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The Dermabond Prineo Skin Closure System: Benefits and Complications

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Abstract

Objective: The Dermabond[™] Prineo[™] Skin Closure System (DP; Ethicon, Somerville, NJ) combines the effectiveness of cyanoacrylate with a self-adhering mesh. DP is used for orthopedic surgery, abdominoplasty, excisional body-contouring procedures, mastopexy, reduction mammoplasty, spine surgery, and obstetrics. Many studies compared DP–type systems with conventional wound-closure methods and found numerous advantages and some complications for the newer system.

Methods: This review covers 22 studies reporting side-effects of DP or comparing this skin-closure system with others.

Results: Superficial- or deep-wound complications, surgical-site infections, cellulitis, delayed wound healing, dehiscence, allergic contact dermatitis, prolonged discharge from wounds, or necrosis were the main side-effects reported.

Conclusions: DP is safe, according to various studies. It has many advantages, such as cost and operating-time reduction, better cosmetic results, and-more-hygienic management of wounds. Several studies claim that there are no significant differences from conventional wound closure in terms of complications. However, there is a potential risk for a type IV hypersensitivity reaction, which is one of the most-important complications related to the DP-type skin-closure system. More research is needed to analyze the adverse outcomes thoroughly, plus analyses of costs, operating times, and cosmetic results of various types of wound-closure system, including this one, to and tailor the best choice of wound closure for each patient following surgery. (J GYNECOL SURG 20XX:000)

Keywords: Dermabond Prineo Skin Closure System, wound care, surgical-site, surgical wound

Introduction

T ISSUE ADHESIVES, usually composed of cyanoacrylates, have been used for 70 years for skin closures in surgical procedures.¹ DermabondTM (2-octyl cyanoacrylate; Ethicon, Somerville, NJ) helps reduce operating time, improves cosmetic outcomes, reduces risk of dehiscence, has lower infection rates, and reduces costs, compared to the standard subcuticular-suture method of skin closure.^{1,2} The DermabondTM PrineoTM Skin Closure System (DP; also Ethicon) is a method of wound closure that combines the effectiveness of Dermabond with a self-adhering mesh called Prineo.³ This system, is designed to combine the advantages of the cyano-acrylate with the mesh to help create a waterproof, microbial barrier for wounds.⁴ The mesh is placed over the incision site and filled with 2-octyl cyanoacrylate, delivered through a pen;

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the medication, according to the production source, should not be removed before the tenth postoperative day.⁵

This wound-closure system is used various fields of surgery, including orthopedic surgery, abdominoplasty, excisional body-contouring procedures, mastopexy, reduction mammoplasty, spine surgery, and cesarean-section, per the current authors' experience.

Many studies compared the DP-type wound closure system with conventional wound closure and noted numerous advantages and some complications for the new system.

Decreasing operative time^{3,6–10} and cost^{1,3,7,9–11} are 2 of the most-evident benefits observed. The DP system enables quick and smooth skin closure, especially for long incisions.^{3,6,7,12} DP's application and removal are fast and easy but painful for patients and, yet, guarantee good cosmetic results in vascularization and pliability, according to various studies.^{3,9,13–15} The skin adhesives also seal wounds, increase wound-closure strength, and minimize wound complications.^{3,8,9,11,12,15,16} Moreover, DP allows patients to shower immediately after surgery^{3,7} and could reduce the need for follow-up visits.¹⁷

Many studies have cited allergic contact dermatitis (ACD) after previous exposure to DP products or in patients who had histories of uneventful exposures to other acrylates.^{5,13–16,18–22} Indeed, DP's complications, in some cases, were related to a type IV hypersensitivity reaction,^{4,8} which was a delayed reaction to a substance that the patients were exposed to previously.²⁰ Dehiscence, necrosis, surgical-site infections (SSIs),^{1,3,6,9,10,12,13,17} and cellulitis¹¹ are other side-effects that have been observed in patients treated with DP. Although various studies on DP have been carried out, the adverse outcomes have never been summarized despite DP's increased applications in several fields of surgery. Therefore, this short review summarizes the adverse outcomes reported after DP use.

Methods

Search strategy

To conduct this review, the methodological framework developed by Arksey and O'Malley²³ was adopted. Arksey and O'Malley's framework²³ includes 6 stages (the sixth being optional) as follows:

- (1) Formulating a research question that is generally broad in nature
- (2) Identifying relevant studies as comprehensively as possible
- (3) Establishing inclusion/exclusion criteria, based on familiarity with the literature, to selecting relevant studies
- (4) Charting the data, which includes sifting and sorting information according to key issues and themes
- (5) Collating, summarizing, and reporting the results to provide a descriptive and numerical summary of the data and a thematic analysis
- (6) Performing a consultation exercise, an additional, parallel step involving key stakeholders to inform and validate study findings.

A systematic review of peer-reviewed articles was therefore carried out using the PubMed database. An initial systematic search was conducted using following query: dermabond prineo AND (adverse reaction OR side effect OR allergy OR dermatitis OR rash OR reaction OR complication) [Title/Abstract]. All articles, without a limit of time were selected in April 2023. Twenty-one studies were obtained. Another article from Google Scholar, regarding some of the current authors' experience, was added.¹⁰

Eligibility criteria, study selection, and data extraction

Selection criteria was based on PICo [Population, phenomenon of Interest and Context].²⁴

Population. Patients who had DP applied as a skin closure system after surgery comprised the population.

Phenomenon of Interest. Inclusion criteria were information about and adverse outcomes of DP use. Exclusion criteria were adverse outcome of other methods of skin closure that were different from DP and studies of other methods of skin closure.

Context: The studies focused on the use of DP. Data were collected without a limit time up till April 2023. The filters were as follows: (1) study and publication types were primary studies of all types (including preprints of non-randomized interventions and randomized controlled studies); and (2) publications in the English-language.

The process

If it was not clear from the abstract whether an. article contained relevant data, the full article was assessed. Preliminary examination of titles and abstracts according to the review questions was carried out. A.L. and L.T. independently assessed and subsequently discussed the quality of all eligible studies. Then the analytic process was completed by categorizing relevant issues and summarizing the findings. Twenty-two articles were included in the systematic review, corresponding to this review's purpose. A narrative synthesis of the selected studies was, therefore, conducted summarizing findings based on different adverse outcomes.

Evidence Synthesis

ACD

ACD is a type IV delayed-type hypersensitivity reaction.¹⁶ For sensibilization to a chemical substance, in allergic people, at least 2 contacts are needed. Once the contacts have occurred, any successive exposure to the allergenic substance induces an ACD. A case series of lowerlimb orthopedic surgery showed the occurrence of an ACD reaction to DP.¹⁶ Dermatitis was confirmed by patch test (showing a positive reaction to the DP glue) in 6 patients with 5 suspected of having ACD. Of these 6 patients, 5 had previous exposure to Dermabond products: 4 patients during earlier orthopedic surgery and 1 patient during repair of a skin laceration. The remaining 1 patient had no previous exposure to DP but had a history of exposure to other cyanoacrylates.

These patients' symptoms included peri-incisional itching (within 4 days of surgery) and rash (within 5 days) that had variable local extensions: 3 patients had rashes below the

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site of glue application and 5 patients had autoeczematization (a disseminated eczematous reaction), with the eczema spreading to a site distant from the original one. All of these ACD reactions resolved within 2 weeks after early removal of the adhesive mesh and corticosteroid treatment without any complication in the patients' surgical outcomes. Two patients were treated with systemic corticosteroids, 1 with both systemic and topical corticosteroids, and 3 with topical corticosteroids only. Four patients were also treated with systemic antibiotics, but only 1 had *Staphylococcus aureus* cultured on swab testing. No patient had a systemic infection.

Only 1 case of ACD was reported in a study that compared DP and interrupted polypropylene suturing in a group of 108 patients undergoing ankle arthroplasty (2.8% versus 0%).¹³ The patient who developed ACD followed by a deep SSI recovered after repeated debridement and polyethyleneliner exchange without implant removal; however, local-flap surgery was needed for removal of soft-tissue necrosis.

Twenty-nine patients with ACD from DP were reported in a wide study in which DP was used in 6088 patients following elective orthopedic surgeries from 2013 to 2016. The ACD incidence was 0.5%.¹⁹ The ACD symptoms included erythema, infiltration, papules and vesicles, bullous reactions, and pruritus. Of the 29 patients, 8 (28%) had previous contact with DP because of previous surgeries, 3 (10%) had previous reactions to skin adhesives, and 7 (24%) were suspected to have had previous contacts with DP because health care workers believed that DP was used during previous surgeries. In 14 patients (48%), previous contacts were not determined. No patch testing was performed to confirm the diagnosis. Most reactions were moderate (48%) or severe (38%). The mean time from surgery to diagnosis was 11.8 days (range: 2-42 days). Removal of DP was performed for all of these patients together with a daily dressing change. Twenty patients (69%) received oral antihistamines.

Sixteen patients (55%) required topical corticosteroids, 5 patients (17%) required oral corticosteroids, and 7 patients (24%) were referred to a dermatologist. All cases of ACD resolved in a mean of 22 days postoperatively. No cases of further complications were reported.

ACD from DP was also described by a retrospective study published in 2021.²⁰ The researchers analyzed 143 cases of patients who underwent orthopedic lower-extremity surgery. Only 4 patients (2.8%) developed postoperative contact dermatitis. Symptoms included eczema and pruritus around the surgical wound. The average postoperative time to the diagnosis was 3.9 weeks. The mesh was removed immediately once the reaction occurred, and the patients were treated with antihistamines and topical steroids. All cases were resolved without complications.

A case report analyzed a severe wound complication in a 61-year-old woman who underwent a left-shoulder hemiarthroplasty.⁴ The wound presented with an intense allergic skin reaction to the dressing material. The first symptoms included redness, drainage, erythema, and mild gapping. The initial impression was a superficial infection or a reaction to the material. The wound was cleaned, the dressing was changed, and the patient was treated with oral antibiotics. Day after day, the wound got worse, and a brown eschar tissue appeared. Fifteen days after surgery, the patient underwent debridement and skin grafting. The outcome was good, and the wound was completely healed. A similar case of ACD was reported for a 72-year-old woman who underwent left-knee arthroplasty.²¹ She had a reaction to the liquid form of acrylate related to a previous exposure during a right-knee arthroplasty. This patient was treated with topical corticosteroids, and she responded over 4 weeks.

Another case was reported in the context of spine surgery.²² It occurred in a 68-year-old woman who underwent, 10 days prior, a cervical discectomy for cervical radiculopathy. After the removal of the DP, she was treated with diphenhydramine, systemic steroids, and oral antibiotics, and had complete resolution.

Three cases of rash consequently to the use of DP in reduction mammoplasty were described in 1 article.¹⁴ In 1 of these patients, a prior adhesive reaction was reported, suggesting an ACD. All of the cases resolved with steroid treatment.

The same results occurred in another report of 2 cases of ACD after knee arthroscopy in pediatric patients.¹⁵ Both patients presented with the reaction as a second exposure to DP and both cases were resolved with administration of diphenhydramine together with a daily dressing change.

Sixty patients who underwent breast procedures were reported in a study on DP.⁵ Four patients (6.6%) developed signs and symptoms of ACD in their second postoperative week. Suture lines had erythema, pruritic rashes, and skin inflammations. Only 1 patient had a history of preexisting exposure to Dermabond. Patients received oral antihistamines and topical steroids. Acute symptoms subsided on average within 2 weeks, while the inflammatory hyperpigmentation that occurred took \sim 3–6 months to resolve.

The efficiency of using DP in excisional body-contouring procedures was demonstrated by an observational study published in 2012.⁸ The researchers analyzed the outcomes of 224 procedures in 180 patients. Intense local allergic reactions were reported in 4 of the 224 procedures (1.8%; 2 reduction mammoplasties, 1 upper-arm lift, and 1 vertical thigh lift). The symptoms occurred after previous exposure to the DP. The patients' wounds had considerable itching, which required early removal and topical corticosteroid treatment. Only 1 patient required treatment for hyperpigmentation in the inframammary fold.

A group of researchers compared DP (n=35) and staples (n=35) in patients undergoing tumor resection and endoprosthesis reconstruction of the proximal femur because of metastatic bone disease.²⁵ Skin closure with DP resulted in a lesser degree, and faster resolution, of wound discharge. On average, patients who had wound closure with staples, required 2.6 additional days to achieve dry wound status, 0.9 additional days of intravenous (IV) antibiotics, and 1.7 additional days of recovery. Of the 8 cases in which major wound discharge was observed, none (0%) occurred in the DP group and the 8 (23%) occurred in the staples group (Table 1).

Wound healing disorders (dehiscence, necrosis, and SSIs)

Wound complications between DP and subcuticular sutures were compared in 100 total knee arthroplasties (n=50and n=50, respectively).⁶ Although there were 5 cases of wound complications with DP (4 dehiscence and 1

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TABLE 1. ARTICLES INCLUDED IN THE STUDY, COMPLICATIONS, AND CONCLUSIONS

Article #, authors, year & ref.	Type of article	Type of surgery	Skin-closure system	# of surgeries	# of complications (%)	Type of complications	Conclusions
1: Michalowitz A,	Retrospective	Arthroplasty	DP	160	20 (12,5%)	Superficial wound	No significant
cl dl., 2020	conot study		exofin fusion [®] skin closure system ^a	121	19 (15.7%)	complications	(p > 0.05)
			DP ^b	160	4 (2.5%)	Cellulitis	Significant
			exofin fusion	121	0 (0%)		(p=0.033)
2: Ricciardo BM, et al., 2020 ¹⁶	Case series	Lower-limb orthopedic surgery	DP	9	v	ACD	
3: Choi KY, et al.,	RCT	Total knee	DP	50	5 (10%)	4 dehiscence, 1 necrosis	No significant
1707		ai uu opiasty	Subcuticular sutures	50	3 (6%)	1 necrosis, 2 wound infections	(p > 0.05)
4: Lee G-W, et al.,	RCT	Ankle arthroplasty	DP	36°	5 (13.9%)	3 dehiscence, 2 SSIs	Significant
707			Interrupted polypropylene suture	72°	2 (2.8%)	Dehiscence	Sufficiences for (p=0.04) No significant differences for other variables (p>0.05)
			DP	36 ^c	1 (2.8%)	ACD	No significant
			Interrupted polypropylene suture	72°	0 (0%)		(p > 0.05)
5: Knackstedt RW, et al., 2015 ¹⁴	Case series	Reduction mammoplasty	DP	ю	ю	ACD (cutaneous rush)	

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Article #, authors, year & ref.	Type of article	Type of surgery	Skin-closure system	# of surgeries	# of complications (%)	Type of complications	Conclusions
6: Meffert L, et al., $\frac{1}{20200^{17}}$	Retrospective	Hip surgery	DP	86	7 (not specified if DP	Wound complications	No significant
0202	conor study		Sutures	110	(%C.C. (Samue Io		butterieuces butteren DP & sutures in superficial nor deep SSIs, respectively, p = 0.9072; p = 0.5064
7: Eichinger JK,	RCT	Shoulder surgery	DP	46	1 (2.1%)	Wound complications	No significant differences
N 41.; 2022			Dermabond ^{TMa} alone or staples	43	0 (0%)	(9700)	(p > 0.05)
8: Robinson J, et al. 2021 ¹⁵	Case series	Knee arthroscopy	DP	7	2	ACD	
9: Dear K, et al., 2020 ¹⁸	Letter to the editor	Orthopedic surgery	DP			ACD	
10: Chalmers BP, et al., 2017 ¹⁹	Retrospective cohort study	Orthopedic surgery	DP	6088	29 (0.5%)	ACD	
11: Lee JC, et al.,	RCT	Reduction	DP	21	0 (0%)		
0107		mannoprasty	Subcuticular suture				
12: Anderson FL, $a_{1} = 2020^{12}$	Retrospective	Total knee	DP	176	2 (1.14%)	Wound complications	Significant
Ct all, 2020			Silver- impregnated occlusive dressings	171	16 (9.36%)		(p < 0.0001)
13: Pate RC, et al., 2020 ⁴	Case report	Shoulder hemiarthroplasty	DP	-		ACD	

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			TABLE	TABLE 1. (CONTINUED)	(
Article #, authors, year & ref.	Type of article	Type of surgery	Skin-closure system	# of surgeries	# of complications (%)	Type of complications	Conclusions
14: Parvizi D, et al., 2013 ³	RCT	Abdominoplasty	DP	30	4 (13.3%)	Purulent wound infection (2), hematoma (1) & delayed wound healing (1)	Statistics not performed
			Resorbable intracutaneous suture with strips	30	5 (16.6%)	Purulent wound infection (1), hematoma (1) & delayed wound healing (3)	
15 : So SP, et al., 2021 ²⁰	Retrospective cohort study	Orthopedic lower- extremity surgery	DP	143	4 (2.8%)	ACD	1
16: Davis MD, et al., 2016 ²¹	Letter to the editor (case report)	Knee arthroplasty	DP			ACD	
17: Huemer GM, et al., 2012 ⁸	Retrospective cohort study	Excisional body-contouring	DP	224 (180 patients)	4 (2.2%)	ACD	
18: Alotaibi NN, et al., 2022 ⁵	Retrospective cohort study	Plastic-surgical breast procedure	DP	60	4 (6.6%)	ACD	I
19: Zhang AS, et al., 2023 ²²	Case report	Spine surgery	DP	1	-	ACD	
20 : Stricker S, et al., 2022 ⁹	Prospective cohort study	Spine surgery	DP	50	17 (34%)	16 minor wound-healing disorders and 1 CSF fistula	
21: Libretti A, et al., 2022 ¹⁰	Clinical trial	Cesarean section	DP	13	1 (7.7%)	Wound complications (1 SSI)	
22: Hettwer WH,	RCT	Resection &	DP	35	0 (0%)	8 cases of prolonged discrementation wound	Significant differences
		proximal femur in metastatic bone disease	Staples	35	8 (23%)	closures with staples	(p < 0.003)

^aexofin fusion[®] skin closure system, Chemence Medical, Inc., Alpharetta, GA ^bBoth DermabondTM PrineoTM Skin Closure System, and Dermabond,TM Ethicon, Somerville, NJ. ^cNumber of *ankles* operated on. DP, DermabondTM PrineoTM; ACD, allergic contact dermatitis; RCT, randomized controlled trial; SSI, surgical site infection; CSF, cerebrospinal fluid.

necrosis), no statistical differences were found comparing DP with subcuticular suture. All cases but 1 were treated with per oral antibiotics. One was treated with IV antibiotics. Three cases were treated with resuturing, 1 with a Steri-Strip (3M, Two Harbors, MN) appliance.

No differences were found in another study in which 2 surgeons compared DP with Dermabond alone (surgeon 1) and with sutures (surgeon 2) in shoulder surgeries.¹ Surgeon 1's patients were randomized to Dermabond (n=21) and DP (n=25), whereas surgeon 2's patients were randomized to staples (n=22) or DP (n=21). Two SSI were reported, 1 in each cohort of surgeon 1 and no complications occurred in the cohort of surgeon 2.

The incidence of wound complications was also studied in 108 total ankle arthroplasties comparing DP and polypropylene sutures.¹³ Dehiscence was reported in 8.3% of DP use and in 2.8% of conventional sutures. Three cases of wound dehiscence, and 1 case of a superficial SSI in the DP group were reported. Among them, 3 finally progressed to deep SSIs. Three cases of wound dehiscence were also reported in the suture group; however, there were no cases of SSIs. In the DP group, 1 case of dehiscence was treated with per oral antibiotics and wound care, another case progressed to an SSI (treated with revision of the arthroplasty and an antibiotic-impregnated cement spacer). Daily dressing changes and antibiotics were needed for 4 cases of dehiscence in the DP group. DP showed significantly high wound-complication rates and no other clinical benefits, compared to interrupted polypropylene sutures in the cases of total ankle arthroplasties, according to the researchers.

SSI rates were compared between DP and sutures in 208 hip fracture care in elders (110 sutures and 98 DP) resulting in 4 superficial and 3 deep SSIs (not specified if DP or sutures group), with no significant differences noted between the DP and sutures groups.¹⁷

Dehiscence of wounds after total knee arthroplasty occurred in 2 of 176 cases of DP use (1.14%), in a study that compared DP with silver-impregnated occlusive dressing (Aquacel,[®] Convatec, London, UK) plus N-butyl-2-cyanacrylate adhesive (SwiftSet,[™] Covidien/Medtronic, Dublin, Ireland).¹² In this latter group (Aquacel plus SwiftSet) dehiscence occurred in 16 patients of 171 (9.36%).

DP-type wound closure and conventional-suture wound closure in abdominoplasty were compared in a clinical study published in 2013.³ The patients were randomized into 2 groups: (1) 30 had conventional skin closure and (2) 30 had cutaneous closure with DP; all patients received prophylactic antibiotics and preoperative bowel preparation. None of these patients had previous exposure to DP. The overall complication rate was 15% (9 of 60 patients): 3 patients (2 in the DP-type group and 1 in the conventional-suture group) developed purulent wound infections 2 weeks after surgery, 2 patients (1 in the DP-type group and 1 in the conventional suture group) had hematomas, and 4 patients (1 in the DP-type group and 3 in the conventional suture group) had delayed wound healing in the middle third of their scars. Although DP-type closure tended to have a higher occurrence of infection, statistical analyses were not performed and the researchers claimed that there were no statistical differences between the groups.

A group of neurosurgeons analyzed use of DP related to pediatric spine surgery.⁹ Minor wound-healing disorders

occurred after 16 of 50 surgeries (32%) and none of them needed surgical-wound revision. The disorders included 10 cases of minimal cutaneous dehiscence, 1 maceration of cutaneous hemangioma adjacent to the surgical wound, and 5 postoperative pseudomeningoceles. Only 1 patient underwent revision surgery for a cutaneous cerebrospinal fistula and a pseudomeningocele (2%).

The DP skin-closure system was compared to exofin fusion[®] (Chemence Medical Inc., Alpharetta, GA)—a 2-ctyl-2-cyanocrylate liquid monomer adhesive combined with a nonwoven polyester mesh—in a study of the 2 methods in 281 total joint arthroplasties (160 DP versus 121 exofin fusion).¹¹ The overall rate of superficial-wound complications was similar for the 2 groups (DP n=20; exofin fusion n=19). No significant differences were found for wound complications.

Furthermore, an SSI was reported in a preliminary study by 2 of the current authors that described the use of DP in cesarean section.¹⁰ Thirteen high-risk obstetric patients were selected; only 1 of them developed an SSI, 10 days postsurgery (7.7%). It resulted in complete healing after a 7-day course of oral antibiotics (Table 1).

Cellulitis

Cellulitis rate was significantly higher in the DP skinclosure group, compared to the exofin fusion group, in the study cited above.¹¹ Researchers compared the 2 methods in 281 total joint arthroplasties (DP n = 160 and exofin fusion n = 121) reporting 4 cases of cellulitis in the DP group versus 0 in the exofin fusion group. Diabetes was reported as a possible limit in the wound healing (33 patients with diabetes in the DP group versus 17 in the exofin fusion group). See Table 1.

Conclusions

DP is a safe type of wound-closure system according to various studies.

It has many advantages, such as cost and operating-time reductions, better cosmetic results, and more-hygienic management of wounds. Diverse studies claim that there are no significant differences from conventional wound closure in terms of complications; and that these results justify DPs increasing use in various fields of surgery.

Nevertheless, both medical professionals and patients should be warned of the potential risk of a type IV hypersensitivity reaction, which is one of the most-important complications related to the DP-type skin closure system.

Other possible complications are dehiscence, necrosis, SSIs, and cellulitis.

Patients' symptoms usually resolve without a significant impact on wound healing if they are recognized and treated early.

Moreover, it is important that all patients for whom DP use is proposed, are asked whether they have previously developed a skin reaction to a similar medication. Patients who do not report histories of skin reaction could be patchtested to a small amount of glue.

Further research is needed to analyze the adverse outcomes deeply together with analyses of costs, operating times, and cosmetic results of diverse types of woundclosure systems, including DP, in order to tailor the best choices for patients following their surgeries.

Authors' Contributions

All of the authors visualized this project. Dr. Libretti conceptualized this review and, with Dr. Troìa, designed the methodology and performed the investigation. Both authors, with Dr. Remorgida, administered the project, and Drs. Remorgida and Surico supervised it. Drs. Libretti and Bracci obtained resources. Dr. Libretti curated the data, and, with Dr. Troia, performed the formal analysis. All of the aforementioned researchers, with Dr. De Pedrini, validated the results. An original draft of this article was composed by Drs. Libretti, Bracci, and Troìa; then, all of the researchers edited and reviewed the article.

Author Disclosure Statement

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