

Comparative Evaluation of Gingival Depigmentation by Tetrafluoroethane Cryosurgery and Surgical Scalpel Technique. A Randomized Clinical Study

Abstract

Introduction: Importance of good smile cannot be underestimated in enhancement of beauty, self-confidence and personality of a person. Health and appearance of gingiva is an essential part of attractive smile. Gingival pigmentation gives rise to unesthetic smile line. In present world, with increasing awareness to esthetic, people have become highly concerned about black gums. Various treatment modalities like abrasion, scrapping, scalpel technique, cryosurgery, electrosurgery and laser are available for treatment of gingival pigmentation. The present study was conducted with an objective of comparing efficacy of gingival depigmentation by cryosurgery and scalpel technique.

Method: A Randomized control split mouth study was conducted for 25 patients with gingival pigmentation. Gingival pigmentation Index (GPI) for pigmentation and Visual Analogue Scale (VAS) for pain was evaluated for both test (Cryosurgery) and control sites (Scalpel technique) at baseline, 1month, 3months and 6 months. **Results:** GPI score was 3 and 2 for 21/25 and 4/25 control sites and was 22/25 and 3/25 test sites respectively at baseline. Both the groups showed significant reduction in GPI score i.e., 0 at 1 and 3 months interval after treatment. GPI score increased to 1 for 5/25 sites treated with scalpel technique and 2/25 sites treated with cryosurgery at 6 months interval ($P=0.0691$). This indicates recurrence rate for pigmentation is higher after scalpel treatment. VAS Score was 3 for 10/25 sites treated with scalpel and was 2 for 12/25 sites treated with cryosurgery ($P<0.001$). **Conclusion:** It can be concluded that cryosurgery can be effectively and efficiently used for depigmentation by keeping patients acceptance and comfort in mind and also the long term results and ease of use when compared to scalpel technique.

Keywords: Cryosurgery, gingival pigmentation index, surgical scalpel, tetrafluoroethane, visual analog scale

Introduction

Gingival health and appearance are the essential components of a charming smile. Although clinical gingival pigmentation does not indicate a medical problem, “black gums” may cause complaints regarding esthetic problems, particularly in patients with a high smile line. According to Dummett and Barends,^[1] the distribution of oral pigmentation in dark individuals is as follows: gingiva, 60%; hard palate, 61%; mucous membrane, 22%; and tongue, 15%. Gingival pigmentation occurs as a diffuse, deep-purplish discoloration or as irregularly-shaped brown and light brown patches.

Melanin pigmentation can be treated by various methods that include chemical methods using phenol, alcohol, ascorbic acid, and surgical methods of depigmentation such as gingival abrasion technique,^[2]

split-thickness epithelial excision,^[3] combination technique (gingival abrasion and split-thickness epithelial excision),^[4] free gingival grafting,^[5] and recent methodologies in gingival depigmentation lasers,^[6,7] cryosurgery,^[8] and radiosurgery.^[9]

In recent years, cryosurgery, an effective method of tissue destruction by freezing, is gaining importance as a therapeutic technique. Cryosurgery leads to cell destruction and tissue death attributable to physical and chemical changes induced by freezing. Most vital tissues are frozen at approximately 2°C. The use of cryogen tetrafluoroethane (TFE) is easy, practical, and inexpensive as compared to lasers and other conventional methods such as scalpel or chemical methods. Kumar *et al.* in 2013 concluded by a case series that ultra-low temperature of TFE causes controlled cryonecrosis of

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gingival epithelium and effectively eliminates gingival pigmentation without any significant side effects and esthetically pleasing results.^[10]

There are a number of case reports and case series conducted to evaluate the efficacy of TFE, but there is limited availability of higher level evidences. Hence, this randomized controlled split-mouth clinical study was carried out with an objective to compare the efficacy of gingival depigmentation by TFE cryosurgery and surgical scalpel technique.

Methods

A randomized clinical split-mouth study was carried out in the Department of Periodontics, K M Shah Dental College and Hospital, Sumandeep Vidyapeeth, after obtaining approval from the Institutional Ethics Committee. A total of 25 patients with age range between 20 and 60 years were included in the study, and the sample size calculation was done by the following formula $n = (Z_{\alpha/2})^2 \cdot \sigma^2 / L$, with 95% confidence interval and 20% relative precision.

The patients who complained of hampered esthetics due to “black gums” and had healthy periodontium were included in this study. Exclusion criteria for the study were pregnancy, breastfeeding, systemic diseases which were associated or not associated with the gingival melanin pigmentation, malignancy, medications, uncontrolled diabetes, and the adverse reactions to cryosurgery. The relative contraindications such as cold intolerance and cold urticaria were considered thoroughly. A personal history regarding the smoking habit of the patients was recorded and also habits such as chewing tobacco in any form were also considered and patients with those were excluded from the study. Each patient signed a written informed consent prior to his/her participation in the study, and he or she was duly explained the procedure with its merits and demerits.

Detailed extraoral/intraoral examinations which included the evaluations of the skin pigmentation to correlate with intraoral pigmentation, the perioral pigmented lesions, and the characteristics of the shape, color, surface, and borders of the gingival melanin pigmentation were recorded. Before undertaking any of the depigmentation procedures, all the patients underwent Phase I therapy, following which oral hygiene instructions were given to them.

Gingival pigmentation index (GPI)^[11] was recorded for all the 25 patients before the treatment and at 3, 9, and 12 months after the treatment.

- 0 - Absence
- 1 - Spots of brown to black
- 2 - Brown to black patches but not diffuse
- 3 - Diffused brown to black pigmentation and attached.

Then, the patients were randomly allocated into control and test groups using coin toss method. Allotment was done by

a co-investigator into test group (cryosurgery) and control group (scalpel technique). The primary investigator was blinded with respect to the site selection for the technique that was employed.

Surgical procedure for depigmentation was carried out in maxillary arch from canine to canine. Now, in each patient, TFE cryosurgery was carried out in three anterior tooth regions comprising central incisor, lateral incisor, and canine. The contralateral teeth region was treated using surgical scalpel technique [Figure 1].

The test site before the TFE application was isolated and air-dried. Topical anesthesia with 15% lignocaine spray was used to minimize the discomfort. TFE was sprayed on a cotton swab, which was immediately rolled gently over the pigmented area to include the papillae as well. A freezing zone was continuously maintained for 30–40 s in each area by rolling the dampened swab continuously at the site. This technique was continued along the pigmented gingiva. The procedure took about 15–20 min. The patients were prescribed analgesics if there was any pain.

Before scalpel technique, skin preparation was carried out by 15% povidone-iodine. Local infiltration with local anesthetic solution was carried out. Precautions were taken to prevent soft-tissue injury. Number. 15 surgical blade on a Bard-Parker handle was used. The procedure was performed by scraping the epithelium with the underlying pigmented layer. The raw surface was thoroughly irrigated with normal saline. Results were evaluated, and GPI was recorded at intervals of 3 and 6 months [Figure 2]. Patient perception for pain was recorded on the visual analog scale (VAS). The digital images were taken using a standard magnification and a distance. The total area of the gingival pigmentation was traced and measured with image-analyzing Photomatix software for accurate evaluation of the outcome achieved after the procedure.

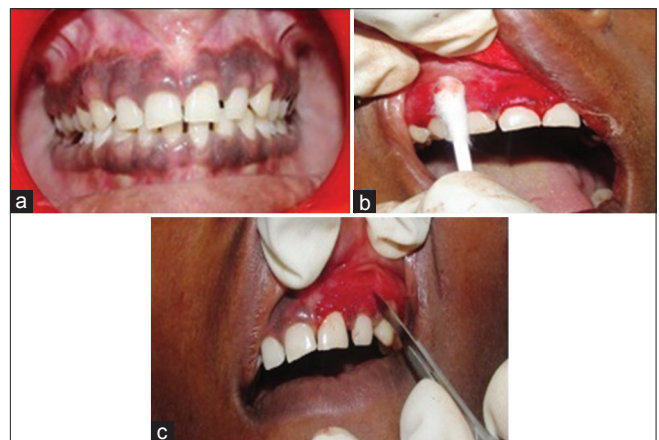


Figure 1: Pre- and intra-operative photograph. (a) Preoperative, (b) depigmentation by cryosurgery on the right side, (c) depigmentation using scalpel on the left side

Observation and Results

The total number of participants included in this randomized split-mouth study was 25. The chief complaint of the participants was “black gums” and they were concerned about their esthetic smile window, and consent was obtained before starting the procedure from each of them. Out of the

25 participants, 20 were males and 5 were females. The parameter used for evaluating gingival pigmentation was GPI, and the perception of pain was evaluated using VAS.

The GPI score was 2 at baseline for four control sites and three test sites and was of 3 for 21 control sites and 22 test sites [Table 1].

Similar GPI scores were noted in both the test and control groups. Hence, there was no reoccurrence at 30 days. The statistical test used was Pearson’s Chi-square test [Table 2].

The GPI scores showed no reoccurrence in both the groups at 90 days using Pearson’s Chi-square test [Table 3].

GPI scores at 180 days were recorded, and the results denoted that only 8% of cases showed reoccurrence in TFE group when compared to scalpel group which showed 20% of reported cases with reoccurrence. However, it is interesting to note that, out of the 25 cases treated, 92% of cases in TFE group and 82% in scalpel group did not show any reoccurrence at 180 days (6 months). The statistical test used was Pearson’s Chi-square test with $P = 0.417$ and this clearly showed that there was no statistical significant difference between the groups [Table 4].



Figure 2: Postoperative photograph showing follow-up at (a) 30 days, (b) 90 days, and (c) 180 days

Table 1: Gingival pigmentation index at baseline

Group	GPI at baseline				Total
	0, n (%)	1, n (%)	2, n (%)	3, n (%)	
Scalpel	0	0	4 (16.0)	21 (84.0)	25 (100.0)
Tetrafluoroethane	0	0	3 (12.0)	22 (88.0)	25 (100.0)
Total	0	0	7 (14.0)	43 (86.0)	50 (100.0)

GPI: Gingival pigmentation index

Table 2: Gingival pigmentation index at 30 days

Group	GPI at 30 days				Total
	0, n (%)	1, n (%)	2, n (%)	3, n (%)	
Scalpel	25 (100)	0	0	0	25 (100.0)
Tetrafluoroethane	25 (100.0)	0	0	0	25 (100.0)
Total	0 (100.0)	0	0	0	50 (100.0)

GPI: Gingival pigmentation index

Table 3: Gingival pigmentation index at 90 days

Group	GPI at 90 days				Total
	0, n (%)	1, n (%)	2, n (%)	3, n (%)	
Scalpel	25 (100)	0	0	0	25 (100.0)
Tetrafluoroethane	25 (100)	0	0	0	25 (100.0)
Total	0 (100)	0	0	0	50 (100.0)

GPI: Gingival pigmentation index

Table 4: Gingival pigmentation index at 180 days

Group	GPI at 180 days				Total
	0, n (%)	1, n (%)	2, n (%)	3, n (%)	
Scalpel	20 (80)	5 (20)	0	0	25 (100.0)
Tetrafluoroethane	23 (92)	2 (8)	0	0	25 (100.0)
Total	43 (86)	7 (14)	0	0	50 (100.0)

GPI: Gingival pigmentation index

Table 5: Mean±standard deviation for 0, 30, 90, and 180 days

	GPI at baseline	GPI at 30 days	GPI at 90 days	GPI at 180 days
Scalpel	2.84±0.374	0	0	0.12±0.332
Tetrafluoroethane	2.88±0.332	0	0	0.16±0.374

GPI: Gingival pigmentation index

Table 6: Visual analog scale scores for perception of pain

Group	VAS scores for perception of pain										Total	
	0, n (%)	1, n (%)	2, n (%)	3, n (%)	4, n (%)	5, n (%)	6, n (%)	7, n (%)	8, n (%)	9, n (%)		10, n (%)
Scalpel	0	5 (20.0)	7 (28.0)	10 (40.0)	3 (12.0)	0	0	0	0	0	0	25 (100.0)
Tetrafluoroethane	4 (16)	9 (36.0)	12 (48.0)	0	0	0	0	0	0	0	0	25 (100.0)
Total	4 (8.0)	14 (28.0)	19 (38.0)	10 (20.0)	3 (6.0)	0	0	0	0	0	0	50 (100.0)

VAS: Visual analog scale

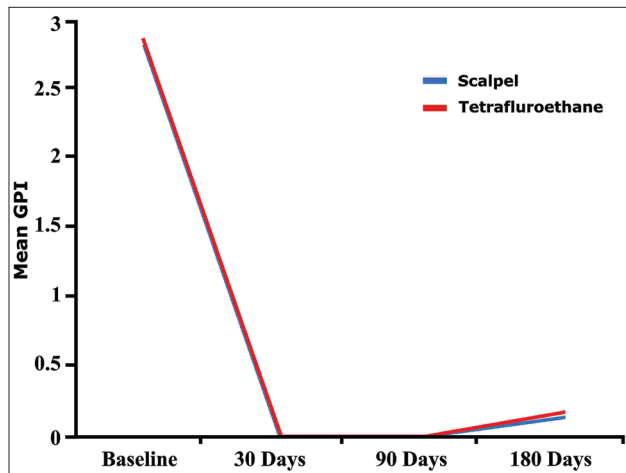


Figure 3: Bar graph showing mean visual analog scale score for both scalpel and tetrafluoroethane groups

The mean GPI at baseline, 30, 90, and at 180 days clearly indicates that there is no reoccurrence at 30 and 90 days, and reoccurrence observed at 180 days showed no statistical significance between both the groups [Figure 3].

Comparing the perception of pain in between the two groups using the VAS, participants preferred the test modality of TFE as compared to scalpel. Majority of the participants gave a VAS score of 3 for scalpel whereas a score of 2 for TFE, indicating a preference for the newer treatment modality of using TFE. When mean scores for VAS were calculated, the graphical outcome showed the same results [Table 6 and Figure 4]. VAS score at 180 days suggests minimal pain and discomfort in TFE group ($P < 0.001$).

Hence, with the results, we can conclude that in the present study the test group (TFE) has shown better results and outcome in all the parameters considered when compared with conventional surgical scalpel technique.

Discussion

We know that physiologic gingival melanin pigmentation is not a medical problem, but patients may complain of

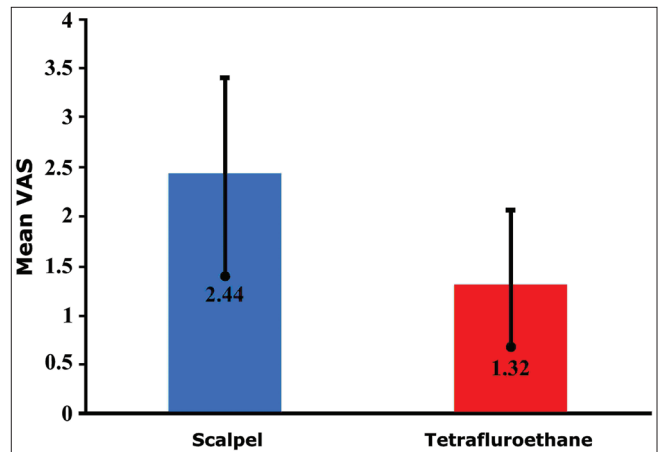


Figure 4: Line graph showing mean gingival pigmentation index at baseline, 30 days, 90 days, and 180 days

unesthetic “black gums.” The patients’ smile window is directly hampered. People nowadays are getting more aware of the esthetics and that has given rise to the dawn of various treatment modalities for the management of gingival hyperpigmentation. In the present study, we have tried to compare the conventional scalpel surgery technique with the recently introduced cryogen TFE technique.

The use of cryosurgery has been incorporated for the treatment of a wide range of lesions in the oral and maxillofacial region. Several researches have been done in the later half of the previous century. Dr. James Arnott (1851) was the pioneer to report the therapeutic use of extremely cold solutions. He had used a mixture of ice and sodium chloride to treat tumors. Dr. Arnott had noticed that cold temperatures have beneficial analgesic along with anti-inflammatory effects.^[11]

By 1950s, liquid nitrogen was taken as an alternative to liquid air as well as oxygen. Nowadays, liquid carbon dioxide remains a commonly used cryogen. Simple methods, such as direct application to the gums with a cotton wool bud (open), and/or use of expensive probes (closed), have been tried with a fair bit of success in dentistry. With several animal and human studies, the

safety and biocompatibility of TFE have been evaluated and concluded to be safe to use as a cryogen. TFE was recently used in dentistry in the field of periodontics for depigmentation.

In the present study, GPI scores were recorded at 30 and 90 days. Recurrence of pigmentation was observed in five cases in scalpel group and two cases in TFE group; the GPI score recorded was 1 in both the groups. Pigmentation may reappear in some cases as a result of the presence of active melanocytes in the basal cell layer of the epithelium, which may not have been removed completely. In general, the ultra-low temperature (-818°C for 10 s) formed by the cryosurgery method resulted in complete epithelial destruction. Complete elimination of the gingival epithelium along with the melanocytes could be achieved. However, in some cases, active melanocytes could have survived and hence could have become active again over time.^[12]

Patient compliance in this study was determined using VAS for pain. The results showed minimal pain following cryosurgery. Hence, there was better patient compliance following cryosurgery.

Most of the past studies carried out on depigmentation modalities are case reports and case series with short- and long-term follow-up. The study done by Kumar *et al.* in 2013 is a case series with ten patients, comparing gingival abrasive technique with TFE, which showed spots of melanin pigment in four patients with the use of gingival abrasion, and in TFE group, three cases showed very minimal spots of pigmentation at 30 days. However, at 90 days, seven cases were reported with recurrence in abrasive technique, but in TFE group, the results showed healthy pink gingiva and no more spots of recurrence. GPI scores at 180 days showed reoccurrence in all the cases treated with gingival abrasion, but only one case showed spots of reoccurrence in cryosurgical group. Follow-up after 2 years in cryosurgical group showed no signs of any repigmentation and only one case was reported with GPI score of 1.^[12]

In a recently carried out study, the perception of pain and discomfort was evaluated by simple questionnaire and/or using VAS. Singh *et al.* (2013) carried out a study comparing TFE and diode laser. The authors used a simple questionnaire to evaluate the perception of pain and found that the cryosurgical approach by TFE was more acceptable, caused less discomfort, and was less painful as compared to diode lasers.^[13]

Another recent study carried out by Kumar *et al.* in 2013 is a case series with 12 patients where they histologically assessed and correlated the effectiveness of the TFE for gingival depigmentation and they concluded that TFE can effectively destroy the gingival epithelium without any harm to the underlying connective tissue and clinically the results were more satisfactory with the color, healing, and

longevity of the results. Hence, TFE can be efficiently and safely used for depigmentation procedure.^[12]

Thus, it can be concluded from the study that the cryosurgical treatment for depigmentation is more effective, easy to perform, and had better patient compliance when compared to scalpel technique.

A randomized controlled trial evaluating the long-term results of cryosurgery, using efficient delivery system for TFE and evaluating histological events in the process of healing after treatment, should be planned to prove the external applicability of results of the present study.

Conclusion

The present study evaluates the effectiveness and efficiency of the newly introduced cryogen TFE with conventional scalpel technique which is till now considered to be most widely used and accepted. The results of this study gave us the vision to think beyond these conventional techniques and also newer modalities such as lasers. The cryosurgical group (test) showed more convincing results in the perception of pain and discomfort in TFE group when evaluated with VAS. Hence, the advantages of TFE not only stick to its storage, transport, ease of use, less technique sensitive, and cost-effectiveness but also the acceptance and compliance of the patient is greater when compared to scalpel technique.

Hence, there is nothing wrong to establish the statement that cryosurgery with TFE has shown better and effective results in every aspect to conventional scalpel technique in the present study. And so, we should be prospectively looking forward to use the novel material (TFE) widely and wisely to treat gingival hyperpigmentation and correction of “smile window” of the patient.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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