T.C.
YEDITEPE UNIVERSTY
INSTITUTE OF HEALTH SCIENCES
DEPARTMENT OF PERIODONTOLOGY

NON-SURGICAL TREATMENT OF PERIODONTITIS PATIENTS WITH DIFFERENT MECHANICAL INSTRUMENTS: A PARALLEL DESIGN CLINICAL STUDY

DOCTOR OF PHILOSOPHY THESIS

DİLA ÖZBOZDOĞANLI, DDS

Istanbul-2021

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DECLARATION

I hereby declare that this thesis is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person nor material which has been accepted for the award of any other degree except where due acknowledgement has been made in the text.

25/08/2021

Dila ÖZBOZDOĞANLI

DEDICATION

To my spirited mother *Serap* who gives me strength and courage with sparkles,

To my warm-hearted father *Can* who always has my back even before I fall,

To my joyful twins *Lalique and Can* who support and believe in me unconditionally,

To my granny *Selma,* who teaches me the happiness is the only thing matters,

And to my precious other half;
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for whom I always want to say more, but prefer to conclude with one quote
'You are priceless.'

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TABLE of CONTENTS

LISTS of TABLES

LISTS of FIGURES

LIST of SYMBOLS and ABBREVIATIONS

®	Registered Trademark
AAP	American Academy of Periodontology
BoP	Bleeding on Probing
CAL	Clinical Attachment Level
DPB	Dental Plaque Biofilm
EFP	European Federation of Periodontology
Er:YAG	Erbium-doped Yttrium Aluminum Garnet
FMPS	Full mouth plaque score
GI	Gingival Index
OH	Oral Hygiene
OHI	Oral Hygiene Instruction
PI	Plaque Index
PPD	Periodontal Pocket Level
PMN	Polymorphonuclear Leukocytes
Rc	Rockwell Scale
SS	Stainless Steel Curette
TiN	Titanium Nitride
UD	Ultrasonic Device

ABSTRACT

ÖZBOZDOĞANLI, D (2021). Non-Surgical Treatment of Periodontitis Patients with Different Mechanical Instruments: A Parallel Design Clinical Study. Yeditepe University, Institute of Health Sciences Department of Periodontology, PhD thesis, İstanbul.

Non-surgical periodontal treatment can be performed with many different tools such as hand instruments, sonic/ultrasonic devices, air abrasives and lasers. There are no clinical studies in the literature comparing the effects of four different instruments as titanium nitride (TiN) -coated curette, ultrasonic device (UD) with a specifically designed tip, Er:YAG laser and stainless steel (SS) curette in one study with respect to the clinical outcome measures on residual pockets in periodontitis patients under supportive periodontal care (SPC) program. We aimed to evaluate the clinical effectiveness of four different instruments for subgingival debridement in a randomized, controlled, parallel design clinical trial during 6-month period. A total of 40 SPC patients diagnosed as *Stage* II or III, *Grade* B periodontitis with probing pocket depths (PPD) of ≥5mm on minimum 3, maximum 8 teeth were included in the study. Patients were randomly divided into 4 groups. Full-mouth supragingival debridement was performed followed by subgingival instrumentation with TiN-coated curette (TiN curette group) (n=10) or UD (UD group) (n=10) or Er:YAG laser (Er:YAG group) (n=10) or SS curette (SS curette Group) (n=10). Plaque Index (PI), gingival Index (GI), probing pocket depth (PPD) and bleeding on probing (BoP) were evaluated at baseline and after 6 months. No statistically significant differences were found between the groups at baseline and at 6 months in terms of clinical measurements ($p>0.05$). All groups responded treatment with statistically significant changes ($p<0.05$). Within the limits of this study, it can be concluded that residual pockets between 5-7mm responded to all tested non-surgical periodontal treatment modalities and reduced the need of further surgical interventions with the minimization of the surgical area.

Keywords: subgingival debridement, supportive periodontal care, mechanical instruments

ÖZET

ÖZBOZDOĞANLI, D. (2021). Periodontitisli Hastalarda Başlangıç Periodontal Tedavide Kullanılan Farklı Araçların Klinik Etkinliklerinin Değerlendirilmesi: Kontrollü, Paralel Dizayn Klinik Çalışma. Yeditepe Üniversitesi Sağlık Bilimleri Enstitüsü, Periodontoloji Anabilim Dalı, Doktora Tezi, İstanbul.

Cerrahi olmayan periodontal tedavi kapsamında sonik/ultrasonik cihazlar, air abrazyon cihazları ve lazerler gibi birçok farklı aletler kullanılmaktadır. Literatür incelendiğinde, periodontitis hastalarında, destekleyici periodontal tedavi (DPT) sırasında rezidüel ceplerde titanyum nitrit (TiN) kaplı küret, uç kısmı özel olarak dizayn edilmiş ultrasonik cihaz, Er:YAG lazer ve paslanmaz çelik küret olmak üzere dört farklı aletin klinik etkinliğini karşılaştıran herhangi bir çalışma bulunmamaktadır. Bu randomize, kontrollü, paralel dizayn çalışmanın amacı subgingival olarak uygulanan bu dört farklı aletin etkinliğinin 6. ayın sonunda klinik parametrelerle değerlendirilmesidir. Çalışmaya *Evre* II veya III, *Derece* B periodontitis tanısı konan minimum 3, maksimum 8 dişte cep derinliği ≥5 mm olan toplam 40 DPT hastası dahil edilmiştir. Hastalar rastgele 4 gruba ayrılmıştır. Tüm ağız supragingival debridmanı takiben sadece çalışmaya dahil edilen dişlere TiN kaplı küret (TiN küret grubu) (n=10), ultrasonik cihaz (ultrasonik cihaz grubu) (n=10), Er:YAG lazer (Er:YAG lazer grubu) (n=10) veya paslanmaz çelik küret (paslanmaz çelik küret grubu) (n=10) ile subgingival debridman uygulanmıştır. Plak indeksi, gingival indeks, cep derinliği ve sondalamada kanama değerlerini içeren klinik ölçümler başlangıç ve 6. ayda değerlendirilmiştir. Başlangıç ve 6. ay klinik ölçümler değerlendirildiğinde gruplar arasında anlamlı bir fark bulunmamıştır ($p>0.05$). 6. ayın sonunda tüm gruplar tedaviye istatistiksel olarak anlamlı cevap vermiştir ($p<0.05$). Bu çalışmanın sınırları dahilinde, kullanılan alet fark etmeksizin, 5-7 mm arasındaki rezidüel ceplerin, cerrahi olmayan periodontal tedaviye yanıt verdiği görülmüş, cerrahi gereksinimin en aza indirildiği ve cerrahi alanı küçülttüğü sonucuna varılmıştır.

Anahtar Kelimeler: subgingival debridman, destekleyici periodontal tedavi, periodontal aletler

1. INTRODUCTION and PURPOSE

Periodontitis is dental plaque biofilm (DPB) induced chronic inflammatory disease, which can cause progressive destruction of tooth-supporting tissues and eventually tooth loss (1). Periodontal treatment aims to prevent disease progression, restore tissues and maintain periodontal health (2). It starts with individually tailored oral-hygiene instructions (OHI), motivation and non-surgical periodontal treatment which includes professional supragingival debridement and subgingival debridement for probing pocket depth (PPD) ≥5 mm (2). Non-surgical periodontal treatment aims resolution of inflammation with reduced PPD together with the absence of bleeding on probing (BoP), elimination of etiological agents in order to create a microbial shift towards a healthy periodontal microbiota, prevention of disease progression and minimization of surgical area (34). With non-surgical periodontal treatment, significant amount of periodontal disease can be reduced. However, periodontal pockets ≥5 mm which are defined as 'residual' pockets can remain even after non-surgical periodontal treatment and they are potential risk factors for further disease progression and tooth loss (2,5). During supportive periodontal care (SPC) program, the number of residual pockets can increase and residual PPD can deepen (5).

There are various types of periodontal instruments and systems that are introduced and continue to be introduced to increase the effectiveness of non-surgical periodontal treatment, such as new hand instruments, ultrasonic devices (UD) with new technologies, lasers and air abrasives. Stainless steel (SS) curettes are the most commonly used hand instruments for many years and accepted as gold standard for debridement. Titanium nitride (TiN) coated curettes are one of the promising hand instruments which claim long-term performance without sharpening (6). There are also new developments for UDs. H3 tip is one of the new gentle tips which is designed for subgingival debridement and aims to minimize sensitivity and discomfort while enhancing the efficacy. Additionally, Er:YAG laser is one of the most promising and prominent lasers for removing DPB and calculus with a tissue friendly mechanism (6). However, there is still no gold standard among those instruments and to the best of our knowledge, there are no studies comparing various types of instrumentations and brand-new instruments in a multi-armed clinical study.

The aim of the study is to investigate the clinical effectiveness of four different instruments for subgingival debridement and total disease resolution outcomes in a randomized, controlled, parallel design, examiner-blinded clinical trial during 6 months follow-up period.

2. LITERATURE REVIEW

2.1. Non-surgical Treatment of Periodontitis

Periodontal diseases contain a broad range of inflammatory conditions which could result in tooth loss by involvement of teeth and supporting structures (the gingiva, cement, bone and periodontal ligament) (7). Ultimately, the primary goal of periodontal treatment is to provide and maintain a healthy periodontium (8).

Periodontal disease initiation and propagation is through a dysbiosis of the commensal oral microbiota (7). Since the role of microorganisms in periodontal disease pathogenesis is well known, treatment objective primarily constitutes of decreasing the amount of pathogenic microorganisms that are in contact with periodontal tissues. Therefore, removal of dental plaque mechanically is the basis and foundation stone of successful periodontal treatment to lead the oral microflora compatible with health (9).

Non-surgical treatment has long been documented as a part of periodontal therapy (8). However until mid-1980s non-surgical periodontal treatment was an additional therapy and it was considered as mal-practice without periodontal surgery (10). Dr. John Riggs was the pioneer who advanced the prophylaxis concept and reported his method of non-surgical periodontal therapy in a paper in 1876 (11). However the Minnesota group was the one who changed this paradigm with a study in 1981 (10). Pihlstrom et al.(12) published a randomised controlled clinical study which compared surgical and non-surgical periodontal treatment first time and demonstrated that up to PPD ≥6 mm there was no statistically significant difference between surgical and non-surgical treatment. This result was substantiated with many further studies and ever since, non-surgical treatment became an accepted and important part of periodontal therapy (6). There are many studies that show the ability of non-surgical periodontal treatment in regard to decrease in gingival index (GI), BoP and PPD which are the parameters to determine periodontal health.(413–15) According to a meta-

analysis, sites with initial 4-6 mm PPD have 1 mm or slightly more PPD reduction after non-surgical treatment (16).

Considering the organisms notable resistance in DPB to anti-microbial agents and host defence mechanisms, the reasonable first step would be their physical removal to control DPB organisms. Fortunately, DPB differs from many other biofilms by being accessible for physical removal in the oral cavity. This is why in periodontal therapy the most common infection control measure is mainly based on reduction of supragingival and subgingival DPB by mechanical disruption (17).

Non-surgical periodontal therapy aims to control the periodontal inflammation by reducing the periodontopathogen microorganisms and their products (18). This is usually achieved through a combination of assisting patients to perform effective oral hygiene (OH), and mechanical debridement to remove supragingival and subgingival microbial deposits (19). OH is the backbone of the successful periodontal treatment and lack of self-oral hygiene can worsen the outcome of the treatment (2). Cercek et al.(15) showed 25% decrease in BoP with only adequate OH. However, most of the patients' self-performed OH is not adequate and deteriorates over time. It can be concluded that without professional intervention, only self-administered OH is not adequate to maintain periodontal health (20,21). Regular professional mechanical debridement and OH reinforcement are prerequisite for long-term stability of periodontium (22,23). Therefore, a patient centred approach is required for periodontal therapy in patient education, motivation and sustained behaviour change, as well as performing the most effective DPB removal methods from the marginal, sub-marginal and interproximal areas of tooth and implants (24). However, besides OH, to maintain periodontal health and preserve obtained active periodontal treatment outcomes, SPC is prerequisite (10).

2.1.1. Supragingival and Subgingival Debridement

In 1950's plaque accumulation or existence of calculus was associated with periodontal disease progression. Therefore non-surgical therapy is considered as first step of

the periodontal treatment (8). The objective of the treatment is reduction of the bacterial load mechanically and healthy alteration of the microbial flora composition. In turn of microbiological changes, lowered inflammation levels and periodontal attachment levels relative stability are expected (9,25).

Control of periodontitis with non-surgical therapy consists of supragingival and subgingival debridement with combination of OH instruction (26). The supragingival component of non-surgical periodontal treatment consists of meticulous removal of supragingival plaque and calculus (2). Supragingival control of plaque depends both on professional removal of calculus with DPB and self-performed OH measures (25). Subgingival debridement concentrates on subgingival plaque and calculus, yet with limited access and visibility (27). Subgingival debridement aims the disruption and/or removal of DPB to reduce periodontal inflammation and obtain a root surface for the (re)attachment of periodontal tissues that is biologically acceptable (28).

It is clear that without the removal of pre-existing DPB and calculus, OH cannot be performed. Presence of calculus creates a retainer for DPB and this constitutes a barrier for appropriate OH manoeuvres (2). Many studies indicate that supragingival debridement enhances tooth-brushing effects and reduces gingival inflammation in patients who do not perform good OH (29). Additional studies with 1 year follow-up, show the similar results that self-performed OH in conjunction with professional supragingival plaque control results in reduced plaque levels compared with baseline values (30,31).

Supragingival dental plaque provides the microorganisms to colonize in the subgingival area and mature subgingival biofilms have immune-subversive and proinflammatory roles, which may cause damage to the periodontium (32). A successful periodontal therapy depends on mechanical disruption of the subgingival biofilm (33). Thus, periodontal disease cannot be controlled only with supragingival plaque removal, but also with subgingival debridement (34). Elimination or adequate suppression of putative periodontopathic microorganisms in subgingival plaque is virtually impossible for the patient to achieve on their own (35). At sites with 3mm of PPD, removal of supragingival plaque both professional and self-performed have an effect on subgingival microflora. However, in

the presence of 4mm or more PPD, bacterial load reduction is significantly achieved by subgingival debridement (9). According to Heitz-Mayfield and Matuliene et al.(36,37), subgingival debridement is recommended for residual pockets ≥5 mm, yet for PPD <4 mm subgingival debridement is not recommended due to prevent attachment loss (38,39). Highly organized subgingival DPB is difficult to reach, as it forms at the apical part of the periodontal pocket with a close proximity to connective tissue and alveolar bone. Therefore, control of the subgingival biofilm is crucial to prevent periodontal disease progression (35,40). It is the cornerstone of non-surgical periodontal therapy as and it is considered as gold standard (2).

2.2. Supportive Periodontal Care

Regularly attended SPC program is the keystone for long-term success of the periodontal treatment and stability of the treatment outcomes (41). SPC (also known as maintenance therapy, maintenance care or supportive periodontal treatment) starts once treatment of periodontitis has been provided satisfactorily by keeping inflammation under control and arresting the tooth supporting tissues destruction (19).

SPC is based on: (i) nature of periodontal diseases; (ii) patient's inability to maintain effective OH to preserve periodontal health; and (iii) dentist's effort and willingness to motivate the patient (41). SPC aims to prevent or minimize the disease occurrence and recurrence (42). Patients with periodontitis history have higher risks for further episodes of disease (19). With regular SPC, probability of reinfection and disease progression risk can be reduced for people who have been treated for periodontitis earlier (19). SPC monitors dentition and maintains tooth in function without persistent infection, excessive mobility or pain for long term and reduces the risk for tooth loss (19). Success of SPC program for maintaining periodontal health and preventing tooth loss for long term is well known and supported with many studies (21,41-43). According to retrospective study of Becker et al.(44) periodontal treatment could not be completely successfully without SPC. Lee et al.(43), demonstrated tooth loss incidence was lower for patients who regularly attended SPC. After 30-year follow-up, Axelsson et al.(45,46) also reported that regular SPC

decreased the risk for tooth loss and vice versa in case of SPC was neglected. Rosling et al.(21) evaluated 225 subjects in SPC during 12 years and performed subgingival debridement on ≥5 mm residual pockets with BoP. They concluded that the maintenance of bone and attachment level could be reasonably stable after 12 years. According to Chambrone et al.(47), there were only 1.8% of tooth loss during more than 10 years with the well-attended maintenance care program. With compliant patients during 120 months, König et al.(48) demonstrated that with regular SPC, only 3% of teeth were lost and 66% of plaque index (PI) ended up <30%. Besides, attending regular SPC program helps to diagnose and treat other conditions and diseases located in oral cavity (49).

According to a position paper by the American Academy of Periodontology, at every SPC visit, patient's dental and medical histories should be updated. Extra- and intraoral soft tissues and dental examination should be performed. Radiography needs to be reviewed and most importantly patient's OH performance in combination with periodontal evaluation should be done (50). There are evidences which also propose to evaluate BoP at every visit to decide the SPC intervals (51). Joss et al.(52) suggested that average percentage of BoP ≤ 20% could be stated as healthy and the intervals could be prolonged. A standardized SPC routine cannot be determined and individualized approaches are needed (53). SPC programs should be regulated and improved according to each patient's need to maintain health, yet to prevent over treatment or neglect (49) and visit frequencies should be individualised due to patient's risk profile (10,53). The recommended SPC intervals start with 2 to 3 months and prolong to 18 months (54). The visit frequencies can be kept, prolonged or shortened according to the last visit (55).

Giving OHI is the first of SPC visits. To minimize periodontal disease progression risk and to maintain periodontal health, good OH is required (53). In preventing the deterioration of OH, as a part of SPC, motivating and reinforcing the patients can enhance the outcome of the SPC (55). During 2 years with 3-month intervals, Angst et al.(56) repeated OHI at every visit and reported that 25% of PI was dropped to 15% at final visit. The treatment plan can include supragingival debridement or subgingival debridement or

sometimes even both (49). Subgingival debridement may or may not be included in routine SPC program. There is no scientific evidence on the additional value of routinely performed subgingival debridement at SPC visits unless increased probing depth is present. Therefore, in sites without increased probing depth subgingival debridement should be avoided. Moreover, routine subgingival debridement during SPC, for shallow sites can cause attachment loss (4,57). Self-performed DPB control in combination with frequently repeated professional supragingival debridement have a substantial effect on disease progression (58). OHI and supragingival debridement patient compliance during a 2-year period have showed the efficacy of these treatments by effectively changing the subgingival microbiota amount and composition (58). Gomes et al.(59) also supported that combination of OHI and supragingival debridement have beneficial effect on subgingival biofilm. However, for residual pockets, subgingival debridement can be a need during regular SPC (60). Petersilka et al.(9) suggested that subgingival debridement of ≥4mm PPD was essential to prevent disease recurrence (9) and Jenkins et al.(61) reported that ≥4mm PPD showed 10% of attachment loss after 1 year with 2-month intervals when the only treatment modality was supragingival debridement during SPC.

Susceptibility to periodontal disease and treatment response are difficult to predict. Despite a successful periodontal treatment, sometimes periodontal pockets cannot be transformed into a physiological pocket depth and residual pockets can remain with BoP (55). Residual pockets are known as potential risk for pathogenic flora to repopulate to pre-treatment levels and to disrupt the microbiological balance, so their existence affects the stability of periodontal health. Successful periodontal treatment aims to achieve 4 mm or less PPD (10) and according to Lang and Tonetti's (62) periodontal risk assessment model residual pockets designated as ≥5mm. Many studies advocate that residual PPDs ≥5mm are more prone for further disease progression (36,37,57,63) and emphasize that further attachment loss risk is increased by residual pockets (57). According to Petersilka et al.(9), after periodontal treatment residual pockets which were more than 4 mm monitored and it was demonstrated that the subgingival microbiota composition was similar with the pre-treatment microbiota. Thus, to prevent the recurrence of the periodontal disease in the

residual pockets ≥5mm, subgingival debridement might be necessary with regular intervals (64).

Nevertheless, recurrence of the periodontal disease cannot be completely prevented even in meticulously controlled patient groups in which periodontal stability was maintained for long time periods (21,65). Residual pockets after active periodontal therapy can still be a risk factor for further disease progression. There are many treatment options for the management of residual probing depths and non-surgical periodontal therapy can be one of them (66).

2.3. Treatment Modalities with Different Instruments

One of periodontal therapy's main goal is to decrease the DPB amount to a critical level, aiming to achieve an equilibrium between the host defence and the residual microorganism (67). Treatment modalities aim to control DPB and they are essential for the treatment of periodontitis (68). Meticulous supragingival and subgingival debridement are naturally difficult and time-consuming procedures (69). Success is highly determined by the clinicians skill (4,33) and concentration for detailed instrumentation (70). For these reasons clinicians and industry have been searching for instruments, which provide maximum effectiveness (71).

At present, hand instruments and ultrasonics are still considered the instruments of choice for subgingival debridement. Hand instruments favour their use with the good tactility and manual control. However, they need re-sharpening and their use is time consuming. Different tools are introduced to the market with the developing technology with the recent scientific data to overcome the negative effects of conventional hand instruments and classical ultrasonic tips on root surfaces. Additional to those instruments, lasers can be used for subgingival debridement to remove biofilm in a less aggressive manner (6).

2.3.1. Stainless Steel Curette in Periodontal Treatment

In 10th century Cordova, Spain, Abu I-Qasim, who critically thought about dental calculus and advocated that its presence played a serious role on 'corruption' of the gingiva. He proposed a 'professional' cleaning of the teeth in several days and recommended to perform it with a set of 14 scalers (72). It is strongly estimated that the history of hand scaling instruments has been as long as a thousand year. However, an Egyptian hieroglyphics and medical papyri show that, non-surgical periodontal therapy could be known more than a thousand year and it could be common even 2000 years ago BC (72). Our ancient ancestors did not know the existence of DPB (67). The bacterial aetiology of periodontal diseases has been explored for over 100 years ago and today it is well known that bacteria in DPB are the cause of periodontal diseases (73). Therefore, the main goal of periodontal treatment is to decrease the quantity of bacterial plaque to the level until the equilibrium is provided between the microorganisms and the host defence mechanism (67). This is the reason why periodontal treatment is based on mechanical plaque removal (9).

Conventionally, supragingival and subgingival debridement have been performed with hand instruments and for many years they have been nominated as the gold standard in debridement performing (6). Hand instruments consist of a blade, a shank and a handle which is the working part of the instrument. According to their blade design, hand instruments are categorized as curettes, files, hoes and sickles. Curettes are the most common used instruments amongst hand instruments. They can be used for both supragingival and subgingival debridement while sickle and hoes are generally performed only in supragingival debridement and rarely in subgingival debridement for shallow pockets (6). As for files, they are used for stubborn deposits. They are performed by pushing or pulling the cutting or sharp edge of the instrument towards the surface, thereby they can disrupt and dislodge the DPB and calculus and remove the stains (9).

There are two types of curettes which are called Universal and Gracey curettes. These two types of curettes are distinguished according to the area-specificity, the number of cutting edges, the curve of the cutting edge and the angle of the face to the terminal shank (74).

Universal curette's blade has two cutting edges, a round toe and back. To acquire an approximate 85° angle between the tooth and blade, the facial surface of the blade is tilted toward the tooth (75). In the 1940's Dr. Clayton Gracey, developed Gracey curettes with Hugo Friedman. Despite Universal curettes, Gracey curette's blade is offset at 70˚ and has only one cutting edge (75).

The angulation between the tooth surface and the curettes cutting edge surface affects the efficiency of debridement. The curette is held with a modified pen grasp and the blade is inserted into the periodontal pocket. Blade's face should be parallel to the root with light contact. After periodontal pockets most apical part has been identified with the lower edge of the blade, the instrument is turned into a proper working position, which is when the shank is parallel to the long axis of the tooth. Then the blade should be moved through coronal direction. To cover all sides of the root surfaces, strokes must be made in different directions. Strokes should always start from an apical position and continue in a coronal direction (76).

For subgingival debridement, hand instruments are considered the treatment of choice because they allow a good control over the instrument with a tactile sensation and creates a smoother or less damaged surface (6,77). According to Badersten et al.(4), in comparing the clinical effects of subgingival debridement with hand and ultrasonic instruments, it was reported that there is no difference in terms of gingival recession (GR), clinical attachment level (CAL) and PPD. Reviews of many studies showed the similar results with Badersten et al. and concluded that in terms of efficacy there is no significant difference between hand and ultrasonic instruments for removing subgingival deposits (78–81). However, treatment with hand instruments can be time consuming and exhausting for both clinician and patient. Badersten et al.(4) emphasized that the hand instrumentation took more time to achieve the same clinical outcome with UD. Drisko et al.(82) reported the similar result and demonstrated that debridement with hand instruments could take 20-50% more time than debridement with UD. The working part of curette, the blade, needs to be sharpened correctly and periodically for effective use (6). One of the disadvantages of the SS curette is frequent sharpening, which can cause metal fatigue. However, if sharpening on a regular basis is neglected, performing with a blunt instrument can cause carpel tunnel syndrome (83). O'Leary & Kafrawy (84)

recommended that hand instruments should be sharpened every after five strokes, Coldiron et al.(85) proposed 10 strokes and Rees et al.(86) 12 strokes. Zappa et al.(87) showed that after 20 strokes hard-tissue removal was reduced and the pressure applied every stroke was increased (74). Jacobson et al.(88) studied root surface texture and compared UD with hand instruments and reported that UDs created comparatively smoother surface than hand instruments. They concluded that the irregularities of the blade of the hand instrument due to sharpening could cause this result.

2.3.2. Titanium Nitride Coated Curettes in Periodontal Treatment

The use of hand instruments allows good tactile sensation, but tends to be more time consuming than other methods, and requires correct and frequent instrument sharpening (76). Sustaining the sharp edge is substantial. The sharp edge allows to feel the contour and texture of the root or the tooth when there is no direct visual of the site. In time, these instruments can be accompanied with different amounts of wear. In order to avoid these wear, the instruments are needed to be renewed or re-sharpened (89).

However, sharpening the instrument is not very practical for every 5 to 20 strokes and it can result in damage of the original contour of these expensive instruments. Re-sharpening can weaken the curette and cause breakage during function, or can create metal particles that are potentially harmful for soft and hard tissues (74). Additionally, sharpening procedure can be very difficult, because of the curettes' curved cutting surfaces and oriented different planes (89). Due to the problems above for sharpening the instruments, manufacturers and clinicians seek new instruments that can allow maximum effectiveness in calculus and biofilm removal with less trauma to the soft and hard tissues. Recently, some various instruments with "edge retention" properties have been debuted and advocated that these instruments allow easy maintenance and show long-term effectiveness with little or no sharpening (74). Hand instrument's efficacy and life expectancy depend on its material. Different metal alloys including SS, carbon steel, tungsten carbide and high-speed steel have effect on them (90).

TiN coated curettes are one of the promising hand instruments, which claim little or no sharpening, and long-term performance (83). They are made of a SS alloy and coated with a TiN (71). As conventional SS curettes, TiN-coated curettes are held in a modified pen grasp and strokes are made from apical to coronal direction which should be parallel to the axis of the tooth (71). Conventional instruments are made of SS or carbon and their hardness level is 58 to 63 on the Rockwell scale (Rc). However, TiN curettes can achieve a hardness level of 89 Rc. With this hardness level, TiN-coated curettes are wear-resistant and more durable than many other curettes (91).

To the best of our knowledge there is no study in literature evaluating TiN curette's efficacy in vivo and limited number of studies for in vitro (71,83). According to an in vitro study of Gürsoy et al.,(83) TiN curettes caused the least roughness and the smoothest surface amongst erbium-doped yttrium aluminum garnet (Er:YAG) laser, SS curette and UD. However, another in vitro study by Sisera et al.(71) did not find any statistically significant difference between SS curettes and TiN curettes even after 1,010 strokes in terms of substance removal.

2.3.3. Ultrasonic Devices in Periodontal Treatment

In 1960's, the first sonic, and few years later UDs introduced to the markets and machine-driven instruments quickly became a common choice. They were preferred as alternative or addition to hand instruments for non-surgical periodontal therapy (6). Water cooling to reduce frictional heating is the main difference of machine-driven instruments from hand instruments (80). Water does not only work as coolant during instrumentation, but also creates acoustic turbulence, streaming and cavitation with vibration, that could assist in the process of cleaning (6,74).

Mechanical vibration is created using compressed air in sonic devices which causes vibration of the instrument tip and produce oscillation. They operate at frequencies of vibration ranging from 2 to 6 kHz (cycles per second) (92,93). However, UDs have a different working principle. Electrical current is converted to mechanical energy in high-frequency

form at the tip of the instrument (76). The amplitude of stroke and the frequency, which may be also called speed, are two important parameters for UD choice (74).

UDs consist of two types which are magnetostrictive and piezoelectric instruments. In magnetostrictive instruments the electrical current produces a magnetic field in the handpiece that causes an oscillation generator to create vibration. The vibration frequencies ranging between 18 and 45 kHz with an amplitude range of 10–100μm. The pattern of vibration at the tip is elliptical. Besides magnetostrictive scalers, in piezoelectric instruments the electrical current causes a dimensional change in the handpiece that is conveyed to the working tip in a form of vibration. The vibration frequencies ranging between 25 and 50 kHz with an amplitude range of 12–72μm. The pattern of vibration at the tip is primarily linear. As an advantage, piezoelectric instruments do not create much heat, so require less irrigant when it is compared with magnetostrictive instruments (74). However, according to Busslinger et al.(94) magnetostrictive devices cause less root damage than piezoelectric devices.

Machine-driven devices like sonic devices and ultrasonic instruments, may be performed both supragingival and subgingivally (95). The advised technique while performing the debridement is from a coronal to apical direction. The tip of the device should be placed lateral of the tooth surface with light pressure and it should always be as parallel as possible to the long axis of the tooth. The tip should paintbrush the tooth and the successive strokes need to be applied (74). Even though the water as a cooling irrigant has a washed away effect, the mechanical movement of the machine-driven device tip has the main effect to remove plaque (9). Wear of the ultrasonic tips also affect the working performance of the UDs and cause less controlled water splatter. The degree of dimensional loss of tip should be checked regularly to ensure to obtain the maximum effect of treatment (76).

Modified sonic and ultrasonic instrument tips, like tiny, thin, periodontal probe type are available for use in deep pockets and more efficient for subgingival instrumentation. Gankerseer et al.(92) advocated that different tip designs had different effects on tooth surface due to particular application load on tips. Jepsen et al.(96) reported a similar result

and emphasized that ultrasonic instrument tip design had significant effect on root substance. Recently, prominence has also been given to the new ultrasonic technologies. New gentle tips are designed which are recommended for the subgingival debridement. New developments of ultrasonic technology aim to provide more comfortable treatment procedure for both patient and clinician. There is a new system which is called 'drop-by-drop technique' and controls irrigant flow rate according to tip extremity. It enhances the cavitation while reducing the water splatter. With its gentle vibrations, it minimises sensitivity and discomfort during and after the treatment, cause less damage to the root surface and soft tissue (83).

According to a systematic review, when ultrasonic, sonic and hand instruments' effectiveness were compared for the treatment of chronic periodontitis, with respect to the clinical outcome measures, there were no difference between ultrasonic, sonic and manual instruments (97). In a study by Torfason et al.(98), 18 subjects were treated with either ultrasonic or hand instrument. At the end of 8 weeks, the study failed to show significant difference between the groups for PPD between 4 to 6 mm. Breininger et al.(99) compared the effectiveness of ultrasonic and hand instruments while performing subgingival debridement. For PPD between 4 to 7 mm, the study showed that both instruments were effective. However, according to a study by Drisko (100) UDs have many outstanding advantages when compared to the hand instruments; such as cavitational activity, constant water irrigation to disrupt unattached subgingival DPB and better access to deep narrow pockets, grooves and furcation. Additionally, Schmidlin et al.(101) demonstrated that less root structure is removed and less trauma to soft tissues is provided with UDs compared to hand instruments. Busslinger et al.(94) reported that piezoelectric UDs have significantly worse Ra values when they were compared with hand instruments. On the other hand, UDs are more technique sensitive however, less operator dependent resulting in significant treatment time reductions allowing more time for patient motivation (67). Busslinger et al.(94) showed that UDs needed significantly less time for instrumentation. Class II and Class III furcations treatment have been shown to be superior with power-driven instruments by experienced operators (102). Furthermore, increased efficiency with UDs compared to hand instruments were reported in subgingival instrumentation efficiency due to extended time

requirements to receive same clinical outcomes with hand instruments (95,103). Although power-driven instruments have some advantages for the clinician, there are still some issues needed to be solved. One of them is the development of heat at the tip of the scaler when cooling with water irrigation is not enough. The heat increase may result in injury to periodontal or pulpal tissues. Another drawback of power-driven instruments is the pathogenic bacterial aerosol formation (104). In order to overcome these problems newly developed ultrasonic system (VUS) (Vector-ultrasonic system, Durr Dental, Bietigheim-Bissingen, Germany) have been proposed. The energy from the instrument is transmitted to the root surface and the periodontal tissues by a suspension of hydroxyapatite particles and water, comparable to ultrasonic cleaning baths and the suspension is not sprayed in an aerosol by the instrument (105). However, only very limited data are available regarding the clinical results after non-surgical periodontal treatment with VUS when compared to gold standard hand instruments. Sculean et al.(106) evaluated the effectiveness of a newly developed UD for non-surgical periodontal treatment in a prospective, randomized, controlled clinical study. Thirty-eight patients with moderate to advanced chronic periodontal disease were included. ‘‘One-stage procedure’’ with either a newly developed UD VUS or hand instruments was applied. Clinical parameters including PI, GI, PPD, BoP, GR and CAL were evaluated at baseline and 6 months after treatment. No statistically significant differences were detected in any of the clinical parameters between the two groups. They concluded that the tested UD did not lead to superior clinical improvements when compared with the conventional hand instruments.

2.3.4. Lasers in Periodontal Treatment

The term laser is well known as the acronym for “light amplification by stimulated emission of radiation” (76). Lasers transfer energy from the emitted laser light beam to the irradiated substance (9). For biological effect, it is crucial for tissues to absorb the energy. The degree of absorption in the tissues varies according to the wavelength and target tissues optical characteristics (107).

In 1960's Maiman developed the ruby lasers and from that time on lasers have been started to be used in medicine and surgery in many fields (108). The use of Er:YAG lasers in periodontal disease treatment was introduced in 1974 by Zharikov et al.(109) and its application in subgingival debridement has been reported immediately after. For subgingival debridement Er:YAG laser is the most promising instrument, which can effectively remove DPB and provide feasible selective calculus removal (6,110).

Fiberoptic delivery system is used in Er:YAG lasers along with helium neon laser for aiming beam. To minimize heat generation during tissue removal, use of water irrigant for surface wetting is crucial to achieve maximum effect during laser application (107). Besides that, by keeping the target moist, water irrigant enables hard tissue ablation (111). The Er:YAG laser has a 2,940 nm wavelength that is ideal for water and organic components like hydroxyapatite to absorb it. The absorption of the laser beam results in temperature raise which vaporizes water and increases internal pressure within the deposits, so with the expansion, the deposits detach from the surface of tooth root (6). Thermal influence of Er:YAG laser for surrounding tissues is very low, because the excessive laser irradiation is absorbed into water and heat generation decrease (112). The Er:YAG laser at a low energy level has a high bactericidal effect against periodontal bacteria.(113) It has potential for root surface ablation and with minimal tooth substance loss removes toxins that are diffused into cementum (39).

To prevent the excessive removal of root substance, further studies are required to determine laser irradiation parameters such as pulse rate, energy output and type of contact tip used during Er:YAG laser for subgingival treatment (112). However, for effective and safe clinical use, amount of cementum loss should be kept at minimum whereas ablation of calculus efficiency at maximum for which a combination of low energy output, a higher pulse repetition rate and water spray are recommended. With such conditions, patients do not experience the uncomfortable stress (112). To decrease removal of root substance, application tips angulation is another important factor. Folwaczny et al.(114) reported that during Er:YAG laser irradiation the angle between the tip and the root surface has a strong effect on the root substance amount removed.

It has demonstrated that Er:YAG laser can be successfully used for subgingival calculus removal.(110112115116). Aoki et al.(110) reported that calculus removal with Er:YAG laser was comparable with UDs, yet UD showed significantly higher efficacy. Keller et al.(116,117) also reported that Er:YAG laser was effective for subgingival calculus removal without thermal side effect. Schwarz et al.(118) compared the effectiveness of Er:YAG laser with hand instruments in a split-mouth design over a 6 months follow-up period. 20 patients with moderate to advanced periodontal destruction were included. Clinical parameters including PI, GI, PD, BoP, CAL and GR levels were evaluated at baseline, 3 and 6 months following treatment. At 6 months results demonstrated that Er:YAG laser group showed significantly higher reduction for BoP and CAL. The authors concluded that Er:YAG laser is an suitable alternative for the non-surgical periodontal therapy. In 2004, Sculean et al.(119) evaluated the effectiveness of Er:YAG laser and the UD with a single episode of subgingival debridement in a split mouth design clinical study. Full mouth PI, BoP, PPD and CAL were assessed at baseline, 3 month and 6 months. No statistically significant differences were observed between the groups for the investigated clinical parameters at 6 month following therapy. They reported that, within the limits of the study, both therapies led to significant clinical improvements. In another clinical study which was conducted by Braun et al.(120) subjective pain intensities were assessed during SPC using an Er:YAG laser and a sonic scaler in a split-mouth design. Forty chronic periodontitis patients with two residual periodontal pockets following conventional periodontal therapy were treated. A visual analogue scale was used for pain assessment directly after each treatment procedure. The treatment time per diseased root surface was set to 20 seconds to provide removal of biofilm. The whole circumference of the tooth was divided into six root surfaces, resulting in a maximum treatment time of 2 minutes per tooth. In order to evaluate the clinical effectiveness of the treatments, BOP frequency was evaluated by a blinded investigator who was not involved in the treatment of the patients at baseline and 3 months after treatment. Pain assessment during treatment showed that Er:YAG laser caused less pain than the sonic device with no difference in the treatment time. BoP values significantly decreased for both groups, but no statistically significant differences were found after 3 months, between the groups. Authors concluded that treatment with Er:YAG laser minimizes

the patient discomfort and it might be possible to increase the patient's compliance during SPC. In order to establish the long term clinical results of the Er:YAG laser, Schwarz et al.(121) performed split mouth-randomized clinical trial with a 2 year follow-up. Twenty patients moderate to advanced periodontal destruction were included and either Er:YAG laser or hand instruments was used. Clinical parameters, PI, GI, PD, BoP, GR and CAL were evaluated at baseline, 1 and 2-year after treatment. The authors concluded that the results obtained by both treatment modalities were maintained over 2 years follow up period.

Ultimately, for non-surgical periodontal treatment, lasers are included as one of the most promising new technological systems which has many advantages for both clinicians and patients. They are superior in reaching regions which conventional mechanical instruments cannot (112) and also laser irradiation does not produce a smear layer. Therefore, a more favourable root surface is provided by laser treatment for periodontal tissue attachment (112).

To the best of our knowledge, there are no studies in the literature comparing the effects of four different subgingival instrumentations with TiN curette, UD with the specific designed tip, Er:YAG laser chisel tip and with SS curette in one study, with respect to the clinical outcome measures on residual pockets in periodontitis patients under SPC program. Starting from this standpoint, we aimed to investigate the clinical effectiveness of these four different instruments for subgingival debridement and total disease resolution outcomes in a randomized, controlled, parallel design, examiner blinded clinical trial during 6 months follow-up period.

3. MATERIALS and METHODS

3.1. Study Population

Forty systemically healthy patients who were visiting Yeditepe University Faculty of Dentistry, Department of Periodontology, Istanbul, Turkey, to receive their routine SPC, were included in this randomised, controlled, parallel design, examiner blinded clinical trial for 6 months follow-up. Study protocol was approved by Yeditepe University Ethical Committee (Research number: 2032-1336, Year: 2020) and Turkish Ministry of Health (Year: 2021) (Appendix 1, 2). No changes in the trial design were made after the local Ethics Committee approval. A written informed consent was obtained from all participants after thorough explanation of the purpose, possible complications, the nature and the implication of participating in this study (Appendix 3).

3.2. Patient Selection

Patients who have PPD of ≥5mm on minimum 3, maximum 8 teeth, and diagnosed as stage II or III, Grade B periodontitis according to 2017 World Workshop on Classification of Periodontal disease (122), were included the study.

Patients were selected according to the following inclusion criteria:

- Systemically healthy patients,
- Minimum 3, maximum 8 teeth (123) with PPD ≥5mm
- Radiographically detected horizontal bone loss,
- No furcation involvement,
- Full mouth plaque score (FMPS) <20%,
- Non-smoker,
- Patients who received only non-surgical periodontal treatment 6 months ago as the active treatment and taken into SPC program categorized as medium risk profile (62).

Exclusion criteria for participants were as follows:

- Pregnant and nursing individuals, and systemically compromised patients,
- Prosthesis with technical complications which could contribute to the disease state and not possible to treat before final inclusion,
- Antimicrobial treatment <6 months prior to study
- Previous history of periodontal surgery history (aiming pocket reduction).

3.3. Sample Size Calculation

According to the power and sample size program (G*Power 3.0.10), at least 36 patients recruited into the study (n = 9 in each group) based on the study by Ioannou et al.(124). PPD was set as the primary outcome. PI, GI and BoP were the secondary outcomes. At 80% statistical power and significance level of 5%, the power analysis results indicate 9 subjects when the effect size for PPD is 1.451 with a standard deviation (SD) of 0.4. The final sample size was fixed at 10 patients in order to compensate potential 10% drop-outs during the study.

3.4. Study Groups

TiN Curette Group (subgingival debridement with TiN-coated curette) (n=10):
TiN-coated area specific Gracey curettes[1] were applied with moderate to light pull imbricate strokes with sweeping movements in the apico-coronal direction for 20 seconds per site. After debridement, treated sites were rinsed with sterile saline. (Figure 1)

Ultrasonic Device Group (subgingival debridement with UD) (n=10):
The UD[2] with a specifically designed subgingival steel tip called H3, in the subgingival debridement mode (irrigation flow rate: 5–40 mL/min) was used for 20 seconds per site with moderate to light pull imbricate strokes with sweeping movements. After debridement, treated sites were rinsed with sterile saline. (Figure 2,3)

[1] Gracey Curette American Eagle® XP Technology, USA
[2] Acteon® Newtron P5 XS B.LED, FRANCE

Er:YAG Group (subgingival debridement with Er:YAG laser) (n=10):

Er:YAG laser[3] with a wavelength of 2940 nm was used. The parameters for the Er:YAG laser were set at 20Hz/120mJ, with water irrigation according to the manufacturer's instructions. The pulse width was 200ms. The chisel-type quartz laser tip was selected (1.2x0.4 mm, rectangular shape) and applied in apico-coronal sweeping movements for 20 seconds per site. The strokes were horizontally moving. After debridement, treated sites were rinsed with sterile saline. (Figure 4, 5)

SS Curette Group (subgingival debridement with SS curette) (n=10):

SS area specific Gracey curettes[4] were applied with moderate to light pull strokes with sweeping movements in the apico-coronal direction for 20 seconds per site. After debridement, treated sites were rinsed with sterile saline. (Figure 6)

Figure 1. Titanium Nitride-coated Curette

[3] VersaWave®, Delight; Hoya-Con Bio, USA
[4] Gracey Curette, Hu-Friedy®, USA

Figure 2. Ultrasonic Device

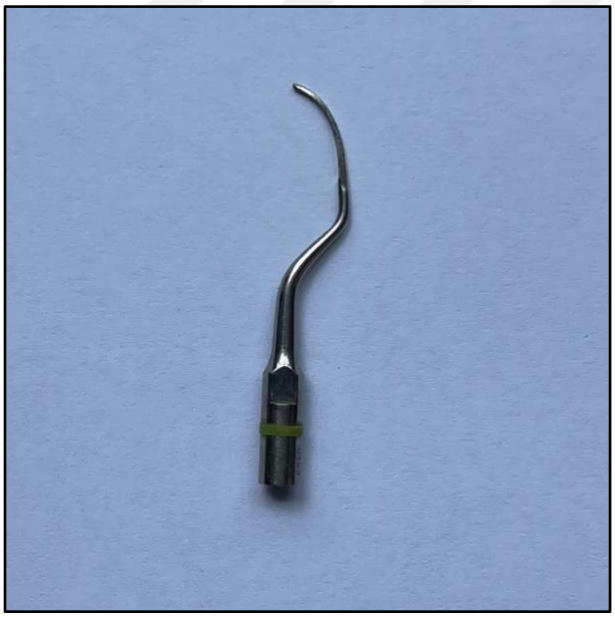

Figure 3. H3 Tip

Figure 4. Er:YAG Laser

Figure 5. Chisel-type Quartz Laser Tip

Figure 6. Stainless Steel Gracey Curette

3.5. Study Design

The study was designed as a randomized, controlled, parallel design, examiner blinded clinical trial. The flowchart of the study is shown in Figure 7. Patients were randomly allocated into four treatment groups according to a computer-based randomization table (www.graphpad.com / ©1994-2000, GraphPad Software, Inc., San Diego, CA, USA) (Appendix 3).

Each patient received detailed information about etiology of periodontal disease. OHI were repeated one week before the treatment period to reinforce the performance. Patients were instructed to brush with modified Bass technique with a medium tooth brush, in combination with flossing and/or interdental brushing twice a day. Full mouth PI and PPD measurements were recorded. Their plaque scores had to be less than 20% before they were included the study. Patients who fulfilled the criteria were randomly divided into four groups as detailed above.

Baseline diagnostic periapical radiographs were taken for only the treatment sites. Intraoral photographs were also taken. Then clinical indices and measurements were recorded including PI, GI, PPD and BoP. Full-mouth supragingival debridement using regular supragingival tip of UD[5] was performed followed by subgingival debridements at

[5] Acteon® Newtron P5 XS B.LED, FRANCE

sites with PPD ≥5mm under local anaesthesia using TiN-coated curettes[6], UD[7] with specific H3 tip or, Er:YAG laser[8], or SS[9] curettes. SS curettes were sharpened by DÖ before usage in every single patient whereas TiN curettes do not require sharpening. At 3 months supragingival debridement was repeated. At 6 months, intraoral photographs and clinical indices and measurements were recorded.

[6] Gracey Curette American Eagle® XP Technology, USA
[7] Acteon® Newtron P5 XS B.LED, FRANCE
[8] VersaWave®, Delight; Hoya-Con Bio, USA
[9] Gracey Curette, Hu-Friedy®, USA

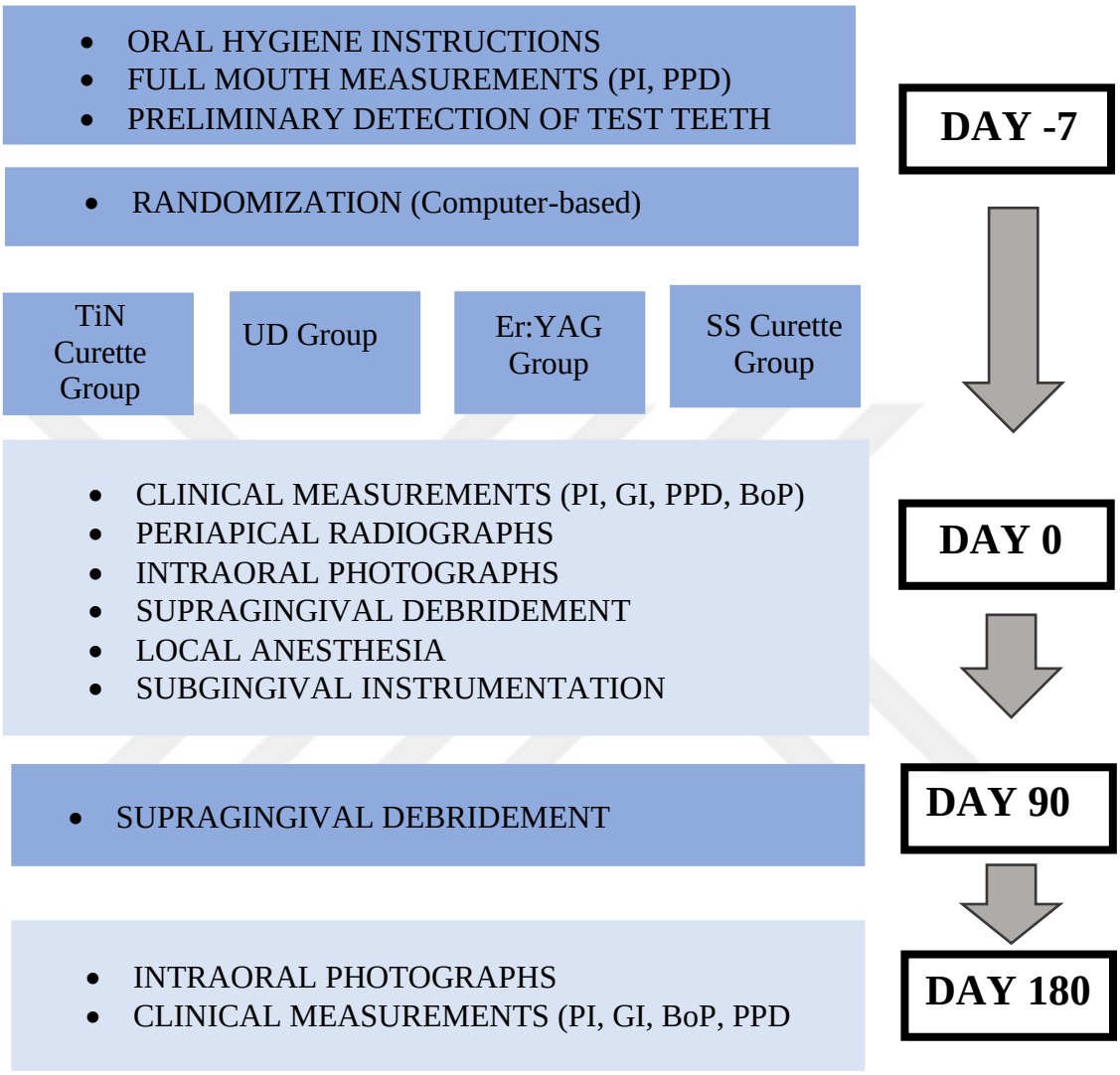

Figure 7. Flowchart of the study

3.6. Clinical Indices and Measurements

Clinical indices and measurements included PI, GI, BoP and PPD. All measurements were performed at baseline and repeated at 6 months by an experienced blinded examiner (HG) using a 0.4mm diameter 15mm long calibrated periodontal probe. Individually prepared acrylic occlusal stents were used to determine a constant reference point to align the probe properly and reduce the possible errors associated with probe placement at different time intervals during recording the indices. The occlusal stent covered the occlusal, buccal and lingual/palatine surfaces of the all teeth. Six grooves were placed on the stent along per tooth to standardize the measurement points and the angulation. Measurements and indices were recorded to the data sheet.

The following indices were used:

3.6.1 Plaque Index

Besides full mouth evaluation for the baseline inclusion criteria, selected sites were isolated with cotton rolls and dried by air syringe. DPB was evaluated with the probe (mesio-buccal, or mid-buccal or disto-buccal or mid-lingual) and scores between 0-3 were given for each point (125).

Scoring was made as follows:

0 – No microbial DPB in the gingival area.

1 – A film of microbial DPB adhering to the free gingival margin and adjacent area of the tooth, recognized only by running a probe across the tooth surfaces.

2 – Moderate accumulation of soft deposits within the gingival pocket and on the gingival margin and/or adjacent tooth surfaces that can be seen by naked eye.

3 – Abundance of soft matter within the gingival pocket and/or on the gingival margin and adjacent tooth surface.

3.6.2. Gingival Index

Periodontal probe was used to assess the bleeding potential together with visional evaluation of inflammatory changes of the tissues from selected sites of the involved teeth (mesio-buccal papilla or mid-buccal margin or disto-buccal papilla or mid- lingual margin) and scores between 0-3 were given for each point (126).

Scoring was made as follows:

0 – Normal gingiva

1 – Mild inflammation, slight change in color, slight edema, no BoP

2 – Moderate inflammation, redness, edema, ulceration; tendency to spontaneous bleeding.

3 – Severe inflammation, ulceration and spontaneous bleeding.

3.6.3. Probing Pocket Depth (mm)

Site specific PPD was measured by the periodontal probe from 6 surfaces of the tooth (mesio-buccal or mid-buccal or disto-buccal or mesio-lingual or mid-lingual or disto-lingual) as the distance between the gingival margin and the bottom of the periodontal pocket.

3.6.4. Bleeding on Probing

Site specific BoP was recorded simultaneously with the probing depth measurements up to 30 seconds after probing. The presence or absence of bleeding was recorded from 6 tooth surfaces (mesio-buccal or mid-buccal or disto-buccal or mesio-lingual or mid-lingual or disto-lingual) and scored as positive (+) or negative (-) bleeding for each point (127).

3.7. Data Analysis

The statistical analysis was performed by a commercially available software IBM SPSS Statistics 22 (IBM SPSS, Turkey). The compliance of parameters to the normal distribution was evaluated by Kolmogorov-Smirnov and Shapiro Wilks tests. It was found that parameters did not show normal distribution. Data analysis (PI, GI, and PPD BoP) was done for only experimental teeth sites. All parameters were measured at baseline and at 6 months. Kruskal Wallis test was used for the evaluation of inter-group comparisons. For intra-group comparisons, Wilcoxon signed-rank test was used. Chi-Square test, Fisher Freeman Halton, Pearson Chi-Square test and Mc Nemar test were used to compare the qualitative data. The level of significance was $p<0.05$.

4. RESULTS

Forty SPC patients (20 females, 20 males) with a mean age of 46.63±8.33 years were included in the study. 168 teeth with 237 sites ≥5 mm PPD were analysed in four groups as follows: TiN curette group (44 teeth, 63 sites), UD group (41 teeth, 54 sites), Er:YAG group (42 teeth, 56 sites) and SS curette group (41 teeth, 64 sites). Mean and range of effected teeth numbers for every patient included in the study groups were: TiN curette (4.4±1.56, 3 to 7), UD (4.1±0.74, 3 to 5), Er:YAG (4.2±0.92, 3 to 6) and SS curette (4.1±0.74, 3 to 5). No PPD greater than 7 mm were found in any of the groups at baseline.

At baseline, the PPD of 237 periodontal sites were found ≥5 mm (5-7 mm) and considered as residual pockets, 122 of which was 5 mm, 92 of which was 6 mm and 23 of which was 7 mm. At 6 months, no sites with 7 mm of PPD were detected. 117 sites were found ≥5 mm of PPD, 99 of which was 5 mm and 18 of which was 6 mm.

There were no complications and no eventful postoperative healing were observed. None of the subjects were excluded from the study. From each group, one representative case with intraoral photographs and radiographs are shown in Figures 8.a.-11.d.

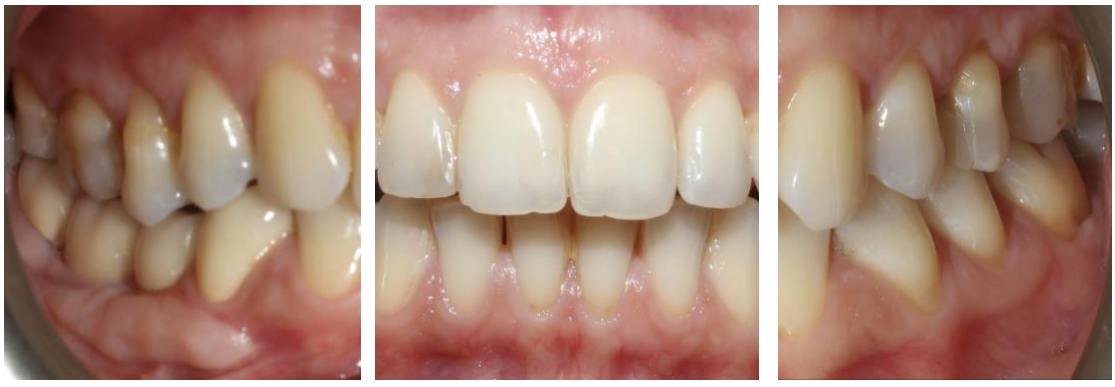

Figure 8. a. Baseline clinical view of a patient in TiN curette group

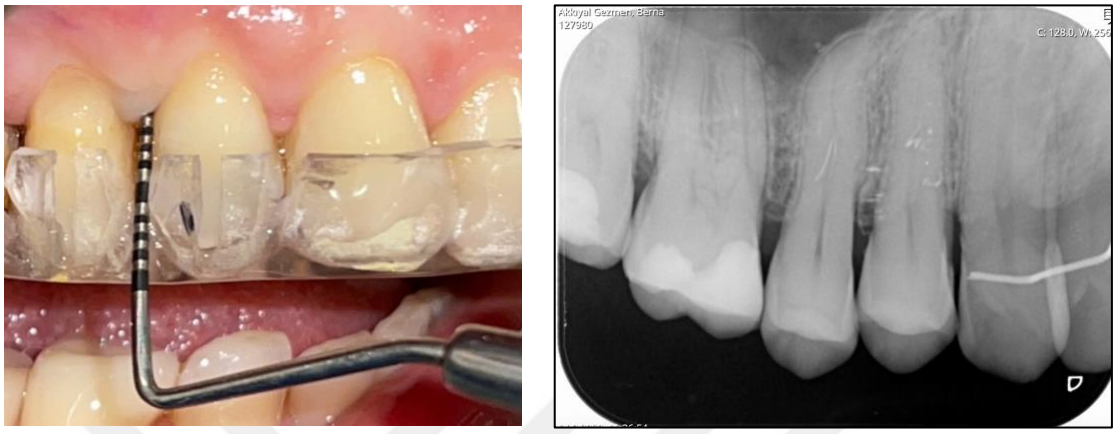

Figure 8.b. Baseline PPD measurements and diagnostic periapical radiographic view

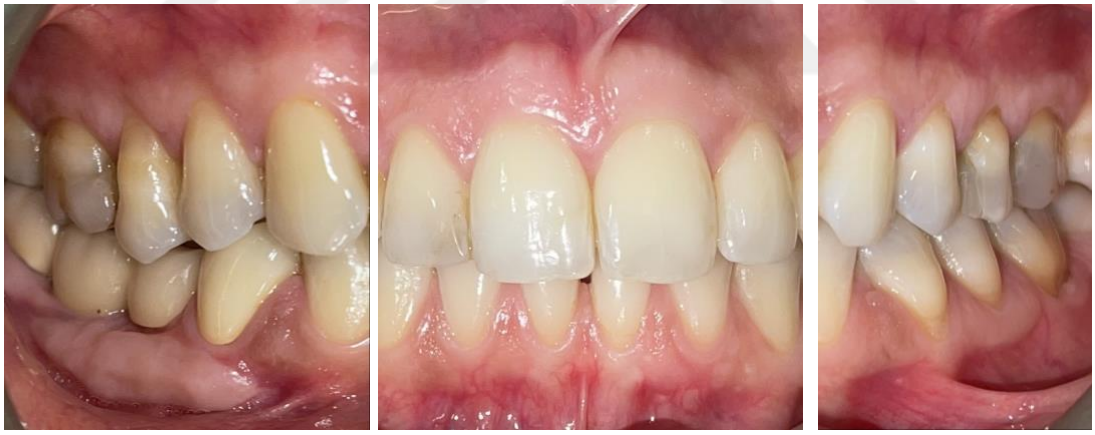

Figure 8.c. 6-month clinical view of the patient in TiN curette group

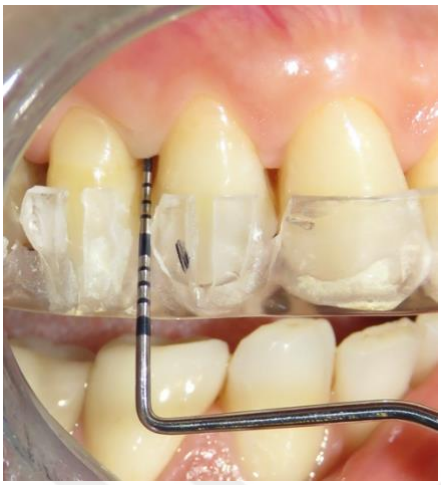

Figure 8.d. 6-month PPD measurement

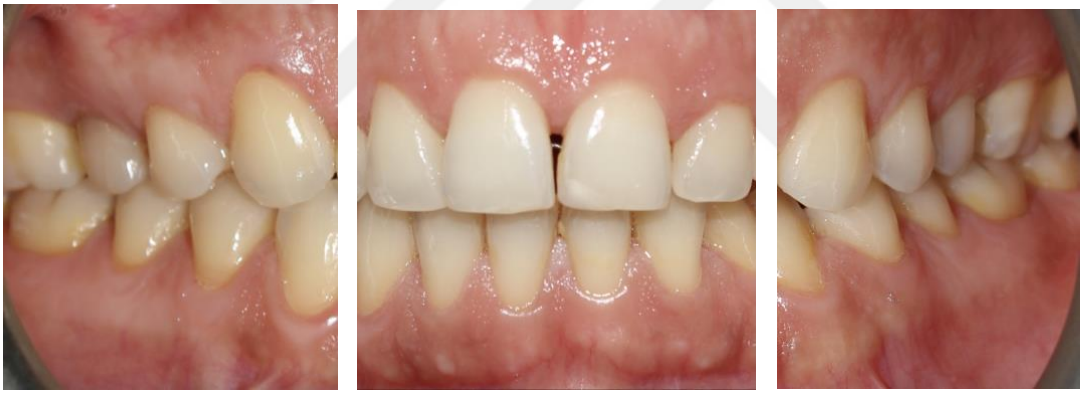

Figure 9.a. Baseline clinical view of a patient in ultrasonic device group

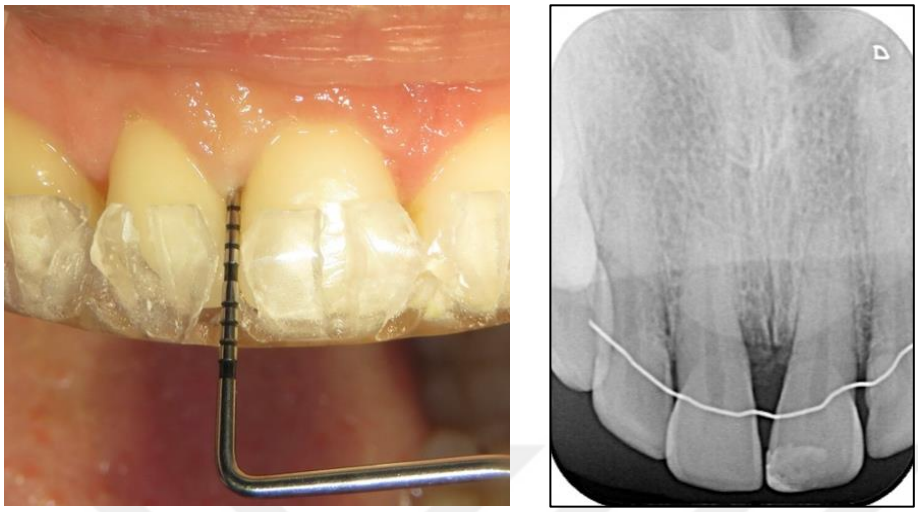

Figure 9.b. Baseline PPD measurement and diagnostic periapical radiographic view

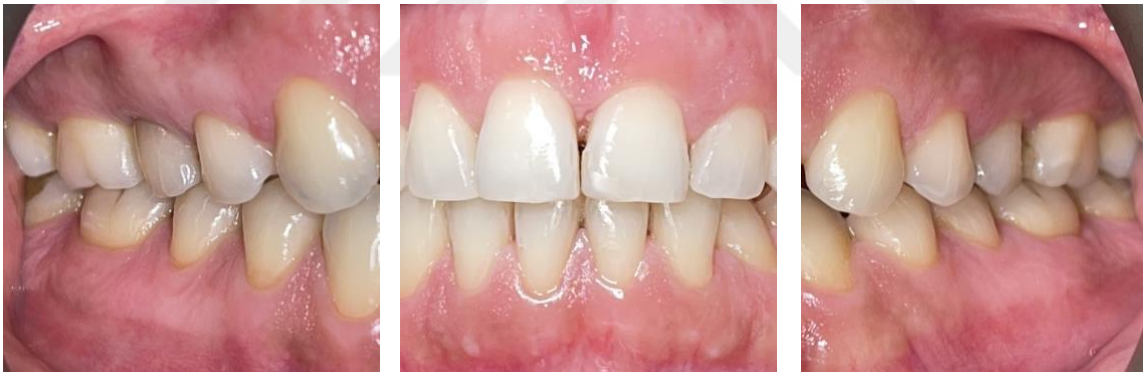

Figure 9.c. 6-month clinical view of the patient in ultrasonic device group

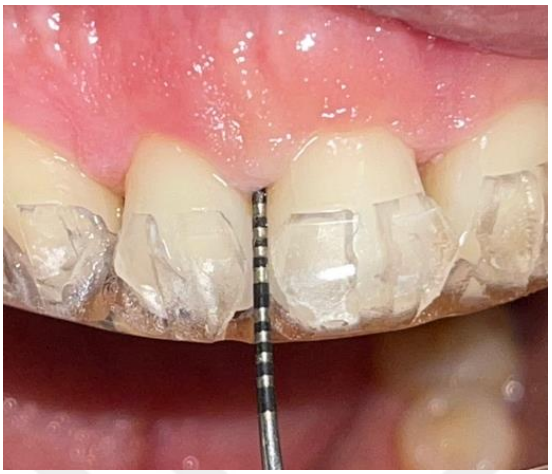

Figure 9.d. 6-month PPD measurement

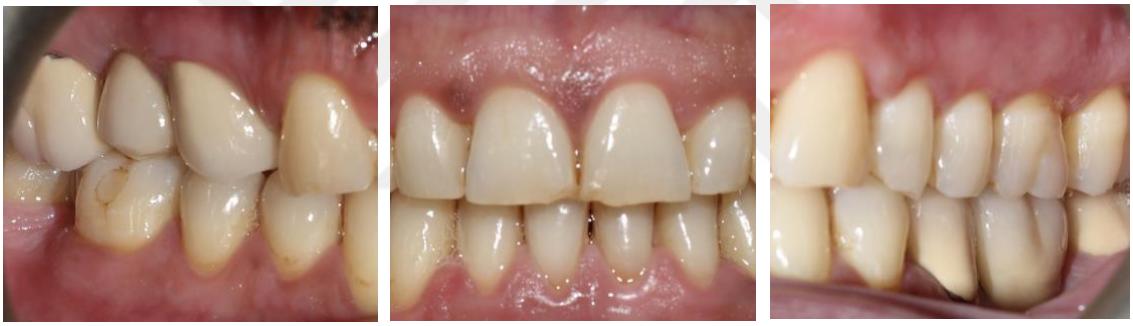

Figure 10.a. Baseline clinical view of a patient in Er:YAG group

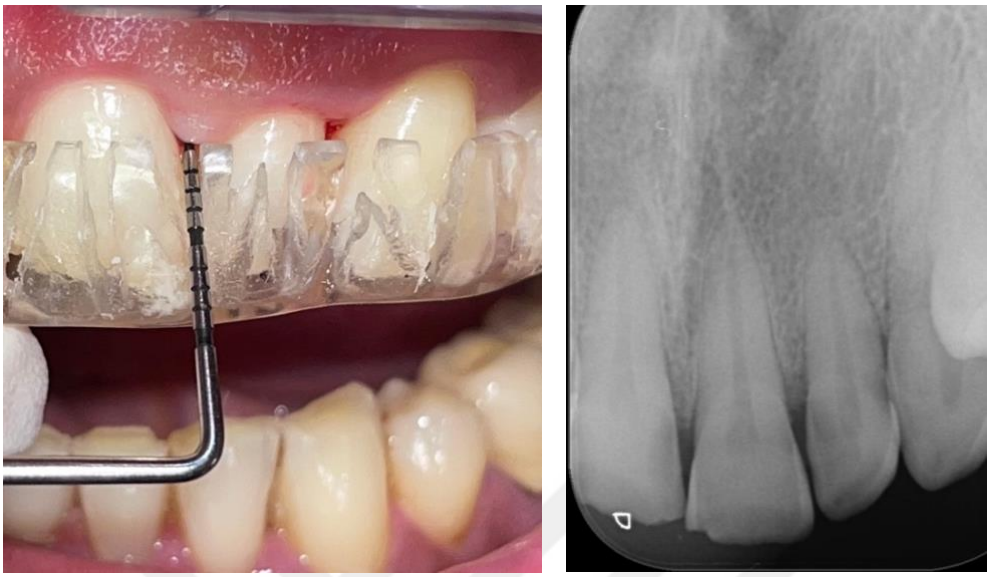

Figure 10.b. Baseline PPD measurement and diagnostic periapical radiographic view

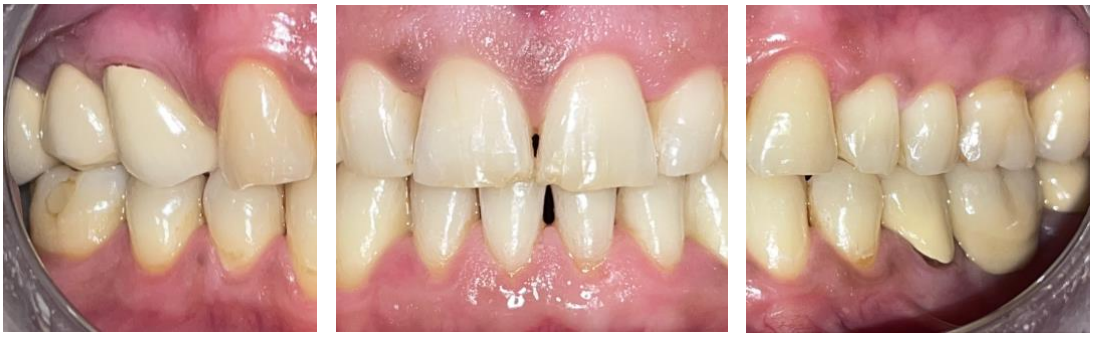

Figure 10.c. 6-month clinical view of the patient in Er:YAG group

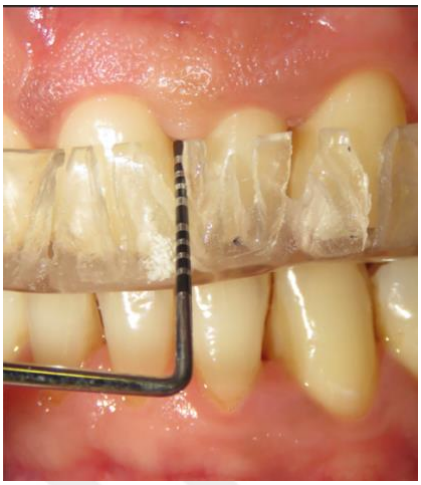

Figure 10.d. 6-month PPD measurement

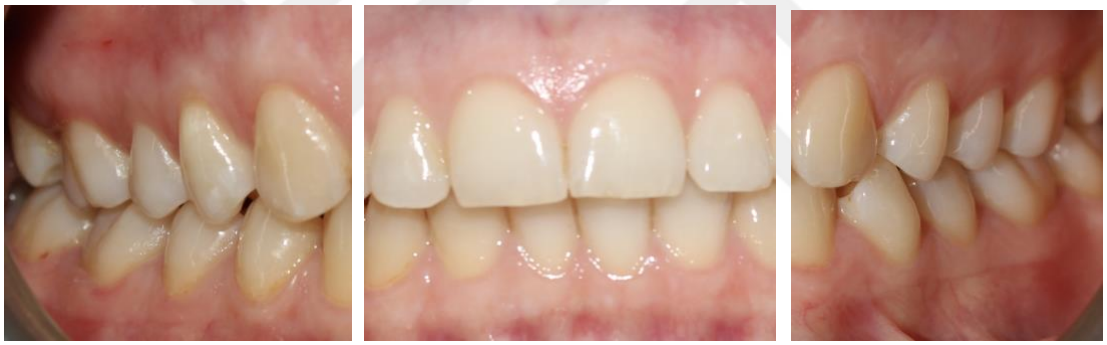

Figure 11.a. Baseline clinical view of a patient in SS curette group

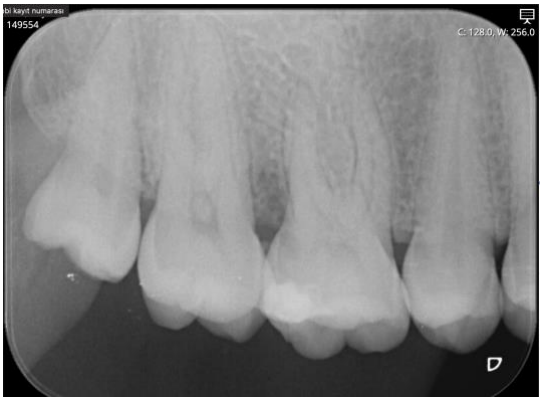

Figure 11.b. Baseline PPD measurement and diagnostic periapical radiographic view

Figure 11.c. 6-month clinical view of the patient in SS curette group

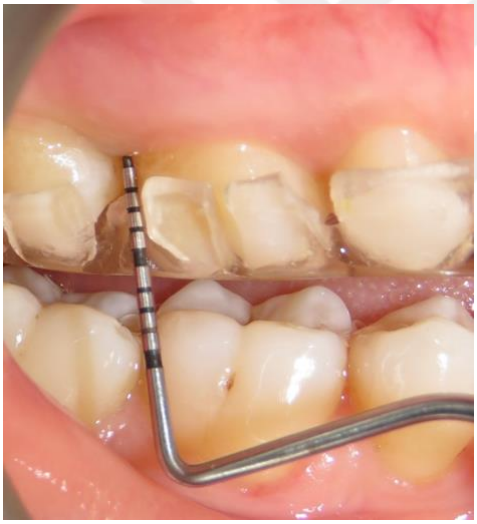

Figure 11.d. 6-month PPD measurement

4.1. Plaque Index

For intra- and inter-group comparisons, the mean ± standard deviations and median values of PI scores at baseline and 6 months, are shown in Table 1. Intra-group comparisons of PI values of all groups showed statistically significant differences between baseline and 6-months ($p:0.000$; $p<0.05$). The PI values at baseline and 6 months after the treatment were respectively 1.43±0.59 and 0.40±0.49 for TiN group, 1.43±0.57 and 0.39±0.49 for UD group,

1.41±0.56 and 0.39±0.49 for Er:YAG group, 1.42±0.50 and 0.41±0.53 for SS curette group (Table 1).

When the inter-group comparison was made, no statistically significant differences were found at neither baseline nor 6-month PI scores (p>0.05) (Table 1).

The differences between baseline and 6 months revealed PI scores of 1.03±0.67 for TiN curette group, 1.04±0.61 for UD group, 1.02±0.52 for Er:YAG group and 1.01±0.63 for SS curette group, respectively. When intra-group changes were compared between the groups, PI scores did not reveal any statistical significance (p>0.05) (Table 1).

Table 1. Intra- and inter-group comparisons of PI scores at baseline and 6 months

		TiN Curette Group (n=63)	**Ultrasonic Device Group (n=54)**	**Er:YAG Group (n=56)**	**SS Curette Group (n=64)**	**p[1]**
		Mean ± SD (Median)	Mean ± SD (Median)	Mean ± SD (Median)	Mean ± SD (Median)	
PI	**Baseline**	1.43±0.59 (1)	1.43±0.57 (1)	1.41±0.56 (1)	1.42±0.50 (1)	0.990
	6 Months	0.40±0.49 (0)	0.39±0.49 (0)	0.39±0.49 (0)	0.41±0.53 (0)	1.000
	p[2]	0.000*	0.000*	0.000*	0.000*	
	Difference	1.03±0.67 (1)	1.04±0.61 (1)	1.02±0.52 (1)	1.01±0.63 (1)	0.998

[1]Kruskal Wallis test *[2]Wilcoxon sign test* **p<0.05*

4.2. Gingival Index

For intra- and inter-group comparisons, the mean ± standard deviations and median values of GI scores at baseline and 6 months, are shown in Table 2. Intra-group comparisons of GI values of all groups showed statistically significant changes between baseline and 6

months (p:0.000; p<0.05). The GI values at baseline and 6 months after the treatment were respectively 1.83±0.38 and 0.65±0.86 for TiN group, 1.87±0.34 and 0.56±0.82 for UD group, 1.91±0.29 and 0.59±0.8 for Er:YAG group, 1.95±0.21 and 0.66±0.86 for SS curette group (Table 2).

When the inter-group comparison was made, no statistically significant differences were found at neither baseline nor 6-month GI scores (p>0.05) (Table 2).

The differences between baseline and 6 months revealed GI scores of 1.17±0.85 for TiN curette group, 1.31±0.80 for UD group, 1.32±0.79 for Er:YAG group and 1.30±0.89 for SS curette group, respectively. When intra-group changes were compared between the groups, GI scores did not reveal any statistical significance (p>0.05) (Table 2).

Table 2. Intra- and inter-group comparisons of GI scores at baseline and 6 months

		TiN Curette Group (n=63)	**Ultrasonic Device Group (n=54)**	**Er:YAG Group (n=56)**	**SS Curette Group (n=64)**	**p[1]**
		Mean ± SD (Median)	Mean ± SD (Median)	Mean ± SD (Median)	Mean ± SD (Median)	
GI	**Baseline**	1.83±0.38 (2)	1.87±0.34 (2)	1.91±0.29 (2)	1.95±0.21 (2)	0.125
	6 Months	0.65±0.86 (0)	0.56±0.82 (0)	0.59±0.8 (0)	0.66±0.86 (0)	0.916
	p[2]	0.000*	0.000*	0.000*	0.000*	
	Difference	1.17±0.85 (1)	1.31±0.80 (2)	1.32±0.79 (2)	1.30±0.89 (2)	0.340

[1]Kruskal Wallis test *[2]Wilcoxon sign test* **p<0.0*

4.3. Probing Pocket Depth (mm)

For intra- and inter-group comparisons, the mean ± standard deviations and median values of PPD scores at baseline and 6 months, are shown in Table 3. Intra-group comparisons of PPD values of all groups showed statistically significant differences between baseline and 6 months (p:0.000; $p<0.05$). The PPD values at baseline and 6 months after the treatment were respectively 5.63±0.66 and 4.51±0.59 for TiN group, 5.54±0.66 and 4.52±0.61 for UD group, 5.64±0.67 and 4.66±0.58 for Er:YAG group, 5.53±0.67 and 4.55±0.66 for SS curette group (Table 3).

When the inter-group comparison was made, no statistically significant differences were found at neither baseline nor 6-month PPD measurements ($p>0.05$) (Table 3).

The difference between baseline and 6 months revealed PPD scores of 1.13±0.58 for TiN curette group, 1.07±0.53 for UD group, 1±0.52 for Er:YAG group and 1.01±0.45 for SS curette group, respectively. When intra-group changes were compared between the groups, PPD scores did not reveal any statistical significance ($p>0.05$) (Table 3).

Table 3. Intra- and inter-group comparisons of PPD scores at baseline and 6 months

		TiN Curette Group (n=63)	Ultrasonic Device Group (n=54)	Er:YAG Group (n=56)	SS Curette Group (n=64)	p[1]
		Mean ± SD (Median)	Mean ± SD (Median)	Mean ± SD (Median)	Mean ± SD (Median)	
PPD (mm)	Baseline	5.63±0.66 (6)	5.54±0.66 (5)	5.64±0.67 (6)	5.53±0.67 (5)	0.606
	6 Months	4.51±0.59 (4)	4.47±0.61 (4)	4.64±0.58 (5)	4.52±0.66 (4)	0.409
	p[2]	0.000*	0.000*	0.000*	0.000*	
	Difference	1.13±0.58 (1)	1.07±0.53 (1)	1±0.52 (1)	1.01±0.45 (1)	0.115

[1]Kruskal Wallis test *[2]Wilcoxon sign test* **p<0.05*

4.4. Bleeding on Probing (%)

For intra- and inter-group comparisons, the mean ± standard deviations and median values of BoP scores at baseline and 6 months, are shown in Table 4. Intra-group comparisons of BoP values of all groups showed statistically significant differences between baseline and 6 months (p:0.000; p<0.05). The BoP values at baseline and 6 months after the treatment were respectively 82.5% and 25.4% for TiN group, 87% and 18.5% for UD group, 91.1% and 19.6% for Er:YAG group, 95.3% and 26.6% for SS curette group (Table 4).

When the inter-group comparison was made, no statistically significant differences were found at neither baseline nor 6 months BoP scores (p>0.05) (Table 4)

Table 4. Intra- and inter-group comparisons of BoP scores at baseline and 6 months

		TiN Curette Group (n=63) n(%)	Ultrasonic Device Group (n=54) n(%)	Er:YAG Group (n=56) n(%)	SS Curette Group (n=64) n(%)	p[1]
BoP	**Baseline**	52 (%82.5)	47 (%87)	51 (%91.1)	51 (%91.1)	0.124
	6 Months	16 (%25.4)	10 (%18.5)	11 (%19.6)	17 (%26.6)	0.651
	p[2]	0.000*	0.000*	0.000*	0.000*	

*[1]Chi-square test [2]Mc Nemar test *p<0.05*

Table 5 shows the inter-group comparison of residual PPD ≥5mm sites revealing no statistically significant difference at 6 months (p>0.05). The number of residual PPD ≥5mm sites was 29 in TiN curette group, 25 in UD group, 34 in Er:YAG group, and 29 in the SS curette group out of 237 sites, respectively.

Table 5. Residual PPD ≥5 mm sites at 6 months

A total of 237 sites	TiN Curette Group	Ultrasonic Device Group	Er:YAG Group	SS Curette Group	P
PPD ≥5mm **n(%)**	29 (12.2%)	25 (10.5%)	34 (14.3%)	29 (12.2%)	0.285
Range	5-6 mm	5-6 mm	5-6 mm	5-6 mm	

Fisher Freeman Halton Exact Test

Table 6 shows the inter-group comparison of residual PPD ≥5mm with BoP (+) revealing no statistically significant difference at 6 months (p>0.05). Number of residual sites with PPD ≥5mm with BoP was 11 in the TiN curette group, 4 in UD group, 8 in Er:YAG

group, and 12 in SS curette group out of 237 sites. There was a total of 22 multi-rooted vs 13 single-rooted teeth with PPD ≥ 5 mm with BoP (+) sites at 6 months.

Table 6. PPD ≥ 5 mm with BoP (+) sites at 6 months

A total of 237 sites	TiN Curette Group	Ultrasonic Device Group	Er:YAG Group	SS Curette Group	P
PPD≥5mm BoP (+) n(%)	11 (4.6%)	4 (1.6%)	8 (3.3%)	12 (5%)	0.372
Range	5-6 mm	5-6 mm	5-6 mm	5-6 mm	
Tooth type	7 multi-rooted 4 single-rooted	2 multi-rooted 2 single-rooted	5 multi-rooted 3 single-rooted	8 multi-rooted 4 single-rooted	

Chi-square test

Table 7 shows the inter-group comparison of residual PPD 4mm with BoP (+). There was no statistically significant difference at 6 months (p>0.05). Number of residual sites with PPD 4mm with BoP was 5 in the TiN curette group, 6 in UD group, 3 in Er:YAG group, and 5 in SS curette group out of 237 sites. There was a total of 11 multi-rooted vs 8 single-rooted teeth with PPD 4 mm with BoP (+) sites at 6 months.

Table 7. PPD 4 mm with BoP (+) sites at 6-month

A total of 237 sites	TiN Curette Group	Ultrasonic Device Group	Er:YAG Group	SS Curette Group	P
PPD 4mm BoP (+) **n (%)**	5 (2.1%)	6 (2.5%)	3 (1.2%)	5 (2.1%)	0.734
Tooth type	3 multi-rooted 2 single-rooted	3 multi-rooted 3 single-rooted	2 multi-rooted 1 single-rooted	3 multi-rooted 2 single-rooted	

Pearson Chi-Square

5. DISCUSSION and CONCLUSION

Periodontal disease is an inflammatory infectious disease which causes destruction of periodontal tissues possibly leading to tooth loss (128). Periodontal treatment aims to minimize symptoms, prevent further disease progression, restore periodontal tissue loss and motivate patients to maintain a healthy periodontium. Periodontal treatment consists of behavioral-change techniques, such as: individually constituted OH instructions (129,130); support for smoking-cessation (131); diet regulations (132); supragingival and subgingival instrumentation (74); systemic and local pharmacotherapy (32); and various types of surgeries (6,133,134). Management of chronic periodontal disease requires a combination of therapeutic modalities and a lifelong commitment to periodontal self-care (2). Among these treatment modalities, non-surgical periodontal treatment is considered as the gold standard and cornerstone for controlling the periodontal disease. Although non-surgical periodontal treatment has been proven to provide significant clinical improvements, deep PPDs can still remain after this treatment and defined as 'residual' PPD (3). The presence of residual pockets may jeopardize tooth survival and be a determinant of further disease progression and ultimately tooth loss (37,135).

In the literature, it was reported that residual PPDs are more prone to disease progression, even when the active treatment has been completed, and it has been shown that residual pockets are predictors for further disease progression (136,137). The depth of the residual pocket is of clinical importance being the reason to be selected as the primary outcome of this study. It has been stated that PPD $\geq$ 5 mm is accepted as residual pockets suitable for subgingival debridement, because pockets <4 mm in depth would lead attachment loss (136,137). In the present study, clinical effectiveness of different periodontal instrumentations have been investigated over a 6 months follow-up period in SPC patients that were put into medium risk profile. At the end of the experimental period, no statistically significant differences were detected between the groups at any measurement time points in terms of clinical evaluations consisted of PI, GI, PPD and BoP.

Periodontal treatment is the combination of active periodontal therapy with SPC (43). Compliance, OH habits, systemic health, residual pockets, and bleeding are all critical factors for the stability and maintenance of periodontal health (53,138). Periodontal disease progression can be inevitable when patients do not adhere SPC program, even though they previously have active periodontal treatment (43). Becker et al.(44) demonstrated that without SPC, periodontal treatment had little value in terms of long-term periodontal health. SPC program have to be scheduled in terms of intervals and procedures according to the patient's risk profile and individual needs. Lang & Tonetti (62) have demonstrated that there is not only one parameter which displays a major role for patient risk assessment. Besides residual pockets, BoP, number of tooth loss, genetic and systemic conditions, environmental factors and age-related bone loss are all risk indicators and needed to be evaluated (62). Patients included in this study were already scheduled for individualized SPC program according to the periodontal risk assessment diagram by Lang & Tonetti (62). Forty patients with residual pockets 6 months after active non-surgical treatment were randomly assigned into 4 treatment protocols and evaluated for the clinical improvements as well as the total disease resolution outcome. The experimental period started with their first session of SPC, 6 months after active non-surgical treatment, for the second evaluation and further treatment needs. Tomasi et al.(139,140) have stated that sites that do not respond to a second session of non-surgical treatment, may require a surgical intervention. Matuliene et al.(37) have investigated residual PPD ≥5 mm with BoP after active periodontal treatment during SPC. The study showed that, PPD may increase in time and PPDs ≥6 mm need further periodontal treatment to achieve healthy periodontium.

For the clinician to decide whether further periodontal treatment is needed or not, PPD should be evaluated together with BoP in decision making (141). GI and BoP scores are for the evaluation of the inflammatory status of the gingiva. BoP is a significant and more reliable parameter for further periodontal detoriation (37). Furthermore, absence of BoP is a strong sign of health and inactivity preventing disease progression (52). Sites without bleeding can be considered as clinically stable and healthy (142). Sometimes, despite meticulous non-surgical periodontal treatment, DPB and calculus may remain, and the

inflammation persists. Badersten et al.(4) have reported that after mechanical debridement, residual pockets exist and present BoP and the frequency of BoP is higher for deeper residual pockets. Lang et. al have advocated that during SPC, persisting BoP is a risk for attachment loss and the absence of BoP indicates periodontal stability (51,143). Ramseier et al.(10) have demonstrated that, the percentage of BoP has to be kept low to reduce residual pockets. In the present study, all groups showed statistically significant improvements in terms of GI and BoP values at the end of 6 months ($p< 0.05$). Accordingly, it may be advocated that supragingival and subgingival debridement with a high standard of OH level did not totally eliminate but reduced the bleeding tendency and inflammation of the periodontium to considerable levels.

Taking the primary outcome of PPD into consideration, 122 out of selected 237 sites had 5 mm PPD, 92 had 6 mm and 23 had 7 mm at baseline. At 6 months, no sites with 7 mm of PPD were detected. 117 sites were found ≥5 mm PPD in total. However, only 35 out of 117 sites had BoP in total (22 sites in multi-rooted teeth without furcation involvement vs. 13 in single-rooted) whereas, 19 sites out of 237 had 4 mm PPD together with BoP at the end of the 6 months which is also put in risk category but without surgical indication, according to the new classification system and current concept (5,144).

According to a meta-analysis, after non-surgical periodontal treatment, mean reduction for baseline PPD of 4-6 mm is expected to be 1 mm and approximately 2 mm for PPD ≥7 mm (16). In the present study, the mean PPD reductions at 6 months were; 1.13 mm, 1.07 mm, 1 mm and 1.01 mm for TiN curette, UD, Er:YAG and SS curette group, respectively in accordance with the literature. According to Heitz-Mayfield et al.(3) in 2013, PPD ≥5.4 mm is a critical probing depth and requires surgical periodontal treatment. Graziani et al.'s(5) review in 2017, this critical point is stated as PPD ≥5 mm suggesting a clear indication of surgical interventions, whereas ≥6 mm as the threshold for definite surgical requirement. It is agreed that surgical approach in deep PPD provides the expected amount of reduction when compared to non-surgical treatment. However, post-operative pain, discomfort, swelling, high treatment cost and patient-related factors are significantly

important for patients to have hesitations about surgical interventions. Thus, reducing the number of sites of periodontal surgery is of critical importance for patient's toleration and acceptability (144–146). Thoroughly removing deposits from root surfaces with mechanical debridement is crucial to reduce surgical area and achieve successful treatment outcomes, (98,147,148) especially during the first session of SPC program for further evaluation (139,140). Rosling et al.(21) performed subgingival debridement for PPD ≥5 mm with BoP in addition to supragingival prophylaxis during SPC every 3 months and succeeded to maintain health for over 12 years with a limited PPD increment and tooth loss. For patients with 'normal' susceptibility, in concomitant with our categorization of medium risk profile according to Lang and Tonetti et al.,(62) >95% of the cases were prevented from major attachment, bone and tooth loss. On the other hand, there are also contradictory studies, which showed no clinical benefits of subgingival debridement during SPC. Jenkins et al.(64) showed that there was no statistically significant difference between the groups with only supragingival debridement and subgingival debridement for the one year outcomes. In the present study, similar to the study of Rosling et al.(21), patients received supragingival debridement throughout the whole dentition and subgingival instrumentation for only sites with PPD ≥5mm. At the end of 6 months, the percentage of sites with PPD ≤4 mm without BoP was 42.6 % (101 out of 237). Since absence of BoP together with PPD ≤4 mm is considered as stable healthy state, (3,149) the aforementioned sites can be excluded from sites requiring surgical treatment after subgingival debridement.

It is well-known that patient's self-oral hygiene has a critical role for DPB control and has significant effect on periodontal treatment outcomes and disease progression even at PPD ≥ 6mm (56,68). PI was used in this study to define the OH level and evaluate the accumulation of DPB throughout the experimental period to exclude the possibility of the impact of DPB on compared treatment outcomes. Therefore, one week before the experimental period, all patients were reinstructed for OH similar to their previous instructions given during the active non-surgical treatment. Brushing their teeth with modified Bass method and the use of interdental brushes were reinforced. At baseline PI scores for TiN curette, UD, Er:YAG and SS curette groups were 1.43, 1.43, 1.41 and 1.42,

respectively. All four groups showed statistically significant intra-group improvements, when baseline and 6 months results were compared ($p< 0.05$), indicating that all subjects were able to increase and maintain optimal OH levels. PI reductions at the end of 6 months for TiN curette, UD, Er:YAG and SS curette groups were 1.03, 1.04, 1.02 and 1.01, respectively. Inter-group comparisons of the mean differences of PI scores revealed no statistically significant difference.

Single-rooted and multi-rooted teeth with intact furcation entrances are easy to maintain and usually respond better than multi-rooted teeth with Class II and III furcation involvements to non-surgical treatments (5). The multi-rooted teeth that were included in our study had no furcation involvements and well-responded to the non-surgical therapy. However, when compared with single-rooted teeth, total disease resolution outcome was better in the latter. In this present study, at the end of 6 months, 22 multi-rooted vs. 13 single-rooted teeth presented sites with PPD ≥5 mm with BoP. According to the literature, regardless of instrument choice, multi-rooted teeth are tend to exhibit more residual calculus and inflammation after non-surgical treatment (150). In a study by Loos et al.,(151) multi- and single-rooted teeth were compared after non-surgical periodontal treatment. For single-rooted teeth with sites of PPD ≥7 mm responded better than multi-rooted teeth showing limited response.

Avoiding periodontal surgery is mostly preferable through the perception of the patients. Pain is an important patient-factor, for a significant number of patients find surgical treatment painful and scary (145,146). Reducing the need for periodontal surgery is thus a significant interest from the patients' point of view regarding both morbidity and economic factors (152). Currently, several non-surgical treatment modalities with brand-new and specifically designed tools are of interest to increase the impact on treatment outcomes, such as air powdered, power driven, hand or laser assisted instrumentations as well as area specific tips coated with gentle and tissue friendly materials.

However, all these treatment modalities should be well accepted by the patients to enhance the patient's compliance and possibly improve the prognosis of SPC (120).

Exclusion of the patients' self-evaluation may be considered as a limitation of this study along with the small sample size of the patients in the groups. Although no statistically significant differences were obtained between the different subgingival modalities, the UD group revealed better outcomes in comparison to the other groups. Since the brand-new ultrasonic tip H3 is specially designed for subgingival area used together with a specific frequency range, the findings would have presented significant differences in larger sample sizes.

In conclusion, non-surgical treatment improved the clinical situation of the patients with residual PPDs between 5 to 7 mm without any significant differences between the tested periodontal instrumentations. Being aware of the different treatment responses between single- and multi-rooted teeth, the future long-term studies can be performed on a larger scale of patient numbers together with patient-centered outcomes. Within the limits of this study, it can be concluded residual pockets between 5 to 7 mm responded to non-surgical periodontal treatment modalities accompanied with a strict self-performed OH and reduced the need of further surgical interventions with the minimization of the surgical area.

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7. APPENDIX

Appendix 1. Ethical Approval

T.C. YEDİTEPE ÜNİVERSİTESİ

Sayı : 37068608-6100-15- 2040
Konu: Klinik Araştırmalar
Etik Kurul Başvurusu hk.

31/12/2020

İlgili Makama (Dila Özbozdoğanlı)

Yeditepe Üniversitesi Diş Fakültesi Periodontoloji ABD Doç.Dr. Hare Gürsoy'un sorumlu araştırmacı olduğu **"Periodontitisli Hastalarda Başlangıç Periodontal Tedavide Kullanılan Farklı Araçların Klinik Etkinliklerinin Değerlendirilmesi: Kontrollü, Paralel Dizayn Klinik Çalışma"** isimli araştırma projesine ait Klinik Araştırmalar Etik Kurulu (KAEK) Başvuru Dosyası **(2032)** kayıtlı Numaralı KAEK Başvuru Dosyası, Yeditepe Üniversitesi Klinik Araştırmalar Etik Kurulu tarafından **30.12.2020** tarihli toplantıda incelenmiştir.

Kurul tarafından yapılan inceleme sonucu, yukarıdaki isim belirtilen çalışmanın yapılmasının etik ve bilimsel açıdan uygun olduğuna karar verilmiştir. **(KAEK Karar No:1336)**

Prof. Dr. Turgay Çelik

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YEDİTEPE ÜNİVERSİTESİ KLİNİK ARAŞTIRMALAR ETİK KURULU KARAR FORMU

Araştırmanın Açık Adı	**"Periodontitisli Hastalarda Başlangıç Periodontal Tedavide Kullanılan Farklı Araçların Klinik Etkinliklerinin Değerlendirilmesi: Kontrollü, Paralel Dizayn Klinik Çalışma"**
VARSA ARAŞTIRMANIN PROTOKOL KODU	

ETİK KURUL BİLGİLERİ	ETİK KURULUN ADI	**Yeditepe Üniversitesi KAEK (2012-KAEK-70)**
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BAŞVURU BİLGİLERİ	KOORDİNATÖR/SORUMLU ARAŞTIRMACI UNVANI/ADI/SOYADI	Doç. Dr. Hare Gürsoy			
	KOORDİNATÖR/SORUMLU ARAŞTIRMACININ UZMANLIK ALANI	Periodontoloji Anabilim Dalı			
	KOORDİNATÖR/SORUMLU ARAŞTIRMACININ BULUNDUĞU MERKEZ	Yeditepe Üniversitesi Diş Hekimliği Fakültesi			
	VARSA İDARİ SORUMLU UNVANI/ADI/SOYADI				
	DESTEKLEYİCİ				
	PROJE YÜRÜTÜCÜSÜ UNVANI/ADI/SOYADI (TÜBİTAK vb. gibi kaynaklardan destek alanlar için)				
	DESTEKLEYİCİNİN YASAL TEMSİLCİSİ				
	ARAŞTIRMANIN FAZI VE TÜRÜ	FAZ 1	☐		
		FAZ 2	☐		
		FAZ 3	☐		
		FAZ 4	☐		
		Gözlemsel ilaç çalışması	☐		
		Tıbbi cihaz klinik araştırması	☒		
		İn vitro tıbbi tanı cihazları ile yapılan performans değerlendirme çalışmaları	☐		
		İlaç dışı klinik araştırma	☐		
		Diğer ise belirtiniz	☐		
	ARAŞTIRMAYA KATILAN MERKEZLER	TEK MERKEZ ☒	ÇOK MERKEZLİ ☐	ULUSAL ☒	ULUSLARARASI ☐

08.01.2021
ASLI GİBİDİR

Prof. Dr. Turgay ÇELİK
Yeditepe Üniversitesi KAEK Başkanı

YEDİTEPE ÜNİVERSİTESİ KLİNİK ARAŞTIRMALAR ETİK KURULU KARAR FORMU

Araştırmanın Açık Adı	**"Periodontitisli Hastalarda Başlangıç Periodontal Tedavide Kullanılan Farklı Araçların Klinik Etkinliklerinin Değerlendirilmesi: Kontrollü, Paralel Dizayn Klinik Çalışma"**
VARSA ARAŞTIRMANIN PROTOKOL KODU	

KLİNİK ARAŞTIRMALAR ETİK KURULU	
ETİK KURULUN ÇALIŞMA ESASI	İlaç ve Biyolojik Ürünlerin Klinik Araştırmaları Hakkında Yönetmelik, İyi Klinik Uygulamaları Kılavuzu
BAŞKANIN UNVANI / ADI / SOYADI:	Prof. Dr. Turgay Çelik

Unvanı/Adı/Soyadı	Uzmanlık Alanı	Kurumu	Cinsiyet		Araştırma ile ilişki		Katılım *		İmza
Prof. Dr. Turgay Çelik (Etik Kurul Başkanı)	Tıbbi Farmakoloji	Y.Ü. Eczacılık Fakültesi	E☒	K☐	E☐	H☒	E☒	H☐	
Prof. Dr. Ferda Özkan	Patoloji	Y.Ü. Tıp Fakültesi	E☐	K☒	E☐	H☒	E☒	H☐	
Prof. Dr. Pelin Yazgan	Fiziksel Tıp ve Rehabilitasyon	Özel Klinik	E☐	K☒	E☐	H☑	E☑	H☐	
Prof. Dr. Esra Can	Diş Hekimi	Y.Ü. Diş Hekimliği Fakültesi	E☐	K☒	E☐	H☑	E☑	H☐	
Prof. Dr. Hasan Aydın	Endokrinoloji	Y.Ü. Tıp Fakültesi	E☒	K☐	E☒	H☑	E☑	H☐	
Hasan Erdem	Hukuk (Av.)	Serbest Meslek	E☒	K☐	E☐	H☑	E☑	H☐	
Dr. Öğr. Üyesi Gökhan Ertaş	Biyo Medikal	Y.Ü. Mühendislik Fakültesi	E☒	K☐	E☐	H☒	E☒	H☐	
Buket Dirgen	Sivil Üye	Acıbadem Hastanesi	E☐	K☒	E☐	H☐	E☐	H☐	
Prof. Dr. Recep Erol Sezer	Halk Sağlığı	Y.Ü. Tıp Fakültesi	E☒	K☐	E☐	H☒	E☒	H☐	
Prof. Dr. Arzu Tatlıpınar	KBB	Y.Ü. Tıp Fakültesi	E☐	K☒	E☐	H☒	E☒	H☐	
Doç. Dr. Muhammed Hamitoğlu	Eczacı	Y.Ü. Eczacılık Fakültesi	E☒	K☐	E☐	H☑	E☑	H☐	
Dr. Öğr. Üyesi F. Ferda Kartufan	Anesteziyoloji ve Reanimasyon	Y.Ü. Tıp Fakültesi	E☐	K☒	E☐	H☐	E☐	H☐	

*:Toplantıda Bulunma

08.01.2020
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VARSA ARAŞTIRMANIN PROTOKOL KODU	

	Belge Adı	**Tarihi**	**Versiyon Numarası**	**Dili**
DEĞERLENDİRİLEN BELGELER	ARAŞTIRMA PROTOKOLÜ	30.12.2020	2	Türkçe ☒ İngilizce ☐ Diğer ☐
	BİLGİLENDİRİLMİŞ GÖNÜLLÜ OLUR FORMU	30.12.2020	2	Türkçe ☒ İngilizce ☐ Diğer ☐
	OLGU RAPOR FORMU	30.12.2020	2	Türkçe ☒ İngilizce ☐ Diğer ☐
	ARAŞTIRMA BÜTÇESİ	30.12.2020	2	Türkçe ☒ İngilizce ☐ Diğer ☐

	Belge Adı		**Açıklama**
DEĞERLENDİRİLEN DİĞER BELGELER	KLİNİK ARAŞTIRMA BAŞVURU FORMU GÖZLEMSEL RETROSPEKTİF	☒ ☐ ☐	
	TIBBİ CİHAZ TC KLİNİK ARAŞTIRMA (AKADEMİK) TC GÖZLEMSEL KLİNİK ARAŞTIRMA TC İN VİTRO KLİNİK ARAŞTIRMA	☐ ☐ ☐ ☐	
	SİGORTA	☐	
	ARAŞTIRMA BÜTÇESİ	☒	
	BİYOLOJİK MATERYEL TRANSFER FORMU	☐	
	ÖZGEÇMİŞLER	☒	
	HELSİNKİ BİLDİRGESİ	☒	
	ÇIKAR İLİŞKİSİ BELGESİ	☐	
	KURUM İZNİ	☒	
	ARŞİV FORMU	☐	
	CİDDİ ADVERS OLAY (CAO) BİLDİRİMİ	☒	
	KURUM DIŞI ARAŞTIRMACI BAŞVURU FORMU	☐	
	İTHALAT FORMU	☐	
	DEPO BAŞVURU FORMU	☐	
	SONLANIM BİLDİRİMİ BAŞVURU FORMU	☒	

KARAR BİLGİLERİ	**Karar No:1336**	**Tarih: 30.12.2020**
	Yukarıda bilgileri verilen **"Periodontitisli Hastalarda Başlangıç Periodontal Tedavide Kullanılan Farklı Araçların Klinik Etkinliklerinin Değerlendirilmesi: Kontrollü, Paralel Dizayn Klinik Çalışma"** klinik araştırmanın başvuru dosyası ile ilgili belgeler araştırmanın /çalışmanın gerekçe, amaç, yaklaşım ve yöntemleri dikkate alınarak incelenmiş ve uygun bulunmuş olup araştırmanın/çalışmanın başvuru dosyasında belirtilen merkezlerde gerçekleştirilmesinde etik ve bilimsel yönden yeterli bulunduğuna toplantıya katılan etik kurul üye tam sayısının salt çoğunluğu ile karar verilmiştir. İlaç ve Biyolojik Ürünlerin Klinik Araştırmaları Hakkında Yönetmelik kapsamında yer alan araştırmalar/çalışmalar için Türkiye İlaç ve Tıbbi Cihaz Kurumu'ndan izin alınması gerekmektedir.	

08.01.2021
ASLI GİBİDİR

Prof. Dr. Turgay ÇELİK
Yeditepe Üniversitesi KAEK Başkanı

Appendix 2. Turkish Ministry of Health Approval

T.C.
SAĞLIK BAKANLIĞI
Türkiye İlaç ve Tıbbi Cihaz Kurumu

NORMAL
01.03.2021

Sayı : E-68869993-511.06-356639
Konu : 2020-101(O)

Sayın Doç. Dr. Hare GÜRSOY
Yeditepe Üniversitesi Diş Hekimliği Fakültesi Periodontoloji Anabilim Dalı
Caddebostan, Bağdat Cd. No:238, 34728 Kadıköy / İSTANBUL

İlgi : a) Kurumumuza 01.02.2021 tarihli ve E.686660 sayılı başvurunuz.
b) Kurumumuza 19.02.2021 tarihli ve E.725751 sayılı başvurunuz.

Sorumlu araştırmacısı olduğunuz aşağıdaki tabloda bilgileri verilen ilgi klinik araştırma başvuru dosyası ve belgeler; araştırmanın gerekçe, amaç, yaklaşım ve yöntemleri dikkate alınarak 06.09.2014 tarihli ve 29111 sayılı Resmî Gazete 'de yayımlanan Tıbbi Cihaz Klinik Araştırmaları Yönetmeliği gereğince incelenmiş olup **Tıbbi Cihaz Klinik Araştırmaları Başvuru Formunda** belirtilen merkezde araştırmanın başlaması uygun bulunmuştur.

Araştırmanın Adı	Periodontitisli Hastalarda Başlangıç Periodontal Tedavide Kullanılan Farklı Araçların Klinik Etkilerinin Değerlendirilmesi: Kontrollü, Paralel Dizayn Klinik Çalışma
Koordinatör Merkez	Yeditepe Üniversitesi Diş Hekimliği Fakültesi
Koordinatör / Sorumlu Araştırmacı	Doç. Dr. Hare GÜRSOY
Protokol tarihi / versiyon no	30.12.2020 V:2
BGOF tarihi / versiyon no	30.12.2020 V:2
ORF tarihi / versiyon no	30.12.2020 V:2
Araştırma Broşürü tarihi / versiyon no	
Proje Yürütücüsü	--

Bu kapsamda yukarıda ayrıntıları verilen çalışma ile ilgili olarak;

- Araştırmanın başlamaması, iptali veya sonlandırılması halinde tarafımıza bilgi verilmesi,
- Araştırma süresince ortaya çıkan advers olayların/etkilerin tarafımıza bildirilmesi,
- Araştırmanın Helsinki Bildirgesi'nin son metni, İyi Klinik Uygulamalar İlkeleri ve ilgili mevzuata uygun olarak yürütülmesi,
- Araştırmada kullanılan her türlü araştırma ürününün ve ürünlerin kullanılmasına mahsus her türlü malzeme ile muayene, tetkik, tahlil ve tedavilerin bedeli için gönüllüden herhangi bir ücret talep edilmemesi,
- Araştırmaya ait yıllık bildirim formunun düzenli olarak Kurumumuza gönderilmesi,
- Sorumlu araştırmacı olarak yazımızın bir örneğinin ilgili etik kurula iletilmesi hususlarında bilgilerinizi ve gereğini rica ederim.

Dr. Asım HOCAOĞLU
Kurum Başkanı a.

Bu belge, güvenli elektronik imza ile imzalanmıştır.
Belge Doğrulama Kodu: YnUyZ1AxQ3NRZW56ZmxXYnUyZW56 Belge Takip Adresi:https://www.turkiye.gov.tr/saglik-titck-ebys

Söğütözü Mahallesi, 2176.Sokak No:5 06520 Çankaya/ANKARA
Telefon No: (0 312) 218 30 00 Faks No: (0 312) 218 34 60
e-Posta: halkla.iliskiler@titck.gov.tr İnternet Adresi: https://www.titck.gov.tr
Kep Adresi: titck@hs01.kep.tr

Appendix 3. Informed Consent Form

Hastanın veya yerine onam verecek kişinin okuma, anlama, konuşma, dil sorunu mevcut mu? Evet Hayır Cevabınız EVET ise Hasta İlişkileri Sorumlusu ile iletişim kurunuz.	**Tercüman gerektiyse;** Tercümanın adı _____ İmza _____ Tarih _____

Sayın Hastamız,

- Bu belge bilgilendirilme ve aydınlatılmış onam haklarınızdan yararlanabilmenizi amaçlamaktadır.
- Size gerçekleştirilebilecek klinik araştırmalar amaçlı girişimler konusunda, tüm seçenekler ile bu girişimlerin yarar ve muhtemel zararları konusunda anlayabileceğiniz şekilde **bilgi alma hakkınız ve bir kopyasını isteme hakkınız** vardır.
- Yasal ve tıbbi zorunluluk taşıyan durumlar dışında **bilgilendirmeyi reddedebilirsiniz**. Yazılı bildirmek koşulu ile bilgi almama veya yerinize güvendiğiniz bir kimsenin bilgilendirilmesini talep etme hakkına sahipsiniz.
- klinik araştırmalara katılım konusunda bilgilendirildikten sonra bunu kabul edebilirsiniz. Ya da **karar verebilmek için uygun zaman talep edebilirsiniz.**
- Hayatınız veya hayati organlarınız tehlikede olmadığı sürece onamınızı (yazılı talep etme koşulu ile) **dilediğiniz zaman geri alabilir** ya da önceden kabul etmediğiniz herhangi bir tanı/tedavi amaçlı girişimi **tekrar talep edebilirsiniz**.
- Hastanemizde verilen hizmetleri **Hastane Tanıtım Broşürü**nden edinebilirsiniz. Ayrıca Hastanemiz personeli hakkında http://www.yeditepehastanesi.com.tr/ web sayfamızdan daha detaylı bilgilere ulaşabilirsiniz.

Burada belirtilenlerden başka sorularınız varsa bunları yanıtlamak görevimizdir.

TANIMLAMA

Protokol numarası: 375

Araştırmanın Adı: ***Periodontitisli Hastalarda Başlangıç Periodontal Tedavide Kullanılan Farklı Araçların Klinik Etkinliklerinin Değerlendirilmesi: Kontrollü, Paralel Dizayn Klinik Çalışma***

Sorumlu Araştırmacının Adı: *Doç. Dr. Hare GÜRSOY*

Yardımcı Araştırmacının Adı: *Dr. Öğr. Üyesi Ebru Özkan Karaca*

Yardımcı Araştırmacının Adı: *Dt. Dila Özbozdoğanlı*

Araştırma Konusu

Mekanik diş ve kök yüzeyi temizliği ile lokal etiyolojik faktörlerin ortadan kaldırılmasını içeren Başlangıç Periodontal Tedavi (BPT) tüm periodontal tedavinin (dişeti tedavilerinin) ilk basamağı ve temeli olarak kabul edilmektedir. Cep tabanına ve mikroorganizmaların yerleşebileceği her bölgeye ve yapıya mekanik olarak ulaşmak BPT nin etkinliğini artırmakta ve periodontal cerrahi gereksinimini azaltmaktadır. Araştırmamızda BPT kapsamında klasik periodontal el aletlerinin ve bunlara alternatif 3 farklı aracın klinik etkinliğinin değerlendirilmek ve karşılaştırmak esas amacımızdır.

Araştırma konusu ile ilgili başka çalışmalar olup olmadığı:

Konuyla ilgili yapılmış benzer çalışmalar bulunmaktadır. Çalışmamızda çalışmaya katılan kişi sayısı ve etkinliğin değerlendirme yöntemleri değişmektedir.

Araştırmaya Katılımcı Sayısı

Çalışmaya tek merkezde (Yeditepe Üniversitesi Diş Hekimliği Fakültesi Periodontoloji Kliniği) 35 ile 60 yaşları arasında 36 hastanın alınması

planlanmaktadır. Çalışmamızda, kliniğimize başvuran hastalardan çalışmaya dahil edilme kriterine uyanlar seçilecektir.

Bu çalışmaya katılmalı mıyım? (Bu bölüm aynen korunacaktır)

Bu çalışmada yer alıp almamak tamamen size bağlıdır. Eğer katılmaya karar verirseniz bu yazılı bilgilendirilmiş olur formu imzalanmak için size verilecektir. Şu anda bu formu imzalasanız bile istediğiniz herhangi bir zamanda bir neden göstermeksizin çalışmayı bırakmakta özgürsünüz. Eğer katılmak istemez iseniz veya çalışmadan ayrılırsanız, doktorunuz tarafından sizin için en uygun tedavi planı uygulanacaktır. Aynı şekilde çalışmayı yürüten doktor çalışmaya devam etmenizin sizin için yararlı olmayacağına karar verebilir ve sizi çalışma dışı bırakabilir; bu durumda da sizin için en uygun tedavi seçilecektir.

Bu Araştırmanın Amacı:

Bu katıldığınız çalışma bilimsel bir araştırma olup, araştırmanın adı "Periodontitisli Hastalarda Başlangıç Periodontal Tedavisinde Kullanılan Farklı Araçların Klinik Etkinliklerinin Değerlendirilmesi: Kontrollü, Paralel Dizayn Klinik Çalışma"dır. Günümüzde periodontal tedaviler geleneksel cihazların yanı sıra daha güncel alternatif aletlerlede yapılmaktadır.
Altın standart olarak kabul edilen, başlangıç periodontal tedavide kullanılan klasik paslanmaz çelik küretler zaman içinde keskinliklerini kaybeder ve bu da etkilerinin azalmasına neden olur. Belli aralıklarla bileylenmesi gereken bu aletler hekim için hem zaman kaybına hem de alette zamanla metal yorgunluğunun oluşmasına sebep olmaktadır. Ayrıca aletin düzenli olarak bileylenmediği durumlarda hekimde karpal tünel sendromuna sebebiyet verirken, hastaların da yeterli tedaviyi alamamasına neden olmaktadır.
Günümüzde aktif olarak kullanılan, paslanmaz çelik küretlere alternatif olabilicek aletler ve cihazlar bulunmaktadır. Bu çalışmanın amacı paslanmaz çelik küretlere altermatif 3 farklı aletletin klinik etkinliğinin değerlendirilmesi ve karşılaştırılmasıdır. Lokalize Periodontitis'li hastalarda dişeti tedavisi kapsamında subgingival olarak uygulanan TIN küret (American Eagle Instruments, MT, ABD), Er:YAG lazer (VersaWave, Delight; Hoya-Con Bio, ABD) ve özel olarak subgingival bölge için dizayn edilmiş çelik uçlu (H3 uç) ultrasonik piezoelektirik cihazların (Acteon PURE Newtron P5 XS B.LED Scaler Unit, France) klinik etkinliğinin klasik paslanmaz çelik periodontal küretlerle kıyaslanarak randomize-kontrollü, paralel dizayn, klinik araştırma ile değerlendirilmesi amaçlanmıştır.

Süresi

Her gruba ait tedavi protokolü başlangıçta ve 3. ayda yapılacaktır ve değerlendirmeler başlangıç ve 6. ayda gerçekleştirilecektir. Çalışmanın toplam süresinin ise 6 ay olması beklenmektedir.

Bu çalışmaya katılırsam beni neler bekliyor?

İzlenecek Yöntem / Yöntemler

Çalışmamız sırasında ilk seansta ağız bakımınız, dişleriniz ve dişetlerinizin durumunu kaydetmek için periodontal muayene takımının içinde bulunan ve rutin muayenede kullanılan periodontal sond dediğimiz bir aletle ağzınızda bazı ölçümler yapacağız ve bu ölçümleri kaydedip başlangıç periodontal tedavi sonrası 6. ayda tekrarlayarak bulduğumuz yeni sonuçlarla karşılaştıracağız.
Genel sağlık durumunuzu, kullandığınız ilaçları, geçirdiğiniz ameliyatları öğrenmek için size bazı sorular soracak ve bu bilgileri de not edeceğiz.
Teşhisimizden emin olmak ve ölçümlerimizi desteklemek için sizden periapikal röntgen alacağız.
Dişeti hastalıklarının nedeni olan bakteri plağı, bakteri plağından korunma yöntemleri, yapılacak olan diştaşı temizliği işlemi ile ilgili detaylı bilgiler size verilerek çalışma planı anlatılacaktır. Diş fırçalama yöntemi, diş ipi ve/veya arayüz fırçası kullanımı öğretilecektir.
Günde 2 kez dişlerinizi bu tekniğe göre fırçalamanızı ve fırçalamayı takiben ara yüz temizliği yapmanız gerekecektir. Ağız hijyen eğitimi (AHE) verildikten sonra sizleri 1 hafta sonra kontrole çağıracağız. Kontrol seansında ağız hijyeninizi sağlayabildiğinizi gördüldüğü takdirde, çalışmaya dahil olmanız için bilgisayar destekli bir programla rastgele olarak 4 gruptan birine yerleştiriliceksiniz.
Periodontal sond ile gerçekleştirilecektir klinik ölçümleriniz yapıldıktan sonra her dört gruptaki hastalara da önce tüm ağıza ultrasonik cihaz (kavitron) ile diştaşı temizliği işlemini takiben en fazla 8 en az 3 dişinizin dişeti ceplerine 2 dak. süreyle bulunduğu grubun aletleri uygulanarak derin temizlik yapılıcaktır ve işlem sonrası steril serum fizyolojik ile yıkanacaktır. Hangi grupta olursanız olun tedavi protokolü 3. ayda da tekrarlanacak, değerlendirmeleriniz ise 3. ve 6. aylarda gerçekleştirilecektir.

Ne yapmam gerekiyor, sorumluluklarım nelerdir?

Yapılacak işlem sonrası hekiminizin önerilerine uymanız ve kontrol randevularınıza aksatmadan gelmeniz gerekmektedir.

Araştırma Sonunda Beklenen Fayda

Çalışmaya katılmanız durumunda tedavi olarak geleneksel yöntemlere göre daha güncel olan bir materyal ile tedaviniz tamamlanırken herhangi bir ücret ödemeniz gerekmemektedir.

Alternatif Tedavi Veya Girişimler

Başlangıç periodontal tedavi, geleneksel aletler olan paslanmaz çelik küretlerle ya da ultrasonik aletlerle yapıldığında da etkili olmaktadır. Ancak güncel aletlerle yapılan tedavilerde tedavi başarısının ve hasta konforunun arttığını belirten çalışmalar vardır.

Çalışmanın riskleri ve rahatsızlıkları nelerdir, göreceğim olası bir zarar durumunda ne yapılacak?

Yapılan işlem sonrası herhangi bir yan etki beklenmemekte, gönüllünün ağız hijyenini optimal seviyede tutması ve verilen önerilere uyması istenmektedir. Tedavi sonrasında olası bir risk ya da komplikasyon beklenmemektedir.
Çalışmamızdan dolayı herhangi bir zarar veya yan etki görmeniz durumunda her türlü tıbbi müdahale yapılacaktır ve konu ile ilgili harcamalar tarafımızdan karşılanacaktır.

Araştırma Sırasında Karşılaşılabilecek Riskler ve Rahatsızlıklar

Yapılan bu işlem diştaşı temizliği işlemidir. Herhangi bir yan etki görülmemesi için verilen önerilere uyulması ve ağız hijyeninin optimal seviyede tutulması gönüllünün sorumluluğundadır. Tedavi sonrasında olası risk, çalışma sonucunda beklenen sonuçların alınamamasıdır. Bu durumda diğer alternatif tedavi yöntemleriyle tedaviniz devam edilecektir.

Risk / rahatsızlık durumlarında yapılması gerekenler

Aşağıda bilgileri verilen araştırmacıya ulaşılmalıdır.

Aşağıdaki özel durumlara ait katılımcı var mı?

	Evet*	**Hayır**
Çocuk		**X**
Mahkum		**X**
Gebe		**X**
Sosyoekonomik eğitimi olarak yetersiz		**X**
Mental yetersizlik		**X**

*****Ancak çocuklarda, hamilelik, lohusalık ve emzirme dönemlerinde ve kısıtlılık durumunda; gönüllüler yönünden araştırmadan doğrudan fayda sağlanacağı umuluyor ve araştırma gönüllü sağlığı açısından öngörülebilir ciddi bir risk taşımıyor ise, usulüne uygun bir şekilde alınmış bilgilendirilmiş gönüllü olur formu ile birlikte ilgili etik kurulun onayı ve Bakanlık izni alınmak suretiyle araştırmaya izin verilebilir.

Çalışma hakkında yeni bilgiler elde edilirse ne olacak? (Bu bölüm aynen korunacaktır)

Araştırmaya katılmaya devam etme isteğinizi etkileyebilecek, araştırma konusuyla ilgili yeni bilgiler elde edildiğinde siz veya yasal temsilciniz zamanında bilgilendirilecektir.

Araştırmadan kendi isteğim dışında çıkmam gerekebilir mi?

Seanslara düzenli geldiğiniz sürece ve kendi isteğiniz dışında araştırmadan çıkmanız gerekmemektedir.

Bu çalışmaya katılmamın maliyeti nedir? (Bu bölüm aynen korunacaktır)

Çalışmaya katılmakla parasal yük altına girmeyeceksiniz ve size de herhangi bir ödeme yapılmayacaktır.

Kişisel bilgilerim nasıl kullanılacak? (Bu bölüm aynen korunacaktır)

Çalışma doktorunuz kişisel bilgilerinizi, araştırmayı ve istatiksel analizleri yürütmek için kullanacaktır. Çalışmanın sonunda, bu bilgiler hakkında bilgi istemeye hakkınız vardır. Çalışma sonuçları çalışma bitiminde tıbbi literatürde yayınlanabilecektir ancak kimliğiniz açıklanmayacaktır.
İzleyiciler, yoklama yapan kişiler, Etik Kurul, Sağlık Bakanlığı ve diğer ilgili sağlık otoriteleri orijinal tıbbi kayıtlarınıza doğrudan erişebilir. Bu yazılı bilgilendirilmiş gönüllü olur formunu imzalayarak yalnızca adı geçen kişi ve kurumlara erişim izni vermiş olacaksınız. Ancak kimlik bilgileriniz gizli tutulacak, kamuoyuna açıklanamayacak; araştırma sonuçlarının yayımlanması halinde dahi kimliğiniz gizli kalacaktır.

Daha fazla bilgi, yardım ve iletişim için kime başvurabilirim?

Çalışma yöntemi/ilacı ile ilgili bir sorununuz olduğunda ya da çalışma ile ilgili ek bilgiye gereksiniminiz olduğunuzda aşağıdaki kişi ile lütfen iletişime geçiniz.

ADI : Dila Özbozdoğanlı
GÖREVİ : Doktora Öğrencisi
TELEFON :

(Katılımcının/Hastanın Beyanı)

Yeditepe Üniversitesi Periodontoloji Anabilim dalında, Dt. Dila Özbozdoğanlı tarafından tıbbi bir araştırma yapılacağı belirtilerek bu araştırma ile ilgili yukarıdaki bilgiler bana aktarıldı ve ilgili metni okudum. Bu bilgilerden sonra böyle bir araştırmaya "katılımcı" olarak davet edildim.

Araştırmaya katılmam konusunda zorlayıcı bir davranışla karşılaşmış değilim. Eğer katılmayı reddedersem, bu durumun tıbbi bakımıma ve hekim ile olan ilişkime herhangi bir zarar getirmeyeceğini de biliyorum. Projenin yürütülmesi sırasında herhangi bir neden göstermeden araştırmadan çekilebilirim. (*Ancak araştırmacıları zor durumda bırakmamak için araştırmadan çekileceğimi önceden bildirmemim uygun olacağının bilincindeyim).* Ayrıca tıbbi durumuma herhangi bir zarar verilmemesi koşuluyla araştırmacı tarafından araştırma dışı da tutulabilirim.

Araştırma için yapılacak harcamalarla ilgili herhangi bir parasal sorumluluk altına girmiyorum. Bana da bir ödeme yapılmayacaktır.

İster doğrudan, ister dolaylı olsun araştırma uygulamasından kaynaklanan nedenlerle meydana gelebilecek herhangi bir sağlık sorunumun ortaya çıkması halinde, her türlü tıbbi müdahalenin sağlanacağı konusunda gerekli güvence verildi.
Araştırma sırasında bir sağlık sorunu ile karşılaştığımda; herhangi bir saatte, Dt. Dila Özbozdoğanlı'yı, Yeditepe Üniversitesi Diş Hekimliği Fakültesi Periodontoloji A.D veya …. numaralı telefondan arayabileceğimi biliyorum.

Bana yapılan tüm açıklamaları ayrıntılarıyla anlamış bulunmaktayım. Bu koşullarla söz konusu klinik araştırmaya kendi rızamla, hiçbir baskı ve zorlama olmaksızın, gönüllülük içerisinde katılmayı kabul ediyorum.

Bilgilendirilmiş gönüllü olur formundaki tüm açıklamaları okudum. Bana yukarıda konusu ve amacı belirtilen araştırma ile ilgili yazılı ve sözlü açıklama aşağıda adı belirtilen hekim tarafından yapıldı. Araştırmaya gönüllü olarak katıldığımı, istediğim zaman gerekçeli veya gerekçesiz olarak araştırmadan ayrılabileceğimi biliyorum.

Söz konusu araştırmaya, hiçbir baskı ve zorlama olmaksızın kendi rızamla katılmayı kabul ediyorum.

İmzalı bu form kağıdının bir kopyası bana verilecektir.

Gönüllünün Adı / Soyadı / İmzası / Tarih

Açıklamaları Yapan Kişinin Adı / Soyadı / İmzası / Tarih

Olur İşlemine Tanık Olan Kişinin Adı / Soyadı / İmzası / Tarih

Gerekiyorsa Yasal Temsilcinin Adı / Soyadı / İmzası / Tarih