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Cosmetic Outcomes With The Use of 5-0 Polypropylene Versus 5-0 Fast Absorbing Plain Gut During Cutaneous Wound Closure: A Randomized Evaluator Blind Split Wound Trial.

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Summary

Background: Surgeons have mixed opinions regarding cosmetic outcomes of 5-0 fast absorbing plain (FG) gut relative to nonabsorbable suture material, such as 5-0 polypropylene (PP). High quality randomized trials comparing these two suture materials are lacking.

Objectives: To determine whether the use of PP during layered repair of linear cutaneous surgery wounds improves scar cosmesis compared to wound closure with FG.

Methods: A randomized, split wound, comparative effectiveness trial was undertaken. Patients were evaluated 3 months after the intervention by two blinded physicians using the validated patient observer scar assessment scale (POSAS). Patient assessments were also captured using the same instrument as well as scar width and complications.

Results: The mean sum of the six components of the POSAS was 10.26 vs 12.74 for PP and FG, respectively, significantly ($p<0.001$) in favor of PP. Mean observer overall opinion similarly showed better outcomes for PP than for FG (1.88 vs 2.52, respectively ($p<0.006$)). The mean sum of the patient assessed components of the POSAS for PP and FG was 12.3 vs 14.34, respectively ($p=0.11$). Patient overall opinion significantly favored PP (2.41 vs 3.14, $p=0.043$). Scar width was similar in both arms, 1.25 mm for PP and 1.47 mm for FG ($p=0.17$). Most patients reported very low pain scores during suture removal (mean 1.63 in scale of 1–10).

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Conclusions: 5-0 polypropylene resulted in small but statistically significant better cosmetic outcomes than 5-0 fast absorbing plain gut. Pain experienced during suture removal was minimal for most patients. (NCT03303014, clinicaltrials.gov)

Introduction

Both absorbable and nonabsorbable cuticular sutures are commonly used by dermatologic surgeons during layered wound closure to align and approximate the skin edges. Each material has advantages and disadvantages. Nonabsorbable suture material is often cited as being easier to tie, less likely to break, and causing minimal inflammation.[1] Absorbable suture material is advantageous in terms of avoiding the need for suture removal thus saving both physician and patient time incurred during another visit. It also averts patient pain and anxiety associated with suture removal. Animal protein derived absorbable sutures, however, have been well known to cause inflammation as part of the degradation process,[2] and might lead to inferior aesthetic outcomes.

Though numerous randomized trials have been conducted on the cosmetic outcomes of absorbable versus nonabsorbable sutures, most have been of low quality or performed in settings outside of typical dermatologic surgery practice.[3] Therefore, uncertainty exists regarding which material has the best aesthetic outcome. Additionally, there is a wide variety of absorbable and nonabsorbable suture materials, each with different properties that may not be interchangeable in terms of considering outcomes.

Cutaneous surgeons in our practice commonly use both fast absorbing plain gut and polypropylene, a nonabsorbable suture. To our knowledge, there are few or no high quality studies comparing the cosmetic outcomes of these two suture materials for cutaneous wound closure in the dermatologic surgery literature. Thus, a randomized split-wound evaluator-blinded comparative effectiveness trial was undertaken.

Methods

This single-center, investigator initiated, registered (NCT03303014, clinicaltrials.gov) parallel study was conducted at the University of California Davis Medical Center Department of Dermatology outpatient facility. The protocol was approved by the University of California Institutional Review Board prior to starting recruitment and adheres to the principles expressed in the Declaration of Helsinki. We used a split-wound, within person design to minimize potential confounders that occur with comparing interventions in different individuals. Furthermore, this design type reduces the number of subjects necessary to enroll, assures interventions are applied in the same numbers, and equalizes losses due to participant dropout.[4]

Sample Size Determination

An a priori power analysis indicated we would need to enroll 50 patients using a split-scar model to detect a difference of 3 points on the 60-point POSAS observer component scale with the following assumptions: alpha 0.05, beta 0.10, standard deviation 6 or lower (based upon past clinical trials conducted by our group),[5–8] and dropout rate 15%.

Inclusion/Exclusion Criteria

Inclusion criteria included: 18 years of age or older, able to give informed consent, patient scheduled for cutaneous surgical procedure with predicted linear closure, willing to return for follow-up visits. No restrictions were placed on body site. Exclusion criteria were: mental impairment, unable to consent for themselves, inability to understand written and oral English, incarceration, pregnant women, wounds with predicted closure length less than 3 cm.

Data Management/Randomization/Allocation Concealment

Study data were collected and managed using REDCap electronic data capture tools hosted at the University of California Davis Medical Center.[9] "REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources."[9]

Prior to study commencement, a randomization sequence was obtained by a nurse uninvolved in the study from a web-based randomization site (random.org) and uploaded into the REDCap randomization module. REDCap only reveals treatment assignments one subject at a time and only after a randomize button is pressed. Following full enrollment the data administrator restricted access to the treatment assignment page, thus preventing blinded reviewers from determining which side was treated with which suture material.

Description of Procedure/Intervention Undertaken

Recruitment was performed by the surgeon treating the patient or surgery fellow and occurred directly from the dermatologic surgery practices of DE and VS. After enrollment, the patient's wound was divided in half. The side on the left or superior side of the investigator was labeled A and the right or inferior side B. A single subcuticular polyglactin 910 suture was used to approximate the wound edges at the midpoint of the wound. If more sutures were deemed necessary, they were placed equidistant from the midpoint of the wound on both sides such that both sides of the wound had the same number of buried subcuticular sutures placed at the same intervals. After the wound edges were anchored in place with buried vertical mattress subcuticular sutures,[10] a nurse consulted the REDCap randomization module and the surgeon was informed of the suture material to use on side A (either 5–0 fast absorbing plain gut (Ethicon, Bridgewater NJ) or 5–0 polypropylene (Prolene, Ethicon)). The intervention was applied sequentially. Side A was always closed first. A running cuticular suture pattern was used until the midpoint of the wound was reached and then the suture was tied and the other suture material obtained. Suturing was initiated at the midpoint of the wound with the material not used on side A for side B using the same technique as previous. Effort was made to close both halves of the wound in an identical manner in terms of suturing technique, spacing interval, and distance from the wound edges.

Following the procedure, a sterile pressure bandage was applied to the entire wound. The patient was instructed to keep the dressing dry until it was removed 24 hours later. At that time they were asked to apply petroleum jelly from a new tube to the suture sites with a cotton tipped applicator and a new dressing consisting of a sterile non-stick gauze pad and adhesive tape daily after washing the site with tap water and a gentle soap. They were asked to do this until the sutures were removed or dissolved and the site was completely healed. Suture removal for the polypropylene side was performed 5–7 days following the procedure on the head and neck and 10–14 days on the trunk and extremities. The fast absorbing plain gut sutures were left in place until dissolution.

Patients were seen back in most cases 3 months after the procedure for assessment. In extenuating circumstances a 1 month window before or after the 3 month follow up time was allowed.

Assessments Performed

All outcome assessments were prespecified. The Primary outcome measure for our study was the sum of the average of the component observer scores of two blinded observers achieved through use of the patient observer scar assessment scale (POSAS). The POSAS scale is a validated outcome measure developed for assessing surgical scars.[11,12] Scars are rated using 6 criteria on a 1 −10 scale, with one representing normal skin, and 10 the worst scar imaginable. Scores are summed and a number between 6–60 is achieved, with lower numbers being better. Our secondary outcome measures included the sum of the patient component score of the POSAS scale, which is determined similarly to that of the blind observers using only patient opinion, mean blind observer overall opinion, patient overall opinion, scar width, and incidence of complications including superficial and deep dehiscence, infection, bleeding, seroma, hematoma, and suture reactions. Though patients were not told which intervention was applied where, the suture types were visible to the patient after application and at suture removal.

Scar width was measured 1 cm from midline on each side of the wound. Measurements were recorded in 0.5 mm increments given we did not believe we could accurately measure distances less than that, thus the minimum recorded scar width was 0.5 mm. The blinded observers were physicians and were not present at the time the surgical procedure was performed.

Pain incurred with suture removal was measured via a 10 point Visual Analog Scale immediately after the sutures were removed. Patients were instructed that 1 was no pain and 10 worst pain imaginable.

Not all outcomes were analyzed for statistical significance in order to reduce chances of a type I error.[13]

Statistical Methods

Paired t-test was used for POSAS scores. McNemar test was used for analysis of complications (i.e., binary outcome). Both methods handle paired data. We analyzed (pre-

specificed) Summed score and Overall opinion from observers and patients and two other outcomes, and computed statistical significance, without multiple testing adjustment. We presented and summarized individual components scores as well, but did not perform formal testing in order to minimize false positive or negative findings. SAS 9.4 (SAS Institute, Cary, NC) was used in data analysis.

Results

Sixty-six patients were screened to enroll 50 patients into the study (Figure 1). Mean age of study patients was 65, 31 (62%) were male, and 48 (96%) were white (Table I). Thirty-four wounds (68%) were on the head and neck, with the other 16 (32%) located on the trunk and extremities. Twenty-four surgeries (48%) were performed by a micrographic dermatologic surgery fellow, seventeen (34%) by a fellowship trained dermatologic surgeon, and nine (18%) by a dermatology resident under the supervision of a fellowship trained dermatologic surgeon. Mean closure length was 5.8 cm, 34 wounds (68%) resulted from Mohs surgeries and 16 (32%) from excisions.

Forty-four (88%) patients returned for follow up. Three patients were lost to follow up and three could not return within the study evaluation window.

For our primary outcome measure (Table II), the mean sum of six components of the POSAS from 2 blinded observers, we found a numerically (10.26 vs 12.74) and significantly (<0.001) better cosmetic outcome in favor of 5-0 polypropylene. Mean observer overall opinion similarly showed better outcomes for 5-0 polypropylene than for 5-0 fast absorbing plain gut (1.88 vs 2.52, respectively ($p<0.006$)).

Though the mean sum of the patient assessed components of the POSAS also favored 5-0 polypropylene over 5-0 fast absorbing plain gut (12.3 vs 14.34, respectively), the difference was not statistically significant ($p=0.11$). However, patient overall opinion did significantly favor 5–0 polypropylene (2.41 vs 3.14, $p=0.043$). Of note, although we did not test individual components, we find 5–0 absorbing gut yielded uniformly higher values in all components, assessed by observers or patients.

Scar width was similar in both arms, 1.25 mm for 5-0 polypropylene and 1.47 mm for 5-0 fast absorbing plain gut ($p=0.171$).

Thirteen complications occurred on the 5–0 polypropylene side: 3 superficial dehiscences (all at time of suture removal, and very small in size), 3 infections, 1 hematoma, 1 suture reaction, 2 wounds had uneven edges, 1 wound was sunken, 2 wounds had contour irregularities. Nine complications occurred on the 5–0 fast absorbing plain gut sides: 2 infections, 1 hematoma, 1 seroma, 1 suture reaction, 1 uneven edges, 2 sunken scars, 1 contour abnormalities.

Regarding pain incurred during suture removal, most patients reported very low scores (Table II (mean 1.63 in the scale of 1 to 10)).

Discussion

Our study found small but statistically significant better results with the use of 5-0 polypropylene compared with 5-0 fast absorbing plain gut for our primary outcome measure, the mean sum of two blinded observers component scores of the POSAS scale (p=0.001) (Figure 2). This finding was substantiated by statistically significant better outcomes that favored 5-0 polypropylene for mean blinded observer overall opinion (p=0.006) as well as patient overall opinion (p=0.043). Though patient POSAS sum did not reach significance, a statistical trend was observed (P=0.105). Complications were frequent, but mostly minor in nature and not significantly different between groups.

Much has been written about the potential for gut sutures to cause inflammation.[2] Our study found similar vascularity scores (2 vs 2.47, respectively), which are typically associated with inflammation, for both polypropylene and fast absorbing gut. Guyeron and Vaughn who compared 6-0 polypropylene to 6-0 catgut sutures in a prospective, split wound, non-randomized study in patients receiving rhytidectomies in 80 sites on 24 patients, found no significant differences in suture site erythema.[14] Interestingly, many of their patients who developed suture site erythema to catgut also did so with the sides sutured with polypropylene, suggesting that some patients may be inclined to react to any foreign material, whether animal protein derived, or synthetic. A larger study is likely required to definitively determine whether the incidence of erythema and inflammation is greater with fast absorbing gut, than with polypropylene.

We found only two studies specifically comparing fast absorbing plain gut to polypropylene for cutaneous wound closure in patients undergoing dermatologic surgery.[14,15] Unlike our study, each of these studies found no significant difference in outcomes between the two suture materials. The first study, by Guyeron and Vaughn,[14] was limited by lack of randomization, heterogenous assessment times, and only reported complications, not cosmetic outcomes. The second study, by Kouba and all,[15] incorporated a split wound randomized design, but had only 12 patients in the arm that compared polypropylene to fast absorbing gut. Given our a priori power analysis assumptions indicated an appropriate cohort size of 50, Kouba's study was likely underpowered to detect a meaningful difference in outcomes for these two suture materials.

Two systematic reviews compared outcomes of non-absorbable and absorbable sutures.[3,16] These both included a wide variety of different materials other than fast absorbing gut and polypropylene and several were performed in the setting of visceral surgical procedures, limiting drawable conclusions.

Similar to our study, Theopold and all found that suture removal resulted in minimal pain for most patients.[17] While suture removal pain may be cause for patient anticipatory anxiety, pain does not appear to be a significant issue when the procedure is performed.

The primary limitation of our study was its single centered nature. A multi-centered study would have greater power and less chance of bias and also greater external validity/ generalizability. Finally, it should be noted that though a significant difference was found between the two different suture types, the difference was just below the threshold for what

we considered the minimal meaningful clinical difference in our power calculation. Thus, though there was a statistically significant difference in outcomes, it is not clear that the results mandate a change in practice patterns.

Strengths of our study include a high quality design[18] with randomization, allocation concealment, blinded reviewers, a priori power analysis, and use of validated outcome measures. Additionally, the split wound nature of the trial allowed direct comparison of the two suture materials while controlling for confounders such as age, gender, location, etc. Our attrition rate of 12% was relatively low, and less than our power calculation assumptions, reducing the chance of bias from missed study assessments. Furthermore, having a variety of surgeons with different levels of surgical experience and incorporating different anatomical locations, increases the external validity of our findings. Our study appears to provide some of the highest quality information on outcomes related to these two suture materials to date. The best estimates of treatment effects always occur when meta-analysis of well designed studies are performed.[19] Thus, more investigations of these two materials should be encouraged.

Conclusions

Suturing with 5-0 polypropylene results in small but significantly better cosmetic outcomes than suturing with 5-0 fast absorbing gut when used as part of a layered wound closure. Pain during suture removal is relatively minimal for most patients.

Acknowledgments

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References

1. Parell GJ, Becker GD. Comparison of absorbable with nonabsorbable sutures in closure of facial skin wounds. Arch Facial Plast Surg 2003; 5:488–90. [PubMed: 14623686]
2. Byrne M, Aly A. The Surgical Suture. Aesthet Surg J 2019; 39:S67–72. [PubMed: 30869751]
3. Xu B, Xu B, Wang L, et al. Absorbable Versus Nonabsorbable Sutures for Skin Closure: A Meta-analysis of Randomized Controlled Trials. Ann Plast Surg 2016; 76:598–606. [PubMed: 25643187]
4. Pandis N, Chung B, Scherer RW, et al. CONSORT 2010 statement: extension checklist for reporting within person randomised trials. BMJ 2017; 357:j2835. [PubMed: 28667088]
5. Pourang A, Crispin MK, Clark AK, et al. Use of 5–0 Fast Absorbing Gut vs 6–0 Fast Absorbing Gut During Cutaneous Wound Closure on the Head and Neck: A Randomized Evaluator-Blinded Split-Wound Comparative Effectiveness Trial. J Am Acad Dermatol 2019. doi:10.1016/j.jaad.2019.02.037.
6. Sklar LR, Pourang A, Armstrong AW, et al. Comparison of Running Cutaneous Suture Spacing During Linear Wound Closures and the Effect on Wound Cosmesis of the Face and Neck: A Randomized Clinical Trial. JAMA Dermatol 2019. doi:10.1001/jamadermatol.2018.5057.
7. Kappel S, Kleinerman R, King TH, et al. Does wound eversion improve cosmetic outcome?: Results of a randomized, split-scar, comparative trial. J Am Acad Dermatol 2015; 72:668–73. [PubMed: 25619206]
8. Custis T, Armstrong AW, King TH, et al. Effect of Adhesive Strips and Dermal Sutures vs Dermal Sutures Only on Wound Closure: A Randomized Clinical Trial. JAMA Dermatol 2015; 151:862–7. [PubMed: 25875131]

9. Harris PA, Taylor R, Thielke R, et al. Research electronic data capture (REDCap)—A metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009; 42:377–81. [PubMed: 18929686]
10. Zitelli JA, Moy RL. Buried vertical mattress suture. J Dermatol Surg Oncol 1989; 15:17–9. [PubMed: 2642931]
11. Draaijers LJ, Tempelman FRH, Botman YAM, et al. The patient and observer scar assessment scale: a reliable and feasible tool for scar evaluation. Plast Reconstr Surg 2004; 113:1960–5; discussion 1966–1967. [PubMed: 15253184]
12. van de Kar AL, Corion LUM, Smeulders MJC, et al. Reliable and feasible evaluation of linear scars by the Patient and Observer Scar Assessment Scale. Plast Reconstr Surg 2005; 116:514–22. [PubMed: 16079683]
13. Wang R, Lagakos SW, Ware JH, et al. Statistics in Medicine — Reporting of Subgroup Analyses in Clinical Trials. N Engl J Med 2007; 357:2189–94. [PubMed: 18032770]
14. Guyuron B, Vaughan C. A comparison of absorbable and nonabsorbable suture materials for skin repair. Plast Reconstr Surg 1992; 89:234–6. [PubMed: 1732889]
15. Kouba DJ, Tierney E, Mahmoud BH, Woo D. Optimizing closure materials for upper lid blepharoplasty: a randomized, controlled trial. Dermatol Surg Off Publ Am Soc Dermatol Surg Al 2011; 37:19–30.
16. Sajid MS, McFall MR, Whitehouse PA, Sains PS. Systematic review of absorbable vs non-absorbable sutures used for the closure of surgical incisions. World J Gastrointest Surg 2014; 6:241–7. [PubMed: 25548609]
17. Freshwater MF. Theopold C, Potter S, Dempsey M, O'Shaughnessy M. A randomised controlled trial of absorbable versus non-absorbable sutures for skin closure after open carpal tunnel release. J Hand Surg Eur. 2012; 37: 350–3. *J Hand Surg Eur Vol* 2012; **37**:705; author reply 705–706.
18. Jadad AR, Moore RA, Carroll D, et al. Assessing the quality of reports of randomized clinical trials: is blinding necessary? Control Clin Trials 1996; 17:1–12. [PubMed: 8721797]
19. Gopalakrishnan S, Ganeshkumar P. Systematic Reviews and Meta-analysis: Understanding the Best Evidence in Primary Healthcare. J Fam Med Prim Care 2013; 2:9–14.

What's already known about this topic?

Fast absorbing gut sutures eliminate the need for a suture removal visit and many believe that they result in equivalent cosmetic outcomes to permanent sutures, such as 5–0 polypropylene.

What does this study add?

Our study indicates small but significantly better cosmetic outcomes with 5–0 polypropylene than with 5–0 fast absorbing gut.

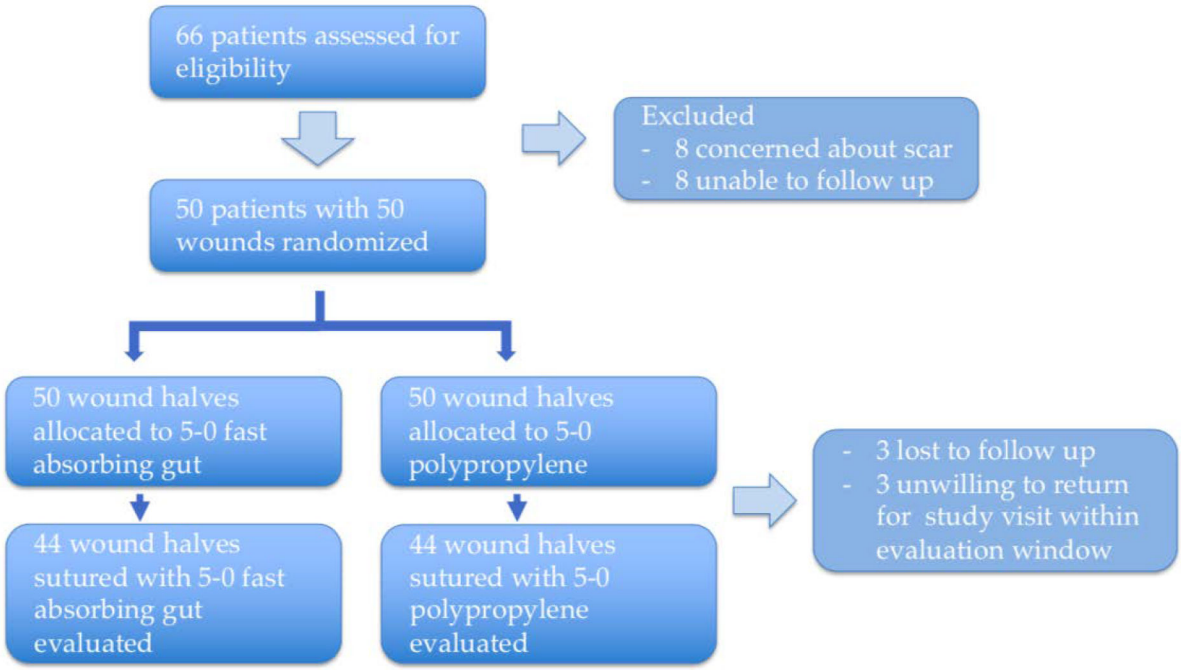

Figure 1.

Flow diagram of patient enrollment and assessments. Since each patient received both interventions follow-up and attrition was identical for both suture types.

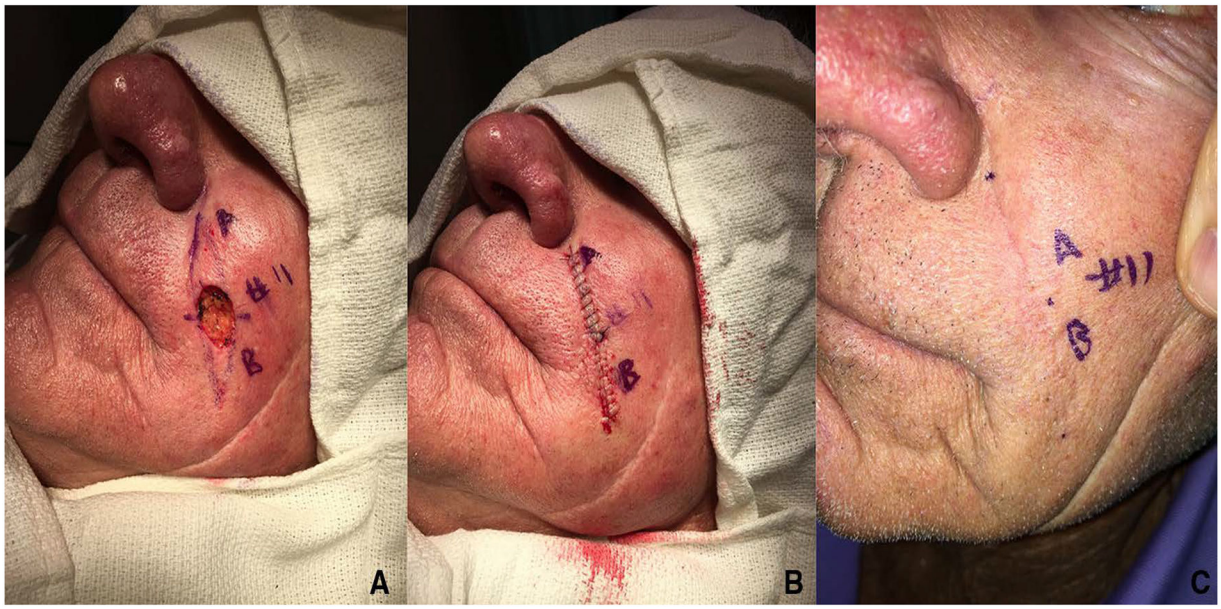

Figure 2.

Panel (a), defect following Mohs micrographic surgery. Panel (b), sutured wound following the applied interventions. 5-0 polypropylene is used on the superior half and 5-0 fast absorbing plain gut on the inferior portion. Panel (c), results at the 3 month assessment visit.

Table I.

Characteristics of Enrolled Study Population.

Male, %	31 (62%)
Mean age, y	64.3
Race	Asian 2 (4%) Caucasian 48 (96%)
Location	Face 28 (56%) Extremities 6 (12%) Neck 4 (8%) Scalp 2 (4%) Trunk 10 (20%)
Mean closure length	5.8 cm
Surgeon experience	Attending 17 (34%) Fellow 24 (48%) Resident 9 (18%)
Indication	Mohs 34 (68%) Excision 16 (32%)

Table II.

Outcomes

Blinded Observer POSAS results at 3-month follow-up;			
Components at 3 months	**Mean(+/− SD)**		
	5-0 Polypropylene	**5-0 Fast-absorbing gut**	**P value**
Vascularity	2 +/− 1.23	2.47 +/− 1.62	
Pigmentation	1.61 +/− 0.93	1.91 +/− 1.33	
Thickness	1.61 +/− 1.06	1.96 +/− 1–31	
Relief	1.56 +/− 0.85	2.03 +/− 1.33	
Pliability	1.72 +/− 1.04	2.09 +/− 1.37	
Surface area	1.79 +/− 1.12	2.30 +/− 1.59	
Sum of POSAS	10.26 +/− 4.16	12.74 +/− 5.82	0.0009
Overall opinion	1.88 +/− 1.13	2.52 +/− 1.62	0.006
Patient POSAS results at 3-month follow-up;			
Components at 3 months	**Mean (+/− SD)**		
	5-0 Polypropylene	**5-0 Fast-absorbing gut**	**P value**
Pair	1 +/− 0	1.02 +/− 0.15	
Itching	1.09 +/− 0.36	1.11 +/− 0.44	
Color	3.25 +/− 2.43	3.55 +/− 2.42	
Stiffness	2.57 +/− 2.29	2.95 +/− 2.27	
Thickness	2.20 +/− 1.73	2.86 +/− 2.26	
Irregularity	2.13 +/− 1.77	2.84 +/− 1.96	
Sum of POSAS	12.3 +/− 7.63	14.34 +/− 8.14	0.105
Overall opinion	2.41 +/− 1.66	3.14 +/− 2.01	0.043
Other outcomes of Interest			
	5-0 Polypropylene	**5-0 Fast-absorbing gut**	**P-value**
Average scar width (mm)	1.25	1.47	0.171
Number of complications	13	9	0.356
Suture removal pain (1–10)	1.63 +/− 1.61	NA	