10-14).*
Clinical finding on the first postoperative day in most patients of compared groups was characterized by the presence of local pain symptom of different intensity. During the traditional set of DI and placebo laser therapy activities patients from control group suffered pain symptom on the 2nd - 3rd day (T2-3) after surgery the most frequently (93.3%), while pain magnitude of 66.6% of patients was biased towards moderate and severe manifestation. On the 5th - 7th day of postoperative period pain symptom detection frequency of patients decreased by 28.5%, its structure was prevailed (60.0%) by poorly defined pain. 10-14 days (T10-14) after DI 13.3% of patients suffered feeble pain symptom.

As a general rule, patients with slight and moderate pain symptom suffered aching, blunt pain strictly localized in implantation site with no evidence of pain radiation. One patient suffered pain in the implantation site that radiated along the branches of the trigeminal nerve and persisted for week after implant installation. Half (53.3%) of the patients of control group in the setting of moderate pain symptom on the 2nd -3rd day of postoperative period changed their 'pain' behavior due to the oral use of analgesics, functional loads limitations, eating behavior change; 26.7% of patients with persisting pain symptom continued taking pain management medication until the 5th day of postoperative period.

It should be pointed out that patients of the experimental group had significantly more positive clinical symptomatology, in terms of detection frequency, magnitude of intensity and pain symptom dynamics. As well as among the patients of control group, the pain symptom was the most considerable in terms of detection frequency and clinical evidence on the 2nd - 3rd (T2-3) day of postoperative period. However, at this reference point (26.7%) its detection frequency was accurately lower (p<0.01) than among the patients of control group (93.3%); in addition, pain magnitude was biased towards mild forms of manifestation (0 ≤ VAS <3). One week (T5-7) after DI surgery merely 2 patients experienced pain symptom which was presented in mild forms only. By the 10th day (T10-14) of postoperative period only one patient experienced mild pain sensations. None of the patients of experimental group felt the need for analgesics-taking in the setting of home application of B-Cure Laser Dental Pro apparatus.

As a key feature of post-traumatic inflammation of the tissues in DI region, the pain usually combined with local edematous and inflammatory manifestations, occurring as combined edematous pain symptom. The last manifested itself as a local edema of peri-implant tissues and/or of facial soft tissues, resulting in varying degrees of asymmetry (Fig. 9).
Fig. 9. Detection frequency of clinical evidences of orofacial edema (local edema and hyperemia of peri-implant tissues, edema of facial soft tissues) among the patients of compared groups (DI + LR; DI + LR-placebo) during postoperative dental implantation stage (T2-3 -T10-14).

On the 2nd -3rd (T2-3) day of postoperative period most of the patients (66,7%) of control group experienced local inflammations (edema, hyperemia) of various intensity in the implantation site. Signs of inflammation were predominantly mild (33.3%) or moderate (26.7%). One week after the surgery detection frequency of local inflammations significantly decreased (by 2,5 times). In 73.5% of cases local inflammation of peri-implant tissues combined with mild or moderate facial edema, that manifested itself as facial asymmetry in 33.3% of cases. One patient of the control group experienced moderate edema of facial soft tissues by the 5th - 7th day of observation (Fig. 10).

Fig. 10. Patient K., 58 years old (control group). Condition on the 5th day (T5-7) after dental implantation surgery in the region of absent teeth 4.5, 4.6, 4.7: moderate edema, facial asymmetry due to the soft-tissue swelling on the right side. In overwhelming majority of cases (80.0%) laser
therapy with the use of B-Cure Laser Dental Pro apparatus's defocused beam, included into preoperative preparation complex for DI and postoperative management of patients of the experimental group, prevented local edema and inflammatory complications in the implantation and fascial edema site (Fig. 11). By the 2nd - 3rd day (T_{2,3}) of postoperative period symptoms of local, predominantly mild inflammation in peri-implant zone were revealed merely among 20.0% of patients, i.e. 3.3 times less than among the patients of control group (Fig. 12). Also, at this point 20.0% of patients of experimental group experienced edema of facial soft tissues, i.e. 3.7 times less than patients of control group.

On the 5th day (T_{5,7}) after the surgery local inflammations were found among none of the patients of experimental group, during external examination a mild facial edema in the projection of root segment with installed implants was detected only in 1 patient.

**Fig. 11**. Patient Ch., 41 years old (experimental group). 1.6, 1.7 teeth absent, dentition defect of the III class, after Kennedy: (a) Laser therapy conducted in prophylactic mode under B-Cure Laser Dental Pro technology: implantation site's condition before the surgery (T_0); (b) condition after the surgery (T_1): the wound after implantation surgery and single-step sinus lift procedure was sewed up with thread “Polyamide 4/0”; (c) Laser therapy conducted in therapeutic and rehabilitative mode: condition on the 3rd (T_{2,3}) day after surgery – mild edema and hyperemia of peri-implant tissues; (d) Good condition of peri-implant tissues after the removal of sutures.
Fig. 12. Patient R., 49 years old (control group). 4.5, 4.6 teeth absent; dentition defect of the III class, after Kennedy: (a) placebo laser therapy conducted in prophylactic mode: condition before the surgery (T₀); (b) condition after the surgery (T₁): the wound was sewed up with thread “Polyamide 4/0”; (c) Placebo laser therapy conducted in therapeutic and rehabilitative mode: condition on the 2nd (T₂) day after surgery – moderate edema and hyperemia of peri-implant tissues.

By the 2nd - 3rd day (T₂₃) of postoperative period only two patients (13.3%) of the experimental group experienced small, quickly absorbable hematomas of the oral mucosa in the area of postoperative wound and its perifocal zones. The detection frequency of postoperative hematomas among the patients of control group was accurately higher (p <0,05) – 33.3%; one patient was diagnosed with extensive hematoma of mucous membrane of alveolar bone of the maxilla and upper lip (Fig. 13). Virtually all patients experienced hematomas of oral mucosa up to the 5th day of postoperative period.
Fig. 13. Patient I., 57 years old (control group). 1.6, 1.5, 1.4, 2.1, 2.2, 2.3, 2.4 teeth absent; dentition defect of the III class 1 subclass, after Kennedy: (a) condition before the surgery ($T_0$); (b) condition after the surgery ($T_1$) - the wound was sewed up with thread “Polyamide 4/0”; (c) condition on the 3rd ($T_{2.3}$) day after the surgery – extensive hematoma of mucous membrane of alveolar bone of the maxilla and upper lip.

In the early postoperative period during the implantation 3 patients (20.0%) of the control group experienced transient sensory-paresthetic symptom on the mandible in the areas of lower lip and chin. One patient experienced paresthesias in the chin area combined with typical neurological pain, radiating along the inferior alveolar nerve. Similar neurological disorders were not identified among the patients of the experimental group.

The limitation of mouth opening persisting 3 or more days after the surgery was accurately more pronounced in comparison with the source data and was considered as the evidence of early postoperative complications of DI. Fig. 14 displays the dynamics of indicator of maximum distance between the incisors (MDBI), correlated with the degree of limitation of mouth opening in patients of the compared groups.
Fig. 14. The degree of opening of the oral cavity (MDBI, mm) in patients of compared groups (DI + LR, DI + LR-placebo) on the stages of postoperative period (T₀ – T₁₀–₁₄).

The absolute majority of patients of the experimental and control groups with dentition defects planning treatment with dental implants the amplitude of the vertical movements of the mandible, equivalent to distance between the interincisal distance at the maximum opening of the mouth initially (T₀) corresponded to the "Unlimited" criterion, after A.P. Arushunyan et al. [38], and fell within the range of 38-56 mm. Patients who formed the experimental group and were suggested to use pre- and post-operative laser therapy in the complex of planned DI, had average quotients of MDBI (per T₀) of 43.83 ± 5.75 mm, which were not significantly different from those in a control group of patients (45.50 ± 6.22 mm).

Within the first three days of the postoperative period (T₂-₃) the absolute majority of the patients of control group experienced accurately limited mouth opening (criterion "Moderate limitation") as compared to the source quotients (up to 29.32 ± 4.40 mm vs. 45.50 ± 6.22 mm; p <0.05), and moreover, objective data corresponded to the subjective feelings of patients. In individual cases (6.7%) patients of the control group experienced substantial (up to 16.5 mm) difficulty in opening the mouth on the T₂-₃, continuing for a week after DI (Fig. 15).
**Fig. 15.** Patient I., 58 years old (control group).

Condition on the 3rd ($T_{2.3}$) day after the DI surgery and placebo laser therapy: pronounced decrease (by 56.6% as compared with initial, $T_0$) of MDBI quotient.

During laser therapy under B-Cure Laser Dental Pro technology in complex of prophylactic, therapeutic and rehabilitation activities individuals of the experimental group did not have accurate limitations in mouth opening, according to subjective feelings of patients, as well as to objective quotients of MDBI, just as on the 2nd-3rd ($T_{2.3}$) day after surgery (32,51 ± 3,60 mm), so on the 5th-7th (40,22 ± 2,53 mm) and 10th-14th (44,17 ± 3,01 mm) day after its completion ($T_{5-7}$ and $T_{10-14}$). It is permissible to assume that the latter may be associated with anti-inflammatory, anti-edematous, analgesic action of low-intensity laser radiation by the defocused beam of B-Cure Laser Dental Pro, optimizing conditions of reparative regeneration of soft-tissue complexes of oral cavity, TMJ and face traumatized to a varying degree during implantation of endosseous implants.

Thus, professional use (prophylactic mode) and home application by the patient (therapeutic and rehabilitative mode) of B-Cure Laser Dental Pro apparatus, generating infrared laser light by the defocused beam, prevents the development of clinical, functional and aesthetic disorders associated with limitation of mouth opening, during the whole surgical stage of DI, whereas all the patients of control group in the setting of placebo laser therapy experienced early postoperative period of DI ($T_{2.3}$) being complicated by problems of difficulty of mouth opening and functional and aesthetic disorders associated with this.

The quality of surgical stage of DI, implant osseointegration success rate were assessed basing on quotients of primary and secondary implant stability (PIS and SIS), resonance frequency analysis (RFA), the dynamics of which in patients of compared groups is shown in **Fig. 16**. Source ($T_1$) PIS quotients were calculated for implants installed on the upper and mandibles. However, given the limited (to an average of 3 months) period of dynamic observations, the points $T_1$ and $T_{90}$ were assessed only in terms of sustainability of mandibular dental implants.
Fig.16. Quotients of primary and secondary stability (PIS, SIS; ISQ units.) of mandibular implant in patients of compared groups in the dynamics of the surgical stage of dental implantation (T₁ – T₉₀).

The quotients of primary implant stability (ISQ) of T₁, immediately following implant installation on the upper and mandible and specified in intraoperative way, were not significantly different in patients of compared groups (61,5 ± 2,3 units in patients of the experimental group and 62,4 ± 1,5 – patients of control group respectively) and reflected high stability of all 136 implants installed during the surgery.

After installation of 47 implants on the maxilla of patients of experimental group primary stability quotient ISQ as of T₁ equaled 59,3 ± 2,4 units, patients of control group (with 33 implants installed on the maxilla) - 61,2 ± 2,1 units. Initially, as of T₁ primary stability of 32 mandibular dental implants among the patients of the experimental group equaled 63,4 ± 1,8 ISQ units, among the persons of control group (with 24 implants installed on the mandible) - 65,5 ± 1,2 ISQ units (p> 0,05).

Within 3 months (T₉₀) all mandibular dental implants in patients of the experimental group were clinically stable (70,3 ± 1,4 ISQ units; ISQ increase of 9,8%; p <0,01, in comparison with quotients of T₁), that objectified the bond strength of implant and bone and progress of a full osseointegration.

By this observation time implant stability quotients ISQ of patients of the experimental group correlated with the clinical and roentgenologic findings and indicated feasibility of loading the implants with appropriate prosthetic restorations.
3 months (T₀₀) after the installation of the mandibular dental implants in patients of control group ISQ quotient, on average, amounted to 64.6 ± 5.7 units. By this time ISQ values in 93.3% of patients exceeded the initial PIS quotients, that was indicative of successful osseointegration and the possibility of fixing prosthetic restorations on them. However, after the implant uncovering in 4.2% of cases (one implant) ISQ quotient equaled 29 units (38 units less), and after roentgenologic findings illumination zone up to 2 mm was detected at the periphery of the implant, with the resorption of bone tissue in the cervical region (roentgenologic conclusion on the implant disintegration and clinical conclusion on the DI failure).

Thus, according to the RFA data, the use of laser radiation of B-Cure Laser Dental Pro apparatus’s defocused beam in complex of DI provided the complete osseointegration of all installed implants, and correspondingly the success of the DI surgical stage in 100% of cases. The indicator values of individual and group SIS quotients, reflecting the high level of osseointegration when combining DI with pre- and postoperative radiation of peri-implant tissues by the defocused beam under B-Cure Laser Dental Pro technology, were accurately higher (p <0.05), an average of 9.8%, than PIS quotients. Whereas in the control observations successful implant osseointegration using placebo laser therapy was noted in 95.8% of cases by the 3rd month of observation, no significant growth of ISQ quotient with respect to its initial values was observed, and the DI failure with the disintegration and the implant loss was fixed in 4.2% of cases.

In assessing the impact of oral health on quality of life, it was determined that initially (T₀), patients of both groups had a comparable decrease in quality of life, objectified by the index “Oral Health Impact Profile” OHIP-49-RU (Tab.1).

**Table 1. Initial and integrated on-the-scale indicators of OHIP-49-RU index.**

<table>
<thead>
<tr>
<th>OHIP-49-RU</th>
<th>Observation groups</th>
<th>Modification of QOL (quality of life) (%)</th>
<th>Scale rank in reduce of QOL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control (DI+LR)</td>
<td>ΣOHIP-49-RU/ OHIP-49-RU scale, scores</td>
<td>Experimental (DI+LR-placebo)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ΣOHIP-49-RU/ OHIP-49-RU scale, scores</td>
<td>Modification of QOL (quality of life) (%)</td>
</tr>
<tr>
<td>Functions Limitation</td>
<td>90.3±4.9</td>
<td>46.1</td>
<td>92.7±5.2</td>
</tr>
<tr>
<td>Physical Discomfort</td>
<td>14,7±2.1</td>
<td>39.4</td>
<td>15.1±3.1</td>
</tr>
<tr>
<td>Psychological Discomfort</td>
<td>13,1±1.9</td>
<td>75.3</td>
<td>15.9±2.6</td>
</tr>
<tr>
<td>Physical Disorders</td>
<td>21.9±3.0</td>
<td>60.8</td>
<td>22.3±3.3</td>
</tr>
<tr>
<td>Psychological Disorders</td>
<td>12.3±1.7</td>
<td>31.3</td>
<td>12.8±2.0</td>
</tr>
<tr>
<td>Social Disadaptation</td>
<td>7.4±1.5</td>
<td>37.0</td>
<td>7.1±1.3</td>
</tr>
<tr>
<td>Harm</td>
<td>8.6±1.8</td>
<td>35.8</td>
<td>8.2±2.1</td>
</tr>
</tbody>
</table>
The most significant reduction of dental components of QOL among the patients of compared groups was observed according to the scales, reflecting the psychological state of patients ("Psychological discomfort" and "Psychological disorders"), as well as to the scale of "Physical disorder" reflecting the physical limitations and discomfort in connection with secondary partially edentia in these patients.

On the 2-3rd day after the installation of dental implants (T2-3) the patients of both groups, in the settings of severe edematous and inflammatory symptoms, were observed with significant increase in the integral indicator ΣOHIP-49-RU (Table 2) that objectified a subjective feeling of reduction of QOL among the patients during postoperative period. The indicator ΣOHIP-49-RU was significantly higher (p <0,05) among persons of control group (135,9 ± 4,8 vs.115,2 ± 6,1 among the persons of the experimental group). At this point restructuring of on-the-scale ΣOHIP-49-RU indicators rank position was observed in the patients of both groups, with the dominance of the scales of values, reflecting the degree of physical discomfort and dysfunctional disorders during the postoperative period.

**Table 2. Integral and on-the-scale ΣOHIP-49-RU index indicators on the 2-3rd day after the dental implantation surgery.**

<table>
<thead>
<tr>
<th>OHIP-49-RU</th>
<th>Observation groups</th>
<th>Control (DI+LR)</th>
<th>Experimental (DI+LR-placebo)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ΣOHIP-49-RU</td>
<td>OHIP-49-RU scale, scores</td>
<td>Modification of QOL (quality of life) (↑, %)</td>
<td>OHIP-49-RU scale, scores</td>
</tr>
<tr>
<td>ΣOHIP-49-RU</td>
<td>115,2±6,1</td>
<td>↓ 58,8</td>
<td>135,9±4,8</td>
</tr>
<tr>
<td>Functions Limitation</td>
<td>20,7±2,9</td>
<td>↓ 57,5</td>
<td>22,7±2,9</td>
</tr>
<tr>
<td>Physical Discomfort</td>
<td>24,5±2,1</td>
<td>↓ 68,1</td>
<td>27,5±2,1</td>
</tr>
<tr>
<td>Psychological Discomfort</td>
<td>16,3±1,9</td>
<td>↓ 81,5</td>
<td>17,3±1,9</td>
</tr>
<tr>
<td>Physical Disorders</td>
<td>26,4±3,0</td>
<td>↓ 73,3</td>
<td>28,4±3,0</td>
</tr>
<tr>
<td>Psychological Disorders</td>
<td>12,1±1,7</td>
<td>↓ 50,0</td>
<td>13,1±1,7</td>
</tr>
<tr>
<td>Social Disadaptation</td>
<td>9,2±1,5</td>
<td>↓ 46,0</td>
<td>11,2±1,5</td>
</tr>
<tr>
<td>Harm</td>
<td>12,4±1,8</td>
<td>↓ 51,7</td>
<td>14,4±1,8</td>
</tr>
</tbody>
</table>

On the 10th -14th day after DI surgery no accurate differences between the ΣOHIP-49-RU indicators among the patients of control group was observed (105,6 ± 4,3 and 107,7 ± 4,8, respectively). Reduction of ΣOHIP-49-RU, reflecting the improvement in the dental patient's quality of life, was consistent with relief of edematous and pain symptom, that was more pronounced in patients who received laser therapy under B-Cure Laser Dental Pro technology treated during the
pre- and postoperative period.

3 months after dental implants installation $\Sigma_{OHIP-49-RU}$ indicators among the patients of compared groups constituted 85.1 ± 3.9 and 90.2 ± 4.3, respectively. The major contribution to the improvement of dental components of quality of life has brought reduction of indicators reflecting the improvement in the psycho-emotional state of the patient, in connection with the completion of the surgical stage of treatment and willingness to prosthetics.

SUMMARY

1. The results of the conducted study are consistent with the known data that in certain cases a surgical stage of DI may cause problematic situations for the physician and the patient, revealing itself in stable and severe pain symptom, orofacial edema and hematomas, difficult mouth opening, sensory and paresthetic complications, reduction of secondary implant stability during the postoperative period.

2. The application of laser therapy of B-Cure Laser Dental Pro apparatus's defocused beam original technique during the prophylactic mode and therapeutic-rehabilitation mode, before and after dental implantation surgery (efficiency suggestion No. 2739 as of October 5th, 2016) accurately, by 3.5 times, reduces pain symptoms' the detection frequency and intensity on the first days after the installation of intraosseous implants, promotes its earlier and full relief without receiving of additional pain-relieving medication within the first 5 days of the postoperative period as compared to placebo laser therapy.

3. The inclusion of laser therapy in complex of DI activities under B-Cure Laser Dental Pro technology reduces the incidence, duration and intensity of preservation of local evidences of edematous and inflammatory processes in peri-implant region and of facial soft tissues by 3.3-3.7 times.


5. The inclusion of prophylactic, therapeutic and rehabilitation activities of DI laser therapy under B-Cure Laser Dental Pro technology in complex prevents the development of clinical, functional and aesthetic disorders associated with limitation of mouth opening throughout the whole surgical stage of DI.

6. Professional and home use of B-Cure Laser Dental Pro apparatus in the relevant therapeutic and prophylactic modes, improves the quality of the surgical stage of DI, including by
increasing the stability and successful osseointegration of endosseous implants according to the data of resonance frequency and roentgenologic analysis.

7. During early postoperative period some patients experience severe physical and psychological discomfort, pain symptom, functional and aesthetic disorders, that reveal themselves in decrease dental components of quality of life according to integral and on-the-scale indicators of dental QOL index OHIP-49-RU. Effective relief of edematous and pain, sensory and paresthetic symptoms, and related aesthetic, functional and psychological disorders in the settings of laser therapy by B-Cure Laser Dental Pro apparatus minimizes subjective feelings of reduced quality of life and accurately \( p < 0.05 \) lower its objective indicators according to \( \Sigma_{\text{OHIP-49-RU}} \) in the early postoperative period.

8. The advantages of using the infrared radiation by defocused beam of B-Cure Laser Dental Pro apparatus during DI is associated with:

- implementation of multifactor impact of pulsed laser radiation infrared range capacity of 250 mW at the basic links of the pathogenesis post-traumatic inflammation and reparative regeneration of all structures of peri-implant tissue complex;
- technological capabilities of the apparatus providing the laser beam penetration into the tissue to a depth of 40 mm and its specific spatial distribution over the area of 4.5 cm x 1 cm congruent with a particular segment in maxillary implantation zone;
- portable laser device of ergonomically reasonable and optimal aesthetic design, that provides the simplicity, convenience and use safety with the minimum volume of user's operational actions: dentist - during the polyclinic reception and (or) patient - at home;
- the feasibility of the use of portable laser device in home therapy mode, during which patients can independently conduct the assigned medical treatments, under the initial physician's instruction and periodical medical supervision, with a minimum of clinic visits, the possibility of continuing treatment on non-visiting days (holidays and weekend days, etc.).

The findings of the conducted study in terms of objectification of analgesic, anti-inflammatory, decongestant effect of laser therapy with defocused beam of B-Cure Laser Dental Pro apparatus optimizing the conditions of reparative regeneration of tissues of peri-implant complex, demonstrate the possibility of expanding the indications for its use in the dental practice, opens up prospects for inclusion in complex of inflammatory diseases and mucous mouth membrane, TMJ, endodontic, dental and neurological diseases, traumatic injuries of organs and
tissues of the maxillofacial region in the direction of which we will continue our investigations.
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