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Efficacy of Topical Cyanoacrylates Compared to Topical Silicone Gel in the Treatment of Hypertrophic Scars

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Abstract. *Aim: The effectiveness of cyanoacrylates compared to silicone gel in improving healing of hypertrophic scars was evaluated. Patients and Methods: Patients presenting hypertrophic scars 6 to 24 months old were enrolled. Asymmetrical scars were treated with cyanoacrylates, linear scars were divided in two parts, one treated with cyanoacrylates, the other with silicone gel. For 3 months, cyanoacrylates were applied every 3-5 days, silicone gel twice a day. Patients' and external observers' assessments were recorded over one year, and photographic records taken. Objective evaluations included width, length and elevation measurements. Statistical significance of parameter modifications was analysed with the Wilcoxon test. Results: A total of 150 patients were enrolled. Positive effects of both tested products were observed without major adverse effects, achieving final scars of better quality. Scar elevation was reduced significantly for both tested products, but apparently more for topical cyanoacrylates. Conclusion: Cyanoacrylates have a positive effect on pathological scars at least comparable to that of silicone gel.*

Normal cicatrization may require up to 6 months before maturation to a flat and inconspicuous scar is attained. When wound healing is distorted, an overabundance of scar tissue results in a hypertrophic scar or keloid (1). Many mechanisms underlying wound healing have yet to be understood, the main difficulty being the lack of an experimental animal model. Moreover, it is impossible to know how a scar will evolve in advance. Hypertrophic scars are unaesthetic stigmata that are among the most common and frustrating problems after an injury and impair quality of life (2).

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Nowadays, patients' expectations in wound care have risen and wound management has become increasingly important to avoid excessive scar formation (3). A fine scar may be the demarcating line between acceptable and unacceptable aesthetic outcomes (4). All known preventive and therapeutic measures should be applied to ensure normal scar maturation. Such measures include correct scar orientation along skin lines of greatest resistance and lowest tension (Langer's lines), correct approximation of wound margins, and use of atraumatic sutures that minimise trauma of the surrounding skin (5). Moreover, as viral/bacterial invasion is presupposed to have a negative influence on cicatrization, proper prevention of wound infiltration is an important preventative measure (6).

More than one hundred clinical studies on hypertrophic scar and keloid therapy have been published over the last 25 years, but only few have been prospective controlled studies based on corroborated data (7). The assessment of therapy efficacy has been limited by the difficulty in quantifying changes in scar appearance, and by the natural tendency for scars to improve over time. Thus, cutaneous scar management has relied heavily on the experience of practitioners rather than on the results of large-scale randomized controlled trials and evidence-based techniques (8). As a satisfactory response to therapy has never been clearly defined, it is difficult to compare different treatment modalities and clinical studies. A partial response, which may still leave a cosmetically unacceptable scar, is considered as therapeutic success in most studies.

Silicone gel sheeting and intra-lesional corticosteroid injection play a primary role in the battle against pathological scars. Many authors agree on the effectiveness of these two therapies, which has also been reported in long-term studies (8). The occlusive action of silicone gel has a positive effect on scar maturation, although its mechanism of action remains unknown (9, 10). In recent years, multiple silicone gel products have been marketed with the implication that they are equivalent to silicone gel sheeting in efficacy (11, 12).

Another therapy considered to be effective, although not on the basis of prospective studies on large series, is the use of a hypoallergenic micropore tape, fixed perpendicularly to the wound edges. This tape is believed to help the cicatrization process by reducing tension on the scar (13, 14). In practice, it exploits the same principle as directing scars along Langer's lines. Indeed, scars oriented along expression wrinkles or sites not subjected to traction evolve more satisfactorily.

Every attempt must be made to prevent the development of hypertrophic scars or keloids after surgery or trauma. An accurate surgical technique and prevention of post-surgical infection are of primary importance (15). Moreover, special attention should be paid to high-risk patients. We believe that the ideal therapy for pathological scarring should be minimally invasive and effective, as well as easily applicable, even by the patient himself. Silicone gel and hypoallergenic tape share these features, explaining their extensive use.

In a previous prospective pilot study, we reported the effectiveness of a cyanoacrylate-based product in improving hypertrophic scars (16). Based on the hypothesis that topical cyanoacrylates combine resistance to traction, occlusive action and antibacterial properties (17, 18), in a prospective study, we tested the effectiveness of such product in improving hypertrophic scars compared, when possible, to topical silicone gel.

Patients and Methods

The study has been presented to and approved by the local Ethical Committee. A prospective pilot study designed to test the effects on hypertrophic scars of Wipescar® (Fasel S.r.l., Bologna, Italy) compared to Dermatix® (Valeant Pharmaceuticals International, Aliso Viejo, CA, USA) was conducted from July 2005 to November 2009.

Wipescar® characteristics. Before use, it is in a liquid form and is composed of 2-cyanoacrylate of methyl monomer [CH_2= C(CN)$COOCH_3$] with a molecular weight of 111.1 Da, a melting point of 79˚C and a density of 1.1 g/cm^3. It is rapidly acting and is highly adhesive as it polymerizes, forming long chains when exposed to humid air or hydroxyl ions.

Dermatix® characteristics. This is a silicone gel for local application, which is transparent and self-dries on the skin. It is a silicone polysiloxane derivative, FDA registered, and a substantial equivalent to the basic long-chain silicone polymer used for silicone gel sheeting. It is applied in a thin layer to the skin.

The patient inclusion criteria were: age between 18 and 65 years, presence of pathological hypertrophic scars of 6 to 24 months old, good health condition, no scar infection, and no previous surgery to improve the scar. The exclusion criteria were: presence of collagen diseases, immunodeficiency, pharmacological treatment affecting the cicatrisation process (*e.g.* corticosteroid, chemotherapy), local radiotherapy, acute or chronic dermatosis, pregnancy, and sensitivity to cyanoacrylate or formaldehyde.

Before enrolment, patients were informed of product features, the necessity for follow-up, and possible risks and side-effects. After study enrolment, they signed a specific informed consent.

Patients affected by asymmetrical scars were assigned to group A and treated with Wipescar®. Patients affected by linear scars that could be divided into equal parts were assigned to group B; the scar was randomly divided into two halves, and halves randomly assigned to be treated with Wipescar® or Dermatix®. For three months, Wipescar® was applied in three successive thin layers (waiting for the product to dry between each application) every 3-5 days, and Dermatix® twice a day.

Three physicians assessed scar characteristics. Evaluations were made before and 1, 3, 6 and 12 months after treatment began. Scars were photographed before treatment and at each follow-up visit. Evaluation included colour, and overall softening for all scars and, width, length and elevation for linear scars only. Scar width was measured objectively with a magnification lens that had a ruler on the contact side. Measurements were made at four predetermined points of each linear scar half (the centre of each quarter) and the average value was calculated. Scar length was measured with a calliper. Skin surface texture and architecture were measured using a computer-assisted digital imaging program (optical profilometry) and scar elevation was evaluated (12, 19). Scar elevation was estimated measuring this value at four different points as previously mentioned.

Furthermore, a global judgment of the scars, including itchiness, colour, pliability, thickness and relief, was expressed by means of a visual analogue scale (VAS) yielding scores from 1 (very hypertrophic bad-looking scar, worst scar imaginable) to 10 (normal flat inconspicuous scar, similar to normal skin) before treatment and 12 months later. In addition, patients expressed their own opinion on the scars by assigning a VAS score at the same time points.

Statistical significance of parameter modifications was evaluated by using the Wilcoxon sum rank test.

Results

A total of 150 patients (89 women, 61 men) with an age ranging between 18 and 52 years (mean: 32 years) were enrolled. All hypertrophic scars were 6 to 24 months old. One patient dropped out of the study for unknown reasons. Two other patients interrupted the treatment: one found the application procedure of Wipescar® too difficult, the other developed erythema and perilesional burning after applying it.

Of the patients that concluded the study, asymmetrical scars were present in 107 patients, included in group A and treated with Wipescar®. After starting the treatment, most patients reported a rapid improvement of scar appearance. Indeed, the scars started losing their reddish colour, in some cases even after the first application, and became flatter and softer. The physicians also noticed improvements in scar appearance, in most cases from the first follow-up visit; the redness was the first feature to improve, followed by softness and thickness.

The patients' judgments of scars before treatment and 12 months after showed a clear improvement (Table I). The physicians' global judgments also reflected an improvement in scar appearance (Table II; Figures 1 and 2).

Table I. *Self assessment of scar global judgment by visual analogue scale (VAS) of patients before treatment (above) and at follow-up end (below).*

	VAS									
Body area (no. of cases)	1	2	3	4	5	6	7	8	9	10
Baseline										
Head (12)		6	2	4						
Neck (16)		4	6	6						
Thorax (22)	4	10	6	1	1					
Shoulder (30)		6	10	8	6					
Back (16)	4	4	6	4						
Limb, superior (6)	1	2	3							
Limb, inferior (5)	1	3		1						
Follow-up end										
Head (12)			2	2	2	4	2			
Neck (16)			2		2	6	5	1		
Thorax (22)				1	2	4	11	4		
Shoulder (30)		1	2	6	7	10	3	1		
Back (16)	1	1	1	3	5	4	1			
Limb, superior (6)			1	2	2	2				
Limb, inferior (5)			1	1		2	1			

Table II. *Global assessment of scars before and after treatment by visual analogue scale (VAS) according to physicians.*

	VAS									
Body area (no. of cases)	1	2	3	4	5	6	7	8	9	10
Baseline										
Head (12)		4	2	5	1					
Neck (16)	1	4	7	4						
Thorax (22)	2	8	6	4	2					
Shoulder (30)	2	2	10	10	6					
Back (16)	2	2	6	6						
Limb, superior (6)	1	2	2	1						
Limb, inferior (5)	1	1	2	1						
Follow-up end										
Head (12)			2	3	3	3	2			
Neck (16)			1	2	4	5	4			
Thorax (22)			2	2	3	4	7	4		
Shoulder (30)		1	4	5	8	8	4			
Back (16)		1	2	4	5	4				
Limb, superior (6)		1	1	2	2					
Limb, inferior (5)			1	1		3				

Overall, a scar improvement was observed in 96 patients (89.7%) at the end of follow-up. Of the 11 patients (10.3%) without improvement, 6 did not display any change in scar appearance at any time, whilst 5 displayed an initial positive response during the first month of treatment followed by a reversal to the initial state in the subsequent months.

Table III. *Assessment by visual analogue scale (VAS) of scars of patients of group B before and one year after starting treatment with Wipescar® on one scar half and Dermatix® on the other half by patients (above) and physicians (below).*

		VAS									
Product used to treat scar		1	2	3	4	5	6	7	8	9	10
Patients											
Wiperscar®	Baseline				2	5	13	14	5	1	
	Endpoint						1	4	28	7	
Dermatix®	Baseline				2	3	11	15	8	1	
	Endpoint						2	3	27	8	
Physicians											
Wiperscar	Baseline				2	5	13	14	5	1	
	Endpoint						2	4	25	9	
Dermatix	Baseline				1	4	12	15	6	2	
	Endpoint						3	5	24	8	

Table IV. *Scar elevation in millimetres (above) on each treatment side at baseline (t0), after one month of treatment (t1) and after one year of treatment (t12). Scar width in millimetres (below) on each treatment side at baseline (t0) and one year after (t12) Statistical significance of modifications from previous values were evaluated by using the Wilcoxon sum rank test.*

	t0, M±SD	t1, M±SD	t12, M±SD
Scar elevation			
Wipescar®	2.338±0.2281	1.245±0.2205	0.822±0.0628
p-Value	-	<0.0001	<0.0001
Dermatix®	2.332±0.2230	1.552±0.2503	1.095±0.0615
p-Value	-	<0.0001	<0.0001
Scar width			
Wipescar®	3.5±0.952	-	3.3±0.861
p-Value	-	-	>0.5
Dermatix®	3.5±0.932	-	3.4±0.904
p-Value	-	-	>0.5

M, Mean; SD, standard deviation.

Linear hypertrophic scars were present in 40 patients, included in group B and treated with Wipescar® on one scar half, and with Dermatix® on the other half. The scars were caused by surgery in 30 cases (55%), and by accidental trauma in 10 cases (25%). Patients noticed that both scars sides started to improve in appearance during treatment. In particular, they reported that scars progressively lost their reddish colour, in two patients even after the first application on the Wipescar® side, and became softer. The patients' overall judgments of scars after 12 months showed the apparent superiority of the side treated with Wipescar® as these appeared flatter and less reddish (Table III; Figure 3). The physicians' global judgments also pointed to the superiority of the scars on the sides treated with Wipescar® (Table III).

Objective measurements demonstrated that scar elevation tended to consistently decrease on both sides in the first month of treatment (Table IV). Scar elevation tended to be reduced progressively in the following months, to stabilise one year after. In fact, the average elevation of scars of both treatment sides was lower after one year compared to 1 month of therapy, with statistical significance (Table IV).

Moreover, scar width tended to slightly decrease over time on both sides, but without statistically significance (Table IV). Scar length remained unchanged.

After starting the treatment, the majority of patients initially encountered some difficulty in applying the topical cyanoacrylate; in particular, they felt a heating sensation lasting a few seconds, due to the polymerization of the product. When necessary, patients were reinstructed on how to correctly apply the product and, thus, this sensation gradually decreased during the subsequent applications and finally disappeared. At the end of the study, the majority of patients were more comfortable applying Wipescar® every 3-5 days compared to applying Dermatix® twice a day.

The 147 patients who completed the treatment and follow-up protocol did not display any adverse effects, such as allergic reactions, prolonged local hyper- or hypothermia, or sense of constriction.

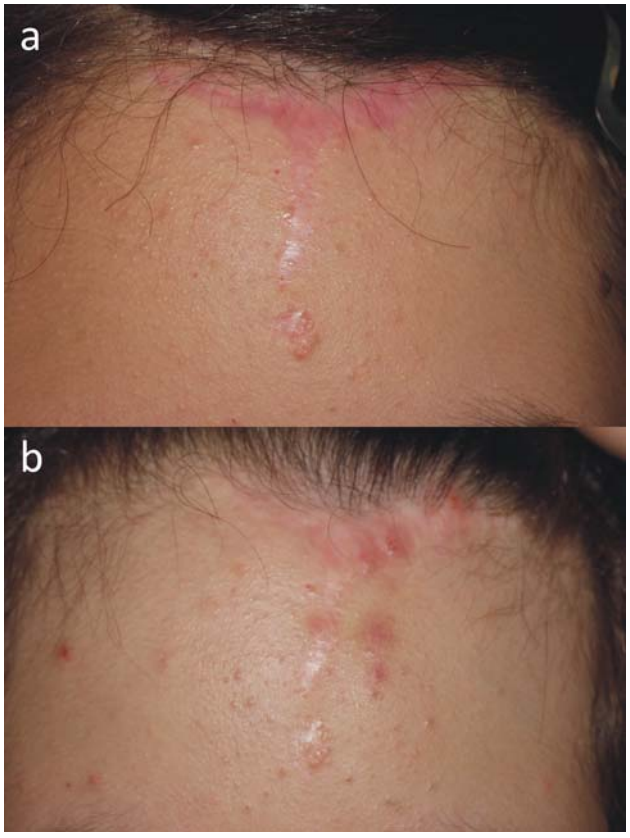

Figure 1. *a: Scar of the frontal area, following the removal of a hemangioma one year earlier, already treated with silicone gel sheeting before staring Wipescar® therapy. b: Clinical appearance 12 months later at the end of follow-up.*

Discussion

The ideal first-line treatment in the cure of hypertrophic scars should be effective, minimally invasive (*e.g.* products applied topically), and easily applicable, even by the patients themselves. Indeed, the widespread use of topical silicone gel is due to the fact that this therapy presents the aforementioned features. This treatment is, nevertheless, but partially effective. Definitely, what should be more effective is a product that combines the properties of silicone gel to others product against pathological scarring (*i.e.* the occlusive action to the resistance to traction and the antibacterial action).

In the medical field, topical cyanoacrylates have been used as tissue adhesive with the scope of external skin suturing material in alternative to conventional suturing materials. The efficacy of these products as suturing material has been proved by many studies (20-27). Such tissue adhesives have also been used as wound dressing material (28) and to form a barrier against microbial infiltration (17, 18, 29, 30).

In our practice, we routinely have used topical cyanoacrylates as external skin suturing and wound dressing material and have noted that surgical wounds and recent scars on which cyanoacrylates have been applied had apparently a better scar maturation process. Based on this observation, we performed a pilot study on the effect of a topical cyanoacrylate-based product named Wipescar® on the maturation process of hypertrophic scars evidencing the positive effect of this therapy (16). In that study we assumed that the positive action on hypertrophic scars was due to the resistance to traction and the occlusive action of Wipescar®. Moreover, several studies have proved that cyanoacrylate-based tissue adhesives serve as a barrier against bacterial infiltration (17, 18, 29, 30). One hypothesis suggests that infectious agents, such as a virus or a bacterium, may act as a triggering cause of keloids on a healing wound (6). It should also be borne in mind that the sites most likely to be affected by keloids are those rich in sebaceous glands, such the thorax and the earlobe. These glands are a bacterial receptaculum that may represent the aforementioned triggering cause during the wound healing process. On the basis of these considerations, a cyanoacrylate-based product may effectively combat the infiltration of infectious agents, thereby preventing and treating pathological scarring. These observations encouraged us to keep evaluating the efficacy and safety of Wipescar® in the treatment of hypertrophic scars on a larger patient population, comparing its effects, whenever possible, to a topical silicone gel. Silicone gel

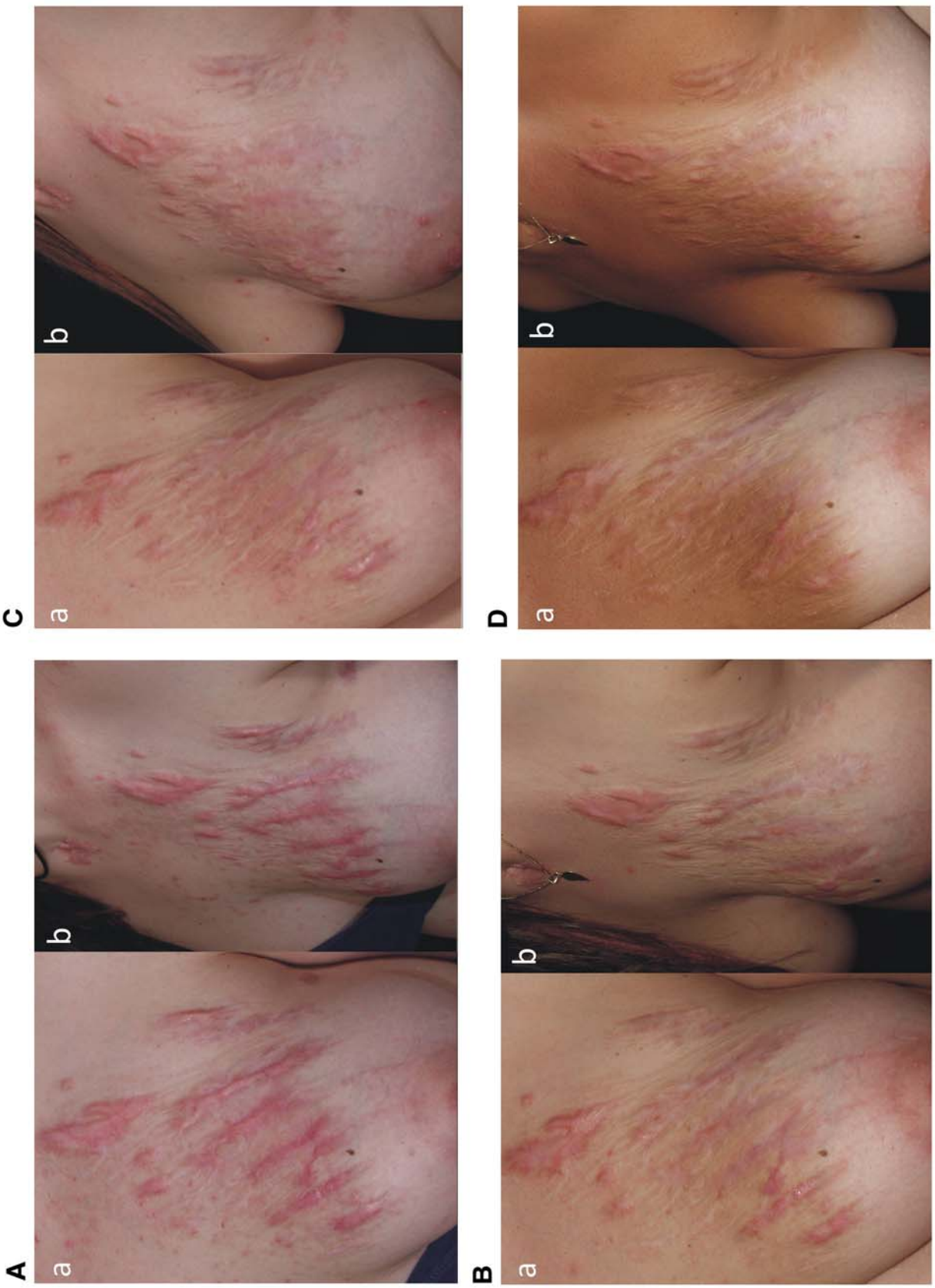

Figure 2. *A: Scars deriving from accidental trauma of the thorax sustained two years earlier, unsuccessfully treated with silicone gel sheeting, before staring Wipescar® therapy: (a) frontal view, (b) oblique view. B: Follow-up after 1 month of therapy: (a) frontal view, (b) oblique view. C: Follow-up 6 months after commencing therapy: (a) frontal view, (b) oblique view. D: Follow-up one year after commencing therapy: (a) frontal view, (b) oblique view.*

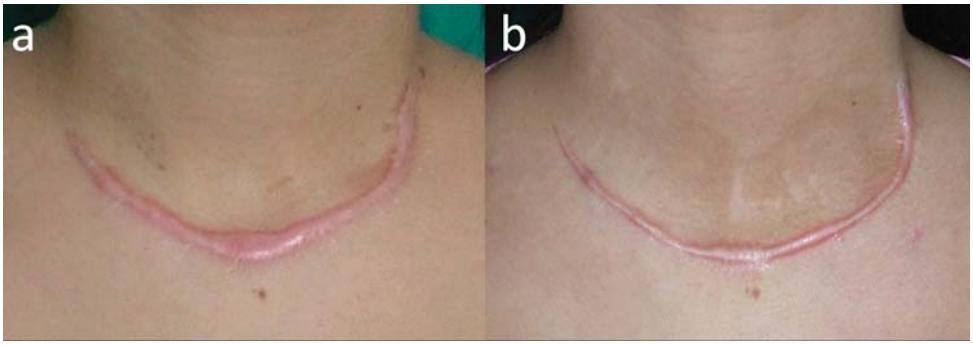

Figure 3. *a: Clinical view of a neck scar 12 months after surgery before starting treatment on the right side with Wipescar® and left side with Dermatix®. b: Clinical view one year after commencing treatment.*

sheeting is considered the first-line treatment in the prevention and cure of pathological scarring and topical silicone gel showed comparable results but gained more patient compliance due to its ease of use (8-12).

The study we are reporting in this article highlighted the following results: i. The silicone-based product was absolutely well tolerated without any case of local intolerance; the cyanoacrylate-based product was well tolerated by patients, with just one case of immediate local intolerance. ii. The majority of patients referred an initial difficulty in applying the topical cyanoacrylate, mainly due to the transient heat sensation, but in the end they were more comfortable in applying this product every 3-5 days, instead of applying the topical silicone gel twice a day. iii. Results summarised in Tables demonstrated the positive effects of both tested products on hypertrophic scars. Both products permitted to reduce scar redness and elevation, to achieve scar softness and to contrast scar widening, obtaining final scars of improved quality. Positive effects persisted during follow-up visits over one year. Moreover, these results are supported by the patients' satisfaction, which was considerable, the physicians' positive judgment and the photographic documentation (Figures 1-3). Furthermore, Wipescar® proved to be more efficacious then Dermatix® in reducing scar elevation (Table IV).

We recognize that assessment measures were subjective and potentially biased in one patient group, but it was not possible to compare the effect of both products on asymmetrical and unequal hypertrophic scars. We performed a blinded randomized control trial only in the group of patients in which linear symmetrical scars were present and used objective measurements to assess these.

In conclusion, the results yielded by this clinical study support the fact that Wipescar® has a positive effect on hypertrophic scars, proving to be at least as effective as Dermatix®. Wipescar® also better reduced scar elevation. These effects would appear to be due to the properties of topical cyanoacrylates, the occlusion effect similar to topical silicone gel, and the resistance to traction as for micropore taping in association with the anti-bacterial properties. Therefore, we consider topical cyanoacrylates useful in improving outcomes in patients with pathological hypertrophic scars.

Acknowledgements

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