

Reduction of ‘Dead Space’ and ‘Shear’ Through Flap Adhesion may Reduce Short Term Complication Rates in Flap-Based Reconstruction for Stage IV Pressure Sores: A Retrospective Comparison Cohort Series

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Abstract

Early complications such as dehiscence, seroma and flap failure requiring revision are a troubling aspect of flap repair surgery for Stage IV pressure ulcers. They increase patient suffering in an already difficult context and place a great burden on the health care provider as well. Reduction or elimination of the dead space between tissue planes has been shown to aid in wound healing in tissue flap procedures involving extensive undermining. In late 2013 we began using a new lysine-based urethane tissue adhesive to hold the tissue planes in approximation, in the belief that this could reduce rates of early complications. To confirm our positive initial impressions we undertook a retrospective study of consecutive cohorts, 22 with adhesive and 28 from an earlier period, with a focus on early (30 day) complications and time to discharge. We documented a 50% reduction in the need for revisions ($p=0.186$, ns) and an 8 day reduction in average length of stay ($p=0.022$, significant). This is the first series report of the use of this fixation method in decubitus flap surgery and suggests that this is an approach which merits further evaluation.

Keywords: Decubitus; Flap fixation; Complications; Adhesive; Seroma

Level of Evidence: Therapeutic, Level III (This is based on ASPS Evidence Rating Scales).

Introduction/Background

Pressure sores (decubitus ulcers) represent an enormous cost in both human and economic terms, mostly affecting elderly and/or severely impaired patients [1-5]. While much attention has rightly been focused on prevention and care at early stages, many of these wounds still advance to a stage involving deep tissue necrosis (Stage IV) requiring debridement and surgical repair [6]. These patients are usually referred to specialized plastic surgery centers for treatment.

Surgery utilizing local or distant fasciocutaneous or myocutaneous flaps for coverage and closure is the recommended treatment [5]. Reported complication rates after these procedures vary widely [7-12] but remain high as compared to many other surgical procedures, in large part due to the remaining underlying causes and the generally compromised status of these patients. Dead space between tissue planes where fluid can accumulate and shear forces from patient movement are contributing factors to poor wound healing [13], sometimes leading to major complications and the need for revision surgery. Flap fixation or adhesion has been shown to reduce wound healing complications after mastectomy [14,15] and some donor site flap procedures [16] and in abdominoplasty closure of dead space with adhesive has been demonstrated to even allow elimination of the use of drains without an increase in the need for postoperative clinical interventions [17].

‘Revision surgery’ for the purposes of this article is surgery required due to inadequate healing of the surgical wound and falls within the “complications” window, in Germany generally considered to be 30 days after the surgical procedure. ‘Recurrence’ presents at a later stage and is, from a management and economic perspective, considered a new event related to overall patient conditions or patient care. Our focus here is on short term outcomes and wound healing after the surgical repair with a tissue flap rather than on longer term follow up or recurrence rates.

Our group recently reported on the successful use of a synthetic resorbable tissue adhesive (TissuGlu® Surgical Adhesive, Cohera Medical, Inc., Pittsburgh PA, USA) to close the dead space and hold

the tissue planes in approximation during wound healing after surgical repair of a Stage IV pressure ulcer in a patient requiring a second revision surgery subsequent to seroma formation and dehiscence. At 7 weeks post-surgery the wound was healing well and no subsequent complications were reported [18].

We have been using this adhesive in flap surgery for decubitus repair as our standard of care since October 2013. In order to verify and quantify what we saw as the evident benefits of this approach, we undertook a retrospective analysis of two consecutive cohorts with the objective of documenting whether and to what extent use of TissuGlu in these procedures can reduce complications and revision rates in our practice.

Materials and Methods

Records for patients treated in our department in the two year period prior to our use of TissuGlu were reviewed. Standard demographic, surgical and outcomes data was recorded. Data from patient records for the later consecutive series of similar patients in which TissuGlu was used was also compiled and the two data sets were compared. The use of anonymized, retrospectively collected patient data for the purposes of analyzing our service was authorized by our institutional review board.

A total of 28 patients, from March 2011 to November 2013, were included in the Standard Wound Closure (SWC) group analysis. A standardized data collection form was used to compile information from patient records, including basic demographic data, pressure sore location and type of surgical procedure, known and recorded risk factors, duration of surgical procedure, number of drains placed

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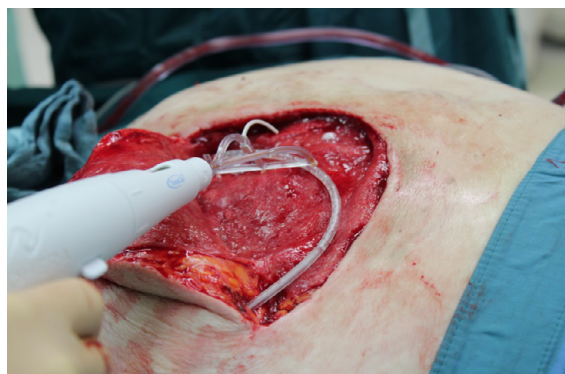


Figure 1: Application of TissuGlu® under the flap for adhesion.

Variable - Demographics	TG (n=22 pts)	SWC (n=28 pts)	p-value
Age*	73.2 (±13.1) 77.0	66.5 (±16.1) 70.5	0.113
BMI*	23.6 (±5.9) 25.4	24.8 (±4.4) 23.6	0.474

Table 1: Basic demographic data for both groups.

Procedure Variables and Risk Factor	TG (n=22 pts)	SWC (n=28 pts)	p-value
Number of pressure ulcers (requiring surgical repair)	1.1 (± 0.3) 1.0	1.1 (± 0.4) 1.0	0.7619
Pressure Ulcer Stage	4.0 (± 0.2) 4.0	3.9 (± 0.4) 4.0	0.8378
Debridement and VAC before 1 st Op.	36.4% (8 of 22)	39.3% (9 of 28)	0.832
Procedure for Recurrence (i.e. not a Primary repair procedure)	22.7% (5 of 22)	25.0% (7 of 28)	0.851
Duration of 1 st Operation (i.e. not considering additional surgeries)	54.7 (± 21.0) 50.0	76.4 (± 29.4) 67.5	0.004
Number of Drains (1 st operation)*	1.5 (± 0.5) 1.0	1.4 (± 0.5) 1.0	0.8345

Table 2: Data on pressure ulcers in both groups.

Outcome Measures	TG (n=22 pts)	SWC (n=28 pts)	p-value
Duration of Drainage	8.7 (± 3.3) 8.0	9.1 (± 3.6) 8.0	0.672
Patients requiring Revisions	13.6% (3 of 22)	32.1% (9 of 28)	0.186
Number of Revisions per Group	3	22	N/A
Mean Number of Revisions/Patient	0.1 (± 0.4) 0.0 (Max: 1)	0.8 (± 1.6) 0.0 (Max: 7)	0.2110
Total Number of Procedures (including debridement and VAC)	1.5 (± 0.7) 1.0	2.0 (± 1.7) 1.5	0.5909
Duration of Stay	15.7 (± 8.3) 15.0	23.6 (± 14.7) 17.0	0.022

Table 3: Detailed comparison of the results.

and duration of drainage and the requirement for and number of procedures for revision during the early follow up period (Figure 1).

A total of 22 consecutive patients in the period from October 2013 through July 2015, in which TissuGlu was used for approximation and adhesion of the flaps, (TG Group) were similarly reviewed and this data was compiled using the same format.

Statistical means, standard deviations and median values were calculated for each data group. P values were calculated using Student's T-Test, Mann-Whitney or Fisher's exact test, as appropriate to the data set.

Results

The groups were found to be comparable for basic demographic values: Age (TG Mean 73.2 vs. SWC Mean 66.5, $p=0.113$) and BMI (TG Mean 23.6 vs. SWC 24.8, $p=0.474$) (Table 1).

Values for procedure variables and risk factors were also mostly comparable: Number of pressure ulcers per patient treated surgically (TG Mean 1.1 vs. SWC 1.1 $p=0.762$), Stage of pressure ulcer (TG Mean 4.0 vs. SWC 3.9, $p=0.838$), whether VAC and debridement had been performed prior to the flap surgery (TG Mean 36.4% vs. SWC 39.3% $p=0.832$), whether the procedure in question was for a recurrence (TG Mean 22.7% vs. SWC 25% $p=0.851$) and in the number of drains placed (TG Mean 1.5 vs. SWC 1.4 $p=0.835$). The procedure duration was somewhat longer in the SWC group (TG Mean 54.7 minutes vs. SWC 76.4 mins $p=0.004$) (Table 2).

Regarding outcomes, the duration of drainage was similar (TG Mean 8.7 days vs SWC 9.1 $p=0.672$). The percentage of patients requiring revisions in the TG group was less than half that of the SWC group, but this difference did not reach significance in our sample size (TG Mean 13.6% [3 of 22 pts] vs SWC 32.1% [9 of 28 pts] $p=0.186$) and the total number of revisions was 3 in the TG group vs 22 in the SWC group (avg. 2.4 revisions per patient requiring a revision procedure in the SWC group vs 1 in the TG group). The Mean number of revision procedures per patient was 0.1 in the TG group vs. 0.8 in the SWC group. The duration of stay was significantly shorter in the TG group (Mean 15 days) vs the SWC group (Mean 23.6 days), $p=0.022$ (Table 3).

Discussion

The reduction of more than 50% in the need for revision surgery in the TissuGlu group (from 32% of patients to less than 14%), though it did not quite reach significance in this limited series, strikes us as being important. The fact that this data point is supported by a corresponding and statistically significant reduction in average length of stay of greater than 1 week (from an average of 23.6 days to 15.7 days) gives us the confidence to draw conclusions for our own practice (Figures 2 and 3).

There was one patient in the SWC group who could be considered an 'outlier'. This patient required a total of 7 surgical procedures before the wound was successfully healed and was in the hospital for a total of 77 days. With this patient removed from the analysis the results were not substantially changed however. The number of revisions in the group drops from 22 to 15, as compared with 3 in the TissuGlu group and the percentage of patients requiring revision drops from 32.1% to 29.6% as compared with 13.6% in the TG group. The average duration of stay in the hospital drops from 23.6 days to 21.6 days, as compared to the 15.7 days for the TG group.

Dead space between tissue planes in the post-surgical period will naturally fill with fluid. This fluid accumulation, if present in a large volume, can separate the tissue planes, impeding the wound healing process. Multiple approaches to eliminating dead space and holding tissue planes in approximation have been reported and extensively analysed [14]. Standard surgical drains with suction are thought to assist in the elimination of dead space and the prevention of seroma. While the efficacy of drain use for prevention of postoperative complications has been challenged in the literature [19] and strong evidence supporting their use is lacking, they are still used as standard of care in most practices. While the prospect of no-drain closure is of interest and may prove to be an additional benefit associated with use of the adhesive, for now we continue to use suction drains in all of our flap surgeries, in conjunction with TissuGlu.

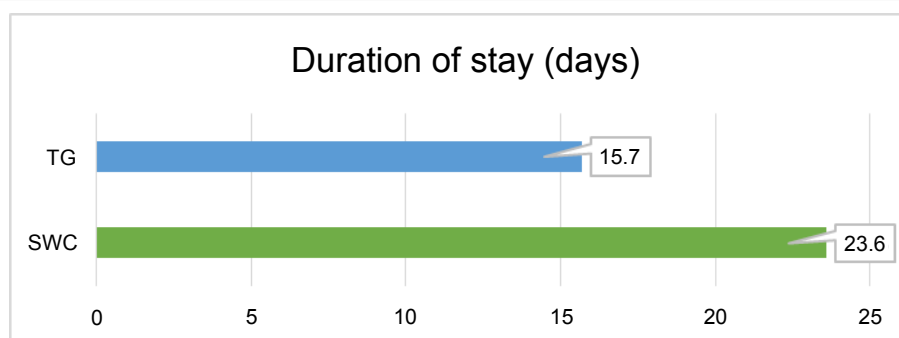


Figure 2: Significant shorter time in hospital for the TG-group patients.

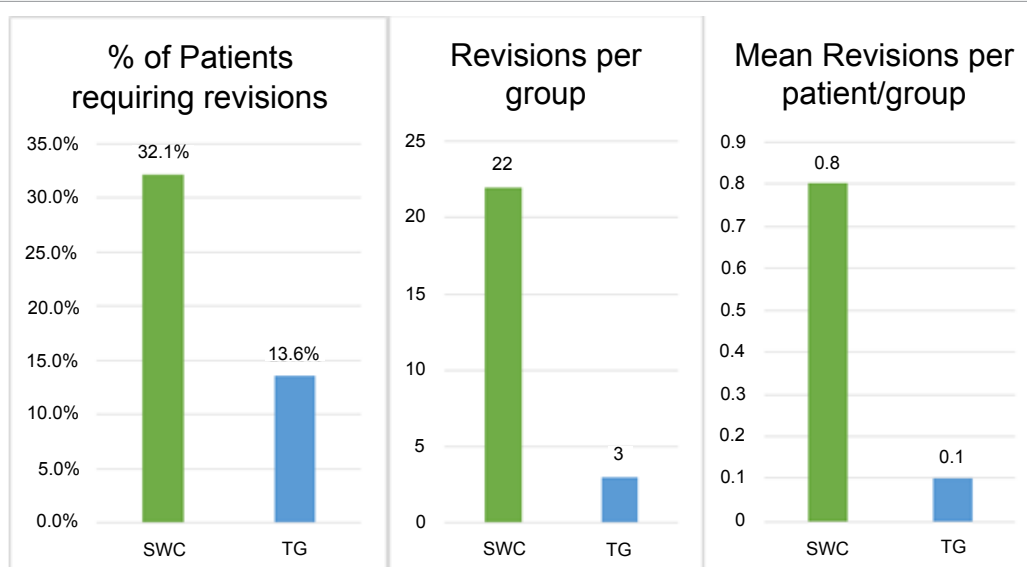


Figure 3: Less revision surgery in the TG-group.

Post-operative movement and associated shear forces have been indicated as factors in delayed wound healing and seroma formation [20]. In large flap surgery such as abdominoplasty, suturing techniques are sometimes used for elimination of dead space [15,21] and to resist shear. Use has also been reported in latissimus dorsi donor site flap surgery and mastectomy closure [16]. These techniques, variously referred to as “Baroudi”, “Progressive Tension” or “Quilting” sutures, have been shown to be effective, even in meta-analyses and review articles [14], demonstrating that the principle of flap fixation is a valid approach to improving healing in procedures involving extensive undermining between tissue planes. In flap surgery for decubitus the underlying tissue is often inadequate for this kind of technique however and, if done with care and attention it can add substantial time to the procedure. In fact we found no reports in the literature of suturing techniques being used for the closure of dead space or as prevention against the effect of shear forces in the postoperative period after Stage IV decubitus flap surgery. It is also believed that sutures create zones of tissue necrosis due to compression under the knot. We feel that a less invasive technique would be preferable in decubitus repair.

Alternatives to suturing techniques for closure of dead space have been evaluated. Use of fibrin sealants has been widely reported and some investigators have found them to be useful [22], but the review and meta-analysis data generally conclude that this type of product does not provide any measurable benefit, other than perhaps a lower volume

of drainage in the first few days [23]. The period of adhesion required in order to maintain approximation of the tissue planes during the full wound healing process is longer than the duration of fibrin based products, which are largely broken down through fibrinolysis within a few days. In healthy patients the critical phase of wound healing takes approximately 10 days; however in most decubitus patients, due to underlying nutritional and circulatory factors, this timeframe can be significantly longer. In order to be appropriate for this indication, an adhesive should remain at full strength for 3 weeks or more. In addition, the strength required to resist some shear forces is greater than what a fibrin clot can provide.

Higher strength adhesives, such as cyanoacrylates, are generally limited to external use, due in part to the potential for toxic by-products such as formaldehydes in the breakdown phase and also due to the very short curing times, which would generally render them difficult to use in these larger flaps.

A high strength adhesive which maintains its strength for several weeks, is biocompatible and relatively easy to apply would seem to respond ideally to the requirements of this type of surgery. We have found TissuGlu® to be easy to apply in these procedures, where extensive undermining is often required in order to approximate the edges and close a defect, resulting in a large wound surface in the subcutaneous space. Adhesive drops are laid out in a grid pattern on

the tissue surface with the aid of an applicator prior to flap closure. The flap is then lowered onto the underlying tissue surface, taking care to avoid smearing of the drops, and the flap is held still by an assistant while the wound edges are sutured. As the adhesive takes approximately 30-45 minutes to reach fully cured strength, care is also taken in the immediate postoperative period to avoid shear force on the wound. The adhesive remains at high strength for 3-4 weeks before being gradually broken down through hydrolysis into biocompatible components that are easily eliminated [24,25]. From an economic perspective the savings in reduced procedure costs and reduced time in the hospital far outweigh the cost of the device.

As will always be the case with retrospective analyses, the quality of the data sets is not perfect. The size of the sets is not matched (22 vs. 28 patients) and some potentially important values, such as smoker status and total surface area of the wound prior to final closure, were rarely recorded in the earlier patient charts and were not able to be used in assessing the two groups for baseline equivalence. A difference in duration of surgery between the two groups was noted, but we do not consider it to be indicative of either a speed advantage from the adhesive or a real difference in the surgical procedures themselves. It is possible that different staff over time had somewhat different interpretations or different methods for measuring and recording some values. Consequently, this data analysis should be considered as indicative of possible associations rather than as conclusive evidence. This said however, we do not believe that our patient population, our criteria for surgery or the type and size of wounds we see has changed significantly over these 4 years. Our surgical approach has remained fairly consistent and most of the procedures in both the earlier set and the later set were performed by the same surgeons. Our discharge criteria have remained consistent throughout the study period considered. The only relevant change in practice between the SWC group and the TissuGlu group is the use of the surgical adhesive.

With the caveats and considerations mentioned above in mind, we feel that the data support our original impressions – that the use of the adhesive aids in faster and better wound healing on average after this type of surgery. A greater than 50% reduction in the number of patients requiring revision surgery, even though it did not reach statistical significance, and a reduction in average length of stay of greater than 1 week, are hugely valuable improvements for these patients and represent significant savings for the health system as well.

Post-surgical complications related to wound healing after surgical repair with tissue flaps in decubitus patients remain disturbingly high. One consequence of this is that surgery is often avoided or seen only as a last resort. Attempts at healing through use of VAC wound therapy or other 'less invasive' approaches are sometimes protracted for months without achieving wound closure. If complication rates can be brought down and success rates increased, would more patients be considered candidates for surgery earlier in the clinical experience? In our practice the answer is 'yes'.

Conclusion

In this particularly vulnerable and problematic patient population any developments leading to improved outcomes are important. The highest priority is successful healing of the surgical wound in as short a time as possible. Successful wound healing, or at least clear progress towards successful wound healing, is generally considered the minimum criterion for patient discharge.

The data reported here support the empirical observations of our medical and nursing staff, many of whom have noticed and commented

on the improvement in wound healing outcomes with the use of TissuGlu in decubitus patients. While the retrospective nature of this analysis as well as the lack of available data on some potentially relevant risk factors limits the study conclusions, the data is nonetheless valuable as it is the first report on a series of decubitus repair surgeries using this adhesive to maintain approximation of the tissue planes during the healing process. The results, although preliminary in nature, are considered suggestive of a potentially beneficial approach to improving surgical outcomes for these difficult patients, as indicated by the significant reduction in hospital stay. We hope that this report will lead to further investigation and validation of our observations through larger prospective, and where appropriate, randomized studies.]

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