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ORIGINAL PAPER

Closure of cutaneous incision after thyroid surgery: a comparison between metal clips and cutaneous octyl-2-cyanoacrylate adhesive. A prospective randomized clinical trial

Annamaria Pronio · Annalisa Di Filippo · Piero Narilli · Daniela Caporillli · Annarita Vestri · Bernardo Ciamberlano · Fabio Pelle · Chiara Montesani

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Abstract Octyl-2-cyanoacrylate (Dermabond, Ethicon Inc.) has been introduced in clinical practice as an ideal system of closure of wounds, but no studies have confirmed the advantages of wound closure performed with Dermabond compared to skin staples (Proximate, Ethicon Inc.) in thyroid surgery. The objective of this study is to evaluate the short- and long-term results of wound closure in thyroid surgery performed with Dermabond (DERM) versus Proximate (PROX). Seventy patients after thyroidectomy were randomly assigned into the two groups (DERM vs PROX). The postoperative and the long-term outcomes were clinically evaluated by physicians, and the Stony Brook scar evaluation scale has also been used. The patients' satisfaction with the early postoperative management and with the cosmetic outcomes has been assessed by a numerical scale ranging from 0 to 10. Results were compared using appropriate statistical tests. Thirty-two patients used DERM, while 38 patients used PROX. Immediate results showed difficult application in two cases DERM (6.2%) and hyperemia in one case DERM (3.1%). Early results showed edema in eight cases DERM (25%) vs two cases PROX (5.2%; $p<0.05$); patients' satisfaction: optimum judgement in 100% DERM vs 15.7% PROX ($p<0.001$); patients' self aesthetic evaluation: PROX higher percentage of excellent results vs DERM ($p<0.005$). After one month, results showed edema in nine cases DERM (28.8%) vs two cases PROX (5.2%; $p<0.01$), while after 6 months, DERM had lesser symptoms than PROX ($p<0.01$). Octyl-2-cyanoacrylate has proven to be effective and reliable in the skin closure of cervical incision similar to suture with staples and yields similar final cosmetic outcomes. Because Dermabond offers the advantage of better management in the early postoperative phase, the patients' satisfaction is clearly better.

Keywords Octyl-2-cyanoacrylate adhesive · Thyroid surgery · Wound closure · Cervical incision repair

A. Pronio · A. Di Filippo (✉) · P. Narilli · D. Caporillli · A. Vestri · B. Ciamberlano · F. Pelle · C. Montesani
Sapienza University of Rome,
Rome, Italy
e-mail: annalisa.difilippo@alice.it

Introduction

One of the most important outcomes of wound repair is the long-term aesthetic or cosmetic appearance of the scar [1]. It is particularly relevant in thyroid surgery since the patients are mostly women and young adults; in that, the aesthetic outcome of the cutaneous scar should be discussed at the initial discussion.

All the different methods of wound closure are designed in order to obtain an ideal reconstruction and should have the following characteristics: simple and fast technique, closure without tension, no subsequent adverse reactions, the creation of a protective barrier to pathogenesis, simple postoperative management, simple atraumatic dressing and suture removal, and optimal cosmetic appearance of the scar [2–13]. Adhesives such as cutaneous cyanoacrylates were already proposed for wound stabilization in the middle of the twentieth century, but were abandoned because of their histotoxicity. The problem was a strong inflammatory skin reaction and inflexibility [14]. A new long-chained chemical formulation of cyanoacrylates re-

cently introduced, obtained by adding a new substitute to the lateral chain, have characteristics which permit their use in clinical practice: e.g., biologic compatibility with the human skin, flexibility, effectiveness in the presence of liquids, impermeability, easy conservation [15–19]. Octyl-2-cyanoacrylate (Dermabond, Ethicon, Inc.) is painless, usually detaches within 5 to 10 days, and does not require crust removal [10, 11]. This appears to be an ideal means of repair. A wide variety of studies have compared the aesthetic outcomes obtained with this compound and those obtained with other standard wound closure methods in skin excisions, e.g., facial plastic surgery, breast surgery, traumatic laceration, and surgical incision repair [10, 11, 20–27]. Evidence-based surgery requires randomized controlled trials [28], and there have been no studies to confirm the advantages of wound closure performed with Dermabond compared to skin staples in thyroid surgery.

The aim of this study was to compare the short- and long-term clinical results of cervical incision repair in thyroid surgery performed with Dermabond versus staples. The following areas were assessed—patient satisfaction with postoperative management, the overall appearance of scars, and whether Dermabond provided better scars than staples.

Material and methods

Prospective randomized trial

There were 70 patients who had undergone thyroid surgery from November 2005 to May 2007. Informed preoperative consent concerning the system and objectives of the study was obtained from all the study participants.

In all cases, a cervical incision was made following the Kocher technique; the average length of the incision was 5 cm (range 4.5–10). After thyroidectomy, the platysmal suture was closed with interrupted buried sutures. In all patients, short-term antibiotic prophylaxis with ceftriaxone was instituted. Only when the surgical procedure was completed, after the closure of the platysma, each patient was randomly assigned to the two treatment groups: in the first group (DERM group) cutaneous adhesive octyl-2-cyanoacrylate (Dermabond, Ethicon Inc.) was used, and in the second group (PROX group) skin staples (Proximate, Ethicon Inc.) were used.

At the end of the procedure, various aspects of skin closure were evaluated: ease of use, rapidity of closure and adverse tissue reactions (hyperemia around the surgical wound). In addition, the approximation of the wound edges was evaluated.

In the PROX group, clips were removed on the second postoperative day and Steri-Strips were placed for 5 days. A dry gauze dressing was used for 1 week after surgery. In the DERM group, Steri-Strips and wound dressing were not used. All patients in both groups spread escina gel on the scar and the surrounding tissues daily for 1 month to decrease post-surgical edema, and they also had protective cover from sun for 6 months to avoid hyperpigmentation of the scar.

In the follow-up over 7 and 15 days, 1-month, 3, 6, and 12-months periods wound-healing process was monitored by clinical assessment and documented by digital photographs. In the early postoperative period over 7 days, wound dehiscence and infection, presence of fever (T> 37.5°C), adverse skin reactions (erythema and phlyctenae), intercurrent adverse reactions in the surrounding tissues (edema, ecchymosis and seroma), symptoms (discomfort and pain), and Non Steroidal Anti Inflammatory Drugs (NSAIDs) or corticosteroids requirement were evaluated.

Patients were asked to rate their level of satisfaction with the early postoperative management of the wound (regarding the requirement of a return visit for medications, the possibility to wash oneself, the suture removal) using a numerical scale ranging from 0–10. In the late postoperative check, over a 15-day period, and in the long-term checks, over a 1-month, 3, 6, and 12-month periods, the following outcomes were evaluated:

1. Appearance of the scar; the scar was classified as regular when all these three features were present: normotrophy (flat scar), some color or lighter than the surrounding skin, linear cicatricial contour; it was classified as irregular when at least one of these features was present: hypertrophy (raised scar in relation to the surrounding skin), color red or purple (darker than the surrounding skin) and contour irregularities;
2. Intercurrent diseases in the surgical site tissues: edema, ecchymosis and seroma;
3. Symptoms: discomfort and pain.

To determine patients' satisfaction with cosmetic appearance of the scar at each assessment, they were asked to provide a score using a verbal rating response and a numerical scale ranging from 0 to 10: 0–4, poor; 5–6, mild; 7–8, good; and 9–10, excellent.

To assess the long-term outcome of scars (over a 1-month to 12-month periods), data have also been translated into the Stony Brook scar evaluation scale (SBSES) that is composed of five dichotomous, evenly weighted categories [1]. Scars are assigned 0–1 point for the presence or absence of a width greater than 2 mm at any point of the scar, a raised (or depressed) scar, a darker coloration than surrounding skin, any hatch or staples marks, an overall poor appearance, the total score ranging from 0 (worst) to 5 (best).

The data collected were compared in the two groups of patients. For statistical analysis, the X^2 Pearson test was used or the exact Fisher test, when appropriate.

Results

Thirty-two patients were enrolled in the DERM group and 38 patients in the PROX group. The average age of the patients was 49 years (range 20–72 years), 53 (75.7%) patients were women. The two groups were similar in baseline characteristics such as age, sex, thyroid disease, cutaneous appearance, inflammatory indexes, coagulation disease, smoke custom. In no case was there a previous history of pathological scarring such as keloid or delayed wound healing, and no patient received radiation after surgery (Table 1).

Immediate results There were no cases of operative death. There were no differences between the two groups regarding the rapidity of application. The application of Dermabond was difficult in two cases (6.2%) because of bleeding from the wound edges. A mild hyperemia around the surgical wound occurred in one patient (3.1%) in the DERM group. The approximation of the wound edges was linear in all cases. The results are shown in Table 2; the differences between the two groups are not statistically significant.

The early outcomes over a 7-day period are shown in Table 3. In the PROX group, an intense skin reaction as phlyctene occurred in three patients (7.8%), whereas in the DERM group, a mild cutaneous reaction as erythema occurred in two patients (6.2%).

Edema around the surgical wound appeared in eight patients (25%) in the DERM group and in two patients (5.2%) in the PROX group ($p<0.05$). There was no evidence of ecchymosis or seroma in either group. There were no differences between the two groups in terms of fever and the requirement of NSAIDs for postoperative pain management or corticosteroids for post-intubation tracheolaryngeal phlogosis management. There were no cases of surgical site infections or wound dehiscence.

A minor incidence of symptoms occurred in the DERM group (discomfort in 11 cases, 34.3%; pain in three cases, 9.3%) versus the PROX group (discomfort in 16 cases, 42.1%; pain in ten cases, 26.3%), although these data did not achieve statistical significance.

Patient satisfaction with the early postoperative management of the wound was very high in the DERM group, an optimum judgement was expressed by all these patients versus 15.7% of patients in the PROX group ($p<0.001$).

At the late postoperative check (over a 15-day period) in the PROX group, the staple marks were only slightly present, and in the DERM group, the glue film was completely dissolved.

The results of the late postoperative and the long-term periods are shown in Table 4. The late outcomes at 15 days

Table 1 Baseline characteristics

No. of patients	DERMABOND $n=32$	PROXIMATE $n=38$	p
Sex, *n* (%)			
Female	24 (75.0)	29 (76.3)	NS
Male	8 (25.0)	9 (23.6)	NS
Average age (years)	47	51	NS
Thyroid disease, *n* (%)			
Benign	28 (87.5)	31 (81.5)	NS
Malignant	4 (12.5)	7 (18.4)	NS
Cutaneous appearance, *n* (%)			
Normotrophic	31 (96.8)	36 (94.7)	NS
Dystrophic	1 (3.1)	2 (5.2)	NS
Normoelastic	27 (84.3)	30 (78.9)	NS
Hypoelastic	5 (15.6)	8 (21.0)	NS
History of previous cheloid and delayed wound cicatrization, *n* (%)	0 (0)	0 (0)	
High inflammatory indexes, *n* (%)	6 (18.7)	11 (28.9)	NS
Coagulation disease, *n* (%)	2 (6.2)	3 (7.8)	NS
Smokers, *n* (%)	12 (37.5)	10 (26.3)	NS
Radiation after surgery, *n* (%)	0 (0)	0 (0)	

NS not significant

Table 2 Immediate results (at the end of the skin closure)

No. of patients	DERMABOND $n=32$	PROXIMATE $n=38$	p
Application, *n* (%)			
Rapid (range 30–60 s)	32 (100)	38 (100)	
Easy	30 (93.7)	38 (100)	NS
Difficult (bleeding from wound lips)	2 (6.2)	0 (0)	NS
Adverse skin reaction, *n* (%)			
Hyperaemia	1 (3.1)	0 (0)	NS
Approximation of the wound edges, *n* (%)			
Linear	32 (100)	38 (100)	

NS not significant

regarding symptoms and intercurrent diseases in the surgical site tissues are similar to the early outcomes, except for the presence of seroma in two patients in DERM group (6.2%) and in one patient in PROX group (2.6%). There were no differences between the two groups in relation to the appearance of the scar. The comparison between the two groups is not statistically significant.

At 1 month, there was a higher incidence of edema in the DERM group (nine cases, 28.8%) versus PROX group (two cases, 5.2%) ($p<0.01$), while the seromas had resolved in both groups. There were no differences between the two groups in terms of symptoms.

Results over 3, 6, and 12 months did not show statistically significant differences regarding the appearance of the scar in the two groups.

With regard to the SBSES over all the long-term observation periods, in both DERM and PROX groups, all patients had scar widths of ≤2 mm, in no patients were there hatch marks or suture marks, and the overall appearance was always good. The total score ranged from 3 to 5.

The DERM group patients had less symptoms than the PROX group patients at the 3-month check (p=ns) and at the 6-month check ($p<0.01$), while no differences were reported at the 12-month check.

The patients' self aesthetic evaluation scores of the cicatricial site are exposed in Table 5.

The PROX group showed a higher percentage of excellent results at the early check ($p<0.005$).

Both groups have shown an increasing satisfaction with the scars at the final follow-up. These data do not achieve statistical significance.

The cosmetic appearances of the scars at the early and late checks are shown in Figs. 1 and 2, respectively.

Table 3 Early postoperative results (over a 7-day period)

No. of patients	DERMABOND $n=32$	PROXIMATE $n=38$	p
Wound dehiscence, *n* (%)	0 (0)	0 (0)	
Infection of surgical site, *n* (%)	0 (0)	0 (0)	
Adverse skin reaction, *n* (%)			
Erythema	2 (6.2)	0 (0)	NS
Phlyctenae	0 (0)	3 (7.8)	NS
Intercurrent disease in the surrounding tissues, *n* (%)			
Edema	8 (25.0)	2 (5.2)	*
Ecchymosis	0 (0)	0 (0)	
Seroma	0 (0)	0 (0)	
Symptoms, *n* (%)			
Discomfort	11 (34.3)	16 (42.1)	NS
Pain	3 (9.3)	10 (26.3)	NS
Fever (T>37.5°C), *n* (%)	9 (28.1)	11 (28.9)	NS
Requirement of NSAIDs or corticosteroids, *n* (%)	26 (81.2)	27 (71.0)	NS
Patients' satisfaction with wound management numerical scale, *n* (%)			
10–9	32 (100)	6 (15.7)	**
8–7	0 (0)	21 (55.2)	
6–5	0 (0)	9 (23.6)	
4–0	0 (0)	2 (5.2)	

NS not significant

*$p<0.05$, **$p<0.0001$

Table 4 Late postoperative (over a 15-day period) and long-term results (over 1-month to 12-month periods)

PERIODS	15 days			1 month			3 months			6 months			12 months		
No.of patients	DERM	PROX		DERM	PROX		DERM	PROX		DERM	PROX		DERM	PROX	
	n=32	*n*=38		*n*=32	*n*=38		*n*=32	*n*=38		*n*=32	*n*=38		*n*=32	*n*=38	
Appearance of the scar, *n* (%)															
Regular	30 (93.7)	NS	36 (94.7)	30 (93.7)	NS	36 (94.7)	32 (100)		38 (100)	30 (93.7)	NS	36 (94.7)	30 (93.7)	NS	34 (89.4)
Irregular	2 (6.2)	NS	2 (5.2)	2 (6.2)	NS	2 (5.2)	0 (0)		0 (0)	2 (6.2)	NS	2 (5.2)	2 (6.2)	NS	4 (10.5)
Intercurrent disease in the surrounding tissues, *n* (%)															
Edema	8 (25.0)	*	2 (5.2)	9 (28.1)	**	2 (5.2)	0 (0)		0 (0)	0 (0)		0 (0)	0 (0)		0 (0)
Ecchymosis	0 (0)		0 (0)	0 (0)		0 (0)	0 (0)		0 (0)	0 (0)		0 (0)	0 (0)		0 (0)
Seroma	2 (6.2)	NS	1 (2.6)	0 (0)		0 (0)	0 (0)		0 (0)	0 (0)		0 (0)	0 (0)		0 (0)
Symptoms, *n* (%)															
Discomfort	12 (37.5)	NS	19 (50.0)	11 (34.3)	NS	12 (31.5)	5 (15.6)	NS	10 (26.3)	0 (0)	**	7 (18.4)	0 (0)		0 (0)
Pain	1 (3.1)	NS	6 (15.7)	1 (3.1)	NS	1 (2.6)	0 (0)		0 (0)	0 (0)		0 (0)	0 (0)		0 (0)
SBSES															
Total score, *n* (%)															
3				0 (0)		0 (0)	0 (0)		0 (0)	1 (3.1)	NS	0 (0)	0 (0)		0 (0)
4				2 (6.2)	NS	2 (5.2)	0 (0)		0 (0)	1 (3.1)	NS	2 (5.2)	2 (6.2)	NS	4 (10.5)
5				30 (93.7)	NS	36 (94.7)	32 (100)		38 (100)	30 (93.7)	NS	36 (94.7)	30 (93.7)	NS	34 (89.4)

NS not significant

*$p<0.05$, **$p<0.01$

Table 5 Patients' self aesthetic evaluation. Numerical score and verbal response expressed over the follow-up periods

Patients' self aesthetic evaluation	Excellent (10–9), *n* (%)			Good (8–7), *n* (%)			Mild (6–5), *n* (%)			Poor (4–0), *n* (%)		
	DERM	PROX		DERM	PROX		DERM	PROX		DERM	PROX	
	n=32	*n*=38		*n*=32	*n*=38		*n*=32	*n*=38		*n*=32	*n*=38	
7 days	7 (21.8)	*	23 (60.5)	16 (50.0)	NS	7 (18.4)	6 (18.7)	NS	7 (18.4)	3 (9.3)	NS	1 (2.6)
15 days	9 (28.1)	NS	20 (52.6)	17 (53.1)	NS	12 (31.5)	6 (19.7)	NS	6 (15.7)	0 (0)		0 (0)
1 month	21 (65.6)	NS	20 (52.6)	6 (18.7)	NS	14 (36.8)	5 (15.6)	NS	4 (10.5)	0 (0)		0 (0)
3 months	21 (65.6)	NS	22 (57.8)	8 (25.0)	NS	14 (36.8)	3 (9.3)	NS	2 (5.2)	0 (0)		0 (0)
6 months	24 (75.0)	NS	28 (73.6)	7 (21.8)	NS	8 (21.0)	1 (3.1)	NS	2 (5.2)	0 (0)		0 (0)
12 months	30 (93.7)	NS	34 (89.4)	2 (6.2)	NS	3 (7.8)	0 (0)	NS	1 (2.6)	0 (0)		0 (0)

NS not significant

*$p<0.005$

Discussion

The clinical application of Dermabond has been studied on various types of wounds, and its efficacy has been demonstrated as is shown in a recent meta-analysis and review [11, 29, 30]. The conditions for the application of cyanoacrilates are intraoperative bleeding control to obtain optimal adhesion of the skin surface, subcutaneous sutures in deep tissue defects to minimize tension in both the epidermis and the film of the glue (the tension of the wound is seen as one of the main limits of the cutaneous adhesive), and crack-free adaption of wound margins to avoid a flow of glue in the wound region [11, 17].

Thyroid surgery is suitable for this type of comparison since it is an aseptic surgery and is a very standardized technique, the surgical incision is always made according to the lines of minimal relaxed tension, the approximation of platysma helps to obtain a wound with minimal tension, and there is little in the way of bias which could alter the outcomes.

We agree with Coulthard, et al in their review of the Cochrane Collaboration [31] that the impact on operation time may not be so important unless the wound closure time is a significant proportion of the operation time. This is in disagreement with the study by Ridgway et al. [27], where the authors conclude that skin staples would be favored over tissue glue for closure of cervicotomy wounds because the cosmetic and functional outcome is similar, and this is attained in a shorter operative time.

In our study, the wound closure time was similar between the two groups in terms of rapidity of application, ranging from 30 to 60 s. Our study also confirmed that octyl-2-cyanoacrylate has negligible histotoxicity. In fact, in the immediate and in the early postoperative period, only a mild skin reaction such as hyperemia and erythema occurred. The metal clips were a cause of intense adverse reactions as phlictene in the early postoperative phase.

The antimicrobial barrier activity of Dermabond for the first 72 h after application is another property which has been shown in recent in vitro studies [14].

In our study, it has not been possible to provide evidence of Dermabond superiority in the prevention of surgical site infections because we have had no cases of infection in either group. In our experience, we have never had wound infection after thyroidectomy, and this data is confirmed by a study of over 1,000 thyroidectomies in our series.

The major reported disadvantage of octylcyanoacrylate tissue adhesive is its reduced tensile strength comparable to 5-0 sutures [30]. In DERM group, we used it alone so that the absence of wound dehiscence in the early postoperative period could be ascribed to the minimized wound tension obtained by the platysma suture.

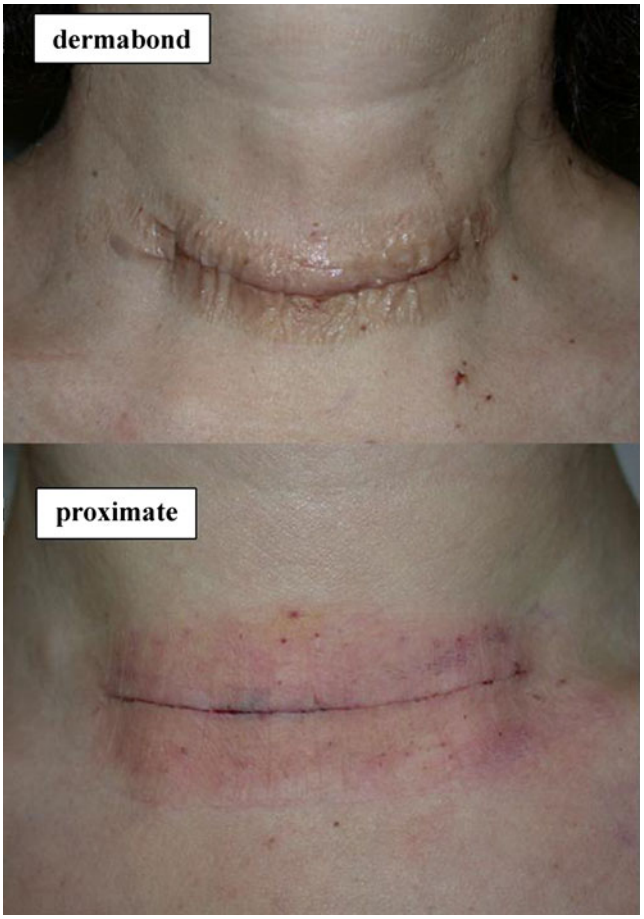

Fig. 1 Cosmetic appearances of the scars at the early checks

No pathologic scarring has been recorded in the long term in all patients, and the irregularities of the scars were negligible in both groups.

In comparison, Dermabond has proven to be effective and reliable in skin closure similar to "traditional" closure with staples. In our opinion, there was no difference on the quality between staples and glue not because the material used for closure is equivalent, only because the healing process is non-specific, in this case, of the type of material used.

The medical literature provides data regarding the painless management of tissue adhesive [11, 18, 19, 30], and this data emerged also in our study. In fact, in the DERM-group patients, a lower level of discomfort and of pain was found at 1 week and 15 days than in the PROX group patients, even if this result does not reach statistical significance.

The DERM group did not require Steri-Strips, owing to the stability and flexibility of the glue film. Also, they did not require wound dressing, owing to the protective impermeable layer created by the glue film. In this way, the most favorable result was the possibility to wash oneself from the first day after operation and the lack of any further wound management.

The aesthetic score expressed in the early postoperative period was better in the PROX group rather than in the DERM group, but both groups of patients scored similar results over the follow-up periods. This initial disappointment can be explained by the fact that the glue gives a wrinkled appearance to the surrounding skin and to the wound, with time, this effect progressively disappears while the adhesive sloughs off. The aesthetic results were excellent in most cases.

Conclusions

In our study, the analysis of the results allows us to affirm that, in thyroid surgery, cutaneous synthesis with 2-octylcyanoacrylate (Dermabond) yields similar clinical results and final aesthetic scarring outcomes of skin staples (Proximate), suggesting that quality of healing of this type of scar is more dependent on the genetics of the patient than on the means of closure [32]. Further trials should be undertaken to investigate this hypothesis.

Because Dermabond offers the advantages of better management in the early postoperative phase, the patient satisfaction is clearly better.

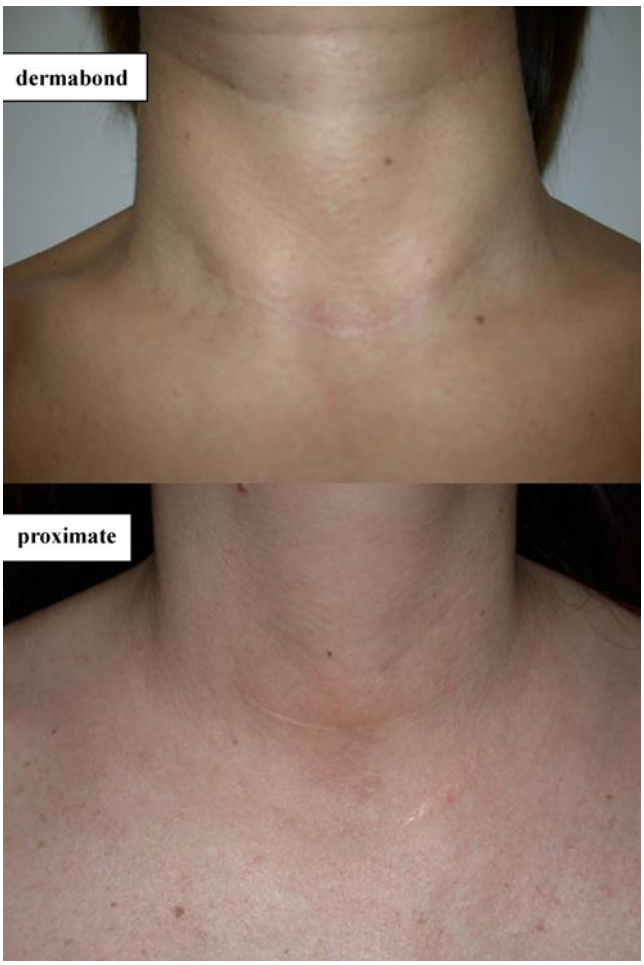

Fig. 2 Cosmetic appearances of the scars at the last checks

Disclosure The authors have no competing financial interests.

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