Title: **Utilization of a Periodontal Endoscope in Nonsurgical Periodontal Therapy: A Randomized, Split-Mouth Clinical Study**

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Running title: Utilization of Perioscopy® in Nonsurgical Periodontal Therapy

Summary: The use of Perioscopy® as an aid for non-surgical scaling and root planing had the greatest effect on interproximal sites of maxillary multi-rooted teeth.

Abstract: [MP2]

Background: The removal of calculus to obtain gingival health has long been proven as an integral part of non-surgical periodontal therapy. However, literature on non-surgical approaches to enhance access to effectively remove calculus are still lacking. The use of a periodontal endoscope (Perioscopy®) is one such very promising approach.

Methods: Twenty-five (25) patients were recruited for the study that exhibited mild to moderate periodontitis with probing depth not greater than 6mm and at least one multi-rooted tooth per arch. This study aimed to evaluate clinical parameters after traditional scaling and root planing (SRP) using loupes for visualization, with Perioscopy® aided SRP using a split mouth design. Therapy was rendered by the same hygienist, while the evaluations were done by the same periodontal resident at baseline, one month, three months, six months, and twelve months after therapy. Results: In general, an increased benefit was found with the use of Perioscopy® at posterior multi-rooted sites compared to anterior single rooted teeth. Maxillary multi-rooted interproximal sites favored the use of Perioscopy® at the three month time period, in terms of clinical attachment level (CAL). Mandibular multi-rooted interproximal sites showed more improvement with traditional SRP in terms of CAL than with the use of Perioscopy®. Conclusion: Greater improvement was seen with the use of Perioscopy® in multi-rooted sites compared to single rooted and Perioscopy® was specifically beneficial in maxillary multi-rooted sites.

Key Words: non-surgical periodontal treatment; periodontal endoscope; perioscopy, scaling and root planing

Introduction[MP3]

The primary etiologic factor for periodontal disease is bacterial plaque. Calculus is considered a secondary etiologic factor, as it does not cause periodontal disease by itself, but rather harbors disease causing bacteria (Caffesse 1986). Calculus formation is the result of calcification of dental plaque biofilm, with mineral ions provided by saliva or gingival crevicular fluid (GCF). Calculus is composed of organic components, inorganic components, and water. The organic components (15-20%) of calculus are: leukocytes, epithelial cells, mucin from saliva, and non- vital microorganisms. The inorganic components (75-85%) of calculus are: hydroxyapatite, octocalcium phosphate, magnesium whitlockite, and brushite. There are four means of attachment of calculus to a root surface: acquired pellicle attachment, penetration of the calculus into the root surface cementum, mechanical interlocking into the calculus and/or tooth surface irregularities, and attachment to unaltered cementum (Selvig 1970). The mineralized deposits are difficult to remove due to the mechanical interlocking on root surfaces as well as calculus embedded into cementum that can become analogous during removal.

Disease-producing bacteria are harbored within surface irregularities of calculus. Supragingival calculus perpetuates inflammation of the adjacent tissues resulting in gingivitis and subgingival calculus that is close to the periodontal pocket lining epithelium promotes periodontitis (Friskopp 1980). Specifically, subgingival biofilm contains pathogenic bacteria that cause inflammation and destruction of the soft tissue and lead to loss of attachment to the tooth surface with further deepening of the pocket. Due to the tenacious attachment of calculus to root surfaces, simple home care of brushing and flossing cannot remove calculus. Complete removal of calculus is a primary part of achieving a “biologically acceptable” tooth surface in the treatment of periodontitis (Caffesse 1986). If left behind, calculus will inhibit attachment of the junctional epithelium to the root surface and continue to harbor for bacteria, subsequently compromising the periodontium. Subgingival scaling and root planing (SRP) is a major part of nonsurgical periodontal therapy in order to remove plaque, bacteria, and calculus from the diseased root surfaces.

With emphasis on good oral hygiene and routine professional removal, low levels of supragingival and subgingival calculus have been demonstrated on a long-term basis. Traditionally, SRP is performed using direct vision or loupe magnification. Removal techniques consist of conventional non-surgical treatment such as SRP with curettes and either powered scalers (ultrasonic or piezoelectric). However, non-surgical therapy will only allow clinicians to remove calculus within a certain level of probing pocket depth. It has been demonstrated that both experienced and inexperienced operators leave calculus behind, especially in periodontal pockets ≥4mm (Caffesse 1986). Surgical intervention is the next step in treatment as the clinician must gain visibility and access. Residual calculus has been shown to be the greatest following SRP using a closed approach with no access flap and at the cementoenamel junction(CEJ) or in association with grooves, fossae, or furcations (Caffesse, 1986). This study also showed that only 32% of calculus free surfaces were obtained on teeth with pocket depths of >6mm without access flap surgery and 50% calculus free surfaces were obtained even with access flap surgery . Premolars and molars are more difficult to debride non-surgically and that more than 60% of molar sites presented with residual calculus (Buchanan and Robertson, 1987). Another study reported that more than 90% of cases had deposits of plaque and calculus remaining in sites with pocket depths greater than 5mm after SRP (Waerhaug, 1978). These findings provoke the need for more efficient bacterial plaque and calculus removal. Being able to better visualize calculus in deeper pockets could potentially enhance the outcomes of non-surgical periodontal therapy and reduce the need for surgical therapy.

Periodontal endoscopy (Perioscopy®) is a conservative therapy that prompts a new era of debriding root surfaces more efficiently primarily due to better visualization. Visibility with this technique is similar to surgical therapy but without the need for an access flap. The procedure involves the use of an endoscope that allows root magnification of 24x to 48x by a 0.99 mm fiber optic bundle that is a combination of 10,000 -pixel capture bundle surrounded by multiple illumination fibers (Kwan 2006). The fiber is attached into the “explorer” that is placed into the gingival sulcus. The image is relayed to a screen that the user views as the explorer moves around the tooth while simultaneously scaling and root planning with an ultrasonic scaler. The ability to visualize pockets non-surgically theoretically improves chances of success.

Few previous clinical studies have been done comparing SRP with the adjunctive use of Perioscopy® to traditional SRP . A pilot study showed that Perioscopy® resulted in less bleeding on probing (BOP) and gingival inflammation, but no difference was reported for other clinical parameters (Blue 2013). Better visualization of calculus on tooth surfaces has been reported with the use the Perioscopy® when compared to tactile explorer used traditionally to detect calculus (Osborn 2014). A higher percentage of residual calculus was found remaining on root surfaces following traditional SRP when compared to the use of a periodontal endoscope (Geisinger 2007). A split-mouth controlled clinical trial evaluating SRP using Perioscopy® showed no significant differences between the two groups. The sites with more than 6 mm probing depth (PD) in anterior teeth presented significantly shallower PD at the end of 3 months compared to the control group. Liao et al. also concluded that the use of Endoscope® was effective in medium and long-term prognosis of deep pockets (>6mm) of single rooted teeth (Liao 2016). Michaud et al. conducted a study using Perioscopy® in multi-rooted teeth and found less residual calculus using the endoscope. However, these findings were significant only for interproximal pockets with <6mm depth. (Michaud 2007). A recent systematic review included eight randomized controlled trials, four of which compared the ability to remove subgingival calculus by using the periodontal endoscope or traditional SRP on hopeless teeth. The other four studies compared clinical outcomes of patients with periodontal disease treated by means of periodontal endoscopy or traditional SRP. The findings included a meta-analysis on four articles that verified the additional benefit of using periodontal endoscopy for calculus removal. However, the use of the periodontal endoscope was more time-consuming than traditional SRP. Comparison of clinical parameters revealed no significant difference between periodontal endoscope and traditional SRP. (Kuang et al.). Although studies have demonstrated certain advantages with the use of Perioscopy® for SRP, there is still a need for well-designed long term controlled clinical trials to establish these findings. Therefore, this study aims to compare the long term clinical outcome of SRP using Perioscopy® vs the traditional SRP using loupes, utilizing a split mouth design.

Materials and Methods

This study was designed as a prospective randomized split mouth clinical trial, aimed to compare the results of SRP using Perioscopy® vs SRP using loupe magnification. Approval was obtained from the Louisiana State University Health Sciences Center – New Orleans Institutional Review Board (IRB#9587). A total of twenty-five (25) subjects were recruited in the study. IRB-approved written informed consent was obtained from each patient prior to enrollment in the study. Inclusion criteria: subjects included were 18 years or older, in good general health, with a diagnosis of mild-moderate generalized chronic periodontitis who needed whole mouth SRP, with a maximum of 6mm PD) at any site, (at least one molar in each arch, excluding third molars). Exclusion criteria: subjects were excluded if they had any requirement for antibiotic premedication prior to dental treatment, uncontrolled hypertension, uncontrolled diabetes, were unwilling to sign the informed consent, or needed any antibiotic intervention for unrelated conditions.

Study subjects underwent a comprehensive periodontal exam, performed by a single periodontal resident recording probing depth (PD), free gingival margin (FGM), clinical attachment level (CAL) and bleeding on probing (BOP). The left or right half was randomly assigned to receive treatment with either loupe magnification or Perioscopy®. SRP was completed by a single experienced dental hygienist trained in Perioscopy®. Follow up re-evaluation visits were performed by the same resident at 4-6 weeks, 3 months, 6 months, and 1 year.

Twenty three (23) subjects completed the 3 month follow-up this study while 17 and 8 completed the 6 month and 12 month follow-ups, respectively (Table 1). We chose to analyze our data on the basis of number of sites, rather than on individual patients or average clinical parameters measured. Since each tooth could have a possible 6 sites, and patients varied in their number of missing teeth (with no sites), this was the most appropriate approach for analysis of our data. Thus, of a possible 3,864 sites, we examined 3,573 sites at the 3 month follow-up appointment, 2,600 sites at the 6 month follow-up and

1,128 sites at the 12 month follow-up.(table 1). Since patients were randomly assigned to study groups for Perioscopy® aided SRP on either there right or left sides of their mouths, this could have resulted in an imbalance of sites examined in one group or another. However, 14% of sites were examined on multi-rooted teeth for both study groups, while 36% of sites were examined on single-rooted teeth for both study groups, resulting in no statistical bias in either group.

Furthermore, since we were only interested in periodontally involved teeth (defined as having PDs of greater that 3 mm on either their initial visit or at their 1 month follow-up). The 1 month follow-up was considered to be a more reliable starting value in some cases, due to the potential for errors where subgingival calculus may have obstructed proper measurements on their initial examination. All further analysis was performed only on these 1,267 periodontally involved sites, that were evenly distributed between the traditional SRP and Perioscopy® aided SRP study groups (Table 2). This analysis also revealed that ~25% of single rooted teeth sites were periodontally involved, while ~62% of multi-rooted teeth sites were periodontally involved. Furthermore, ~80% of sites were periodontally involved for interproximal regions of multi-rooted teeth, while facial/lingual sites on these teeth or any sites on single rooted teeth were significantly less likely to be periodontally involved (15%-32%, Table 2). Furthermore, despite the smaller numbers of teeth involved when comparing multi-rooted maxillary and mandibular teeth, all groups had over 100 periodontally involved sites and displayed similar percentages of interproximal involved sites (77%-81%, Table 2)

Results:

All sites:

Overall, when the average values of clinical parameters from all teeth were considered, the percentage of sites that displayed improvement were very similar between those treated with traditional SRP and those treated using Perioscopy® (Figure 1). Single-rooted Teeth (1R) displayed significantly less improvement (P <0.05) that multi-rooted teeth (MR) for PD (Figure 1A), CAL (Figure 1B), and BOP (Figure 1D). However, there was no significant difference between those teeth treated with traditional SRP or those treated using Perioscopy® (P > 0.05). Measurements of the FGM displayed no significant differences between any of the groups examined (Figure 1C).

Facial and Lingual sites:

When only the average values of clinical parameters from the facial/lingual surfaces of all teeth were considered, the percentage of sites that displayed improvement were very similar between those treated with traditional SRP and those treated using Perioscopy® (Figure 2). Single-rooted Teeth (1R) displayed significantly less improvement (P <0.05) that multi-rooted teeth (MR) for PD (Figure 2A), and CAL (Figure 2B), but not for FGM (Figure 2C) or BOP (Figure 1D). There was no significant difference between sites treated with traditional SRP or those treated using Perioscopy® (P > 0.05). In general, the difference observed between single-rooted teeth and multirooted teeth was less for the facial/lingual surface sites.

All interproximal sites:

When the average values of clinical parameters from the interproximal sites of all teeth were averaged, the percentage of sites that displayed improvement were very similar between those treated with Traditional SRP and those treated using Perioscopy® (Figure 3). Single-rooted Teeth (1R) displayed significantly less improvement (P <0.05) that multi-rooted teeth (MR) for PD (Figure 3A) and CAL (Figure 3B), but not for FGM (Figure 3C) or BOP (Figure 3D). Again, there was no significant difference between those teeth treated with traditional SRP or those treated using Perioscopy® (P > 0.05). In general, the difference observed between single-rooted teeth and multi-rooted teeth for the interproximal sites was greater than that the facial/lingual surface sites.

Single rooted interproximal sites:

When the average values of clinical parameters from the interproximal sites of single rooted teeth were considered, the percentage of sites that displayed improvement were very similar between those treated with traditional SRP and those treated using Perioscopy® (Figure 4). Very little improvement was seen for any of the measurements evaluated, including PD (Figure 4A), CAL (Figure 4B), FGM (Figure 4C), or BOP (Figure 4D). Again, there was no significant difference between those teeth treated with traditional SRP or those treated using Perioscopy® ($P > 0.05$).

Multi-rooted interproximal sites:

When the average values of clinical parameters from the interproximal sites were segregated into maxillary multi-rooted teeth and mandibular multirooted teeth, the percentage of sites that displayed improvement were very similar between those treated with traditional SRP and those treated using Perioscopy® (Figure 5). Interproximal sites of multi-rooted teeth displayed no difference in improvement between the mandible and the maxilla for PD (Figure 5A), FGM (Figure 5C) nor BOP (Figure 5D). However, and analysis of CAL (Figure 3B) revealed some interesting trends.

Clinical attachment level interproximal sites of multi-rooted teeth:

When the CAL in interproximal sites of multi-rooted teeth were compared, significant differences were observed (Figure 6). Specifically, use of Perioscopy® on the maxilla significantly improved clinical attachment levels at 3 months ($P < 0.05$), and displayed a general increase in CAL for 10% more of the sites examined (Figure 6A). In contrast, use of the traditional SRP on the mandible significantly improved clinical attachment levels at 1 and 3 months ($P < 0.05$), and displayed a general increase in CAL for 10% more of the sites examined (Figure 6B). Thus, the use of Perioscopy® as an aid for traditional SRP had its greatest effect on the interproximal sites of maxillary multi-rooted teeth.

Discussion:

This study compared the use of traditional SRP using loupe magnification with Perioscopy® assisted SRP in mild to moderate periodontal patients. We evaluated percentage of improved sites, which is a different approach from previous studies. Moreover, we focused on the evaluation of only diseased sites and of those sites, only improved sites were evaluated. This focused analytical approach was used because, by comparing overall average values of clinical parameters, true changes may get diluted and therefore may not be accurately represented.

A recent systematic review evaluated 8 articles that revealed no significant differences in terms of clinical parameters (PD, BOP, GI). However, less residual calculus was detected with the use of the periodontal endoscope. (Kuang et al.) Our overall results demonstrated that that multi-rooted sites showed greater improvements in clinical parameters, regardless of the use of Perioscopy®. This finding can be attributed to posterior sites having more sites with >3mm PD compared to single rooted teeth in our study population, which is usually the general finding as well. Single rooted teeth showed little to no change in terms of all clinical parameters, this is again due to less anterior or single rooted sites that were counted initially having >3mm in our patient population.

Perioscopy® assisted SRP resulted in a significant increase in in the of percentage of sites with improved CAL in maxillary multi-rooted interproximal sites at the 3 month time period in comparison to traditional SRP. In contrast, traditional SRP showed a significant increase in the of percentage of sites with improved CAL compared to Perioscopy® assisted SRP in mandibular multi-rooted interproximal sites, at both 1 month evaluations and 3 month time periods. This trend may be related to better accessibility conditions for maxillary posterior teeth when using Perioscopy® equipment, when compared to mandibular posterior teeth. The hygienist performing all treatments also noted that maxillary posterior sites were easier to clean with the use of Perioscopy®. This is likely due to lack of anatomical obstructions (mainly the tongue and increased salivary flow) in the maxilla, which better facilitates the use of Perioscopy® that requires more instrumentation at a given site. The Perioscopy® method requires both the insert (shield + fiber optic bundle) and the cavitron tip in the gingival sulcus as opposed to traditional SRP requiring only the instrumentation of the cavitron tip in the sulcus. Based on a previous study, the use of the periodontal endoscope outperformed the use of a traditional explorer for calculus detection (**Osborn** et al). Therefore, when the clinician is able to use it optimally, it is understandable that the use of the endoscope can improve the clinician's ability to remove calculus with better visualization and detection.

At the 6 month and 12 month time periods, we had a decline in sample size as some patients were lost to follow-up, which is a possible explanation for significance of the1 and 3 month results not being sustained. . This sample size decline at 6 and 12 months was largely due to the COVID-19 pandemic, which made recall intervals impossible to fulfill. Future experiments are needed to confirm the clinical relevance of Perioscopy® with larger sample sizes and with long-term follow-up time periods. The systemic review by Kuang et al. discusses the need for longer evaluation duration studies to explore the effects of periodontal endoscopy on clinical parameters. We report the results of non-surgical periodontal therapy with or without the use of Perioscopy® for up to one year, which is a longer time period than reported by previous studies. Blue et al. and Liao et al. report results up to 3 months. Previous studies by Stambaugh et al. and Kwan et al. of longer evaluation time were retrospective in nature. Therefore, more randomized clinical trials with larger sample sizes and long-term follow-up are needed.

Conclusion:

Single-rooted teeth displayed significantly less improvement than multi-rooted teeth for PD, CAL, and BOP. However, there was no significant difference between those teeth treated with traditional SRP or those treated using Perioscopy®. Reduction of PD and BOP was achieved for all treatment modalities, although no statistically significant differences were found between traditional SRP or adjunctive use of Perioscopy®. There was a statistically significant greater decrease in CAL at interproximal maxillary molar sites treated with Perioscopy® than with traditional SRP . However, traditional SRP was more effective with greater decrease in CAL at interproximal mandibular molar sites Overall, this study supports the use of Perioscopy® for nonsurgical periodontal therapy to visualize the subgingival root surface for adequate calculus removal, especially in maxillary molar interproximal sites.

Conflict of Interest: Drs. Wright, Maney, Lallier and Ms. Mayer report no conflicts of interest related to this study.

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Table 1 - General Information

	3 month	6 month	12month
Patients	23	17	8
Possible Teeth	28	28	28
Sites per tooth	6	6	6
Possible Total Sites	3,864	2,856	1,344
Sites Examined	**3,573**	**2,600**	**1,128**
	92%	**91%**	**84%**

	SRP *	PS †			SRP%	PS%
Multi-rooted sites	498	483			14%	14%
Single-rooted sites	1,302	1,290			36%	36%
Total	**1,800**	**1,773**	**3,573**			

Multi-rooted interproximal sites	332	322			9%	9%
Multi-rooted facial/lingual sites	166	161			5%	5%
Single-rooted interproximal sites	868	860			24%	24%
Single-rooted facial/ lingual sites	434	430			12%	12%
Total	**1,800**	**1,773**	**3,573**			

Maxillary multi-rooted interproximal sites	150	172			4%	5%
Mandibular multi-rooted interproximal sites	172	160			5%	4%
Single rooted interproximal sites	837	846			23%	24%
Total	**1,159**	**1,178**	**2,337**			

Table 1 legend:
*SRP scaling and root planing
†PS Perioscope

Table 2

Periodontally Involved Sites (>3mm PD)	**1267**	**35%**

	SRP*	PS†			SRP%	PS%
Multi-rooted sites	308	296			62%	61%
Single-rooted sites	325	338			25%	26%
Total	**633**	**634**	**1,267**			

Multi-rooted interproximal sites	259	257			78%	80%
Multi-rooted facial/ lingual sites	49	39			30%	24%
Single rooted interproximal sites	244	272			28%	32%
Single-rooted facial/lingual sites	81	66			19%	15%
Total	**633**	**634**	**1,267**			

Maxillary multi-rooted interproximal sites	119	132			79%	77%
Mandibular multi-rooted interproximal sites	140	125			81%	78%
Single-rooted interproximal sites	244	272			29%	32%
Total	**503**	**529**	**1,032**			

Table 2 legend:
*SRP scaling and root planing
†PS Perioscope

Figure 1 - Single rooted vs. multi-rooted Teeth (SRP vs. Perioscope – All Surfaces).

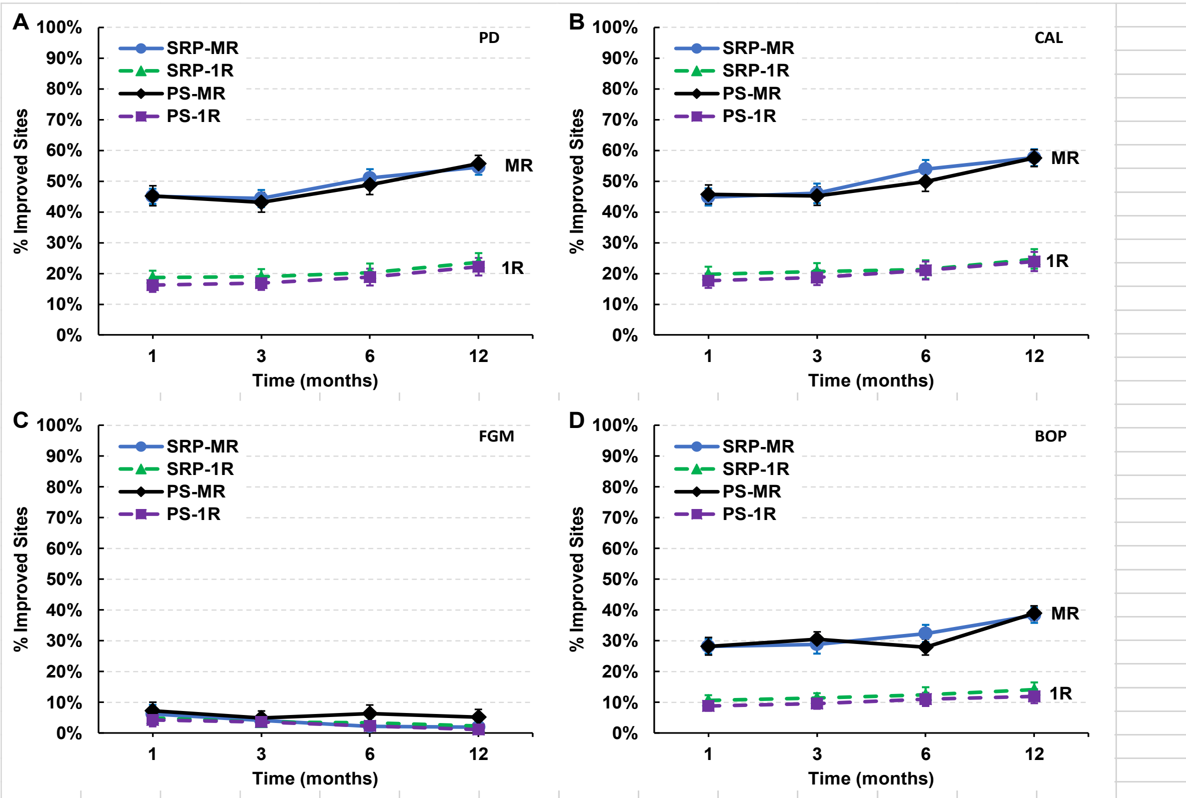

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Figure 1 legend:

SRP-MR Scaling and root planing multi-rooted sites
SRP-1R Scaling and root planing single rooted sites
PS-MR Perioscopy multi-rooted sites
PS-1R Perioscopy single rooted sites
Probing depth (PD), Free gingival margin (FGM), Clinical attachment level (CAL), Bleeding on probing (BOP)

<u>Figure 2 - Single rooted vs. multi-rooted Teeth (SRP vs. Perioscope - Facial/Lingual Surfaces).</u>

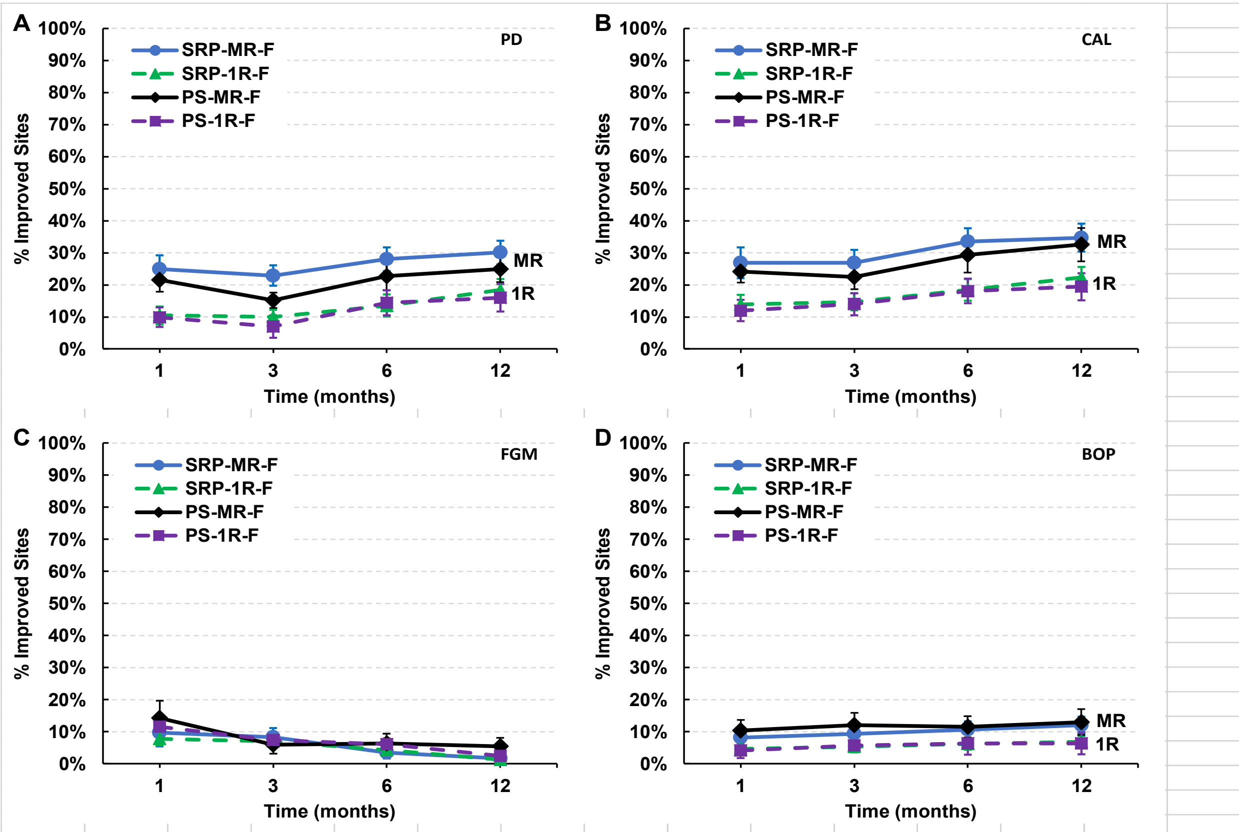

Figure 2 legend:

SRP-MR-F Scaling and root planing multi-rooted facial/ lingual sites
SRP-1R-F Scaling and root planing single rooted facial/ lingual sites
PS-MR-F Perioscopy multi-rooted facial/ lingual sites
PS-1R-F Perioscopy single rooted facial/ lingual sites
Probing depth (PD), Free gingival margin (FGM), Clinical attachment level (CAL), Bleeding on probing (BOP)

Figure 3 - Single rooted vs. multi-rooted Teeth (SRP vs. Periscope - Interproximal Surfaces).

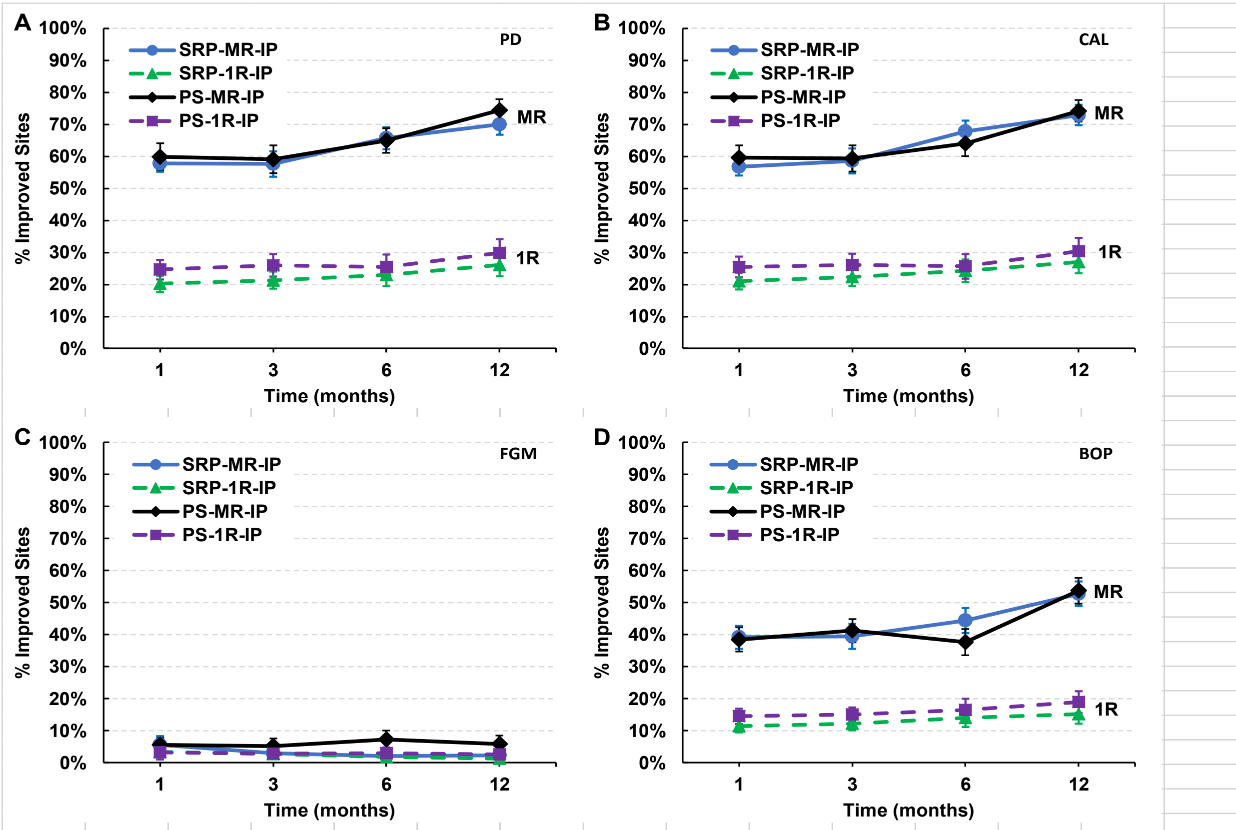

Figure 3 legend:

SRP-MR-IP Scaling and root planing multi-rooted interproximal sites
SRP- 1R-IP Scaling and root planing single rooted interproximal sites
PS-MR-IP Perioscopy multi-rooted interproximal sites
PS-1R-IP Perioscopy single rooted interproximal sites
Probing depth (PD), Free gingival margin (FGM), Clinical attachment level (CAL), Bleeding on probing (BOP)

Figure 4 - Single rooted teeth (SRP vs. Perioscope - Facial/Lingual Surfaces).

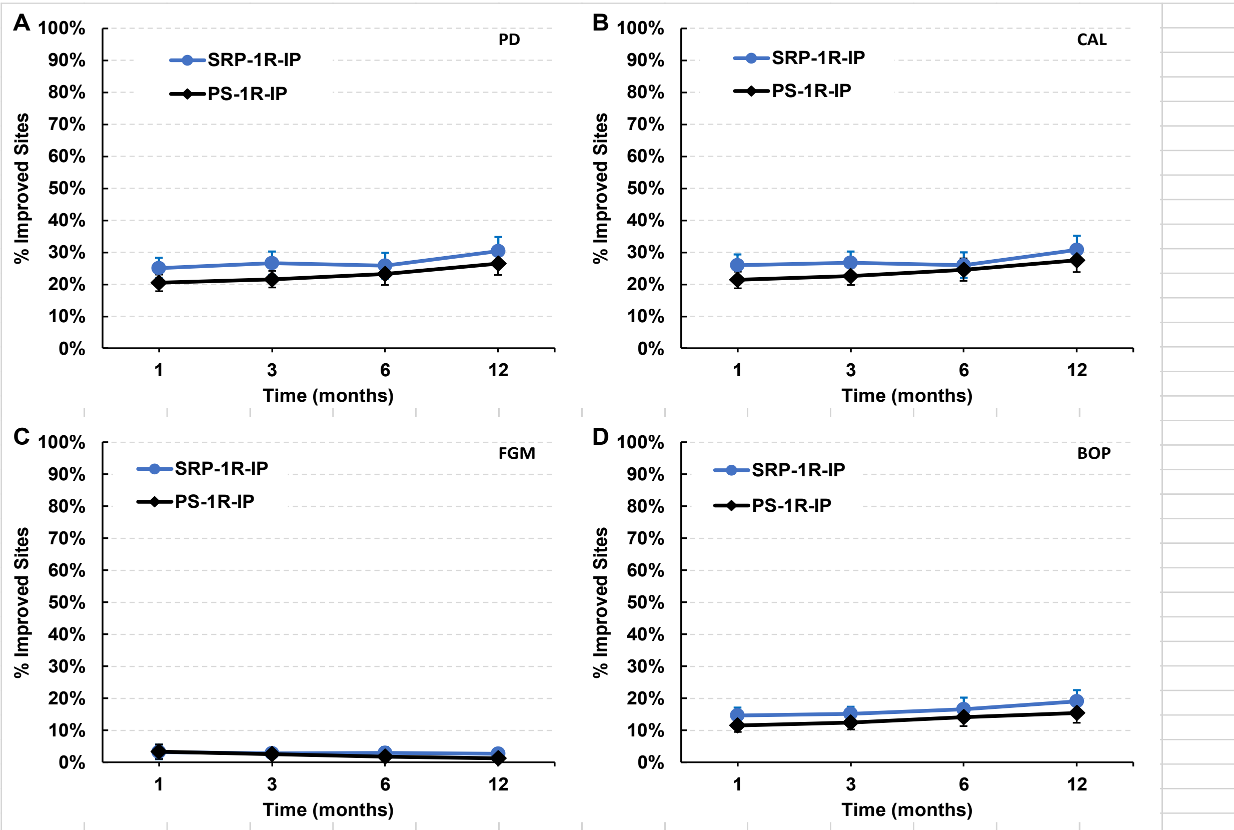

Figure 4 legend:

SRP-1R-IP Scaling and root planing single rooted interproximal sites
PS-1R-IP Perioscopy single rooted interproximal sites
Probing depth (PD), Free gingival margin (FGM), Clinical attachment level (CAL), Bleeding on probing (BOP)

Figure 5 - Multi-rooted teeth ()(SRP vs. Perioscope - Interproximal Surfaces, Mandible vs Maxilla)

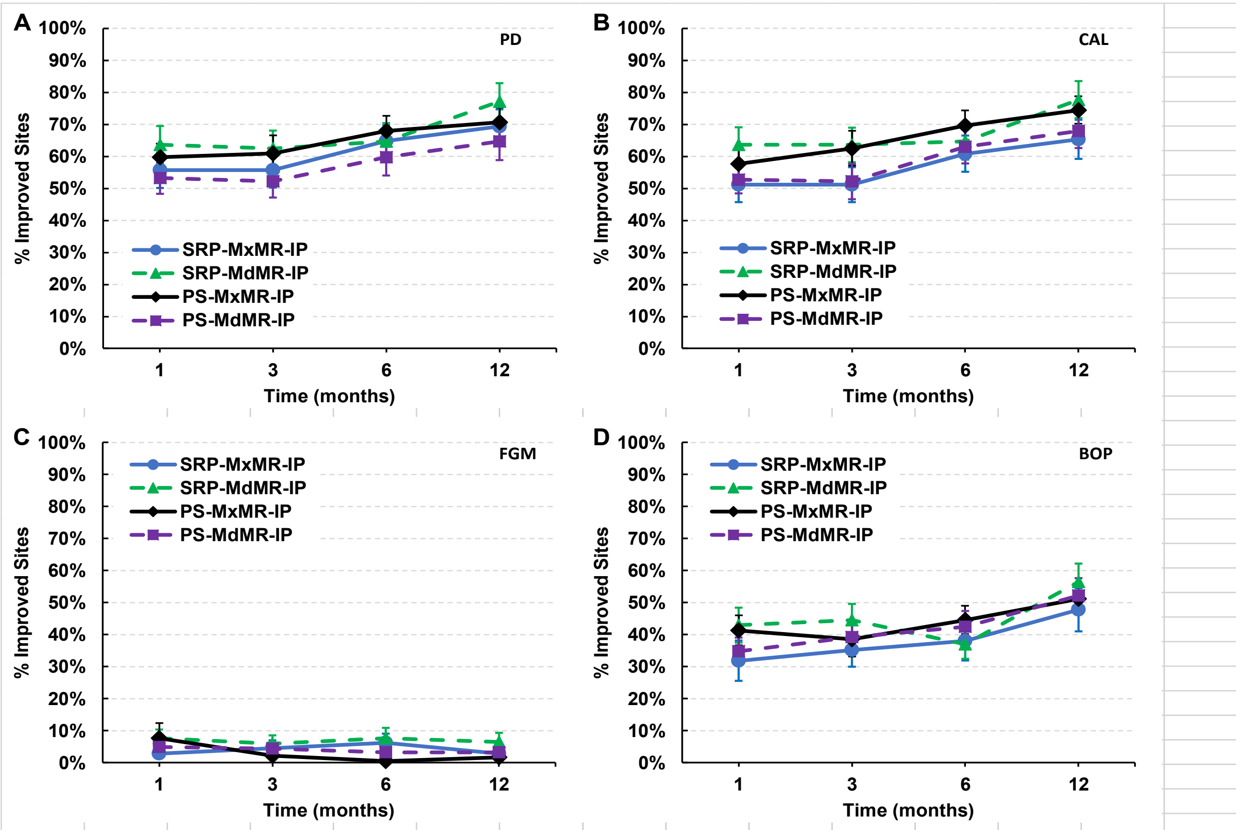

Figure 5 legend:

SRP-MxMR-IP Scaling and root planing maxillary multi-rooted interproximal sites
SRP-MdMR-IP Scaling and root planing mandibular multi-rooted interproximal sites
PS-MxMR-IP Perioscopy maxillary multi-rooted interproximal sites
PS-Md-MR-IP Perioscopy mandibular multi-rooted interproximal sites
Probing depth (PD), Free gingival margin (FGM), Clinical attachment level (CAL), Bleeding on probing (BOP)

Figure 6 –Multi-rooted Teeth (SRP vs. Perioscope - Interproximal Surfaces CAL only, Mandible vs Maxilla)

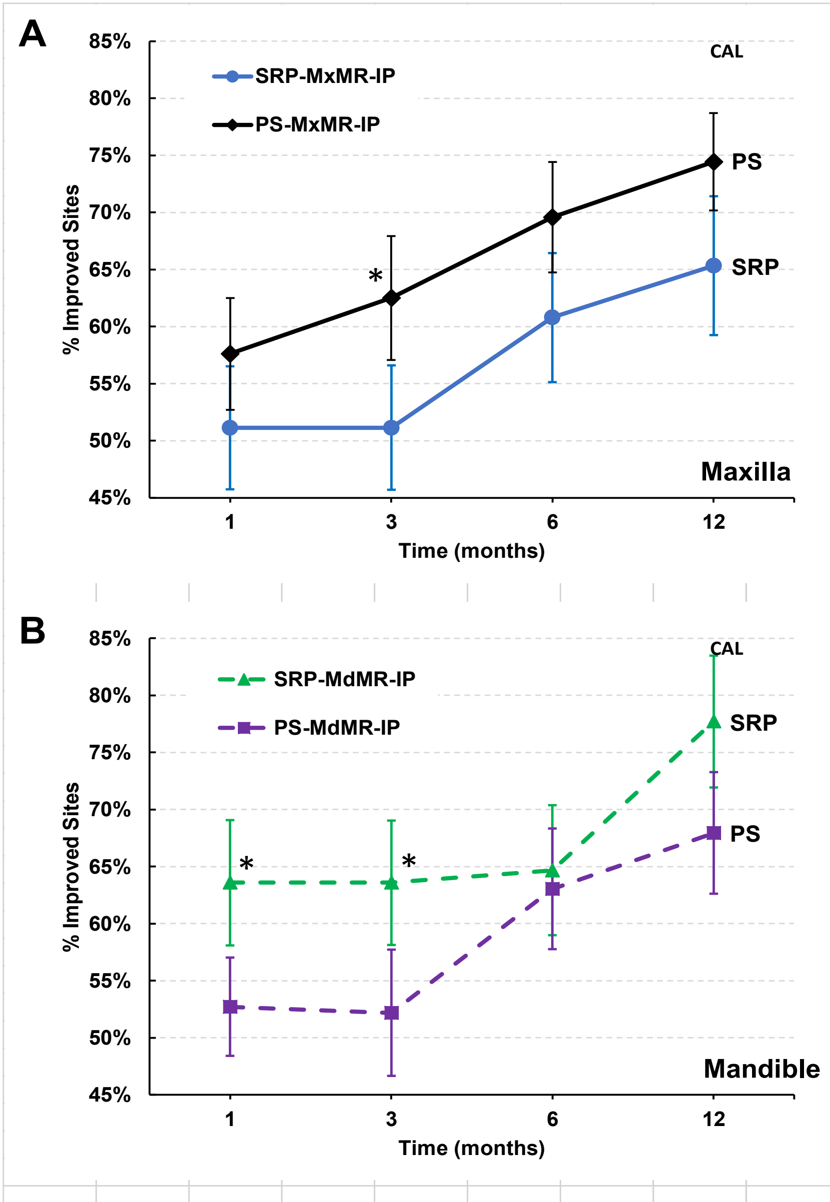

Figure 6 legend:

A. SRP-MxMR-IP Scaling and root planing maxillary multi-rooted interproximal sites
PS-MxMR-IP Perioscopy maxillary multi-rooted interproximal sites
B. SRP-MdMR-IP Scaling and root planing mandibular multi-rooted interproximal sites
PS-MdMR-IP Perioscopy mandibular multi-rooted interproximal sites
Clinical attachment level (CAL)
*statistically significant difference