The results of four clinical studies performed with Histoacryl® are summarized below.

1. Amiel et al[1]

A. Study Design

The study was an open-label retrospective trial designed to evaluate the safety and effectiveness of Histoacryl® Blue in approximating surgical incisions at three Israeli centers.

The study population included pediatric patients undergoing elective surgical incisions (i.e., orchidopexy, inguinal hernia, umbilical hernia or hydrocele repair). All incisions were 2 and 5 cm in length and closure was achieved with standard surgical techniques by attending physicians. Final cutaneous closure was performed with Histoacryl®.

Patients were discharged after 4-6 hours of observation. Follow-up visits were 7 days and 4 to 8 weeks (if needed) after surgery. A 12-item questionnaire was completed during a telephone interview with a family member within 6 months after treatment.

B. Study Results

Patient Accounting and Demographics

A summary of patient accounting and demographics as well as wound characteristics are presented in Table 2.

Table 2: Summary of Patient Accounting, Demographics and Wound Characteristics Reported by Amiel et. al[1]

Accounting	**No. of pts (%)**
Patient records reviewed	1098
Patients treated with Histoacryl	1033 (100%)
Wounds treated with Histoacryl	1150
Patients completing 7 day follow-up	905 (87.6%)
Patients attending 4 week follow-up	401 (38.8%)
Surgical Procedure	**N (%)**
Right inguinal hernia repair	407 (37%)
Left inguinal hernia repair	199 (18%)
Bilateral inguinal hernia repair	119 (11%)
Umbilical hernia repair	43 (4%)
Hydrocele repair	167 (15%)
Orchidopexy	163 (15%)
Patient Age	1 mo – 16 yrs
Wound Characteristics	
Length	2 - 5
Depth	ND
Width	ND
Class	ND
Incisions	1050
Lacerations	0
Local Anesthetic use	
Patients using local anesthetic	1033 (100%)

Study Outcomes

The adverse reactions observed in patients are described in Table 1. 1022/1033 (98.9%) of the patients treated with Histoacryl® achieved wound closure without dehiscence or wound edge separation requiring re-treatment.

2. Barnett et al.[2]

A. Study Design

The study was a prospective, randomized trial designed to compare the safety and effectiveness of Histoacryl® Blue and sutures in closing simple pediatric lacerations in an emergency room setting at three facilities in Australia and New Zealand.

Patients between the ages of 4 -12 years were enrolled if they had a clean laceration on any part of the body that was less than 5 cm in length. Patients were excluded if: the wound occurred on the eyelid, mucous membrane or a joint margins (i.e. under any added tension) or if the wound required debridement or plastic surgery.

Patients were assessed after wound closure and at 1 week, 3 and 12 months after treatment.

B. Study Results

Patient Accounting and Demographics

A summary of patient accounting and demographics as well as wound characteristics are presented in Table 3.

Table 3: Patient Accounting, Baseline Demographics and Wound Characteristics Reported in Barnett et al[2]

	Histoacryl Blue	**Control Sutures**
Patient Accounting		
N, patients enrolled	83	80
N, patients treated	83	80
Patients completed:		
1 week	62 (74.6%)	49 (61.2%)
90 days	46 (55.0%)	44 (55.0%)
12 months	36 (43.0%)	34 (43.0%)
Patient Demographics		
Mean Age in months (std. dev.)	69.5 (29)	68.4 (30)
Males	48 (57.8%)	68 (85%)
Wound Characteristics		
Length in cm - mean	1.54	1.68
Depth in cm - mean	ND	ND
Width in cm - mean	0.34	0.28
Wound Class: Clean	100 (100%)	100 (100%)
Incisions	0	0
Lacerations	100 (100%)	100 (100%)
Body Part		
Face	49	64
Scalp	35	29
Other	16	7
Use of Anaesthesia		
General	0	0
Local only	0	80 (100%)
None	83 (100%)	0

Study Outcomes

The adverse reactions observed patients are described in Table 1. Closure of all 200 (100%) wounds was achieved in both treatment groups without dehiscence. (i.e., a wound that came apart by the 7 day follow up visit).

3. Quinn et al[3]

A. Study Design

This study was a prospective, randomized controlled trial comparing closure of pediatric facial lacerations with Histoacryl® Blue and sutures in a single Canadian Emergency room facility.

Patients, under the age of 18, with clean facial lacerations less than 4 cm in length and 0.5 cm in width were eligible for enrollment. Patients with wounds requiring deep layer closure, caused by animal bites, lacerations on hair-bearing surface, crossing mucocutaneous junctions or heavily soiled and requiring debridement were excluded from enrollment.

Patients were evaluated immediately after treatment as well as 5 days and 3 months after wound approximation.

B. Study Results

Patient Accounting and Demographics

A summary of patient accounting and demographics as well as wound characteristics are presented in Table 4.

Table 4: Summary of Patient Accounting, Baseline Demographics and Wound Characteristics Reported by Quinn[3] et al.

	Histoacryl Blue	Control Sutures
Patient Accounting		
N, patients enrolled	41	40
N, patients treated	37	38
Patients completed: 90 days	33 (89.1%)	36 (94.7%)
Patient Demographics		
Age (years)	0.7-16	0.5-15
Mean (years)	4.7	4.5
Sex (Male)	58%	42%
Wound Characteristics		
Length in cm - mean	1.53	1.52
Depth	ND	ND
Width	ND	ND
Wound Class	ND	ND
Incisions	0	0
Lacerations-facial	37 (100%)	38 (100%)
Use of Anaesthesia		
General	0	0
Local only	0	38 (100%)
None	37(100%)	0

Study Outcomes

The adverse reactions observed in patients are described in Table 1. Wound closure without dehiscence was achieved in 34/37 (91.9%) of the Histoacryl and 36/38 (94.7%) of the suture-treated patients.

4. Bruns et al[4]

A. Study Design

This study was a prospective, randomized trial comparing closure of pediatric lacerations with Histoacryl Blue and sutures at three Emergency rooms within the U.S.

Patients between the ages of 1 – 18 years old with lacerations less than 5 cm were enrolled. Wounds requiring the use of subcutaneous sutures were enrolled in this study. Patients with lacerations in areas of high skin mobility or tension (e.g., joints, hands, feet, eyelids, ears, nose, mouth or perineum) were excluded from the study as were lacerations caused by dog bites or extending to the muscle or bone.

Patients were evaluated after wound closure and at 1 week and 2 months after treatment.

B. Study Results

Patient Accounting and Demographics

A summary of patient accounting and demographics as well as wound characteristics are presented in Table 5 .

Table 5: Summary of Patient Accounting, Baseline Demographics and Wound Characteristics Reported by Bruns et al[4]

	Histoacryl	Sutures
Patient Accounting		
N, patients treated	30	31
N, wounds treated	30	31
Attending 2 month visit	30	25
Baseline Demographics		
Median Age	4 years	3 years
Gender (G: male)	24 (80)	25 (80)
Race		
White	14 (47)	19 (61)
Black	16 (53)	12 (39)
Wound Characteristics		
Length in cm - median	1.5	1.5
Depth, (mm)		
<5mm	22 (73%)	22 (71%)
>5mm	8 (27%)	9 (29%)
Width	ND	ND
Wound Class	ND	ND
Incisions	0	0
Lacerations (Facial)	37 (100%)	38 (100%)
Local Anesthetic used		
Patients treated with anesthetic	13/30 (43%)	31/31 (100%)

Study Outcomes

The adverse reactions observed in patients after surgery are described in Table 1. Wound closure without dehiscence was achieved in 29/30 (96.7%) of the Histoacryl and 30/31 (96.8%) of the suture-treated patients.

References

1. Amiel GE, Sukhotnik I, Kawar B, and Siplovich L, "Use of N-Butyl-2-cyanoacrylate in Elective Surgical Incisions- Longterm Outcomes," *J Am Coll Surg*, **Vol 189**, 21-25 (1999)

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