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ORIGINAL ARTICLE

Gingival Recession Treatment with the Use of Xenogeneic Matrix: Optimization of Patient-Centered Outcomes by the Digital Soft Tissue Design

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ABSTRACT

Objective: To evaluate the impact of the originally-developed approach aimed at pre-treatment graphical modelling of soft-tissue changes (digital soft tissue design) for the optimization of patient-centered outcomes after Class I and Class II single gingival recessions treatment with the use of a xenogeneic dermal matrix. **Material and Methods:** Patients enrolled in the study group received single gingival recession treatment via CAF+XDM method supported by pre-treatment graphical modelling of potential soft-tissue changes (digital soft tissue design), while patients enrolled in the control group received single gingival recession treatment via CAF+CTG method with no pre-treatment graphical modeling of gingival level changes. Patient-centered outcomes were measured by visual analogue scale, OHIP-14, and Mahajan's scales. **Results:** Realization of pre-treatment graphical modelling of soft-tissue changes supported the achievement of better patient-centered outcomes, such as root coverage ($p<0.05$), surgical phase ($p<0.05$), post-surgical phase ($p<0.05$), cost-effectiveness ($p<0.05$) and diagnostics and patient-orientation ($p<0.05$) based on patient's personal perception grades. **Conclusion:** Patient-centered results were found to be more successful within the group using the xenogeneic type of graft accompanied with the implementation of pre-treatment graphical modeling of soft tissue changes, which helped to balance patients' pre-operative expectations and post-operative satisfaction with the received results, reduce post-operative morbidity and improve oral health-related quality of life.

Keywords: Gingival Recession; Patient Outcome Assessment; Heterografts.

Introduction

Recent trends in dental care focused on the aspects of iatrogenic intervention minimization and on reaching so-called patient-centered outcomes, which include not only the esthetic and functional results of rehabilitation but also patients' level of satisfaction regarding provided treatment [1-5].

Relevant personalized dentistry approach covers phases of complex patient-oriented diagnostics with further individual-based treatment, but methodologies for practical implementation of such during different dental procedures are still under development and in need of further modifications and improvement. Recent studies have already described the usage of personalized medicine principles during the treatment of different oral pathologies considering individual-based risk factors panel, genetic variations within different phenotypes, role of OMICS profiling, and the impact of oral microbiome changes [2,4,6-8].

Also, a significant amount of data was already represented regarding the use of personalized dentistry to improve the outcome of jawbone regeneration, dental implant osseointegration, scaffolding technologies for alveolar bone reconstruction, and 3D printing for restoring hard tissue defects in the oral region [6-10]. Nevertheless, most personalized dentistry studies were dedicated either to normalizing microbiome patterns within the oral cavity or optimizing interventions within bone tissues. Furthermore, only a few studies have focused on applying personalized dentistry principles during the manipulations with the soft tissues [11-13].

The modality of applying connective tissue graft (CTG) together with coronally advanced flap (CAF) has approved its clinical efficiency as a "golden standard" for single gingival recession treatment considering obtained results of root surface coverage, improvements of recession reduction and esthetic outcomes [14]. Nevertheless, a recent systematic review presented the facts that xenogeneic matrix (XM) could be considered as a valuable alternative to use together with CAF procedure during gingival recession treatment; at least no statistically approved differences were noted regarding mean root coverage values and recession reduction levels during the meta-analysis of studies comparing CAF+CTG and CAF+CM [15]. Also, data extracted from individual studies together with pooled evidences substantiate that a combination of CAF+XCM (xenogeneic collagen matrix) provides better clinical outcomes for root coverage, keratinized mucosa width and gingival thickness compare to CAF alone, which additionally highlights role of xenogeneic graft as an alternative option to connective tissue graft during Miller's Class I and II gingival recession treatment [16].

Due to the recent meta-analysis data, CTG, XCM, and ADM (acellular dermal matrix) provide relative equivalent clinical effectiveness for Class I and II Miller's localized defects treatment [11], but there is still no consensus considering how different are above-mentioned approaches in relation to patient-centered outcomes, if we expand the spectrum of such beyond the level of just patient post-operative morbidity and discomfort criteria. A systematic review by Atieh et al. [17] highlighted the improvement of esthetic parameters and patient's satisfaction level with using xenogeneic matrix for different periodontal procedures argumented only by limited evidence.

Nevertheless, to the authors' knowledge, there were no studies aimed at the improvement of patient-centered outcomes for gingival recession treatment with the use of xenogeneic dermal matrix (XDM) by non-invasive patient-oriented approach, while also taking into consideration patients' pre-treatment expectations. Therefore, patients' full informative support realized in the form of complex pre-treatment diagnostics with digital modeling of potential gingival changes may be a key for the patient-centered treatment results optimization with no need for additional invasive interventions. Basically, the above mentioned approach may be interpreted as digital soft tissue design (DSTD) analogical to the concept of the well-known digital smile design (DSD) [18,19]. Previously it was reported that the use of DSD during complex dental rehabilitation was

associated with a greater level of patients' appreciation regarding the final outcome [20,21], so potentially analogical results could be reached with the use of DSTD during gingival recession treatment.

Considering all above-mentioned information null hypothesis of the present study was formulated in the following way: implementation of originally developed approach of pre-treatment graphical modeling for soft-tissue level changes (digital soft tissue design) has no impact on the patient-centered outcomes of gingival Class I and Class II recession treatment with the use of a xenogeneic dermal matrix.

That is why the objective of this study was to evaluate the impact of the originally-developed approach aimed at pre-treatment graphical modelling of soft-tissue changes (digital soft tissue design) for the optimization of patient-centered outcomes after Class I and Class II single gingival recessions treatment with the use of a xenogeneic dermal matrix.

Material and Methods

Study Design and Sample Formation

The research design was formulated as a comparative non-randomized clinical trial following guidelines for reporting non-randomized studies [22]. Also, considering the pilot design of the research regarding the evaluation of the impact of incorporating an originally-developed approach of digital soft tissue design into the complex protocol of gingival recession treatment, guidelines for reporting non-randomized pilot and feasibility studies were taken into account [23]. Clinical part of the study was held on two clinical centers (dual-center study): private dental clinic "VitRus" (Uzhhorod, Ukraine) and private dental clinic "3Dplus" (Cherkasy, Ukraine) during 2021-2022 years.

Non-randomized design of the study was argumented due to the need of pre-treatment explanation to patients all the aspects of gingival recession treatment either by CAF+CTG or CAF+XDM (xenogeneic dermal matrix) method with or without implementation of pre-treatment graphical modelling for soft-tissue changes (digital soft tissue design), based on which patients made personal decision/agreement regarding their participation and allocation to either study or control group. Such approach excluded the possibility for randomized allocation of patients, but was approved by the Ethical Committee of the Faculty of Dentistry (Uzhhorod National University, Ukraine). Also, considering that primary end-points were focused on patients' satisfaction parameters evaluated by different scales, it was important to provide full informative support for each group of patients regarding all details of the treatment protocol. Secondary end-points of the study included evaluation of such clinical parameters as recession depth, clinical attachment level, probing depth, mean root coverage deficiency and complete root coverage at 6 months follow-up.

Sample size calculation for the groups included into the research was provided through the following formula:

$n_1=(\sigma_1^2+ \sigma_2^2/K) \times (z_{1-\alpha/2}+z_{1-\beta})^2/\Delta^2$, in which

$\Delta = |\mu_2-\mu_1|$ stated for absolute difference between means of control and study group,

σ_1, σ_2 – for variance of mean in study group and control group,

n_1 – for sample size of study group,

n_2 – for sample size of control group,

α – for probability of type I error occurrence (pre-established as 0.05),

β – for probability of type II error occurrence (pre-established as 0.2),

z – for critical Z-value for a given α or β,

k – for ratio of sample size for control group and study group.

Anticipated means for study and control group were formulated based on the data previously provided in literature regarding patients' satisfaction with received gingival recession treatment, while difference of 1 point regarding patient-centered outcomes and standard deviation equaled to 1.2 considered to be statistically significant. Also, the ratio of sample size for the study group to control group (enrollment ratio) was pre-planned to be 1, and primary end-point was considered to be represented in continuous values, while the probability of type I error occurrence (alpha) was pre-established at 0.05 level, and probability of a type-II error (beta) pre-established at 0.2 level, and power equaled to 80%. Such approach followed analogical ones previously described within already reported clinical trial and protocol of such [24-26].

Due to the above-mentioned approach minimal needed sample size for the study and control group was calculated to be 23 subjects each. Considering the risk of possible drop-out 6 months after treatment, 25 patients were included in study and control groups. Considering the non-randomized character of research filling of study and control groups was provided by the block design principle controlling parameters of age, gender, recession Miller's Class and topography to minimize imbalance between the groups regarding potential cofounders.

The following criteria were used for including the patients into the primary cohort before allocation into study or control group: 1) ager over 18 years (minimally required age for legal approval of personal participation within the clinical study by signing an informed consent form); 2) absence of any allied somatopahologies which restrict or limit the possibility for gingival recession treatment (periodontal surgery); 3) Miller's Class I or Class II recession in the area of incisors or canines diagnosed by the previously established clinical criteria [13,27]; 4) presence of minimum 1 mm of keratinized tissue width apically to the recession site; 5) adequate oral hygiene level maintenance (plaque and bleeding scores lower than 20%); 6) no previous periodontal surgery facts in the anamnesis; 7) patient's agreement and assurance to maintain a good level of oral hygiene and attending control clinical visits. As exclusion criteria next parameters were followed: 1) age under 18 years old; 2) smoking status independently of number of smoked cigarettes per day; 3) pregnant or breastfeeding status; 4) presence of any kind of dental prosthetic restoration at the tooth with recession signs; 5) presence of any kind of dental restoration in the projection of cemento-enamel junction at the tooth with recession; 6) gingival recession of III or IV Miller's Class or such accompanied with critical tooth malposition; 7) recessions in the area of premolars and molars; 8) presence of allied somatopathologies that potentially may compromise the results of provided gingival recession treatment; 9) diagnosed periodontitis with no adequate treatment; 10) patient's personal disagreement to participate in the study after in-detail explanation of all research design aspects.

Patients enrolled in the study group received single gingival recession treatment via CAF+XDM method supported by pre-treatment graphical modelling of potential soft-tissue changes (digital soft tissue design) and further in-depth discussion regarding possibility to achieve prognosed results, while patients enrolled into control group received single gingival recession treatment via CAF+CTG method with no pre-treatment graphical modeling of gingival level changes.

Surgical Intervention

Surgeries have been provided by experienced periodontists with more than 10 years of practical experience at private dental clinic "VitRus" (Uzhhorod, Ukraine) and private dental clinic "3Dplus" (Cherkasy, Ukraine).

CAF+XDM and CAF+CTG interventions followed the principles of standardized gingival recession treatment protocols previously described in the number of clinical trials. Patients of both study and control

groups have undergone the same surgical procedure of coronally-advanced flap formation due to the approach described in the study of De Sanctis and Zucchelli [28], except in the study group such approach was accompanied by applying XDM into the recession site, and in control group – by applying CTG. CTG was gathered from the palate by single incision technique and further adapted to 1 mm thickness, needed form and size considering parameters of area of interest. Commercial "IBT lyophilized porcine skin-derived xenoimplantat" (IBT, Ternopil, Ukraine) was used as a xenogeneic dermal matrix (XDM) [29]. Before the application, it was immersed into a sterile saline solution for 5 minutes, and after that, it was contoured and trimmed to receive a form needed for a specific recession area (Figure 1).

Figure 1. XDM material soaked into saline solution.

XDM and CTG were positioned to cover site of recession to the level of CEJ and 3 mm over surrounding tissue in the lateral and apical directions. Grafts were secured by interdental and lateral bioresorbable sutures (PGA Resorba, Resorba®, Domažlice, Chezh Republic). Coronally advanced flaps in both groups were positioned 2 mm coronally over CEJ and with full coverage over installed grafts, and secured by the interrupted non-resorbable sutures (Profimed, Medipac, Kilkis, Greece) without excessive tension. Analogical sutures were also placed over donor palate site.

Patients were informed regarding avoiding trauma at the site of intervention and the need for using chlorhexidine 0,12% mouthwashes (2 times per day for 2 weeks), antibiotics (Amoxiclav Quicktab, Sandoz, Ljubljana, Slovenia (amoxicillin+ clavulanic acid in proportion 500 mg/125 mg), 1 pill per day for 7 days), and painkillers based on the need.

Sutures were removed 14 days after treatment, and patients were provided with oral hygiene instructions and recommendations of using a soft brush for the next six months.

Pre-Treatment Graphical Modelling of Soft-Tissue Changes (Digital Soft Tissue Design)

A personalized planning approach for pre-treatment graphical modelling of soft-tissue changes (digital soft tissue design) was originally developed by the first and second authors of the present manuscript (O.K. and M. G.-K.) with the objective to optimize patient-centered outcomes of single gingival recession treatment and to balance them with patients' expectations. The approach is based on the combined usage of an intraoral scanner and intraoral clinical photographs. Medit i500 scanner (MEDIT Corp., Seoul, Korea) was used for the intraoral scanning procedure, while Canon 600D photo camera (Canon, Tokyo, Japan) was used for the photo-documentation. Digital scans and photographs were obtained before any invasive iatrogenic intervention and imported into the specialized software (Autodesk Meshmixer software (Autodesk Inc., San Rafael, CA, USA) for

digital scans, and Paint.net (dotPDN, LLC) for intraoral photographs). In each of the software contours of the gingival margin and CEJ were marked as references (Figure 2).

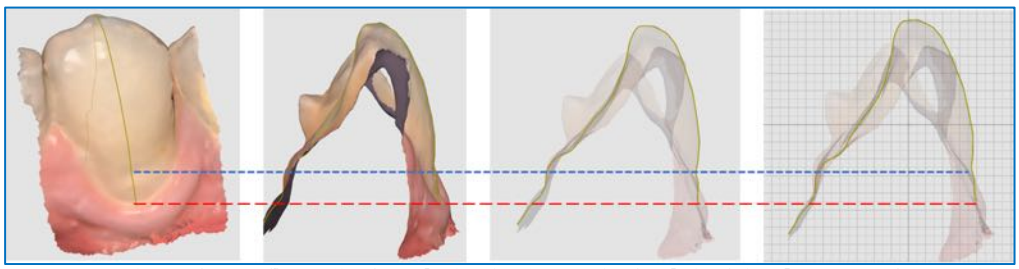

Figure 2. Contouring of CEJ (blue line) and gingival margin (red line) in the area of recession on the received digital scan.

The essence of pre-treatment graphical modelling for soft-tissue changes (digital soft tissue design) is based on the imitation of potential soft tissue level changes on the received scan and on the clinical photo in the area of recession with its representation to the patients. For the digital scans such approach was held in the Autodesk Meshmixer software (Autodesk Inc., San Rafael, CA, USA) with the use of "Sculp" option → "Brush" instrument → "Drug" function (Volumetric), basically providing a graphical overlaying of exposed root surface by soft tissue located apically to recession site (Figure 3).

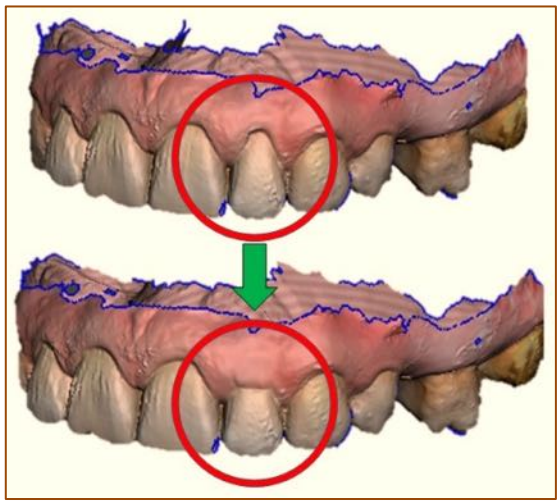

Figure 3. Graphical modelling of soft-tissue changes (digital soft tissue design) on the obtained digital scans provided via adapted software.

For the clinical photo, such approach was provided by a graphical layering technique within Paint.net (dotPDN, LLC) software, which included fragmentation of the most apical part of the exposed root surface together with adjacent soft tissue portion and further graphical dislocation-superimposition of such image fragment coronally for the imitation of gingival recession coverage. Modification of dislocated (superimposed) graphical fragment may be needed considering size, position and magnification parameters to optimize patient perception and to overcome the critical visual discrepancies with surrounding soft tissues. Results of successive imitation of gingival recession coverage provided over digital photos are presented in Figure 4.

After demonstrating to the patient all the possible changes of gingival level in the site of recession, it was discussed in detail all the possibilities and limitations regarding outreaching the result, which in the patient's

opinion, would be enough esthetically successful. Minimal results, which in patients' opinion could be considered as esthetically successful, were proposed to be named "patient-critical results".

All aspects of the above-described approach were implemented in the planning phase in the study group of patients, while in the control group, only clinical photo-documentation was provided with no in-depth graphical manipulations and comparative analysis.

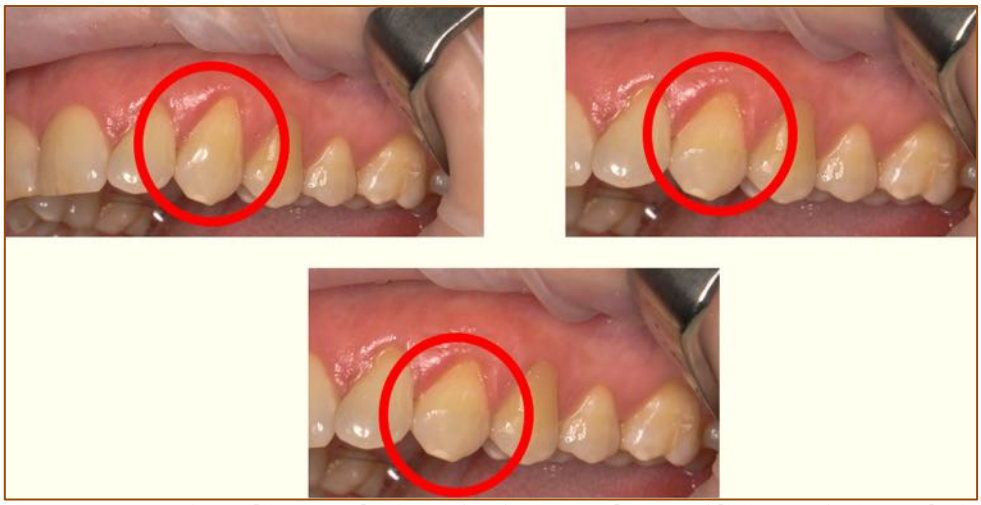

Figure 4. Outcomes of graphical modelling of soft-tissue changes (digital soft tissue design) on the obtained clinical photos provided via adapted software.

Data Collection

A pre-research calibration was provided to the two examinators who evaluated targeted parameters in the area of gingival recession to outreach needed reliability of measurements. Calibration of the investigators helped to reached level of intra-rater agreement equal to 0,91, while inter-rater agreement reached level of 0,82.

All of the following clinical measurements were asses before any iatrogenic intervention and 6 months after received recession treatment: 1) CAL – clinical attachment level (distance between CEJ and the tip of the periodontal probe within the sulcus along central buccal site of the tooth in millimeters): CAL0 – before treatment, CAL6 – 6 months after the treatment; 2) PD – probing depth (distance between gingival margin and the base of gingival sulcus allocated with the tip of the periodontal probe in millimeters): PD0 – before treatment, PD6 – 6 months after treatment; RecDep – recession depth (distance between CEJ and free gingival margin in the projection of recession measured with the periodontal probe in millimeters): RecDep0 – before treatment, RecDep6 – 6 months after treatment. Parameter of Mean Root Coverage Deficiency (MRCD%) was estimated based on the received digital scans as a difference between soft tissue coverage of the root in the area of symmetrical tooth without recession and soft tissue coverage of the root in the area of tooth with recession, represented in percentage (%) before and 6 months after treatment (MRCD0% and MRCD6% respectively), while using CEJ as a reference line. Complete Root Coverage (CRC) criteria demonstrated % of teeth among all with treated gingival recession, where it was possible to receive full soft-tissue coverage of previously exposed root's area.

Patients personal esthetic satisfaction with the obtained result after 6 months of treatment was measured via Visual Analogue Scale (VAS) in the range 0-10 (0 – fully unsatisfied with obtained esthetic results, 10 – totally satisfied with obtained esthetic result) [30]. Objective evaluation of achieved esthetic results after gingival recession treatment were measured with root esthetic score (RES), previously proposed by Cairo et al.

[31], which included evaluation of gingival margin, marginal tissue contour, soft tissue texture, muco-gingival junction alignment and gingival color parameters 6 months after provided treatment.

Patients' general level of satisfaction was estimated using Mahajan et al. [32] approach at the 6 months follow-up considering impact of next six patient-centered criteria: obtained root coverage level; curation of hypersensitivity sign; gingiva color in the area of previously provided intervention; surgical procedure characteristics, personal overview regarding post-surgical phase, and cost-effectiveness. Also, additional criteria of diagnostics and patient-orientation was added to originally proposed Mahajan's set of parameters. Each parameter was graded by patients in the range from 1 to 3: unsatisfied – 1, satisfied – 2, fully satisfied – 3.

OHIP-14 questionnaire was used to evaluate oral health-related quality of life parameters before and 6 months after treatment regarding effect of provided interventions in the area of recession due to the next dimensions: functional limitations, physical limitations, pain, psychological discomfort, physical disability, psychological disability, social disability and handicap. Likert's 5 points grading system was used to categorize the answers of respondents on the OHIP-14 questionnaire regarding frequencies of noting disturbances because of gingival recession before and after treatment [30].

Data Analysis

Descriptive statistical analysis included estimation of mean values and their standard deviations (SD) for clinical parameters (age, RecDep, CAL, PD, MRCD) and patient-centered parameters (RES, VAS, Mahajan's scale, OHIP-14) in study and control groups. The significance of the registered differences (p) regarding pre- and post-treatment parameters and also such between study and control groups was assessed considering applied statistical criteria of Student's t-tests for parametrical variables and Wilcoxon–Mann–Whitney test for nonparametric variables. Paired Student's t-criterion was used to compare the parameters of clinical attachment level, probing depth and recession depth between study and control group. Quantity of teeth with specific levels of mean root coverage and complete root coverage in the study and control groups were compared based on Fisher's exact test. Statistical affirmation regarding differences between compared outcomes was claimed only under $p < 0.05$ (significance level of 0.95) condition. Data systematization, categorization, tabulation with further graphical representation was held within Microsoft Excel software (Microsoft Office 2019, Microsoft Corp., USA) with additional use of Analyse-it (Analyse-it Software, Ltd., Leeds, UK) and XLSTAT (Addinsoft Inc., Long Island, NY, USA) add-ins for inferential statistics procedures.

Ethical Aspects

Design of provided research was approved by the Ethical Committee of Faculty of Dentistry at Uzhhorod National University (#20201021). Furthermore, voluntarily agreement of patients to participate within the research after in-detail explanation of all study design aspects was considered a groundbase for their further evaluation as potential participants taking into account the correspondence with the formulated inclusion and exclusion criteria.

Results

Study group consisted of 14 males (56%) and 11 females (44%), while mean age of participants was 34.53±7.25 years. The control group consisted of 12 males (48%) and 13 females (52%), while the mean age of the participants was 37.24±6.38 years. In both study and control group patients did not abandon any control appointments, including the last one on the 6 months follow-up (drop-out rate equaled to 0). No baseline

statistically approved differences were registered between study and control groups considering criteria of age, gender distribution, topography of recession and type of recession ($p > 0.05$).

Clinical improvements regarding changes of recession depth, probing depth, clinical attachment levels and mean root coverage deficiency were noted in both study and control groups 6 months after provided treatment (Figures 5 and 6).

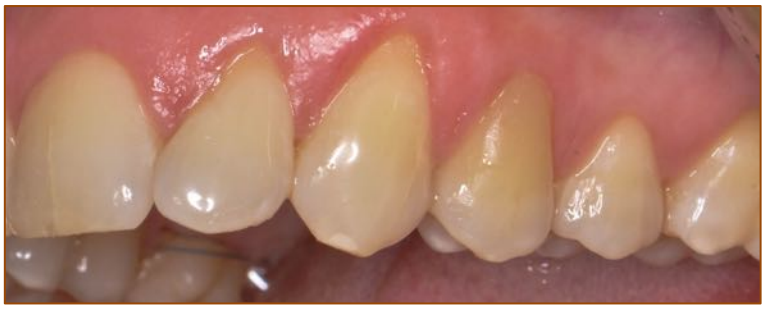

Figure 5. Clinical photo of canine recession before the treatment in study group.

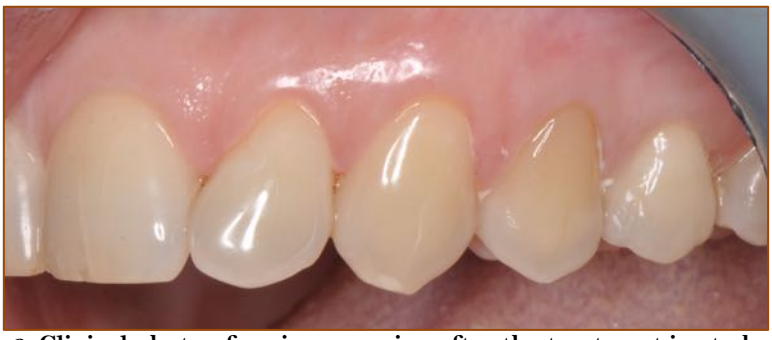

Figure 6. Clinical photo of canine recession after the treatment in study group.

At the 6 months follow-up control group demonstrated better clinical outcomes regarding recession depth reduction for Class I and Class II recessions, clinical attachment level re-establishment for Class II recessions and mean root coverage deficiency decrease for Class I and Class II recessions, superiority of which were statistically approved compare to the parameters registered within study group ($p < 0.05$) (Table 1).

Table 1. Comparison of baseline and 6 months follow-up clinical parameters between study and control groups.

Parameters	Class I Recession		p-value	Class II Recession		p-value
	Groups			Groups		
	Study	Control		Study	Control	
RecDep0, mm	2.18±0.43	2.14±0.39	>0.05	3.62±0.51	3.45±0.49	>0.05
RecDep6, mm	0.47±0.35	0.28±0.41	<0.05	0.89±0.48	0.55±0.45	<0.05
PD0, mm	1.63±0.96	1.75±0.83	>0.05	2.24±1.14	2.21±0.98	>0.05
PD6, mm	0.98±0.57	1.22±0.43	>0.05	1.05±0.63	1.19±0.52	>0.05
CAL0, mm	3.81±1.14	3.89±1.08	>0.05	5.86±1.74	5.66±1.37	>0.05
CAL6, mm	1.45±1.05	1.50±1.12	>0.05	1.94±1.28	1.74±1.25	<0.05
MRCD0, %	46.29%±8.95%	47.34±9.11%	>0.05	58.25%±12.21%	55.16±10.45%	>0.05
MRCD6, %	21.40%±12.31%	15.15±11.74%	<0.05	24.22%±11.75%	18.16±12.54%	<0.05

RecDep0: Recession Depth Before Treatment; RecDep6: Recession Depth 6 Months After Treatment; PD0: Periodontal Depth Before Treatment; PD6: Periodontal Depth 6 Months After Treatment; CAL0: Clinical Attachment Level Before Treatment; CAL6: Clinical Attachment Level After Treatment; MRCD0: Mean Root Coverage Deficiency Before Treatment; MRCD6: Mean Root Coverage Deficiency After Treatment.

In study group CRC was reached in 24% (6 out of 25) of clinical cases, while in control group in 56% of clinical cases (14 out of 25), and difference between them was statistically approved ($p<0.05$).

Statistically confirmed differences between study and control groups were also registered regarding final RES scores obtained after 6 months of treatment, demonstrating higher objective esthetic success of CAF+CTG approach compare to CAF+XDM (7.35±1.27 *vs.* 8.25±1.39, $p<0,05$). Such criteria of RES as "Gingival margin" and "Gingival color" were ones characterized with statistically significant differences between the groups ($p<0.05$), while differences among others were not statistically approved ($p>0.05$), even though study group (CAF+XDM) demonstrated higher average values for soft-tissue texture and muco-gingival junction alignment (Table 2).

Table 2. Comparison of root esthetic index (RES) and its components between study and control groups.

Group	RES	Gingival Margin	Marginal Tissue Contour	Soft Tissue Texture	Muco-Gingival Junction Alignment	Gingival Color
Study	7.35±1.27	3.79±1.57	0.90±0.32	0.86±0.39	0.89±0.25	0.91±0.29
Control	8.25±1.39	4.94±1.04	0.90±0.25	0.80±0.35	0.80±0.31	0.81±0.34
p-value	<0.05	<0.05	>0.05	>0.05	>0.05	<0.05

RES: Root Esthetic Index.

During the systematization of data regarding patients' general satisfaction level, estimated due to the Mahajan et al. approach, it was noted that overall level of such within study group reached 21.69±0.24 points and was statistically higher than in control group ($p<0.05$), in which it equaled to 19.57±0.41. Furthermore, based on patients' personal perception use of xenogeneic type of graft accompanied with the implementation of pre-treatment graphical modeling for soft tissue changes supported achievement of better patient-centered outcomes, such as root coverage ($p<0.05$), surgical phase ($p<0.05$), post-surgical phase ($p<0.05$), cost-effectiveness ($p<0.05$) and diagnostics and patient-orientation ($p<0.05$) (Table 3).

Table 3. Comparison of patients' general satisfaction level and its components between study and control groups.

Groups	Root coverage	Dentinal hypersensitivity	Gums color	Shape and contour of gums	Surgical phase	Post-surgical phase	Cost-effectiveness	Diagnostics and patient-orientation
Study	2.82±0.21	2.49±0.37	2.67±0.26	2.82±0.22	2.71±0.26	2.54±0.31	2.79±0.20	2.85±0.12
Control	2.53±0.35	2.51±0.39	2.54±0.23	2.56±0.26	2.25±0.58	2.18±0.67	2.47±0.44	2.53±0.42
p-value	<0.05	>0.05	>0.05	>0.05	<0.05	<0.05	<0.05	<0.05

Evaluation of patient general satisfaction with obtained results 6 month after provided treatment resulted into following VAS scores: 8.26±1.35 and 8.07±1.57 in study group for Class I and Class II gingival recession cases, while in control group outcomes of 7.54±2.18 and 7.19±2.49 were noted for Class I and Class II gingival recession cases respectively. Registered differences of VAS scores between study and control groups were not statistically grounded ($p>0.05$) both for Class I and Class II gingival recession cases. All patients in study group confirmed that after treatment they received level equal to or greater than "patient-critical results", which were pre-established during digital soft tissue design at pre-treatment phase.

Both in study and in control group patients demonstrated statistically significant improvement regarding changes within OHIP-14 levels 6 months after provided gingival recession treatment compare to the baseline level: from 9.54±1.08 to 3.95±0.46 in study group ($p<0.05$), and from 9.56±1.05 to 5.92±0.71 in control group ($p<0.05$). Outcomes in the study group were statistically lower than in the control group at the 6 months

follow-up period ($p<0.05$), due to the significant differences at domains of psychologic discomfort ($p<0.05$) and psychologic disability ($p<0.05$) registered during control appointment.

Discussion

The objective of present study was to evaluate the impact of originally-developed approach aimed at pre-treatment graphical modelling of soft-tissue changes (also claimed by the authors as digital soft tissue design) on the optimization of patient-centered outcomes after Class I and Class II gingival recession treatment, and based on the received results we may reject previously formulated null hypothesis.

CAF+CTG technique has provided better clinical outcomes in the meanings of recession depth reduction, re-establishment of clinical attachment level (for Class II recession) and soft tissue root coverage, while by all other clinical criteria CAF+CTG was analogically effective to CAF+XDM. Also, CAF+CTG supported more successful gingival margin restoration due to RES scoring approach, which explains how better objective outcomes for the root esthetic scores were achieved in the control group compared to the study group. Nevertheless, higher patient-centered outcomes were obtained in study group due to the used criteria for personal perception of final root coverage, surgical phase, post-surgical phase, cost-effectiveness and diagnostics and patient-orientation, and also due to the OHIP-14 questionnaire results. So, even though use of CTG and CAF provided better clinical results and objective esthetic outcomes, approach of CAF+XDM accompanied with pre-treatment graphical modelling of soft-tissue changes supported optimization of patient-centered outcomes after gingival recession treatment. Such results advocate the previously formulated thesis regarding the significant impact of patient perception factor on the final outcome of gingival recession treatment. That is why it should be included in the comprehensive evaluation protocol for provided treatment effectiveness as an obligatory component.

In number of previous studies CAF+XDM technique used for recession treatment provided inferior or, regarding some clinical parameters, equal clinical effectiveness compare to CAF+CTG [17]. Some researches approved clinical significance of using xenogeneic transplant as sufficiently effective substitution of autologous connective tissue graft with no significant clinical difference between them, while usage of XDM also was supported by lower level of post-operative morbidity, lesser operative time and lower level of iatrogenic surgical trauma [11,16]. Moreover, placement of CAF+XDM was supported by better clinical outcomes for recession treatment compare to the results of using CAF alone [34]. Nevertheless, in randomized clinical trial no additional effect was found while combining modified coronally advanced flap technique with xenogeneic collagen matrix or xenogeneic acellular dermal matrix regarding all clinical and patient-centered outcomes during RT1 gingival recession treatment; except gingival thickness parameters, which improved significantly in respect of using CM or XDM in test groups compare to control group (CAF only) [35]. In our study CAF+XDM demonstrated clinical results practically analogical to CAF+CTG specifically for single recession cases, but due to the other research the use of novel porcine-derived acellular dermal matrix together with CAF could not guarantee achievement of clinical outcomes analogical to CTG+CAF during multiple recession treatment [36]. Systematic review demonstrated that xenogeneic collagen matrix is associated with no less effective results than CTG during its usage together with CAF procedure regarding mean root coverage changes and recession reduction during single gingival recession treatment, which also corresponds with results of our study [15].

Several previous studies have reported patient-centered outcomes among obtained results of recession treatment, mostly in the meaning of measuring post-operative pain intensity and personal satisfaction with final

changes [25,32,37,38]. But few studies were dedicated to the evaluation of patient-centered outcomes while using xenogeneic graft for gingival recession treatment [32,39,40].

In Suzuki et al. [41] study authors have mentioned that xenogeneic dermal matrix (XDM) could be used as successful alternative for connective tissue graft for the treatment of single gingival recessions, while also such approach associated with high VAS scores regarding patients' satisfaction level. In Ferraz et al. [42] study authors also pointed out that mean root esthetic score in their study (CAF+XDM), in study of Suzuki et al. [41] (with the use of different surgical approach – eCAF+XDM), and in study of Pietruska et al. [43] (tunnel technique with XDM for multiple recession) was relatively similar after recession treatment. Such outcome could be interpreted in manner, that despite the differences in the above-listed investigations, authors were able to reach analogical satisfactory esthetics results, or maybe design of used esthetic evaluation score could differentiate obtained results only to some certain level. In our study VAS scoring approach did not demonstrate any statistical difference between study and control groups regarding general satisfaction with obtained treatment outcome, while study group demonstrated superior personal satisfaction level with treatment results due to the Mahajan's criteria. Improvement of esthetic and perception evaluation approach after recession treatment could be reached by using not only some objective scores, like RES or PES/WES, but also by analyzing their correspondence with obtained patient's satisfaction level measured by different approaches.

In the randomized control trial usage of CAF+CTG demonstrated higher outcomes regarding RES and gingival margin values compared to CAF+CM (collagen matrix), which corresponds to data obtained in our study [43]. Nevertheless, in Pietruska et al. [43] study use of CM demonstrated statistically higher outcomes regarding muco-gingival junction alignment, which was not registered in our study. Such non-compliance could be argumented by the differences of CM used in previous study and XDM used in our research, and also by the realization of modified coronally advanced technique in Pietruska et al. trial [43], while in our research we have used classical design of CAF.

Systematic review of randomized controlled trial demonstrated that even though CAF+CTG characterized with superior aesthetic outcomes, it also resulted in less natural soft tissue texture and gingiva color [44]. In our study we also have noted mean soft-tissue texture and gingiva color values to be higher in CAF+XDM than in CAF+CTG group, but statistical difference for soft-tissue texture was not significant. Such outcome could be affected by the non-randomized study design, and calibration issues. Nevertheless, our results were comparable with the data provided by systematic review [44], since CAF+CTG demonstrated higher RES values than CAF+XDM.

In original Mahajan et al. [32] research patients who have undergone procedure of coronally-positioned flap+ADM and coronally-positioned flap alone demonstrated analogical personal cumulative level of satisfaction, while lower levels of comfort during and after operational procedures and cost-effectiveness were noted among ADM group. In our research we compare CAF+XDM and CAF+CTG groups and revealed that patients in CAF+CTG demonstrated lower level of personal satisfaction regarding surgical and post-surgical phase. This outcome could be argumented by the fact that patients in CAF+CTG group received greater amount of surgical trauma, underwent through the longer operational time and demonstrated higher level of morbidity due to the additional intervention aimed at harvesting CTG from the palate area. We have also modified rating system of Mahajan et al. [32] and add "Diagnostics and patient-orientation" component to its structure. It helped us to verify statistically greater level of patient's satisfaction with provided diagnostic procedure, pre-treatment planning and further treatment plan discussion.

Considering above-mentioned data, and also the fact that patients in CAF+XDM group based on their personal perception rated outcome levels of gingival margin higher than in CAF+CTG group, even though in fact CAF+CTG group demonstrated superior clinical outcomes, we may resume following: implementation of originally developed approach of pre-treatment graphical modeling for soft-tissue level changes and direct patient involvement into discussion and representation of potential clinical outcomes supports the optimization of patient-centered treatment results after Class I and Class II gingival recession coverage with the use of xenogeneic graft.

Due to the data provided by cross-sectional study gingival recession demonstrate the impact on patients' quality of life, while misperception of the pathology may cause the deviation within health-related quality of life criteria [45]. Scores of OHIP-14 noted within our study coincide with such reported in randomized clinical study of Rocha dos Santos [33], showing analogical tendency of oral health-related quality of life criteria increase 6 months after received gingival recession treatment.

Limitations of present research associated with relatively small size of study and control groups, but it should be kept in mind that design of this investigation is a pilot one and dedicated in the first place to the hypothesis that originally-developed approach of pre-treatment graphical modelling for soft-tissue changes could have impact on the patient-centered gingival recession treatment outcomes. Also, another limitation includes the fact that obtained results could be associated only with I and II Miller's single types of recessions, while our further study would be dedicated to the approbation of proposed pre-treatment graphical modelling for soft-tissue changes among multiple recessions cases and under Cairo's approach for recession classification. In present study patient-oriented background factors, such as socio-economical and psycho-emotional, which potentially could have influence on the final outcome, were not objectively assessed at the primary phase of diagnostics, which also could be considered as partial limitation of the study.

But despite all the above-mentioned limitations of the study it could resumed that implementation of proposed personalized planning approach based on the pre-treatment graphical modelling for soft-tissue changes supports the optimization of patient-centered outcomes while using CAF+XDM technique for Miller Class I and Class II gingival recession treatment.

Conclusion

Considering limitations of provided study it could be concluded that the use of XDM together with coronally-advanced flap technique demonstrated relatively analogical objective clinical outcomes after Class I and Class II Class single gingival recessions treatment similar to those registered while using autologous connective tissue graft together with coronally-advanced flap for the same purpose. Nevertheless, patient-centered results were found to be more successful within the group of using xenogeneic type of graft accompanied with the implementation of pre-treatment graphical modeling of soft tissue changes, which helped to balance patients' pre-operative expectations and post-operative satisfactions with the received results, reduce post-operative morbidity and improve oral health-related quality of life during Class I and Class II single gingival recessions treatment. Furthermore, Mahajan's approach demonstrated greater possibility to differentiate the results of patients' satisfaction with provided treatment between study and control groups than classical 10-points VAS approach used for the same purpose.

Authors' Contributions

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All authors declare that they contributed to critical review of intellectual content and approval of the final version to be published.

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Conflict of Interest

The authors declare no conflicts of interest.

Data Availability

The data used to support the findings of this study can be made available upon request to the corresponding author.

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