

# Healing by primary closure versus open healing after surgery for pilonidal sinus: systematic review and meta-analysis

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## EDITORIAL by Bascom

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## ABSTRACT

**Objective** To compare open healing with primary closure for pilonidal sinus and optimal closure method (midline v off-midline).

**Design** Systematic review and meta-analyses of randomised controlled trials.

**Data sources** Cochrane register of controlled trials, Cochrane Wounds Group specialised trials register, Medline (1950-2007), Embase, and CINAHL bibliographic databases, without language restrictions.

**Data extraction** Primary outcomes were time to healing, surgical site infection, and recurrence rate. Secondary outcomes were time to return to work, other complications, cost, length of hospital stay, and wound healing rate.

**Study selection** Randomised controlled trials evaluating surgical treatment of pilonidal sinus in patients aged 14 years or more. Data were extracted independently by two reviewers and assessed for quality. Meta-analyses used fixed and random effects models, dichotomous data were reported as relative risks or Peto odds ratios and continuous data are given as mean differences; all with 95% confidence intervals.

**Results** 18 trials (n=1573) were included. 12 trials compared open healing with primary closure. Time to healing was quicker after primary closure although data were unsuitable for aggregation. Rates of surgical site infection did not differ; recurrence was less likely to occur after open healing (relative risk 0.42, 0.26 to 0.66). 14 patients would require their wound to heal by open healing to prevent one recurrence. Six trials compared surgical closure methods (midline v off-midline). Wounds took longer to heal after midline closure (mean difference 5.4 days, 95% confidence interval 2.3 to 8.5), rate of infection was higher (relative risk 4.70, 95% confidence interval 1.93 to 11.45), and risk of recurrence was increased (Peto odds ratio 4.95, 95% confidence interval 2.18 to 11.24). Nine patients would need to be treated to prevent one surgical site infection and 11 would need to be treated to prevent one recurrence after off-midline closure.

**Conclusions** Wounds heal more quickly after primary closure but at the expense of increased risk of recurrence. Benefits were clearly shown with off-midline closure than with midline closure. Off-midline closure should become standard management for pilonidal sinus when closure is the desired surgical option.

## INTRODUCTION

Pilonidal sinus predominantly affects young men of working age. After surgery the wound may be left to heal by primary closure or open healing. Closure methods include midline techniques (suture line within the natal cleft) or off-midline techniques (suture line outside the natal cleft). We determined the relative effects of open healing compared with primary closure for pilonidal sinus and midline versus off-midline wound closure. This paper is based on a Cochrane review.<sup>1</sup>

## METHODS

Eligible studies (see [bmj.com](http://bmj.com) for search strategy) were randomised controlled trials comparing two or more surgical techniques for pilonidal sinus in patients aged 14 years or more. Primary outcome measures were time to wound healing, rate of surgical site infection, and recurrence rate. Secondary outcomes were time to return to work, other complications and morbidity, cost, length of hospital stay, and wound healing rate.

Two reviewers independently assessed study quality, with disagreements resolved by a third. We assessed randomisation, allocation concealment, and completeness of follow-up, and we categorised risk of bias from high to low.

## Statistical analysis

For each outcome we calculated summary estimates of treatment effect (95% confidence intervals). We calculated mean differences for continuous data, and relative risk or Peto odds ratio with 95% confidence intervals for dichotomous outcomes.

We assessed clinical, methodological, and statistical heterogeneity ( $\chi^2$  test and  $I^2$  statistic).<sup>2</sup> Fixed effects models were used unless there was significant evidence of heterogeneity.

## RESULTS

Eighteen trials were included in the review (see [bmj.com](http://bmj.com)).<sup>w1-w19</sup> Sample sizes ranged from 33 to 200 participants (total 1573; see [bmj.com](http://bmj.com)). One group published short term outcomes<sup>w2</sup> and then recurrence data at four years postoperatively.<sup>w3</sup>

Only two studies fulfilled all methodological requirements and were considered at low risk of bias.<sup>w14 w17</sup> Four studies were graded at high risk of bias<sup>w5 w6 w12 w19</sup> and the remaining at moderate risk (see [bmj.com](#)).

Ten studies compared open healing with midline closure techniques,<sup>w2-w12</sup> two compared open healing with off-midline closure,<sup>w1 w13</sup> and five compared midline closure with off-midline closure.<sup>w14-w18</sup> One study compared closed techniques (classic rhomboid with asymmetrical rhomboid).<sup>w19</sup>

#### Time to wound healing

Ten studies reported time to wound healing (data could not be interpreted in one<sup>w10</sup>). Owing to inconsistencies in reporting, data were not pooled but are presented (table). Four trials reported quicker wound healing after primary closure compared with open.<sup>w2 w6 w7 w12</sup> Three studies also showed quicker healing with primary closure although no statistical tests were reported (table).<sup>w4 w8 w9</sup> For the single study using off-midline closure (Z-plasty), a significantly shorter time to healing in the Z-plasty group was found (41 days, 95% confidence interval 20 to 160 *v* 15.4 days, 10 to 34;  $P<0.001$ ).<sup>w13</sup>

One trial (100 participants) reported that midline wounds took significantly longer to heal than off-midline rhomboid flaps (mean difference 5.4 days, 95% confidence interval 2.3 to 8.5 days).<sup>w15</sup>

#### Rate of surgical site infection

Five trials (n=559) assessed the rate of surgical site infection after open healing or primary closure (all techniques).<sup>w2 w5-w7 w13</sup> Infection rates were higher after open healing; this was not statistically significant (1.20, 0.55 to 2.63; see [bmj.com](#)). A single study comparing open healing with Z-plasty reported a non-significant increase in infection after open healing (1.43, 0.58 to 3.55).<sup>w13</sup>

Four trials (n=380) assessed surgical site infection after midline or off-midline closure.<sup>w14-w17</sup> Overall, rates of infection were significantly higher after midline closure (4.70, 1.93 to 11.45; see [bmj.com](#)). Nine patients would need to be treated by off-midline closure to prevent one surgical site infection.

The trial comparing two off-midline procedures (n=68) reported fewer infections after modified asymmetrical flap (3%) than after classic rhomboid flap (23%;  $P=0.03$ ).<sup>w19</sup>

#### Recurrence rate

Recurrence was the most commonly recorded outcome (18 trials). Follow-up of recurrence varied widely. Data were reported in 11 trials (n=994), 10 of which had high follow-up rates (>80%).<sup>w1 w2 w4-w11 w13</sup> Recurrence was a rare outcome (8%) and several trials failed to detect it. Meta-analysis indicated that open healing was associated with a 58% lower risk of recurrence than primary closure (0.42, 0.26 to 0.66; figure). Fourteen patients would require their wound to heal by open healing to prevent one recurrence.

Two trials (n=238) compared open healing with off-midline closure (Karydakias flap,<sup>w1</sup> and Z-plasty<sup>w13</sup>). A random effects model was used for analysis owing to differing surgical technique; no significant difference was shown (0.70, 0.20 to 2.42; figure).

Five trials that assessed recurrence rate for midline and off-midline techniques (n=413) provided data on 24 events (5.8%).<sup>w14-w18</sup> Overall, recurrence rate was significantly higher after midline closure (Peto odds ratio 4.95, 2.18 to 11.24; see [bmj.com](#)). This equates to 11 patients requiring off-midline closure to prevent one recurrence.

#### Time to return to work

Eleven trials reported return to work as an outcome<sup>w1 w2 w4 w5 w13-w15 w19</sup>; data from three could not be pooled.<sup>w6 w8 w17</sup>

Of five trials recording time to return to work (n=563), three used midline closure<sup>w2 w4 w5</sup> and two off-midline closure.<sup>w1 w13</sup> Patients having open healing took longer to return to work (see [bmj.com](#)), regardless of closure type (open *v* closed (all), mean difference 10.48 days, 5.75 to 15.21; midline, 8.56 days, 2.97 to 14.15; off-midline, 15.30 days, 6.44 to 24.16).

Two studies of midline and off-midline closure showed no difference in time to healing (1.68 days, -19.59 to 22.94).<sup>w14 w15</sup>

One study reported earlier return to work after asymmetrical rhomboid flap compared with classic rhomboid flap (9.3 days (SD 0.34) *v* 11.7 (SD 0.45);  $P<0.001$ ).<sup>w19</sup>

#### Other complications and morbidity

Numerous complications were reported by the trials, including maceration, primary failure, wound dehiscence, haematoma, and flap oedema.<sup>w1 w2 w4 w6-w8 w13 w15 w17 w19</sup>

#### Time to wound healing using open healing compared with midline closure techniques

Study	Sample size		Time (days) to wound healing (range)		P value	Result format
	Open healing	Midline closure	Open healing	Midline closure		
Gencosmanoglu <sup>w6</sup>	73	69	79 (21-112)	14 (14-63)	<0.001	Median
Kronborg <sup>w9</sup>	33	32	64 (17-157)	13 (7-203)	NR	Median
Rao <sup>w12</sup>	30	29	61 (34-132)	27 (24-68)	<0.001	Median
Khawaja <sup>w8</sup>	23	23	41 (NR)	14 (NR)	NR	Median
Al-Hassan <sup>w4</sup>	40	42	91 (28-546)	10 (10-15)	NR	Mean
Sondanaa <sup>w2</sup>	59	60	70 (28-266)	14 (14-112)	<0.001	Median
Hameed <sup>w7</sup>	20	23	70 (59-91)	15 (12-21)	<0.05	Mean

NR=not reported.

Owing to heterogeneity of outcomes and reporting of outcomes, a random effects model was selected.

Of seven trials (n=688)<sup>w1 w2 w4 w6-w8 w13</sup> comparing open with closed (all) healing, rates of complications did not differ (0.67, 0.27 to 1.70; see bmj.com).

Two trials reported complications after off-midline rhomboid flaps compared with midline closure.<sup>w14 w15</sup> A clear benefit was shown with off-midline closure (8.94, 2.10 to 38.02). One study reported a higher complication rate (dehiscence) after classic rhomboid flap (23%) than after modified asymmetrical flap (3%; P=0.03).<sup>w19</sup>

**Patient satisfaction**

One study<sup>w15</sup> reported a preference for off-midline closure compared with midline closure, where satisfaction was measured using a 0-10 scale, although a mean difference of one point is unlikely to be clinically meaningful.

**Cost**

Only one trial reported data on cost and found that midline closure was cheaper than open healing.<sup>w7</sup>

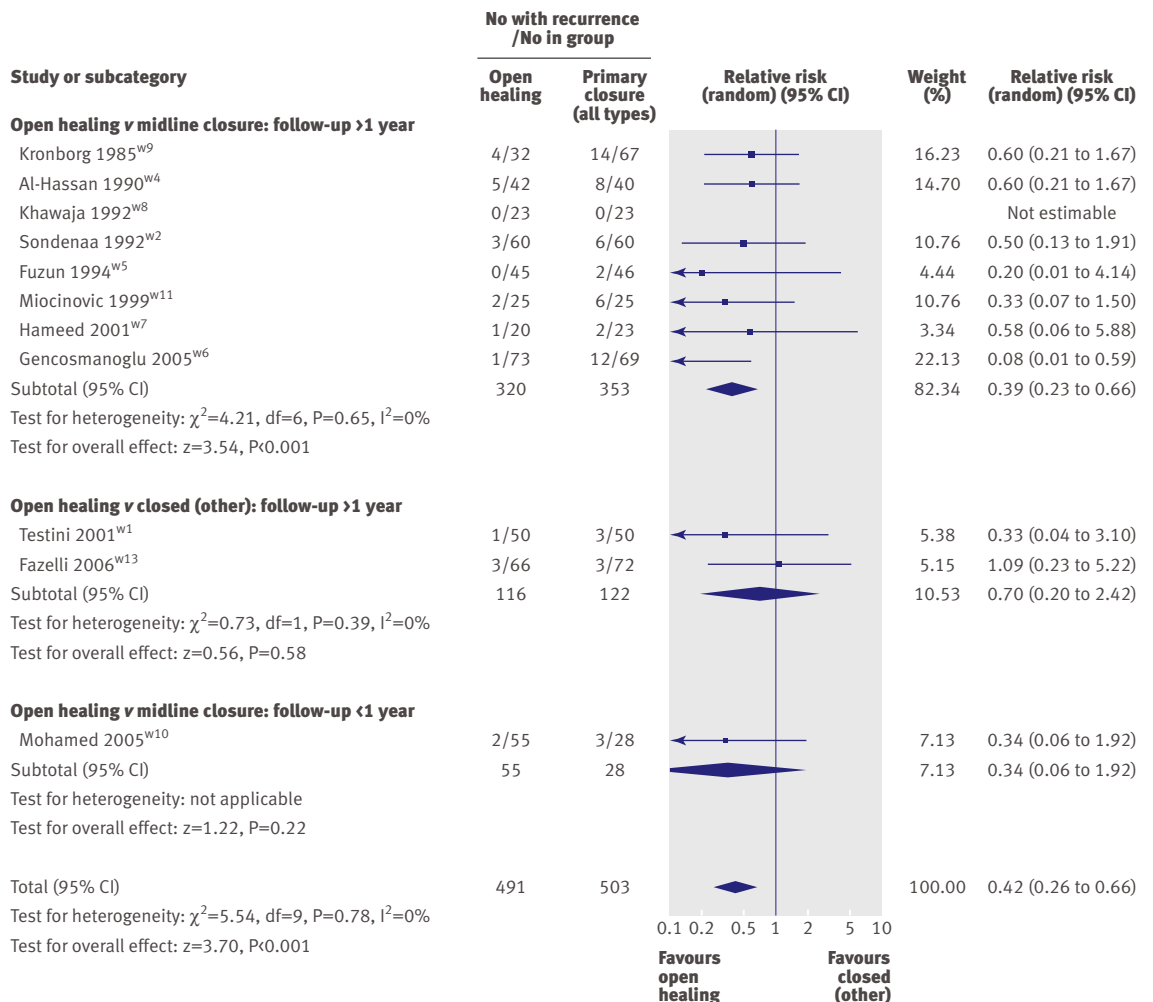
**Length of hospital stay**

Five trials (n=533) assessed length of hospital stay after open compared with closed surgery.<sup>w1 w4 w5 w10 w13</sup> A trend towards a shorter stay was shown in those having open compared with closed procedures; this was not significant (mean difference -1.26 days, 95% confidence interval -2.77 to 0.24; see bmj.com). Two studies reported significantly shorter length of stay after off-midline closure than after midline closure (mean difference 1.95 days, 95% confidence interval 0.21 to 3.69; see bmj.com).

**Pain**

Three studies reported pain data after open compared with closed surgery.<sup>w1 w2 w12</sup> Median (range 0-100) pain scores on postoperative day 4 were significantly lower for closed procedures (10 (0-73) v 35 (0-63); P<0.05).<sup>w12</sup> For two studies (n=220) rate of pain did not differ between open and closed methods (1.13, 0.43 to 2.80).<sup>w1 w2</sup>

Two studies measured pain after midline compared with off-midline closure.<sup>w15 w18</sup> Mean pain scores were only estimable for one trial.<sup>w15</sup> Improved scores were



Recurrence rate of pilonidal sinus after surgery using open healing or primary closure

**WHAT IS ALREADY KNOWN ON THIS TOPIC**

Pilonidal sinus is common and associated with considerable morbidity in young adults

Surgical management offers the best chance of cure, but surgical techniques have limitations and optimal treatment is unclear

**WHAT THIS STUDY ADDS**

After pilonidal surgery wounds heal quicker with primary closure than with open healing but risk of recurrence is increased

The suture line should lie off the midline to ensure trouble free healing and minimal chance of recurrence

reported after off-midline closure although this was not significant (mean difference  $-13.00$ ,  $-19.41$  to  $-6.59$ ).<sup>w15</sup>

**Wound healing rate**

Five trials (n=474) reported wound healing rates after open healing and primary closure (all techniques); overall no difference was found (0.94, 0.84 to 1.05).<sup>w1 w2 w4 w9 w12</sup>

One study compared healing rates after midline closure with those after off-midline closure (rhomboid flap).<sup>w14</sup> A statistically significant improvement was shown with off-midline closure (0.77, 0.62 to 0.97).

**DISCUSSION**

After surgery for pilonidal sinus wounds healed more quickly when primary closure was used but the risk of recurrence was higher than with open healing. No significant difference was found between the two approaches in rate of surgical site infection. A clear benefit was found for off-midline closure.

Overall, recurrence was more common with midline closure (11.7%) than with open healing (4.5%) which showed a 58% lower risk of recurrence at one year postoperatively. This equates to 14 patients experiencing recurrence per 100 undergoing primary closure (5 per 100 for open healing). Early return to normal activity was clearly shown with primary closure. Postoperative infection was not recorded by all trials and the small number of events prevented us from accurately estimating an effect size. Despite differences in wound healing time, rate of infection and other postoperative complications did not differ between open healing and primary closure.

When the choice of treatment for pilonidal sinus was excision and primary closure our review found significant benefit after off-midline closure. Fewer infections, recurrences, and other complications occurred and wound healing was quicker after off-midline closure than midline closure. Recurrence rates were significantly lower (1.4%) than with midline closure (10.3%).

Our systematic review identified infection rates of 10.4% after midline closure and 6.3% after off-midline closure, similar to the aggregated rates (12.4% v 7.6%) reported by one study.<sup>3</sup> Although that review aggregated

rates for infection, early failure, and recurrence by closure method, it included results from case series and retrospective surgical audits and failed to assess the methodological quality of individual studies.

Pilonidal sinus predominantly affects younger populations and therefore has an economic impact. This has not been formally evaluated. No benefit was specifically shown for time to return to work after off-midline closure, although significant heterogeneity existed between the included studies.

Blinding of surgeons, patients, and assessors is not possible with pilonidal sinus and some risk of bias exists. Many small variations in surgical technique occur. We attempted to group interventions to maintain clinical relevance whenever possible. This represents a compromise to provide meaningful comparison. Study groups contain variable interventions, however, and the optimal specific technique for differing severities of disease cannot be inferred from our data.

Most trials were small and risked failing to detect clinically relevant differences as statistically significant. Certain important postoperative outcomes, such as recurrence, are rare and this may lead to imprecise estimation with small sample sizes. Other methodological flaws such as poor randomisation techniques and inadequate follow-up further limit the interpretation of findings.

Many trials failed to accurately record or present outcomes, length of trial, and proportion of sample followed up. None reported follow-up beyond four years. Recurrence may also be underestimated as some studies used telephone or questionnaire follow-up.

Wounds heal more quickly after primary closure and return to work is sooner than with open healing but at the expense of an increased risk of sinus recurrence. Off-midline closure rather than midline closure showed benefit for most clinical and patient outcomes. These data are limited in some areas, although for outcomes where a reasonable degree of evidence has accrued the lack of heterogeneity is reassuring. Available data suggest that off-midline closure should become standard management for pilonidal sinus when primary closure is the surgical option.

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