

Assessment of True End Points in Periodontal Flap Therapy Patients – A DIDL Questionnaire Study

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ABSTRACT

Background and Objective: To assess and compare true as well as surrogate end points for the most commonly performed procedure – the periodontal flap surgery using Dental Impact on Daily Living (DIDL) questionnaire.

Material and Methods: Forty subjects who underwent periodontal flap surgery for generalized chronic and aggressive periodontitis in the Department of Periodontology, Indira Gandhi Institute of Dental Sciences were enrolled in this study. Clinical parameters (surrogate end points) such as gingival index (GI), probing pocket depth (PPD) and clinical attachment level (CAL) were recorded and DIDL questionnaire was administered pre surgery and after six months to assess true end points.

Results: The surrogate end points such as gingival index, probing pocket depth and clinical attachment level showed statistically significant improvement with $p=0.00$. True end points such as bad breath, bleeding gums, food being trapped between teeth had significant improvement after flap surgery whereas sense of loose teeth in the mouth, appearance, sensitivity and confidence while interacting with others did not show improvement post operatively.

Conclusion: Significant improvements in surrogate end points do not always translate to achievement of true end points. Most of the time periodontal therapy alone contributes only to elimination of etiology. True end points in terms of comfort, functionality, esthetics and social interaction can be achieved only through interdisciplinary practice.

Key-words:

Surrogate end points, True end points, Quality of life, Periodontal flap therapy.

INTRODUCTION

Any intervention or therapy can ideally be deemed successful only if it meets true end points. True clinical end points in Periodontology should measure how a patient feels, functions or survives. These points are tangible to the patient and are clinically meaningful to them.^{1,2} On the other hand surrogate endpoints such as probing pocket depth, attachment loss and gingival fluid markers are excellent measures of disease activity.^{3,4} It remains to be clarified with evidence if improvement in surrogate measurements translate to improved quality of living in terms of dental comfort, functionality, appearance and social performance.

True endpoints measure patient's tangible subjective response⁵ and

therefore is directly related to quality of life of the patient than objective changes PPD (probing pocket depth) and CAL (clinical attachment level). Randomized control trials in Periodontics often consider surrogate estimates such as PPD and CAL only. After periodontal therapy, the patient based outcomes like comfort of teeth, functionality, longevity of teeth in the oral cavity and esthetic demands almost are never taken into consideration.

Ideally, periodontal flap surgery should measure reduction in parameters such as bleeding on probing, mobility, malodour, food impaction, improvement in function of teeth and assess improvement in whatever the patient's primary complaint was, as outcome parameter, rather than PPD

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and CAL alone which are only surrogate end points. Similarly, root coverage procedures in periodontics should as much as possible measure patient's satisfaction with esthetics and reduction in sensitivity as outcome parameters rather than assess the height and width of recession or percentage of root coverage which are only surrogates.

There are very few trials in periodontics taking true end points as outcome parameters. There is evidence that clinical attachment loss is a valid surrogate to predict tooth loss in two trials.^{6,7} Other than this, literature search reveals no trials in periodontics validating any of the other surrogate end points used.⁸

Patient based outcomes (PBO) were identified as research priority at the World workshop 2003 on emerging science in Periodontology. In lieu with the above we intended to assess and compare surrogate as well as true end points for the most commonly performed procedure – the periodontal flap surgery. Surrogate end points such as GI (gingival index), PPD and CAL was recorded pre and post surgically. True end points were assessed using Dental Impact on Daily Living (DIDL) questionnaire pre and post surgically.

DIDL was developed by Leao and Sheiham.⁹ The DIDL questionnaire is a validated socio-dental measure which assesses five dimensions of quality of life: appearance, comfort, eating restriction, pain and performance. The measure consists of a questionnaire of 36 items, which assesses the dental impact on daily living.

MATERIAL AND METHODS

Forty subjects, 20 males and 20 females, aged between 25 and 50 years who underwent periodontal flap surgery for generalized chronic and aggressive periodontitis

in the Department of Periodontology, Indira Gandhi Institute of Dental Sciences, Puducherry were enrolled in this study.

All participants met the following criteria of good general health; were non-smoking and non-alcoholic; gingival index (GI) scores ranging between 2.1-3.0 (severe gingivitis); probing pocket depth (PPD) values exceeding 4mm in more than 30% of the sites; clinical attachment loss (CAL) values exceeding 4mm in more than 30% of the sites; radiographic evidence of periodontal bone loss after a full-mouth radiographic periapical examination. Each participant signed a consent form acknowledging their voluntary and non-prejudicial participation in the study and the protocol was reviewed and approved by the Institutional Ethical Committee.

For all the study subjects, periodontal parameters (GI, PPD, CAL) were recorded and DIDL questionnaire was administered pre surgically and 6 months post surgically.

Sample size calculation : Since there is a lack of similar studies in literature the effect size was assumed to be 0.4 with 80% power and 5% alpha error. The sample size was 40 individuals. The sample size was calculated using the G* Power statistical software, Version 3.1.

Data, thus obtained were entered using Microsoft Excel spreadsheet and analyzed using SPSS software (Version 17). Descriptive data is presented as mean and standard deviation for gingival index, pocket probing depth and clinical attachment level. Frequency distribution and percentage were calculated for the questionnaire. Wilcoxon paired signed-rank test was employed to test the statistical significance of responses pre and post surgically.

Table 1. Comparison of surrogate end points pre and post surgery

	Gingival Index n=40		PPD n=40		CAL n=40	
	Pre	Post	Pre	Post	Pre	Post
Mean	2.5275	0.4725	3.5465	1.8992	4.8255	3.4088
Std. Deviation	.29176	.21121	.29693	.11296	1.39319	1.54718
p value	0.00		0.00		0.00	

Table 2a: Comparison of true end points pre and post surgery - appearance and comfort domains [Data within the bracket is in percent]

Sl.No	Content	Pre					Post				
		Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
Appearance Domain											
1	How much are you satisfied with the appearance of the teeth?	29 (72.5)	11 (27.5)				9 (22.5)	14 (35)	17 (42.5)		
2	How much are you satisfied with the colour of the teeth?	26 (65)	14 (35)				28 (70)	6 (15)	6 (15)		
3	How much are you satisfied with the position of the teeth?	21 (52.5)	19 (47.5)				25 (62.5)	6 (15)	9 (22.5)		
4	How much are you satisfied with your gums?	30 (75)	10 (25)						40 (100)		
5	How much are you satisfied with your teeth as a whole?	31 (77.5)	9 (22.5)				14 (35)	15 (37.5)	11 (27.5)		
Comfort Domain											
6	Do any position of your teeth disturb you?				40 (100)			2 (5)	38 (95)		
7	Do you have any problem due to food being trapped in between teeth?				10 (25)	30 (75)	35 (87.5)	5 (12.5)			
8	Do you have bad breath?				12 (30)	28 (70)	40 (100)				
9	Do you feel sensitivity when you eat or drink anything cold or acidic?		9 (22.5)		18 (45)	13 (32.5)		14 (35)		13 (32.5)	13 (32.5)
10	Do your gums bleed?				9 (22.5)	31 (77.5)	40 (100)				
11	Are there any loose teeth in your mouth?			6 (15)	16 (40)	18 (45)	15 (37.5)				25 (62.5)
12	Have your teeth worried you with any problem?				37 (92.5)	3 (7.5)		20 (50)		20 (50)	

RESULTS

The results of this study demonstrated that after 6 months of periodontal flap surgery, the clinical parameters of gingival index, probing pocket depth and clinical attachment level have markedly improved ($p=0.00$, Table.1).

Appearance domain had questions related to appearance, color, position of teeth, satisfaction and comfort of gingiva. 100% of patients were satisfied with gums after flap surgery as compared to pre

operatively. Only 42.5 % of patients were satisfied with appearance of teeth post surgery. Patients were still dissatisfied regarding colour and position of teeth post operatively (Table.2a).

In the comfort domain, 100% of patients agreed there was reduction in bad breath, bleeding gums and food being trapped in between teeth post surgery. When tooth sensitivity was assessed only 35% agreed to have reduction in sensitivity and 65% still had sensitive teeth post operatively. 85% of patients perceived loose

Table 2b: Comparison of true end points pre and post surgery - eating restriction and pain domains
[Data within the bracket is in percent]

Sl.No.	Content	Pre					Post				
		Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
Eating Restriction Domain											
13	How well are you able to chew food without any difficulty?	38 (95)	2 (5)					27 (67.5)		13 (32.5)	
14	How well are you able to bite food without any difficulty?	35 (87.5)	5 (12.5)					27 (67.5)		13 (32.5)	
15	How much are you satisfied with the way of chewing?	38 (95)	2 (5)					27 (67.5)		13 (32.5)	
16	How much are you satisfied with the way of biting?	35 (87.5)	5 (12.5)					27 (67.5)		13 (32.5)	
17	Did you change any food habit?		6 (15)	6 (15)		28 (70)	6 (15)	24 (60)		10 (25)	
18	Did you change the way of cooking?		6 (15)	6 (15)		28 (70)	6 (15)	24 (60)		10 (25)	
Pain Domain											
19	Do you have any spontaneous toothache?	12 (30)	12 (30)			16 (40)	31 (77.5)			9 (22.5)	
20	Do you have any toothache on having cold, hot or sweet food?	12 (30)	12 (30)			16 (40)	31 (77.5)			9 (22.5)	
21	Do you bring about any change in the food habit due to toothache?	12 (30)	12 (30)			16 (40)	31 (77.5)			9 (22.5)	
22	Do you have pain in your gums?				29 (72.5)	11 (27.5)	40 (100)				

teeth before surgery and 62.5% still perceived loose teeth after surgery. Only 37.5% agreed that teeth did not feel loose after surgery (Table.2a).

With regards to eating restriction domain which assessed functionality, only 25-33% of patients agreed to improvement in functionality (chewing and biting of food) post operatively whereas 65-70% of patients felt no improvement with chewing and biting food post operatively (Table.2b).

When pain was assessed, 100% of patients had reduction of pain in gums post surgery as compared to pre surgery (Table.2b).

Performance domain assessed social interaction and 100% of patients agreed that appearance and function of teeth affected their social interaction. Post operatively only 22.5% agreed to improvement in appearance and function. The other 62.5% did not appreciate improvement in appearance and function. To yet another question regarding if teeth have helped them feel confident, 62.5% still responded in negative manner post surgically (Table.2c).

All subjective responses between pre and post surgery were statistically significant ($p < 0.05$).

Table 2c: Comparison of true end points pre and post surgery - performance domain [Data within the bracket is in percent]

Sl.No.	Content	Pre					Post				
		Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
Performance domain											
23	How much are you satisfied in showing your teeth on smiling?	38 (95)	2 (5)					23 (57.5)	10 (25)	7 (17.5)	
24	Have you avoided showing your teeth on smiling?				2 (5)	38 (95)	7 (17.5)	10 (25)	23 (57.5)		
25	Do the appearance of your teeth affect your working capacity?			6 (15)	4 (10)	30 (75)		9 (22.5)	6 (15)	25 (62.5)	
26	Do the function of your teeth affect your working capacity?			6 (15)	4 (10)	30 (75)		25 (62.5)	6 (15)	9 (22.5)	
27	Do toothache affect your working capacity?		16 (40)				24 (60)			16 (40)	
28	Do the appearance of your teeth affect your interaction with people?				2 (5)	38 (95)		9 (22.5)	6 (15)	25 (62.5)	
29	Do the function of your teeth affect your interaction with people?			6 (15)	4 (10)	30 (75)		25 (62.5)	6 (15)	9 (22.5)	
30	Do toothache affect your interaction with people?		16 (40)				24 (60)	24 (60)		16 (40)	
31	Do toothache affect your sleep?	34 (85)			6 (15)			40 (100)			
32	Do toothache cause stress in you?				25 (62.5)	15 (37.5)	24 (60)			16 (40)	
33	Have your teeth caused embarrassment in you?				2 (5)	38 (95)	20 (50)				20 (50)
34	Do the appearance of your teeth affect your romantic life?			6 (15)	4 (10)	30 (75)		9 (22.5)	6 (15)	25 (62.5)	
35	Do toothache affect your romantic life?	12 (30)	18 (45)				10 (25)	38 (95)		2 (5)	
36	Have your teeth helped to feel confident in you?	38 (95)	2 (5)					25 (62.5)	6 (15)	9 (22.5)	

DISCUSSION

We assessed both surrogate and true end points in patients who underwent periodontal flap surgery for both generalized chronic and aggressive periodontitis. Surrogate end points measured were GI, PPD and CAL which showed significant reduction post operatively as expected.

To measure true end points, five domains such as appearance, comfort, eating restriction, pain and performance of DIDL questionnaire were assessed pre and postoperatively in patients who underwent full mouth flap surgery. Pre operatively the questionnaire

was administered before oral prophylaxis and post operatively the questionnaire was administered during six month review visit.

To the best of our knowledge, our study is the first to assess the impact of periodontal flap surgery on the quality of life of patients using DIDL questionnaire. Previous studies have used this tool to rate the impact of implant therapy, complete dentures and dental caries.^{10,11,12} Omiri *et al*¹⁰ investigated the association between satisfaction with the dentition and dental prostheses and personality profiles among patients who received implant-supported prostheses using DIDL and

NEO-FFI scales. Similar tools were used by Hantash et al¹¹ to investigate the association between satisfaction with complete denture prostheses and its impact on daily living and personality profiles. Ganesh et al¹² used this scale to correlate DMFT index and the level of patient's satisfaction.

Despite the significant reduction or improvement in surrogate end points which measure the success of periodontal therapy, when the patient based outcomes were assessed, only the following end points such as bad breath, bleeding gums, food being trapped between teeth had significant improvement. Sense of loose teeth in the mouth, position and colour of the teeth and sensitivity did not show much improvement from patient's perspective.

There are two important inferences from our study. The first inference is that our study points that there is a need to identify appropriate true end point parameters to be assessed after periodontal surgeries. Besides measuring surrogate parameters, appropriate patient based true end points must be included in any study to derive a complete and meaningful picture of effectiveness of any periodontal technique/therapy. Randomized control trials in periodontology should include measurement of true periodontal end points as well.

The second inference is that our study emphasises the need for interdisciplinary practice, catering to the primary complaint of the patient rather than treating the etiology alone. For example in a case of aggressive periodontitis, in addition to periodontal therapy, there is a need for orthodontic & esthetic therapy to correct distolabial migration, which might be the chief complaint of the patient. This will ultimately reflect as achievement of true end points, with significant improvements in domains such as esthetics, functionality & social interaction.

One limitation of this study is that though DIDL questionnaire measures impact of dental therapy on daily living of patients and measures true end points, there are few questions that may not be relevant to periodontal therapy per se. DIDL is not tailor made for measuring periodontal true end points alone. Therefore, there is a need to formulate a custom made questionnaire for measuring the periodontal true end points.

CONFLICTS OF INTEREST

None.

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