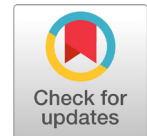




# Improvement in Wellness Following Periodontal Therapy

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## Abstract

**Background:** Periodontal disease is linked to numerous systemic diseases and it is known that periodontal therapy (PT) is effective in reducing the severity of those diseases. We tested the idea that PT also has a positive effect on quality of life and general wellness.

**Methods:** Patients scheduled for PT at the Rutgers Periodontics Clinic (Newark, NJ 07101) were administered the RAND-36 quality of life questionnaire before and at least 3-months after the procedure.

**Results:** The Wilcoxin signed ranks test demonstrates a significant improvement in wellness following Periodontal Therapy with a p-value=0.02.

**Conclusion:** In this sample most patient's general wellness improved following PT. Improvement was in the categories of physical functioning, energy and emotional well-being.

**Keywords:** Periodontitis; Periodontal therapy; Wellness; RAND-36; Questionnaire; Systemic disease

## Introduction

Periodontitis is an infectious disease of the periodontium leading to alveolar bone loss, and the formation of periodontal pockets. Osseous resective surgery became the basis of surgical periodontal therapy since it addressed the importance of alveolar bone reshaping [1]. Barrington [2] identified access for root debridement and pocket elimination as the two major benefits of resective treatment. Ramfjord and Nissle [3] introduced the modified Widman flap. A few years later Yukna and Lawrence [4] introduced excisional new attachment procedure (ENAP) and confirmed its success. Minimally invasive laser-assisted procedures have recently been introduced that are effective at bacterial reduction, [5, 6] reducing inflammation [7] and have recently gained FDA clearance for "true periodontal regeneration" (510(k): K151763) [8].

Transient and recurrent bacteremias of oral origin also generate systemic inflammation and metabolic stress that may initiate or

exacerbate systemic disease [9-11]. The impact of oral infection on numerous medical conditions is well documented [12-15]. Conditions linked to oral infections include diabetes; [16-20] cardiovascular diseases such as atherosclerosis, acute myocardial infarction and stroke; [21-27] rheumatoid arthritis; [28, 29] obstructive pulmonary disease; [30, 31] osteopenia [32, 33] and low birth-weight preterm pregnancies [34-36]. There are indirect benefits of periodontal therapy (PT) for these patients including lower health care costs and fewer hospital visits [37].

It follows that oral infections may also have a negative impact on general wellness and, therefore, we conducted a study to test the hypothesis that PT will also affect general wellness. Patient responses to the RAND-36 questionnaire before and after PT were used to test this idea. The RAND-36 is a self-administered 36 question survey that measures quality of life before and after a medical or surgical intervention. It has been a well validated and accepted instrument in several different medical specialties [38-44].

We conducted a pilot study to test the feasibility of a larger trial. However, in this small sample size results demonstrate an improvement in wellness following PT that is statistically significant ( $p=0.02$ ).

## Methods

Patients included were 18 years of age or older, diagnosed with moderate to severe periodontitis and were scheduled for PT. Excluded were patients that had periodontal therapy within the previous 12 months. Subjects signed an informed consent and were administered the RAND-36 questionnaire. The questionnaire responses were scored and scores were entered into Case Report Forms (CRF) along with demographics, medical history, medications, vital signs and PT details. Patients were offered a free choice of either osseous resective surgery or the laser-assisted LANAP procedure [45, 46]. Patients were scheduled for follow up appointments at 3 and 12 months. Following each visit the CRFs were scanned and uploaded to the statistician for data entry and analysis.

Analysis of the RAND-36 answers to 36 questions yields scores that range from 0-100 for eight health categories: general health, physical functioning, limitations due to physical health problems, limitations due to emotional problems, emotional well-being, social functioning, energy/fatigue, and pain. The eight scores are averaged to provide an over-all score for each visit. Scores for each category are averaged across subjects for baseline and follow-up visits to examine the magnitude and direction of change in the population for each condition. The Wilcoxon signed-rank test was used to compare two repeated measurements on a single sample to assess whether the population means differ from baseline to follow-up. The secondary outcome was to compare the mean difference

between the minimally invasive laser procedure and the invasive scalpel surgery.

## Results

The COVID-19 pandemic epicenter in Essex County, New Jersey affected recruitment, follow-up times and, perhaps, responses to the questionnaire. Recruitment was halted at 20 subjects when the clinic closed due to lock down. There were 5 males and 12 females with a mean age of 57.9 (range 23-85) with follow-ups and three patients lost to follow-up. Local population quarantine disrupted the planned follow-up schedule. The mean follow-up was 163 days with a range of 64-376 days. Also, the resulting sample size was inadequate to statistically evaluate secondary outcome variables.

Overall, thirteen (13) patients improved their RAND-36 scores, two (2) remained the same and two (2) worsened. Patients with baseline scores <80 improved by 14.2, whereas healthy individuals with baseline scores >80 only improved by 1.1. The Wilcoxon signed ranks test was applied to the entire group to see if there was a significant change in wellness scores from baseline to follow-up. Analysis demonstrates a significant improvement in wellness following PT with  $p<0.05$  (Table 1).

Averaged responses to the eight wellness categories are listed in (Table 2) for baseline and follow-up visits. A positive value for change indicates an improvement in wellness. In this sample PT led to improvement mainly in physical functioning, emotional wellbeing and energy. Negative values for role limitations, both physical and emotional, indicate a worsening of the condition. Eleven patients indicated an improvement in general health, two stayed the same and four reported a decrease. Most patients (82%) experienced a substantial improvement in their emotional wellbeing (Table 2).

**Table 1:** RAND-36 wellness summary scores for all subjects (n=17).

The positive change (improvement) and percent change are significant with p-values = 0.022 and 0.015

	MEAN	MEDIAN	RANGE	SD	P-VALUE
Baseline	76.3	80.9	43-93	15.3	
Follow up	82.8	85.5	56-99	13.7	
Change	6.5	5.3	(-22)-38	12.6	0.022
% Change	11.00%	6.50%	(-26%)-66%	19.70%	0.015

**Table 2:** Change in RAND-36 scores by category (n=17).

CATEGORY	BASELINE	FOLLOW-UP	CHANGE	INCR/DECR
General health	75.6	80.7	5.1	11 / 4
Physical functioning	65.3	80	14.7	11 / 2
Role limitation/physical	83.8	81.2	-2.6	2 / 3
Role limitation/emotional	94.1	85.9	-8.2	2 / 5
Emotional wellbeing	57.9	75.2	17.3	14 / 3
Energy/fatigue	71.5	84.1	12.6	11 / 4
Social functioning	83.1	88.6	5.5	6 / 5
Pain	79.3	87.1	7.8	8 / 5

## Discussion

The goal of periodontal surgical therapy is to eliminate periodontal disease and restore the periodontium to normal function so the dentition can be maintained [47]. The success of periodontal therapy can be evaluated by observing the clinical signs of inflammation, bone loss, probing depths, bleeding and suppuration. However, it is important to consider patient-reported outcomes, since what may appear to be successful clinically might not correlate with the patient's own perceptions.

The most widely used survey to measure health-related quality of life is the RAND-36. It is useful in analyzing a patient's current physical and mental health status [48-51]. The RAND-36 is also available in multiple languages and can be used to summarize the outcome of cross-sectional and longitudinal studies [52]. We introduce the RAND-36 to evaluate the patient's perceived outcomes of surgical PT. Using this tool, we discovered that most patient's general wellness improved following PT. Improvement was in the categories of physical functioning, energy and emotional well-being. The survey was easy to administer and evaluate making it a potential asset for the periodontist in private practice.

A recent editorial in *Science* expressed concern about how to account for the impact of COVID-19 on ongoing clinical trial data [53]. The clinic is located at the New Jersey pandemic epicenter and the local spike in COVID cases occurred in the interval between baseline and follow up visits (April 3-24, 2020). (NJ website) [54] In this group of patients the categories of role limitations both physical and emotional did not improve but worsened slightly. It is likely that these role limitations were affected by the mandated lock down and quarantine of the COVID-19 pandemic.

Even though the pandemic exerted a negative effect on quality of life, the benefits of PT still prevailed in the overall outcome. In fact, the effects of PT on wellness must be quite strong to reach significance in this small sample. However, this was a pilot study and the experimental design was disrupted. Please interpret these results with caution. If our findings can be replicated one might add improvement in general wellness and emotional wellbeing to the list of possible benefits of Periodontal Therapy.

## Acknowledgement

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## Conflict of interest

The authors declare that they have no conflict of interest.

## Ethical Standards and Human Rights

The patients' rights and study design were reviewed by the Rutgers University Institutional Review Board (Newark Health Sciences IRB ID: Pro2018000955) and the study was performed in accordance with the 1964 Declaration of Helsinki. This was a non-interventional survey study so registration with ClinicalTrials.gov is not required.

## Informed Consent

Informed consent was obtained from all study participants.

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