COMPARATIVE EVALUATION OF THE EFFECT OF TOPICAL HEPARIN AND ALLANTOIN GEL WITH SILICONE GEL IN THE REDUCTION OF POST-SURGICAL SCARS IN THE MAXILLOFACIAL REGION - A PROSPECTIVE COMPARATIVE STUDY

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Abstract

Background: Excessive Scars such as hypertrophic or keloid scars are frequently the result of dermal tissue proliferating after a skin injury. Patients experience functional and psychological issues from them, and managing them can be challenging.

Aim: To assess the comparative effect on topical Allantoin and heparin gel with that of the silicone gel in the reduction of post surgical scars in maxillofacial region.

Methods: This study was conducted amongst twenty patients, divided into two groups (n=10). Patients in each Group I received heparin + allantoin gel and Group II included patients receiving topical silicone gel. The scar appearance was evaluated prior to starting the intervention and at the end of three months using Vancouver scar scale. The statistics were analysed using the chi-square and Student t tests.

Results: Patients who were included in the silicone group had lower scarring scores according to the Vancouver scale when compared to patients who were given heparin + Allantoin gel, and were statistically significant (p value < 0.05). The response to the treatment was also significantly greater in Group II.

Conclusion: Post surgical scar scores were reduced significantly in patients using silicone gels that those with the heparin-allantoin gel. However, the method of scar reduction differs from each patient and the surgeon. Hence, it must be tailored according to the type of scar and the requirements of the patient.

Keyword: Surgical Scars, Heparin, Allantoin, Silicone, Esthetics

BACKGROUND

A surgical procedure involves incisions and inflammation that leave behind scar tissue. This scar tissue is usually flat and flexible and heals over a period of time. In some individuals, due to certain predisposing factors, this kind of uneventful healing of these scars might not occur [1]. The scars can change in colour, consistency, appearance and may cause itching and pain. Keloids and hypertrophic scars are both types of abnormal scars that are excessive proliferation of tissue that result from an exaggerated response to tissue repair [2]. Keloids extend beyond the original injury site and can be itchy or painful and are seen commonly in smaller injuries like acne, while hypertrophic scars remain within the boundaries of the wound and occur usually after a surgery, trauma and burns [3]. Both types of scar tissue cause functional and esthetic deficits leading to psychological damage to the patient.

Excessive scar tissues are commonly seen in lower face, presternum, pectoral area, upper back, ears, neck and deltoid region of upper arm. 39% to 68% of post surgical patients

exhibited hypertrophic scars, while Post surgical keloids were seen in 5% to 15% ^[4]. Maxillofacial scar management involves a multidisciplinary approach, often including plastic surgeons, oral and maxillofacial surgeons, and dermatologists. Early intervention and close follow-up are key for optimal results. Facial scar treatment depends on the type, size, and characteristics of the scar ^[5]. Various methods have been employed in both the treatment and prevention of such unsightly scars. They include topical agents, corticosteroid injections that flatten and soften scars, LASER therapy that reduce redness, smoother texture and stimulate collagen production, surgical scar revision or excision, dermal fillers to fill depressed scars, microdermabrasion or mechanical exfoliation technique, microneedling that create micro-injuries to stimulate collagen production, cryotherapy and interferon injections ^[6].

Topical agents have been in use for decades for reduction of scars ^[7]. Amongst the various agents available, silicone gel and gel containing a combination of heparin and allantoin. Literature offers various studies evaluating the effectiveness of each of

such topical agents. Silicones work based on the mechanism of action of hydration of the wound and conduction of growth factors to reduce scar formation. A combination of heparin and allantoin gel inhibits the inflammatory process and fibroblast proliferation. The fibroblasts produced are reduced in number and thus scar development is inhibited.

The aim of this study is to determine the comparative effectiveness of heparin and silicone gel with that of allantoin gel for the improvement of post surgical scars and measured using the Vancouver Scar scale.

MATERIALS AND METHODOLOGY

Study setting

The study included patients who presented to the Oral and Maxillofacial Surgery Department at Saveetha Dental College and Hospital, Chennai, Tamil Nadu, India with history of maxillofacial trauma or surgery resulting in a facial scar. The study was approved by the institutional ethics committee (IHEC/SDC/OMFS-2104/22/329) and an informed consent was obtained from each patient.

Intervention

Twenty patients with post surgical/trauma scars were included in the study. All the participants were previously operated for maxillofacial trauma or pathology. The patients were randomly allocated into two groups with scars less than six months of duration - Group I (n=10) and group II (n=10). The patients were allocated into two groups based on sealed opaque envelopes prepared by the investigator and both the operator and the participant were unaware of the study grouping (double blinding). Group I participants were prescribed heparin + allantoin gel and Group II participants received silicone gel. Patients were asked to use the topical gel thrice daily for a period of three months.

Assessment

Photographs were taken at baseline and end of the third month. Patient was periodically reviewed to assess improvement of the appearance of the scar. Scar assessment was done at 0 and 3 months using the Vancouver scar scale. The Vancouver scar scale assesses scars using four variables - Vascularity, height/thickness, pliability and pigmentation. A score ranging from 0 to 13 was given to each of the participants at both time intervals.

Inclusion criteria

Patients aged 18 years or older presenting with facial scars of at least 6 months duration with no signs of infection.

Exclusion criteria

Patients presenting with systemic diseases and patients with irregular follow-up were excluded. Patients with whom follow up was lost were also excluded.

Statistical Analysis

Data were analyzed using SPSS for Windows version 23.0. Normal distribution of continuous variables was assessed using the Kolmogorov-Smirnov test. Categorical variables were compared using Chi-square test. Wilcoxon signed ranks test was used to compare the values between pre-treatment, and post-treatment. Independent groups were compared using Mann-Whitney U test and Student's t-test. A p value of <0.05 was considered significant.

RESULTS

The total participants of the study were divided into two groups - 10 participants in each. Prior to administration of the anti scarring gel, the participants had more and less comparable scores on the Vancouver scar scale. The difference in the intensity of scar was not statistically significant (p value > 0.05). The participants included in Group II (Silicone gel) showed a significant reduction in the scar at the end of three months, while those in the Group I (Heparin +Allantoin gel) showed comparatively lesser reduction in the appearance of the scar. Thus, usage of silicone gel yielded significantly superior values of scar reduction when compared to heparin-allantoin gel (p value = 0.192) (Table 1)(Figure 1A and B). The scar scores before and after treatment for the groups were statistically significant (p < 0.05).

The difference between Group I (Heparin+Allantoin gel) and Group II (Silicone gel) was significant (p < 0.05). In this study, no complications or any adverse effects were reported due to the application of the gel. The response of the scar to either of the treatments can be distinguished as excellent, good, minimal or no response. More number of participants in Group II showed excellent results (40%) while only 20% of participants showed excellent results in Group I (Table 2) (Figure 2 and 3).

Table 1: Mean scar scores

MEAN SCAR SCALE SCORES	GROUP I - HEPARIN + ALLANTOIN GEL	EPARIN + - LLANTOIN SILICON	
PRE OP	10 +/- 0.2	9.5 +/- 1.6	0.09
AFTER 3 MONTHS	4.8 +/- 2.6	3.9 +/- 1.4	0.044
p value	0.025	0.023	



Figure 1 (a): Pre-operative photograph at 3 months



Figure 1 (b): Post-operative photograph after usage of silicone gel

Table 2: Rate of responses of the scar reduction

	GROUP I - HEPARIN + ALLANTOIN GEL		GROUP II - SILICONE GEL	
	SCAR	%	SCAR	%
EXCELLENT	4	40	2	20
GOOD	2	20	3	30
MINIMAL	3	30	4	40
NO RESPONSE	1	10	1	10

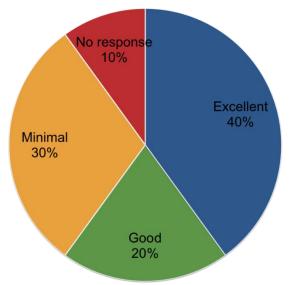


Figure 2: Rate of responses after application of Heparin + Allantoin gel

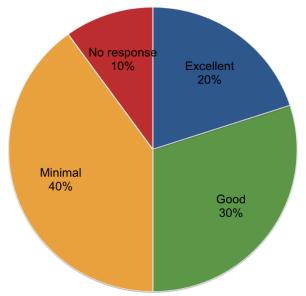


Figure 3: Rate of responses after application of Allantoin gel

DISCUSSION

Keloids and hypertrophic scars predominantly occur in individuals with darker pigmentation, mainly in the South Asian and Hispanic population ^[8]. They commonly occur during and post puberty. The reason for keloids to occur more frequently in

younger individuals is due to the increased rate of collagen synthesis in young adults and due to higher elasticity of the skin ^[9]. They may be seen in a variety of conditions such as post surgical scars, piercings, lacerations, burns, injections, insect bite marks and scars due to chicken pox, acne, etc., Along with any of these, a genetic component also plays a vital role in the development of keloids. Hormonal changes also contribute to keloid formation and they mainly occur in regions with higher concentration of melanocytes ^[10]. Both keloids and hypertrophic scars are caused due to increased wound tension. Inadequate tissue for primary closure increased the tension in between the wound margins. Muscles and bone beneath the skin also exert tension to the overlying skin ^[11].

Wound healing generally takes place in three stages - inflammatory, fibroblastic and maturation. Any alteration in the latter two stages give rise to formation of keloids and hypertrophic scars. In abnormal conditions, the immature fibroblasts continue to proliferate to produce collagen that accumulates over the existing scar tissue [12].

Silicone gels and sheets are synthetic polymers containing dimethyl siloxane monomer. They require dry conditions to work effectively, hence sweating and scars in not easily visible regions are difficult to manage using silicones. In a study by Karagoz et al, there was no significant difference in the usage of silicone gel and sheets for treatment of scars [13]. The heparin and allantoin combination was better than the results provided by the administration of corticosteroid on both new and old hypertrophic scars. They were also used in conjunction with laser to provide reduced scarring in dark skinned patients. On comparison between silicone and heparin-allantoin gel, the former has statistically significant results favouring scar reduction, similar to the results of our study.

In addition to the silicone gel, silicone sheets have also been increasingly used to reduce scar formation. Certain trials have been conducted with the inclusion of Vitamin E to these silicone sheets. One such study by Palmieri et al showed improved results by more than 50% of the cases with incorporation of Vitamin E [14]. The mechanism of action was attributed to the synergistic effect of Vitamin E and the silicone thus preventing synthesis of collagen, proving to be helpful in short time reduction of scarring.

On the contrary to our study, an interventional review by O'Brien et al concludes by providing only weak evidence for the usage of silicone in the reduction of scarring [15]. They included several studies evaluating the effect of silicone gel with that of sheets, with triamcinolone acetonide injections, with lasers and non silicone gels. On comparison with no silicone gels, no statistically significant difference was observed between the two groups in terms of scar width, length or colour. However, the patients treated with silicone gels or sheets reported with irritational dermatitis that was resolved with removal of the gel or sheet.

Newer studies have highlighted the potential of platelet rich plasma in the management of scars. According to Alser et al, the platelet rich plasma (PRP) contains a high concentration of growth factors that promote esthetic outcomes in regions of scar tissue. The study reviewed articles that utilized PRP with fractional CO2 laser to reduce scarring caused due to acne [16]. It increases the quality of the scar and the wound healing properties of the native tissues. The study also found significant improvement by usage of PRP on the texture, colour and contour of the scars and also caused reduction in post operative pain. According to Menchisheva et al, in a randomised controlled trial evaluating the effect of PRP on maxillofacial surgical scars in

the immediate postoperative period ^[17]. Patients receiving PRP showed a two fold better result in scar width at the end of three months thereby improving the patient's satisfaction rates too.

CONCLUSION

Optimal skin closure, flexibility, preservation of underlying structure function, and aesthetically pleasing appearance are the primary goals for wound healing and scar reduction practitioners. In addition to the methods mentioned in our study, there are several treatments available to minimize scarring, such as cryotherapy, laser therapy, pressure therapy, surgical and intralesional corticosteroids. The choice of the treatment depends on a variety of factors from patient to the operator's efficiency. The method must be tailor made according to each patient's requirements and condition.

Conflict of interest:

There are no conflicts of interest.

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Ethical statement:

Not applicable.

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References

- 1. Atiyeh BS. Nonsurgical management of hypertrophic scars: evidence-based therapies, standard practices, and emerging methods. Aesthetic Plast Surg 2007;31(5):468–92.
- 2. Ragoowansi, R., Cornes, P.G., Moss, A.L. et al. Treatment of keloids by surgical excision and immediate postoperative single-fraction radiotherapy. Plast Reconstr Surg 2003; 111: 6, 1853-1859.
- 3. Berman B, Flores F. The treatment of hypertrophic scars and keloids. Eur J Dermatol 1998;8(8):591–5.
- 4. Alster T. Laser scar revision: comparison study of 585 nm pulsed-dye laser with and without intralesional corticosteroids. Dermatol Surg 2003;29(1):25–9.
- 5. Atiyeh BS, Amm CA, El Musa KA. Improved scar quality following primary and secondary healing of cutaneous wounds. Aesthetic Plast Surg 2003;27(5):411–7.
- 6. Eishi, K., Bae, S.J., Ogawa, F., Hamasaki, Y. et al. Silicone gel sheets relieve pain and pruritus with clinical improvement of keloid: possible target of mast cells. J Dermatolog Treat 2003; 14: 4, 248-252.
- 7. Van den Kerckhove E, Stappaerts K, Boeckx W, Van den Hof B, Monstrey S, Van der Kelen A, et al. Silicones in the rehabilitation of burns: a review and overview. Burns 2001;27(3):205–14.
- 8. Nikkonen MM, Pitkanen JM, Al-Qattan MM. Problems associated with the use of silicone gel sheeting for hypertrophic scars in the hot climate of Saudi Arabia. Burns 2001;27(5):498–501.
- 9. Akoz, T., Gideroglu, K., Akan, M. Combination of different techniques for the treatment of earlobe keloids. Aesthetic Plast Surg 2002; 26: 3, 184-188.

- 10. Har-Shai, Y., Amar, M., Sabo, E. Intralesional cryotherapy for enhancing the involution of hypertrophic scars and keloids. Plast Reconstr Surg 2003; 111: 6, 1841-1852.
- 11. Mutalik S. Treatment of keloids and hypertrophic scars. Indian J Dermatol Venereol Leprol 2005;71(1):3–8.
- 12. Malaker, K., Zaidi, M., Franka, M-R.Treatment of earlobe keloids using the cobalt 60 teletherapy unit. Ann Plast Surg 2004; 52: 6,602-604.
- 13. Karagoz H, Yuksel F, Ulkur E, Evinc R. Comparison of efficacy of silicone gel, silicone gel sheeting, and topical onion extract including heparin and allantoin for the treatment of postburn hypertrophic scars. Burns. 2009 Dec;35(8):1097-103. doi: 10.1016/j.burns.2009.06.206.
- 14. Palmieri, B., Gozzi, G. and Palmieri. Vitamin E added silicone gel sheets for treatment of hypertrophic scars and keloids. International Journal of Dermatology, 1995. 34: 506-509. https://doi.org/10.1111/j.1365-4362.1995.tb00628.x
- 15. O'Brien L, Pandit A. Silicon gel sheeting for preventing and treating hypertrophic and keloid scars. Cochrane Database of Systematic Reviews 2006, Issue 1.. DOI: 10.1002/14651858.CD003826.pub2.
- 16. Alser OH and Goutos I. The evidence behind the use of platelet-rich plasma (PRP) in scar management: a literature review. Scars, Burns & Healing, Volume 4, 2018. DOI: 10.1177/2059513118808773.
- 17. Menchisheva Y, Mirzakulova U, Usupova D, Yermukhanova G, Rysbayeva Z. Platelet-rich plasma improves esthetic postoperative outcomes of maxillofacial surgical procedures. Acta Chir Plast. 2021 Fall;63(3):118-126. English. doi: 10.48095/ccachp2021118.