

# Steri-Strip™ versus Subcuticular Skin Closure of Paediatric Groin Wounds: A Randomised Study

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## Abstract

**Background:** A technique that offers the best chance of an optimal result is most appropriate to be employed for wound closure. **Aims:** We set out to compare the cosmetic outcome, and wound complication rates associated with clean paediatric groin wounds closed using Steri-Strip™ or subcuticular suturing. **Settings and Design:** A prospective randomised study. **Subjects and Methods:** Children of African descent with unilateral and bilateral clean groin wounds were randomised into subcuticular suture skin closure and Steri-Strip™ groups and followed up postoperatively. Cosmetic assessment and outcome were scored based on parents' satisfaction using the visual analogue scale (VAS) and a single Plastic Surgeon assessed pictures of the scars using the Hollander Wound Evaluation Scale (HWES). Statistical analysis was used SPSS version 18. **Results:** Seventy-five wounds were assessed, ( $n = 35$ , Steri-Strips™) and ( $n = 40$ , suturing). Closure with Steri-Strips resulted in scars with comparable cosmesis as those with subcuticular suturing. Wound complications were also similar. There was no statistically significant difference between mean VAS scores on the 5<sup>th</sup> day ( $P = 0.320$ ), 2<sup>nd</sup> week ( $P = 0.080$ ), 4<sup>th</sup> week ( $P = 0.070$ ) and 8<sup>th</sup> week ( $P = 0.080$ ). The HWES scores were also comparable at those times. **Conclusions:** We conclude that skin closure of clean paediatric groin wounds with SteriStrips™ gives comparative cosmetic outcomes with subcuticular suturing.

**Keywords:** Cosmesis, groin wounds, Steri-Strips™, subcuticular suturing, wound complications

## INTRODUCTION

The mechanism by which the body repairs itself following an injury is a complex dynamic process.<sup>[1]</sup> The duration and outcome of this process are dependent on various local and systemic factors.<sup>[2]</sup> Wound closure is an integral part of the practice of surgery and the achievement of a cosmetically acceptable and stable scar is as important as the index procedure. Wound-related complications present a significant economic and psychosocial burden to the patient and caregiver consequent on increased morbidity, prolonged hospital stay and the occasional mortality. Suturing aims to achieve layered closure, obliteration of dead spaces and apposition of properly everted wound edges.<sup>[3]</sup> Unfortunately, the use of subcuticular wound closure can sometimes result in puckering and superimposed infection can lead to a local inflammatory response characterised by erythema, cellulitis and pain. Steri-Strips™ are reported to be advantageous for use over fragile skin and in the closure of clean and contaminated wounds.<sup>[4]</sup> In Africa, following the advent of

tissue glues, select studies have demonstrated a comparative cosmetic outcome between its use and standard wound closure using conventional sutures techniques on Class 1 (herniotomy) wounds.<sup>[5,6]</sup> These studies also evaluated wound complication rates as well as cost implications and demonstrated that cosmetic outcomes and wound complication rates were similar.<sup>[5]</sup> Based on these findings, we were interested to document what the comparative cosmetic outcome of similar wounds closed with a skin adhesive tape (Steri-Strips™) and a standard suturing technique would be.

We thus hypothesised that the Steri-Strips™ will be superior to the subcuticular suturing in terms of cosmetic outcome and cost-effectiveness.

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## SUBJECTS AND METHODS

A prospective, randomised, controlled, double-blind clinical study that compared the cosmetic outcome of clean groin wounds closed with Steri-Strips™ (Group 1) and standard subcuticular suturing (Group 2) among children who had groin surgery. This was conducted in eligible children attending a tertiary hospital in southwest Nigeria. Being the foremost teaching hospital in the country, it serves a population of about 2.7 million children from the metropolis as well as from various states in the entire country. The study was approved by the University and Hospital Ethics Review Committee. Consenting patients were recruited during clinic visits from March to October 2014. All healthy children whose parents/guardians gave consent and were between the ages of 1 month and 15 years attending the clinic with a unilateral or bilateral uncomplicated hernia, hydrocoele or undescended testis requiring surgery were included in the study. Patients with complicated hernia (gangrenous, incarcerated, irreducible), previous ipsilateral surgery, allergy to the components of SteriStrips™, perineal wounds or dermatitis, tumours, anaemia or poor nutritional status, on chemotherapy or steroids for other conditions were excluded. Sixty-eight consecutive patients meeting the inclusion criteria and requiring groin surgery as a day case procedure were enrolled. Verbal and written informed consent was sought and obtained from each parent or guardian at the outpatient clinic after due explanation of the study protocol. Assent was obtained from children over the age of 6 years. The patients were randomised into either group using a method of random selection. The parents were blinded before and after surgery as to which closure method was used. Peri-operatively, the side and site of the pathology was confirmed, marked and routine anaesthetic regimen employed. A dip into the random selection bag by the circulating nurse just before skin closure determined the type of closure that would be employed for the wound. Thus the surgeon was blinded to the selected closure method up to that point. In bilateral cases, each side was closed differently. A 'dip' into the bag determined which side was to be closed with what technique and the converse technique was employed for the contralateral side [Figure 1].

General anaesthesia (inhalational) was employed for all patients. All surgical procedures were performed similarly for both groups by Paediatric Surgery Consultants and Senior Registrars.<sup>[7]</sup> In all, 2 (2<sup>nd</sup> year) Senior registrars performed 68 (90.7%) procedures and one Consultant performed 7 (9.3%) procedures in both groups following the unit protocol. The subcutaneous layers were closed in both groups and all ages with the same standard polyfilament Vicryl© 3'0 sutures using interrupted suturing as was the protocol in our unit. Only one suture was used per wound in the subcuticular suturing group. The patients' skin was apposed with either SteriStrip™ or subcuticular continuous sutures using Vicryl© 3'0 with each end buried. There was no tincture of Benzoin employed to enhance the stickiness of the Steri-Strips™ and they were applied directly to the skin wound. Only one pack of Steri-Strip™ was used per wound.<sup>[13]</sup> Each wound was then



**Figure 1:** Intra-operative picture of bilateral groin wound closure using both subcuticular suturing (right) and Steri-Strips (left)

dressed with sterile gauze and adhesive tape (Band-Aid) because we anticipated premature or inadvertent stripping of the Steri-Strips™ tape by curious patients or parents. The Steri-strips™ used was at no cost to the patients. Sutures were provided as was usual in the hospital. The patients were given analgesics either intra-operatively or immediately post-operatively. No antibiotics were prescribed. The patients were discharged after full recovery from anaesthesia the same day. All parents were given verbal instructions and a printed instruction card about standard wound care at discharge.

The wounds were reviewed by doctors on the 5<sup>th</sup> post-operative day for the presence of any early complication. No wound needed re-application of Steri-Strips™ beyond the 5<sup>th</sup> day as all dressings were taken down by the doctors on the 5<sup>th</sup> day as per unit protocol. Thus, the total duration of Steri-Strips application in all patients in that group was 5 days. The scar was assessed on the 5<sup>th</sup> day, 2 weeks, 4 weeks and 8 weeks after surgery for the cosmetic outcome (by the parents) or complications (by the parents or doctors), all documented in the visual analogue scale (VAS) sheets and proforma respectively.<sup>[7,8]</sup> Full healing was assessed by physical inspection and palpation and demonstrated as a dry wound with completely viable tissue that was firmly adherent to the wound base, pale red or pinkish in colour and odorless. The peri-wound edge was also assessed for colour, induration, warmth, oedema, hypopigmentation or hyperpigmentation. Each patient's wound was thus assessed during each clinic visit until the observer concluded the wound had healed. In all, there was no change of dressing employed save for those in whom there were wound complications.

A cosmetic [VAS; Appendix 1] consisting of a single line on a page with verbal and numerical descriptors at each end in the horizontal axis with numbered scaled markers added to the line was used to evaluate the scar in this study.<sup>[10,11]</sup> The parents were asked questions to assess the presence of pruritus, pain, erythema or discharge. If there was any complication of the wound, appropriate intervention was done and this

was also documented. Clinical photographs were taken at standard settings with a Nikon Camera (COOLPIX S2700; NIKKOR 6X. Wide Optical Zoom. 4.6–27.6 mm; 1:3.5–6.5) of 16 megapixels. The pictures were reviewed by the investigator and a Plastic Surgeon (who had been blinded to the method of skin closure the patient had) using the Hollander Wound Evaluation Scale (HWES).<sup>[5,8,9]</sup> The HWES score addressed 5 clinical parameters; scar width, scar height, color/excessive inflammation, hatch marks/suture marks and overall cosmetic appearance with a maximum score of 1 for each parameter. A total cosmetic score was derived by adding the scores of the 5 categorical variables.<sup>[9,10]</sup> A score of 5 was considered optimal while a score of 3 or less was suboptimal. The parents assessed the wounds for cosmesis at each clinic visit while the Plastic surgeon reviewed the clinical photographs of the wounds using the HWES. Only photographs of patients who showed up to the clinic were taken to ensure picture quality and uniformity. The VAS was deployed as a sheet of paper physically to clinic attendees (parents) in person and virtually over the phone for patients who missed their clinic appointments. Thus all responses for the VAS were captured. The VAS sheet was kept in the patients' folders for subsequent visits. The assessment by the Plastic Surgeon was done at the end of the study thus preventing the probability of a scoring bias. The wounds were assessed for complications and healing, independently, on their own merit, without the pro formas thus overcoming observer bias also.

The data were collected using a proforma and analysed using the Statistical Package for the Social Sciences (SPSS version 20) software (IBM SPSS Statistics, Chicago, Illinois, USA). Categorical variables were compared using the Chi-square test while a comparison of continuous data was performed using the independent *t*-test. The primary outcome measures were the VAS scores and HWES scores. Unless otherwise stated, the level of statistical significance was set as  $P < 0.05$ .

## RESULTS

Sixty-eight patients with 75 groin pathologies participated in the study. Thirty-five wounds were enrolled into Group 1 (Steri-Strips™) and 40 in Group 2 (Subcuticular suturing). There were 61 unilateral wounds and 7 bilateral wounds. There were 64 (94.1%) males and 4 (5.9%) females with a male-to-female ratio of 16:1. Curiously, all the females were randomised into Group 2. The participants were aged 3–180 months with a mean age of  $57.6 \pm 43.1$  months. The mean age of the patients in Group 1 was  $57.7 \pm 42.0$  and in Group 2 was  $56.9 \pm 41.5$  months,  $P = 0.931$ . Fifty-three patients (70.7%) had inguinal herniotomy/ligation of patent processus vaginalis (comprising 30 inguinal/inguinoscrotal hernias, 4 inguinolabial hernias and 19 hydrocoeles). Twenty-two patients (29.3%) had groin exploration with orchidopexy. The length of the incision ranged from 2.2 cm to 6.0 cm with a mean length of  $3.90 \pm 0.76$  cm. The length of the incision was comparable in the two groups ( $3.9 \pm 0.7$  cm in Group 1 vs.  $3.9 \pm 0.8$  cm in Group 2,  $P = 0.716$ ) Median value

3.65 cm in both groups. There was predominant involvement of the right side ( $n = 41.54.7\%$ ). In the Steristrips™ group, 19 procedures were done on the right side compared with 22 in the subcuticular suturing group. Table 1 shows the VAS scores.

In the Steri-Strip™ group, there was no complaint nor incidence of premature stripping or separation of the tape nor of loss of stickiness because all wounds were covered with gauze and plaster/Band-Aid. Unfortunately, there was a low follow-up turnout rate, affecting the ability to take follow-up pictures in all patients. Thus, a total of 33 pictures were taken on post-operative day 5, 28 pictures in the 2<sup>nd</sup> post-operative week, nine pictures in the 4<sup>th</sup> week and two pictures in the 8<sup>th</sup> week. The HWES scores were not significantly different between the wounds of patients who had Steri-Strips™ or subcuticular wound closure.

## Wound outcome

By the 5<sup>th</sup> day, all wounds had epithelialised despite the method of closure [Figures 2 and 3] except in those with complications. Wound healing progressed similarly in both groups [Figure 4]. There were early wound complications in 4 wounds (5.3%) of three patients. One of those patients had bilateral groin wounds while the other 2 had one wound each. The complications occurred on the 5<sup>th</sup> day in the three patients. The complications were partial wound dehiscence ( $n = 1$ ),



Figure 2: Post-operative picture, bilateral groin wounds in Figure 1; 5<sup>th</sup> day

Table 1: Mean and *P* values of the visual analogue scale and Hollander Wound Evaluation Scale scores

	5 <sup>th</sup> day	2 <sup>nd</sup> week	4 <sup>th</sup> week	8 <sup>th</sup> week
Mean VAS score				
Subcuticular	8.2±1.2	9.3±0.9	9.8±0.5	9.9±0.2
Steri-Strips™	7.9±1.3	8.9±1.0	9.5±0.7	9.8±0.5
<i>P</i>	0.320	0.080	0.070	0.080
Mean HWES score				
Subcuticular	3.5±1.6	3.7±1.3	4.0±0.7	5.0±0
Steristrips™	3.8±1.5	2.7±1.8	3.5±0.6	3.0±0
<i>P</i>	0.600	0.100	0.290	

VAS: Visual Analogue Scale, HWES: Hollander Wound Evaluation Scale



**Figure 3:** Subcuticular closure, 2<sup>nd</sup> week



**Figure 4:** Bilateral closure, 2<sup>nd</sup> week; Right (Steri-strips); Left (subcuticular)



**Figure 5:** Eight week post-operative Steri-Strips closure

sero-purulent discharge ( $n = 2$ ) and wound haematoma ( $n = 1$ ). The two patients with single wounds were in the Steri-Strip™ group (Group 1) and the third patient had wounds closed with either technique. Both wounds developed complications. He was a 14-year-old with unshaved pubic hair which caught in the wounds. Thus there were 3 wound complications in

the Steri-strip™ group and 1 in the Subcuticular group. All 3 wounds with discharge and haematoma were opened and cleaned with antiseptic solution, dressed with sterile gauze and reviewed subsequently as needed. The dehisced wound cleaned, re-dressed and allowed to heal by secondary intention. Oral Amoxicillin-Clavulanic acid was given to one patient with bilateral wound complications for 5 days. None required secondary closure nor re-application of Steri-Strips™.

## DISCUSSION

A cosmetically appealing scar following surgical intervention is desired both by the surgeon and the patient. Often, parents are worried about scars and their cosmetic appearance whenever surgery is indicated in a child. Our study reveals that in children of African descent with clean groin wounds, the use of Steri-Strips™, while having numerous advantages, was not significantly better than subcuticular suturing. By the 5<sup>th</sup> post-operative day, there was no statistically significant difference in the VAS scores between both groups ( $P = 0.3$ ). Overall, Steri-Strips™, achieved the expectations set out in the objectives. Our unpublished data demonstrates that, in terms of application time and cost efficiency, Steri-Strips™ outranked subcuticular suturing. From our study and in concordance with the literature, the application time for the Steri-Strip™ was shorter than the time taken to complete the suturing of a similar wound length as there was no extra time needed to dry the wound or wait for the Steri-Strip™ to stick, following application. The duration of healing was comparable in both groups of patients. By the 5<sup>th</sup> day, all wounds had epithelialised despite the method of closure [Figures 2 and 3] except in those with complications. Wound healing progressed similarly in both groups [Figure 4]. At each clinic visit the wounds were assessed for tissue viability, evidence of infection, persistent exudation, excess pain or odour. If present, the details were documented in the pro forma and appropriate intervention was done.<sup>[14]</sup>

The aesthetic or cosmetic appearance of scars, are important for a number of reasons. These include the provision of an objective measure of the quality of care given to the patient. It also provides the opportunity to compare outcomes between various interventions thereby helping to determine whether one treatment is more effective than another. Thus, data about wound outcomes are helpful to clinicians, patients and researchers. The use of Steri-Strip™ as an alternative skin closure device in comparison with other standard closure techniques have been well documented in literature where its apparent advantage with regard to application time, painlessness and optimal cosmesis have been lauded.<sup>[10,11]</sup> Various studies in different wounds have revealed a comparable cosmetic outcome between the use of skin adhesives and standard skin closure techniques.<sup>[4-6,14]</sup>

A prospective randomised study undertaken to compare the use of Steri-Strip™ Surgical Skin closure system with a running absorbable subcuticular suture technique for skin

closure following a median sternotomy for cardiac surgical procedures concluded that both Steri-Strip™ and absorbable sutures were effective techniques for skin closure following a median sternotomy incision for cardiac surgical procedures.<sup>[11]</sup> Steri-Strip™ decreased the amount of erythema but resulted in no significant difference in pain, cosmesis or oedema compared to the traditional subcuticular wound closure techniques.<sup>[11,13]</sup> The effect of Steri-Strip™ on a clean surgical wound in children of African descent has not been investigated and the paucity of comparative data about the outcome of cosmesis and wound complications between its use and standard wound closure techniques is the justification for this study. With a paediatric population over 50 million, our country easily has the largest cohort of dark-skinned children in one geographic location. To that end, this study was undertaken to determine whether the previously highlighted advantages of the device could be replicated in paediatric clean groin wounds which had hitherto been traditionally closed with standard suturing techniques. Whilst our study demonstrated a comparable wound outcome and cosmesis between the use of Steri-Strips™ and subcuticular suturing [Figure 5], there was no evidence to show that the Steristrip™ was superior in efficacy. Just as previous studies have shown, the Steri-strips™ did not reduce the rate of superficial wound infection as was hoped considering the abolition of needlestick trauma and reduced manipulation of the skin edges as well as inadvertent bleeding of the skin. Conversely, there was no increased risk of infection with its use either and the complications were equally distributed between both techniques, an outcome reflective of previous studies.<sup>[1,4,11]</sup> Unlike suture placements, the application of a skin adhesive is trauma-free. In addition, a skin adhesive forms its own protective barrier eliminating the need for additional bandages coupled with an excellent outcome.<sup>[1]</sup> It is a time-saving endeavour because it does not require the use of a local anaesthetic before its application and lends itself to a quick application.<sup>[11,12]</sup> In our study, the Steri-Strip™ was pulled off on the 5<sup>th</sup> day by the doctor. This was done as was the practise for wounds repaired normally with the subcuticular suturing technique and we did not want to entertain bias. There was no evidence of pain or discomfort with this manoeuvre.

The limitations of the study were due to the poor follow-up clinic attendance from the 2<sup>nd</sup> week. All patients returned for follow-up after the 5<sup>th</sup> day to be evaluated for early complications if any and to have their wounds assessed at the outpatient department of the division. There were incessant industrial actions during the study period and this made it impossible for clinical pictures to be taken as at when due in some cases. On the other hand, many parents reneged on their agreement to attend outpatient clinics religiously as per the protocol, following the procedures. Many did not return to the clinic despite much appeal, often arguing that since the wound was healing, they could not be bothered to embark on the trip to the hospital because of cost and time constraints. Thus the rate of loss to follow up was >50%. In these cases, verbal assessment of the wound was obtained over the telephone.

This situation is responsible for the reduced number of wounds assessed by the HWES. Most parents were satisfied with the outcome of the wound and did not want to incur transportation costs towards clinic visits.

It is possible that the excluded group of patients in this study may benefit from the Steri-Strips™ use and they are a potential study set who may benefit from the reduced inflammatory response attributed to the Steri-strips™. A highlight of the study was the use of a picture portfolio for assessment of wound healing by the Plastic Surgeon. We opine that this approach can be improved and built upon in future surgical practise where pictures of post-operative wounds or newly emergent complains can be sent on designated social media platforms to the health care provider and online assessment of such can be made.

## CONCLUSION

We conclude that while the Steri-Strip™ is an effective, needle-free, low cost and safe technique for the closure of clean groin wounds in children of African descent, yet we were not able to demonstrate significant superiority to and above the traditional subcuticular suturing method. However, evidence from various studies shows that the Steri-Strip™ retains the advantage of the ease of application, lower cost and reduced application time and lesser inflammatory response over the subcuticular suturing technique.<sup>[4,11,12]</sup> Thus they remain safer and cheaper alternative to subcuticular suturing in select patients.

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## Conflicts of interest

There are no conflicts of interest.

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## APPENDIX

### Appendix 1: Visual Analogue Scale for Parents

Dear Parent,

Please mark the number that represents your satisfaction with your child’s wound on the scale below. Worst scar is 0, Best scar is 10. Thank you.

Eyin Obi,

E jowo, e bu owo lu numba ti o ba fi itelorun yin lori apa omo yin han . Numba 0 (Oodo) buru jai, nigbati numba 10 (Eewa) dara pupo. E seun.

5<sup>th</sup> day/Ojo Karuun

0---|---1|---|---2|---|---3|---|---4|---|---5|---|---6|---|---7|---|---8|---|---9|---|---10|

2<sup>nd</sup> week/Ose keji

-0---|---1|---|---2|---|---3|---|---4|---|---5|---|---6|---|---7|---|---8|---|---9|---|---10|

4<sup>th</sup> week/Ose Kerin

0---|---1|---|---2|---|---3|---|---4|---|---5|---|---6|---|---7|---|---8|---|---9|---|---10|

8<sup>th</sup> week/Ose Kejo

0---|---1|---|---2|---|---3|---|---4|---|---5|---|---6|---|---7|---|---8|---|---9|---|---10|

To be filled by examining doctor; Please tick if there is any of the following or if reported;

Wound status	5 <sup>th</sup> day	2 <sup>nd</sup> week	4 <sup>th</sup> week	8 <sup>th</sup> week
Color (Pink) Y/N				
Excessive Pain				
Oedema				
Hypo/Hyperpigmentation				
Warmth				