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Silk Fibroin Wound Dressing Significantly Decreases Hypersensitivity Compared to 2-Octyl Cyanoacrylate Mesh Dressing

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ABSTRACT

Background: Mesh dressings sealed with 2-octyl cyanoacrylate have been associated with hypersensitivity following total joint arthroplasty. Silk fibroin is a biopolymer available as a novel adhesive woven dressing that does not require skin glue and allows permeability. The purpose of this study was to compare hypersensitivity, delayed wound healing, wound edge separation, reoperations within 90 days, dressing application time, and cost differences between silk dressings and 2-octyl cyanoacrylate mesh dressings.

Methods: We reviewed 261 consecutive patients who received either silk or mesh dressings for the incidence of hypersensitivity, delayed wound healing, wound edge separation, reoperations, dressing application time, and cost after total joint arthroplasty. Silk fibroin dressings were used in 58 patients, while 2-octyl cyanoacrylate mesh dressings were used in 203 patients. Statistical analyses were performed using independent *t*-tests, *Chi*-square tests, two-sided Fisher's exact tests, and multivariate logistic regressions.

Results: The silk group had a lower rate of hypersensitivity (0 versus 9.9%, $P = 0.009$). We observed delayed wound healing associated with hypersensitivity in 1% of mesh patients. There were no cases of wound edge separation in knee cases in either group. There were no differences in reoperations. With silk dressings, the total average cost savings were \$465.91 per case. There was \$327.34 in dressing cost savings and \$138.57 in operating room cost savings, with an average of 3.7 minutes of operating room time saved.

Conclusions: Silk fibroin dressing was associated with less hypersensitivity and shorter application time as compared to the 2-octyl cyanoacrylate mesh dressings, with no cases of wound edge separation on removing the silk dressing, even with early knee motion protocols. Although direct costs will vary with institutional pricing, we found substantial savings with the silk dressing. Eliminating the glue drying time saved 3.7 minutes, which can be impactful in health systems that do not have parallel-processing efficiencies.

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Medical adhesive-related skin injuries (MARSIs) are largely avoidable forms of skin damage caused by medical adhesives such as tapes, glues, wound dressings, and wound closure strips [1]. Skin injuries can manifest as skin tearing, blistering, dermatitis, pruritis, burning, and wound breakdown [1,2]. In addition, trapped antiseptic skin prep beneath adhesive dressings may play a contributory role in skin damage [3–9]. Medical adhesive-related skin injuries and its treatment with topical corticosteroids can compromise the skin barrier and delay wound healing. In extreme

cases, MARSI can lead to increased pain, longer hospital stays, readmissions, reoperations, surgical site infections, and generalized morbidity [1,2]. The MARSI symptoms are often underreported because they are promptly treated in the normal course of recovery, making their true incidence incompletely understood [1]. There was one orthopaedic study that reported a 36% incidence rate of MARSI following spinal surgery [10]. Across different medical specialties, reported rates of MARSI vary widely, ranging from approximately 3% to as high as 60% [10–15].

A 2-octyl cyanoacrylate wound adhesive (Dermabond Prineo, Ethicon, Raritan, New Jersey) is commonly used in total joint arthroplasty (TJA), and when combined with mesh, has been found to improve outcomes compared to other dressings such as plain gauze, silver-impregnated occlusive dressings, or negative pressure dressings [16–19]. However, this dressing has been associated with dermatitis rates ranging from 0.5 to 14%, which can cause discomfort and potentially slow healing after surgery [20–24]. Silk fibroin, approved as a biomaterial by the US Food and Drug Administration in 1993, has been extensively studied in relation to tissue engineering and suturing and is now available as a surgical wound dressing (SYLKE, La Jolla, California) [25–33]. This woven mesh is made of 99.9% sericin-free silk fibroin, coated with a pressure-sensitive adhesive, and designed to remain in place for 2 weeks [34].

The purpose of this study was to compare hypersensitivity, delayed wound healing, wound edge separation, reoperations within 90 days, dressing application time, and cost differences between silk dressings and 2-octyl cyanoacrylate mesh dressings. We hypothesized that silk dressings would reduce hypersensitivity as compared to mesh dressings.

Methods

Patient Selection and Data Collection

This institutional review board-approved retrospective single-surgeon cohort study included 261 consecutive TJA patients from April 30, 2024 to December 17, 2024 and compared silk fibroin ($n = 58$) to 2-octyl cyanoacrylate mesh ($n = 203$) dressings. The TJA patients included all total knee arthroplasty (TKA), total hip arthroplasty (THA), unicompartmental knee arthroplasty (UKA), revision TKA, and revision THA patients. The mesh group included two revision THAs and eight revision TKAs, while the silk group contained no revision cases. We excluded patients who received negative pressure wound dressings or a different wound closure protocol. Data extraction came from the electronic medical record, Health Insurance Portability and Accountability Act-compliant messaging, and office call records. We collected patient demographics, dressing application times, wound outcomes, reoperations, and cost for each dressing.

There were no significant differences in age, sex, or body mass index (BMI) between the two groups (Table 1). Although the mesh group included 10 revisions compared to none in the silk group, there was no hypersensitivity, wound delay, or reoperations among these cases. Multivariate logistic regression analysis was controlled for age, BMI, and sex ($P > 0.05$ for all).

Technique

All knees were performed through a midvastus approach. All knee implants were cemented. A tourniquet was inflated before incision and deflated once the cement had cured. The arthroscopy was repaired with STRATAFIX Symmetric 1-0 PDS suture (Ethicon, Raritan, New Jersey). The superficial fascia and skin were repaired with Quill 0 Monoderm suture and Quill 3-0

Table 1
Demographics.

Variable	Silk Fibroin Dressing Cohort ($n = 58$)	2-Octyl Cyanoacrylate Mesh Dressing Cohort ($n = 203$)	Total ($n = 261$)	P-Value
Sex, n (%)				
Women	34 (58.6)	120 (59.1)	154 (59.0)	0.95
Men	24	83		
Age (mean, years)	68	69	69	0.25
BMI (mean)	29.1	28.2	28.4	0.31
Case type				
TKA	30	100	130	
THA	20	64	84	
Revision TKA	0	8	8	
Revision THA	0	2	2	
UKA	8	29	37	
Cost (\$)				
Cost of dressing	60	387.34		
Time (sec)				
Dressing application time (mean)	40 ($n = 56$)	262 ($n = 105$)		<0.001

Significant values are in bold.

BMI, body mass index; TKA, total knee arthroplasty; THA, total hip arthroplasty; UKA, unicompartmental knee arthroplasty.

Monoderm suture, respectively (Corza Medical, Westwood, Massachusetts). All hip arthroplasties were performed through a direct anterior longitudinal incision. After implantation, the anterior capsule was repaired with a dissolvable suture. The fascia overlying the tensor fascia lata was repaired with STRATAFIX Symmetric 1-0 PDS suture. The superficial fascia and skin were repaired with Quill 0 Monoderm suture and Quill 3-0 Monoderm suture, respectively.

Following subcuticular closure, the iodophor dressing was removed, and the surgical incision was cleansed with a wet sponge and dried. The investigating surgeon switched dressings in October 2024, with 2-octyl cyanoacrylate mesh dressings used before the switch date and silk dressings used after. Both were applied according to the manufacturer's instructions. For the silk dressing, the adhesive backing was removed, and the strip was placed with a one-centimeter overlap of nonincised skin. The excess strip was trimmed, and the dressing was pressed gently to secure. For the mesh dressing, the adhesive backing was removed, and the mesh was placed with a one-centimeter overlap of nonincised skin. The excess was trimmed, and the liquid adhesive was applied. After the skin adhesive cured and immediately after the silk dressing was placed, gauze was applied and either secured with an elastic bandage (knee) or paper tape (hip). Patients were instructed to remove the gauze on day one and were then allowed to shower without replacing the gauze or elastic wrap. Patients were seen at 2 weeks, when the silk dressing was removed, and again 8 weeks after surgery, with additional visits scheduled as needed. The clinical team (surgeon, nurse, and physician assistant) evaluated the skin at each postoperative visit as part of a checklist in the medical record. When a skin complication was noted, photographs of the incision were selectively added to the media section of the medical record. Knee protocols instructed patients to achieve up to 110 degrees of flexion hourly starting the day of surgery.

The duration of dressing application had been recorded as part of an unrelated quality improvement effort to increase efficiency and to provide data to the hospital procurement team in support of changing dressings. These data were retrospectively available in the surgeon's database. The dressing time was recorded by an assistant using a stopwatch for 105 of 203 mesh patients and 56 of 58 silk patients.

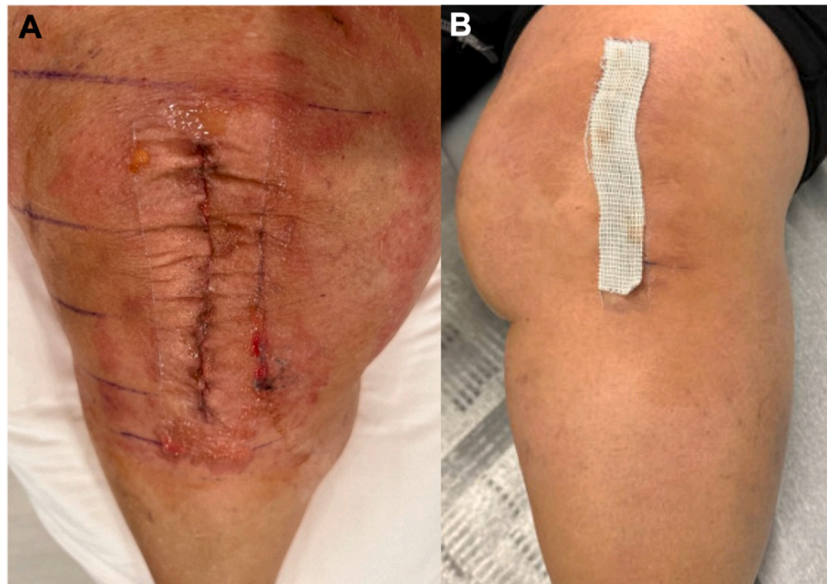


Figure 1. (A) A 69-year-old woman developed hypersensitivity 4 days after a TKA with 2-octyl cyanoacrylate mesh dressing. She was treated with betamethasone valerate 0.1% ointment and 5 days of oral prednisone (40 mg/d), with resolution (image not shown). (B) 56 days later, the same patient had a TKA on the other knee with silk fibroin dressing. At the 2-week follow-up, no hypersensitivity was observed. TKA, total knee arthroplasty.

Data Analyses

The rates of hypersensitivity, delayed wound healing, and reoperations within 90 days were compared between the two cohorts using Fisher's exact tests. *Chi-square* tests and independent *t*-tests were used to compare sex, age, BMI, and time differences between the cohorts. Multivariate regressions were conducted to control for sex, age, and BMI. Overall costs were calculated as the direct expense of each dressing and the indirect expense of time using an average operating room (OR) time cost of \$37.45 per minute [35]. Statistical analyses were performed using Statistical Analysis System (SAS) Studio version 3.81 (SAS Institute Inc., Cary, North Carolina). To ensure adequate statistical power, a two-tailed *post hoc* power analysis was performed using G*Power 3.1 with an alpha error probability of 0.05, yielding a computed power of 0.95.

Results

There was a 0% incidence of hypersensitivity with silk compared to 9.9% hypersensitivity with mesh ($P = 0.009$, Figure 1 and Table 2). Hypersensitivity was found in nine TKA, three medial UKA, and eight THA cases.

Delayed wound healing was 0% with silk dressings compared to 4.9% with mesh dressings ($P = 0.12$, Table 2). Delayed wound healing was found in six TKA and four THA cases. Delayed wound healing associated with hypersensitivity was observed in 1% of the mesh patients. No patients showed any signs of wound edge separation on removal of the silk dressing.

There was a 0% incidence of reoperations within 90 days with silk, as compared to a 1.5% ($n = 3$ of 203, two TKAs, and one medial UKA) reoperation rate with mesh, all for infection. With the numbers studied, this did not reach significance ($P = 1.00$, Table 2).

Our institution paid bulk pricing for the silk dressing at \$60 each, with the manufacturer's suggested retail price (MSRP) listed as \$120. Though there are pricing arrangements that can lower the cost of mesh dressings, our institution obtained the mesh at the

MSRP of \$387.34 each. The difference in direct cost of the dressings was \$327.34 each, in favor of silk.

The average application time for the silk dressing was 40 seconds. The average application time for mesh was 4.4 minutes ($P < 0.001$). Assuming the 3.7 minutes saved translates fully into less OR time used, the indirect cost savings were \$138.57 per silk dressing. The total cost savings were \$465.91.

Discussion

We found that silk dressings resulted in less hypersensitivity, shorter application times, and lower costs compared to mesh dressings. Although the two dressings have different tension strengths, we found that the silk dressing performed well with no cases of wound edge separation. This was notable especially in the knee arthroplasty patients (66% of the cohort) instructed to flex their operative knee immediately after surgery.

These findings confirm the existing literature, which consists of two prospective studies on silk dressings, both published by the inventors. Rouhani et al. conducted a randomized, single-blinded trial on 25 patients having abdominoplasty or reduction mammoplasty, with patients receiving silk on one side of their body and mesh on the other side [29]. They found that silk significantly reduced the incidence of MARS. Corticosteroids or antibiotics were required to treat MARS in 52% of the mesh side and 0% of the

Table 2

Rates of hypersensitivity, Reoperations Within 90 D, and Delayed Wounding Healing.

Variable	Silk Fibroin Dressing Cohort (n = 58)	2-Octyl Cyanoacrylate Mesh Dressing Cohort (n = 203)	Total (n = 261)	P-Value
Complications, n (%)				
Hypersensitivity	0 (0)	20 (9.9)	20 (7.7)	0.009
Reoperations	0 (0)	3 (1.5)	3 (1.1)	1.00
Delayed Wound Healing	0 (0)	10 (4.9)	10 (3.8)	0.12

Significant values are in bold.

silk side [29]. Rouhani et al. conducted a randomized, single-blinded clinical trial of 50 patients having abdominoplasty, reduction mammoplasty, or brachioplasty, with silk used on one side and adhesive strips (3M Steri-Strips, Two Harbors, Minnesota) on the other side [30]. They compared 50 new patients with the silk half of the 25 patients from the prior study for a non-contemporaneous 75-patient analysis [30]. Compared to strips, they found that silk had statistically significantly less erythema (zero versus 20.8%), less triple-point separation (9.3 versus 30.2%), and less partial dressing detachment (zero versus 18.8%) [30].

Our current study found a 10% rate of hypersensitivity to mesh dressings, which was lower than these inventor-led studies but high among all studies investigating hypersensitivity [20–24,29,30]. Our finding of an absence of hypersensitivity in the silk group was consistent with these two inventor-led studies [29,30]. The mesh component is made of woven polyethylene terephthalate, a polymer commonly used in sutures (e.g., MER-SILINE, Ethicon, Somerville, New Jersey), which have not had a concern for hypersensitivity [36]. There is a known allergenicity to 2-octyl cyanoacrylate, confirmed with repeated exposure challenges by patch testing [22,23,37]. The impermeable nature of the mesh dressing is also suspected to have a role in dermatitis reactions. When caustic topical medications, like durable chlorhexidine gluconate skin prep, remain on the skin before mesh application, the impermeable function of the dressing seals the substances against the skin for a prolonged exposure time [3–9]. The more permeable nature of silk may help reduce the impact of any residual substances on the skin. This permeability was not found to have any negative consequences on dressing performance, as all patients were allowed to shower the day after surgery without covering it.

The silk dressing is made of 99.9% sericin-free silk fibroin. Silkworm silk consists of two proteins: fibroin and sericin [26–33,38,39]. Most silk originates from *Bombyx mori*, the domestic silk moth, which consists of around 70% silk fibroin and 30% sericin [32,33,38,39]. The fibroin is a semicrystalline structured protein that contributes to the strength and resilience of the silk, while sericin is an amorphous protein-polymer that acts as a protective coating and gumming agent [26–31,40]. In its naturally occurring form, silk is associated with adverse inflammatory reactions. These reactions are generally attributed to the sericin component of silk [26,28,31].

Prior studies have shown the benefit of mesh dressings over other dressings [16–19]. In those studies, Herndon et al., Anderson et al., and Woelfle et al. found rates of wound healing delay of 3.8, 1.14, and 3.2% and reoperation rates of 1.1, 0, and 0.4%, respectively, with mesh dressings [16–18]. Those studies did not examine hypersensitivity rates. The 4.9% delayed wound healing rate found in this study with mesh dressings was higher than expected. Delayed wound healing can be from several factors, including patient health status, obesity, surgical trauma, flawed closure technique, poor hemostasis, infection, and dressing performance. We do not believe our high rate in this study reflects dressing performance. Within the mesh group, only 1% of patients had delayed wound healing associated with hypersensitivity (i.e., dressing performance).

The tensile strength for the mesh dressing is reported to be 166.53 N [41]. Although the tensile strength for the silk dressing is not currently available, it is probably less due to the differences in material composition and lack of augmentation with glue. Therefore, an important question was whether the silk dressing could protect the wound in high-tension applications like the knee, where the incision is put under tension almost immediately after surgery. We found no signs of wound edge separation on removal of the silk dressing. Average knee flexion at the time of silk removal (around 2 weeks) was 103 degrees.

Our hospital's direct cost savings with silk dressings were \$327.34 per case, and our indirect cost savings were \$138.57 per case. However, it is important to note that the cost of mesh can be well below MSRP when hospitals have umbrella purchasing agreements. Furthermore, with effective parallel processing, the full amount of time awaiting adhesive curing may not be fully additive to the total OR time. Additional savings may accrue from fewer phone calls, office visits, and corticosteroid treatments related to MARS, but these were not investigated in this study.

Potential Limitations

There were several potential limitations with this study. This study was retrospective and has all the associated shortcomings of retrospective studies. Although procedures are generally standardized, the staff performing the closure or dressing application may change. It is possible that some wound issues were missed. These shortcomings are mitigated by the consecutive nature of the study population and the single-surgeon design for technique standardization. Our calculations for the direct cost savings of silk are unique to our pricing structure. Similarly, the indirect savings for shorter application times will vary by institution, and as discussed, may not translate into less OR time used for highly efficient systems. Finally, we did not control for the thoroughness of removal of chlorhexidine from the skin in this study, which may affect our rates of hypersensitivity.

Conclusions

Silk dressings were associated with significantly fewer cases of hypersensitivity as compared to a commonly used mesh adhesive dressing. Furthermore, these dressings were associated with less cost and shorter duration of dressing application.

CRediT authorship contribution statement

Klara I.M. Aastroem: Writing – review & editing, Writing – original draft, Investigation, Formal analysis, Data curation, Conceptualization. **Nana O. Sarpong:** Writing – review & editing, Methodology, Investigation, Conceptualization. **Alexander L. Neuwirth:** Writing – review & editing, Methodology, Investigation, Conceptualization. **H. John Cooper:** Writing – review & editing, Methodology, Investigation, Conceptualization. **Jeffrey A. Geller:** Writing – review & editing, Methodology, Investigation, Conceptualization. **Roshan P. Shah:** Writing – review & editing, Validation, Project administration, Methodology, Investigation, Formal analysis, Conceptualization.

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