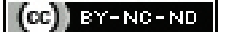


Efficacy of Novel PRP Loop versus Opus Loop for Anterior En-Masse Retraction in Angle's Class I Dewey's Type 2 Malocclusion: A Randomised Clinical Trial Protocol

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ABSTRACT

Introduction: Optimal space closure is a pivotal aspect of orthodontic treatment, particularly challenging in patients with bimaxillary protrusions and Angle's class II division 1 malocclusion. Two primary methods, friction, and frictionless mechanisms, are employed for anterior teeth retraction. However, concerns over prolonged treatment duration and increased anchorage demands have prompted exploration into non-frictional approaches. Biomechanical properties significantly influence the efficacy of retraction loops, with ideal loops exhibiting high Moment-to-Force (M/F) ratios and low Force-to-Deflection (F/D) ratios. The "PRP loop" was developed inspired by existing designs, showing promising biomechanical characteristics in a finite element study. However, its clinical efficacy remains unexplored.

Need of the study: More research is required to assess the clinical efficacy of the recently created PRP loop in promoting retraction. This trial attempts to evaluate the effectiveness of the PRP loop compared to current techniques, focusing on attaining effective anterior en-masse retraction. Through an analysis of the benefits and limitations of both methods, the research aims to shed light on which loop provides the best space closure.

Aim: This study aims to evaluate and compare the PRP loop with the Opus loop for anterior en-masse retraction in Angle's class I Dewey's Type 2 malocclusion.

Materials and Methods: A prospective single-blinded randomised clinical trial will be conducted in the Department of Orthodontics and Dentofacial Orthopaedics at Sharad Pawar Dental College and Hospital, Sawangi, Wardha, Maharashtra from September 2024 to April 2026. Thirty patients between the age of 15-30 years having Angle's Class I Dewey's type 2 malocclusion requiring maxillary premolar extraction will be included and divided into two groups (PRP and Opus loop groups) with the exclusion of Angle's Class II and III cases. Treatment procedures include initial alignment, maxillary premolar extractions, and retraction using respective loops. Evaluation criteria encompass retraction rate, efficacy, and anchorage loss measured through study models and radiographic assessments. Statistical analysis will employ Student's paired and unpaired t-test and Chi-square test with GraphPad Prism 7.0 and SPSS 27.0 software and a significance level of $p < 0.05$.

Keywords: Anchorage loss, Frictionless mechanism, Retraction loops

INTRODUCTION

Achieving optimal space closure remains a complex challenge in orthodontic treatment, particularly for Subjects with prominent bimaxillary protrusions and Angle's class II division 1 malocclusion. This challenge involves retracting anterior teeth, with two primary approaches: friction and frictionless mechanism [1]. Effectively closing the extraction spaces is critical for the success of orthodontic outcomes. Anterior en-masse retraction can be performed using various methods. One of the most commonly used sliding mechanics has concerns regarding prolongation of treatment time and increased anchorage demands and hence has fuelled the investigation of alternative, non-frictional approaches. Irrespective of the anchorage technique, the en masse retraction tends to cause decreased mesial shifts of the anchors [2].

A diversiform lineup of loop designs exists, including opus, K SIR, mushroom, vertical, T, L, teardrop, omega, and others. The efficacy of any retraction loop in facilitating space closure is particularly dependent on its biomechanical characteristics [3]. Among these, superlative retraction loops are characterised by a high ratio of M/F approaching 10:1 in addition to a low rate of F/D [4]. These parameters straightaway influence the loop's efficaciousness in generating controlled tooth movement. Therefore, meticulous computation of both the ratio of M/F and F/D rate before deploying any retraction loop for extraction space closure is pivotal for ensuring foreseeable and effective treatment results.

Inspired by the L loop and Opus loop designs, Dr. Pallavi Daigavane of the Sharad Pawar Dental College developed the "PRP loop" [4,5]. A consequential finite element study by Kumari S et al., compared the PRP loop's biomechanical characteristics to those of the Opus and L loops. Their findings revealed that the PRP loop boasts a considerably higher M/F ratio, potentially making it an efficient tool for tooth retraction [4]. Furthermore, Siatkowski's (1997) Opus loop was created with the innate capacity to provide a desired M/F of 8.0-9.1 mm, avoiding residual moments through bends or twists (also called gable bends) at any point before insertion into the archwire and loop. Hence, these combined benefits are advantageous options for various orthodontic applications [6].

To best of our knowledge, no study has been conducted to assess the clinical efficacy of the new PRP loop. This clinical trial will help determine PRP and Opus loop's advantages and disadvantages in retraction. Thus, the present study aims to evaluate and compare the efficacy of the novel PRP loop with the Opus loop for anterior en-masse retraction in Angle's Class I Dewey's type 2 malocclusion.

Primary objective: To evaluate and compare the rate of anterior en-masse retraction achieved with PRP and Opus loop.

Secondary objective: To assess and compare the anchorage loss associated with PRP and opus loop during anterior en-masse retraction.

Null hypothesis: PRP and opus loop will be equally effective in anterior en-masse retraction.

Alternate hypothesis: PRP loop is better than opus loop in anterior en-masse retraction.

REVIEW OF LITERATURE

The biomechanics of tooth movement for closing extraction spaces are influenced by factors such as the moment/force ratio, the F/D rate, the amount of force generated, and the specific configuration of the loop. These factors combined create a complex biomechanical system that influences the translatory movement of the teeth. Rao PR et al., examined the Snail loop's biomechanical characteristics with those of the Opus and Teardrop loops in a FEM research and found opus loop exhibited a higher ratio of M/F and the lowest F/D rate in comparison to both snail and teardrop loops [7].

Guroo DK et al., compared open with closed loops for incisor retraction, focusing on speed, tooth movement, and anchorage, and found Open loop has faster incisor retraction (0.023 mm/day vs. 0.0194 mm/day), more inter-canine width reduction and molar rotation and increased nasolabial angle (flatter profile) [8]. While closed loop has more controlled incisor retraction with no torque loss and slower retraction and concluded that open loops offered faster retraction but with potential inter-canine narrowing, molar rotation, and profile flattening, while closed loops provided slower but more controlled retraction, minimising unwanted tooth movement.

Alhadlaq A et al., Compared anchorage preservation with transpalatal arches in continuous vs. segmented arch techniques for canine retraction and found significant molar movement forward (4.5 mm) in continuous technique and minimal molar movement (0.2 mm) using a segmented loop [9]. They concluded that T-loops with posterior anchorage bend in segmented arches significantly improve anchorage compared to continuous arches during canine retraction.

Rizk M et al., systematically reviewed and analysed the effectiveness of en masse versus two-step retraction by comparing the anchorage preservation and retraction of Upper Incisors (U1) and concluded that both the methods are in space closing phase have been proved effective [2]. Also, qualitatively stated that less time is required in the first method when compared to the latter.

MATERIALS AND METHODS

A prospective single-blinded randomised clinical trial will be conducted from September 2024 to April 2026, at the outpatient Department of Orthodontics and Dentofacial Orthopaedics at Sharad Pawar Dental College and Hospital, Sawangi, Wardha. All processes related to Subjects will adhere to the 1964 Helsinki Declaration, its later amendments, or comparable ethical norms, in addition to the Institutional Ethics Committee's guidelines. The proposed research (Ref. No. DMIHER(DU)/IEC/2024/250) has been approved by the Institutional Ethics Committee at its meeting on January 30th, 2024. The registered CTRI number is CTRI/2024/07/070006.

Inclusion criteria:

- Subjects between the ages of 15 to 30 years.
- Subjects with Angle's Class I Dewey's type 2 malocclusion.
- Subjects having average growth pattern requiring maxillary premolar extractions.
- Moderate to critical anchorage cases.
- Those with healthy periodontal status, without periodontal pocket depths more than 2 to 3 mm, and the ones who require fixed orthodontic treatment.

Exclusion criteria:

- Angle's Class II and III malocclusion.
- Subjects having inborn and developmental syndromes.

- Systemic disorders like clotting diseases or conditions such as pregnancy.

The treatment modality will be explained to the subjects and those who agree to participate; informed consent will be obtained with a signature.

Sample size calculation: The incisor exposure in relation to the upper lip from Guroo DK et al., study will be taken into consideration while determining the sample size. Where Mean incisor exposure wrt. upper lip at T0=5.83 [8].

Mean incisor exposure wrt. upper lip at T4=4.45.

For detecting mean difference of 1.38 i.e., $\Delta=5.83-4.45=1.38$.

σ_1 =Standard deviation of incisor exposure wrt upper lip at T0=1.60.

σ_2 =Standard deviation of incisor exposure wrt upper lip at T4=1.05.

K=1. Two-sided Z value (eg. Z=1.96 for 95% confidence interval)=power.

$$N = \frac{(1.60*1.60 + 1.05*1.05) (1.96 + 0.84)^2}{1.38*1.38}$$

15.07=15 Subjects needed in each group. Total 30 subjects. Power of the test: 80%. Level of Significance: 5% (95% confidence interval).

Procedure

The materials that will be required in this research are lateral cephalograms, study model investigations, and 0.019×0.025-inch Titanium Molybdenum Alloy wires. A total of 30 subjects will be divided into two groups, with 15 in every group: Group-A: Individuals will receive PRP Loop, and Group-B: Individuals will receive opus loop. PRP and Opus loop randomisation will be done in a 1:1 ratio, and concealment of allocations will be assured by employing a web front-end "sealed envelope" by a centralised online randomisation system. Detailed case histories, radiographs, and study models will be methodically assembled. In all the cases, stainless steel brackets will be placed of 0.022×0.028 slot dimension with MBT prescription (McLaughlin, Bennett, Trevisi). The orthodontic treatment will begin with initial leveling and aligning of teeth by sequentially using 0.016 inch round NiTi, 0.016×0.022 inch rectangular NiTi, 0.017×0.025 inch rectangular NiTi, 0.017×0.025 inch rectangular SS, 0.019×0.025 inch rectangular NiTi, 0.019×0.025 inch rectangular SS, 0.019×0.025 inch rectangular TMA wires. Anchorage preparation will be done using a transpalatal arch. After maxillary premolar extractions, pre-intervention lateral cephalograms and study model impressions will be recorded (T0). Anterior en-masse retraction will be performed using a PRP loop and Opus loop fabricated from 0.019×0.025 inch titanium molybdenum alloy wire. Gable bends of 15° α and 25° β will be incorporated into the PRP loop [4]. No gable bends are required in the Opus loop [6]. A 2 mm activation will be done in both the loops by cinch back, using orthodontic cinch back plier number 10/129. Study model impression will be collected after two months (T2) and post-extraction space closure, while lateral cephalogram will be taken after extraction space closure.

Primary outcomes: The retraction rate will be measured by linear measurement on the study model of extraction space closure using vernier caliper. Anterior en-masse retraction efficacy will be measured by angular measurement on lateral cephalogram from the U1 to SN and linear measurement on lateral cephalogram of incisal exposure concerning upper lip [8].

Secondary outcomes: Anchorage loss will be measured by molar rotation in the transverse plane on the study model [10], Nasal Floor (NF) to upper 1st molar (U6) in the vertical plane, and Pterygoid Vertical (PTV) to the distal surface of upper 1st molar (U6) in the sagittal plane.

STATISTICAL ANALYSIS

The software analysis will be conducted with GraphPad Prism 7.0 and SPSS version 27.0. Statistics will be performed using students'

paired and unpaired t-tests and the Chi-square test with a level of significance of $p < 0.05$.

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