

THE METHOD OF CLINICAL TRIAL OPTIMIZATION AT ORAL OSTEOPLASTIC SURGICAL INTERVENTION

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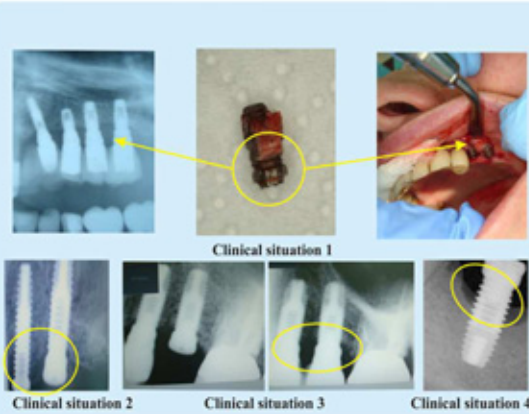
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Introduction.

Analysis of published data shows that the loss of bone tissue in the periosteum during dental operations is usual occurrence. However, some researchers suppose that the bone atrophy was provoked by surgical trauma during the first or second stage of implantation. The extended platform is essential element in the area of periosteum between narrow implant and wide prosthetic construction design, similar to tooth crown. Even in case of wide extended platform for constructive abutment, installation is positioned in the periosteum. According to the results of our preclinical studies, we proposed the methods decreasing traumatic factor in the region of the periosteum during the dental implant operations. The aim of this study was to evaluate the effectiveness in the bone volume preservation in the area of the periosteum during oral implantation with improved medical navigation method.



The pilot unit

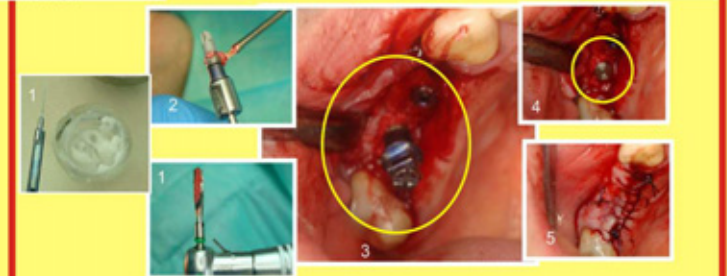
Materials and methods.

We studied condition of bone segments preparations in the area of the periosteum at 30 cases after the previous implantations and 20 cases of experimental group. The study was conducted in the pathomorphology laboratory at the Cologne University (Germany, course of prof. J. Zoeller). The digital dental radiography shots (50 clinical cases) and tomographic studies with densitometry of bone tissues in the periosteum at the implant zone (10 clinical cases) were analyzed. We also used specialized devices, such as dispenser IntraSurg 500 KaVo (Germany) and others for the experiment and physical parameters recording. A standardized protocol in all cases was applied. The implant positioning was controlled by our own methods using the experimental version of the device for medical navigation "Navigator YC" (Patent of Ukraine № 68641). The positioner was integrated together with the tip and the movement was fixed relative to the conventional point on the implant. When planning a clinical trial we assumed that compression of bone tissue by implant in the periosteum zone could be uncontrolled by operator and could be a destroying pathogenic factor during the surgery.

In experimental clinical studies the selection of 20 patients after surgery in the our private dental clinic during 2008-2012 was examined. The male-female ratio was 1:2, the patients mean age was 43±5 years. The descriptive and analytical study design in compliance with the requirements of clinical research was used. The patients were divided into 2 subgroups. The experimental group (10 patients) included those who had operation (root implant) with constant control of the process. The control subgroup (10 patients) consisted of persons for whom we have applied the standard technique of dental implantation. Operative intervention carried out by one operator in standardized conditions. Patients in both subgroups were examined by the same standard scheme. Implants had an extended platform (D=3.5 mm; L=10 mm). To prevent uncontrolled pressure damaging load on the periosteum and bone segment loss a homogeneous layer of autogenous bone material was placed circularly on the back side of the implant platform. The rooting dental implant operation was shut down when the compression arise and the residual layer thickness was about 0.5 mm. A surgical intervention was ended in a normal way.



Pathomorphology research

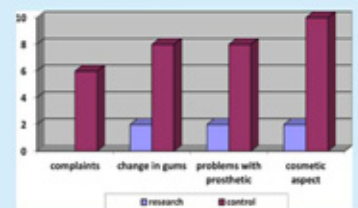
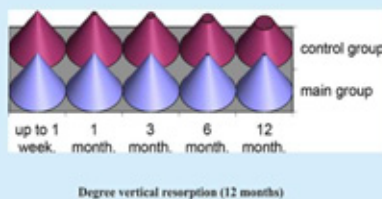


Example of clinical research techniques implantation

Results.

After implantation among the studied 30 cases of bone segments in 22 cases (73%) in the area of the periosteum adjoining to the implant the presence of bone defect was observed. When analyzing DDR shots (50 cases): in 29 cases (58%) we observed the presence of wedge defects, which were formed gradually during three to four months. Further the process of remodeling bone structures was stabilized. The results of bone tissue densitometry in the periosteum zone close to the implant show the bone density increase on 20-30% (compared with surrounding areas). It indicated on deterioration of the bone nutrition in the studied area.

Clinical application of medical device navigation has demonstrated high precision of the implant angular positioning with deviation of less than 25 arcmin - 2,00°, with deviation of less than 5 arcmin - 1,00°. The implant linear positioning precision was 0,500,05 mm when moving at 10 mm. Clinical analysis within 3 months showed that the patients of experimental subgroup had no complaints. The gum changes and the problems with subsequent prosthetics were determined with significantly lower frequency. The cosmetic aspect patients of the experimental group were also benefited. Upon further observation over 12 months the patients of the experimental subgroup had no complaints (p<0.05). To estimate the effectiveness of our implantation method the objective indicators of bone atrophy in patients of experimental and control subgroups (the degree of vertical bone resorption) within 6 months of observation were studied. After evaluating of vertical bone resorption for 2 patients of the experimental subgroup the additional bone augmentation for cosmetic reasons was done. Thus our study allowed us to optimize the process of surgery, to predict the influence of pathogenic factors in the process of an implantation and to offer a method of its elimination. Also the clinical symptoms were eliminated, including the later periods.



Time: 00 min 5 min 10 min 00 min 20 min 10 min 25 min 15 min 30 min 20 min 31 min 21 min 36 min 26 min



Dynamics of the psychological aspect

