

# Head and Neck Wound Reconstruction Using Biodegradable Temporizing Matrix Versus Collagen-Chondroitin Silicone Bilayer

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## Abstract

**Background.** Head and neck reconstruction is challenging because of the functional requirements of movement, sensation, and cosmesis of this highly visible region. This study is the first to compare Novosorb biodegradable temporizing matrix (BTM) and Integra collagen-chondroitin silicone (CCS) skin substitutes for reconstruction of soft tissue head and neck wounds.

**Methods.** This retrospective review included adults who underwent wound reconstruction of the head/neck with either BTM or CCS between 2015 and 2020. Patient-level data, complications, and closure rates were compared.

**Results.** The review identified 15 patients: 5 who received BTM and 10 who received CCS. Mean age at dermal template placement was 55 (range, 28-79) years. Race, sex, smoking status, medical comorbidities, defect size, radiation history, prior surgeries, and follow-up time were not significantly different between groups. Wound etiologies for BTM and CCS included burn (40% vs 60%), trauma (20% vs 20%), surgical wounds (20% vs 20%), and skin cancer (20% vs 0%), respectively ( $P = .026$ ). Skin grafts were placed in 8 (80%) wounds after CCS placement, compared with 3 (60%) after BTM ( $P = .670$ ). Template reapplication was required in 2 (40%) BTM wounds and 3 (30%) CCS wounds ( $P = 1.0$ ). Infection, hematoma, and seroma were comparable between groups, although skin graft failure was higher in the CCS group at 3 (37.5%) compared with 0 for BTM ( $P = .506$ ). More secondary procedures were required after CCS placement (CCS,  $1.9 \pm 2.2$ ; BTM,  $0.9 \pm 0.8$ ;  $P = .090$ ). Definitive closure in patients not lost to follow-up occurred in 4 (100%) BTM and 6 (75%) CCS cases ( $P = 1.0$ ).

**Conclusions.** Head and neck wounds treated with BTM had comparable closure and complication rates as CCS bilayer and required fewer secondary procedures and skin grafts. These findings suggest that BTM is safe and efficacious for application in head and neck wounds and may be considered as an economical alternative.

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**Keywords:** biodegradable temporizing matrix; dermal substitute; head and neck; Integra; Novosorb; wound healing

## Introduction

Complex head and neck wounds can be difficult to reconstruct given the high functional and aesthetic requirements of this anatomic region. Wound reconstruction options include primary closure, skin grafting, local tissue rearrangement, or free tissue transfer. Wounds that are contaminated or lack a vascularized wound bed are not amenable to skin grafting and more complex reconstructive options, which can be complicated by longer operative times and may require patient comorbidities.<sup>1</sup> Alternatively, these wounds can be covered with one of several commercially available skin

substitutes that are often designed with biological and nonbiological components that act as scaffolding for wound regeneration and subsequent skin grafting. Integra collagen-chondroitin silicone (CCS) bilayer (Integra LifeSciences Corp) is the gold-standard skin substitute and has been widely used for decades,<sup>2-4</sup> with reports demonstrating its success in head and neck wounds.<sup>5-7</sup> However, its animal-derived components and slow production drive costliness and infection rates; therefore, other skin substitutes continue to be explored. Novosorb biodegradable temporizing matrix (BTM, PolyNovo Ltd) is a recently developed skin substitute comprising synthetic polyurethane foam and a temporary nonbiodegradable

polyurethane seal.<sup>8</sup> Histological studies have shown that new tissue integrates into the foam through vascularization to form a neodermis,<sup>9</sup> and case series in humans have highlighted its successful wound healing properties.<sup>10-16</sup> This is the first study to compare BTM and CCS in the reconstruction of soft tissue head and neck wounds.

## Methods and Materials

This retrospective study included adults who underwent wound reconstruction of the head and/or neck, with either BTM or CCS bilayer between January 1, 2015, and August 31, 2020, at a level 1 trauma center. Patients were excluded if they were under 18 years of age at time of dermal template placement, received application of multiple or other skin substitutes, or if the wound was not in the head/neck region. Surgeon preference dictated selection of dermal template based on wound and patient features. Patients were identified by searching current procedure terminology codes for skin substitutes.

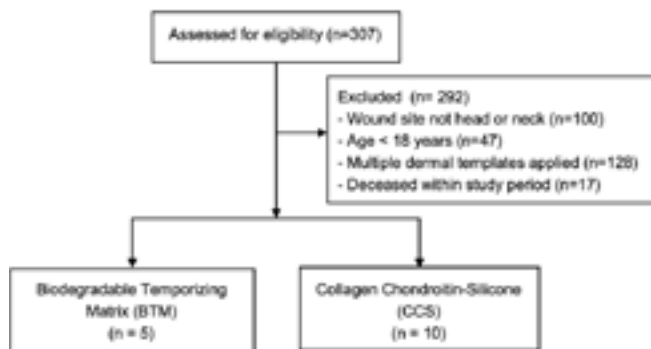
Demographics, comorbidities, wound characteristics, and operative details were recorded from the electronic medical record. The primary outcome was complete wound healing, defined as 100% re-epithelialization of the wound at any postoperative follow-up visit. Secondary outcomes included infection (ie, oral or intravenous antibiotic requirement, positive wound culture, or clinical signs such as purulence), graft or template failure, time to complete healing, number of skin grafts needed, and number of reoperations. Graft or template failure was defined by permanent removal and replacement. Time to complete healing was achieved if evidence of a healed wound was recorded at a postoperative follow-up visit.

### Statistical Methods

Categorical factors were described with frequencies and percentages. Normality of continuous measures was determined by the Shapiro-Wilk test; parametric variables were summarized with means and SD, and nonparametric variables were summarized with median and interquartile range (IQR). Categorical variables were compared using the Fisher exact test and chi-square test where appropriate. Continuous variables (eg, age, body mass index, time to skin grafting, time to closure) were compared using 2-sample *t* tests. All analyses were performed on R software (v4.1.1) with *P* values < .05 considered statistically significant.

## Results

Of the 15 patients who met the inclusion criteria, 5 (33.3%) were treated with BTM and 10 (66.6%) with CCS (**Figure 1**). **Table 1** summarizes the demographic and treatment characteristics. Mean (SD) age at template placement was 66.0 (12.8) years in the BTM group and 49.5 (11.7) years in the CCS group (*P* = .044);



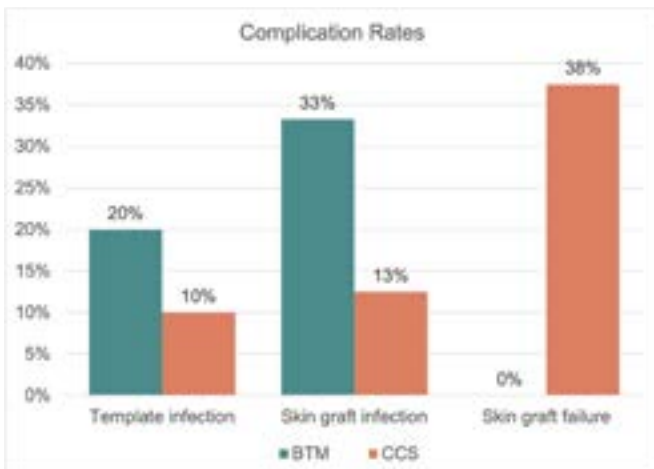
**FIGURE 1.** Patient selection flow diagram.



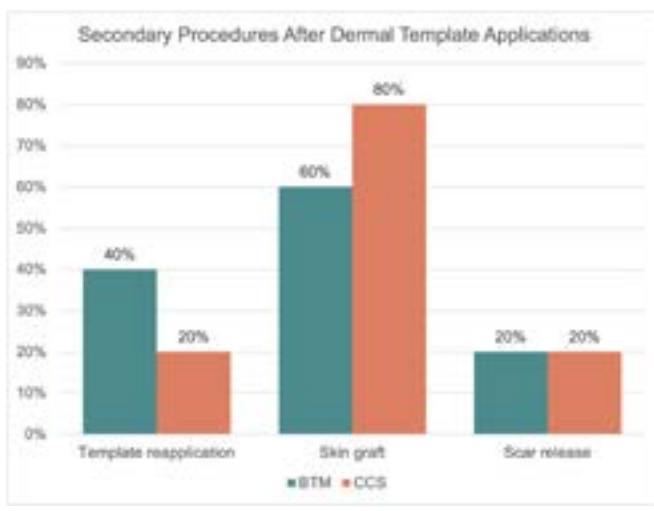
**FIGURE 2.** Skin graft requirements and achievement of complete wound closure rates in head and neck wounds compared between BTM and CCS.

all other comorbidities were not significantly different. Among the 15 patients, 1 (7.1%) had prior radiation history to the surgical site. Median (IQR) follow-up time was 15.3 (3.8-26.8) months in the CCS group and 8.4 (6.8-8.4) months in the BTM group (*P* = .594). There were 2 (20.0%) CCS wounds and 1 (20.0%) BTM wound lost to follow-up (*P* = 1.0). All burns were full-thickness injuries, and most burns were treated with CCS (*n* = 6, 60.0%) rather than BTM (*n* = 2, 40.0%). All BTM cases were applied by plastic surgeons, whereas CCS wounds were applied by both plastic surgeons and burn surgeons. Median (IQR) wound area was 213 (190-369) cm<sup>2</sup> for BTM and 193 (73-265) cm<sup>2</sup> for CCS (*P* = .670). Exposed bone was present in 1 wound treated with CCS and skin grafting; the patient achieved wound healing on postoperative day 28.

Median (IQR) template size was similar between groups, at 238 (147-479) cm<sup>2</sup> for CCS and 225 (200-365) cm<sup>2</sup> for BTM (*P* = .951). Template reapplication was required in 3 (30%) CCS and 2 (40%) BTM wounds (*P* = 1.0). Skin grafts were required in 3 (60%) BTM group patients compared with 8 (80%) CCS group patients



**FIGURE 3.** Template infection, skin graft infection, and skin graft failure rates in head and neck wounds compared between BTM and CCS.



**FIGURE 4.** Template infection, skin graft infection, and skin graft failure rates in head and neck wounds compared between BTM and CCS.

( $P = .560$ ; **Figure 2**). Despite similar wound and template sizes, size of the skin graft was smaller for those in the BTM group ( $P = .776$ ). Median (IQR) time to skin grafting was longer in the BTM group at 39 (30-72) days compared with 18 (14-21) days in the CCS group ( $P = .050$ ). Mean number of skin grafts after template placement was lower in the BTM group than in the CCS group (0.3 vs 0.5,  $P = .724$ ). There were 2 CCS-treated wounds (480 and 6 cm<sup>2</sup>) and 1 BTM-treated wound (200 cm<sup>2</sup>) that did not undergo skin grafting and healed secondarily, and the remaining BTM wound was lost to follow-up. Template complications occurred in 1 (10.0%) CCS and 2 (40.0%) BTM wounds ( $P = .242$ ; **Figure 3**). Evidence of cellulitis or skin infection was present on 1 BTM wound and 1 CCS wound, and 1 BTM wound had inadequate coverage. Skin graft complications occurred in 5 (50.0%) of the CCS wounds and 1 (20.0%) of the BTM wounds ( $P = 1.0$ ). These included 1 infection, 1 contracture, and 3 skin graft failures in



**FIGURE 5.** Patient with a full-thickness burn injury to the entire face and scalp treated with BTM application. a) Initial burn injury prior to BTM application. b) BTM application on postoperative day 0. c) BTM take was observed in all areas without complications. d) The patient had skin-grafting after BTM application and achieved wound healing in all areas. Left eyelid ectropion is noted at 6 months postoperatively.

the CCS group, we well as 1 infection in the BTM group.

CCS wounds required a mean of 0.9 (range, 0-6) secondary procedures, whereas BTM wounds required a mean of 1.9 (range, 0-4) secondary procedures following template placement ( $P = .090$ ). Secondary procedures were most commonly subsequent skin grafting (**Figure 4**). Of the patients with adequate follow-up time, complete wound healing was attained in 6 of 8 (75.0%) CCS cases and 4 of 4 (100.0%) BTM cases ( $P = 1.0$ ).

## Discussion

Complex head and neck wounds pose a unique challenge to plastic and reconstructive surgeons due to the aesthetic and functional requirements, mechanism of injury, and reconstructive options available. Traditional reconstructive techniques, including use of primary closure, skin grafting, loco-regional flaps, and free tissue transfer, achieve varying degrees of functional and aesthetic results. However, they are all impacted by disadvantages including

**TABLE 1. DEMOGRAPHIC AND WOUND CHARACTERISTICS BY DERMAL TEMPLATE TYPE**

Variable	BTM (n = 5)	CCS (n = 10)	P value	All (N = 15)
Mean age at surgery ± SD, years	66 ± 12.8	49.5 ± 11.7	.044	55 ± 14.1
Male sex	3 (60.0%)	4 (40.0%)	.608	7 (46.7%)
Body mass index ± SD	25 ± 6.1	27.5 ± 5.4	.464	26.7 ± 5.6
Smoking			.800	
Current smoker	1 (20.0%)	4 (40.0%)		5 (33.3%)
Former smoker	2 (40.0%)	2 (20.0%)		4 (26.7%)
Never smoker	2 (40.0%)	4 (40.0%)		6 (40.0%)
Median follow-up in months (IQR)	8.4 (6.8-8.4)	15.3 (3.8-26.8)	.594	9.2 (6.6-20)
Lost to follow-up	1 (20.0%)	2 (20.0%)	1.0	3 (20%)
Indication for skin substitute			.026	
Burn	2 (40.0%)	6 (60.0%)		8 (53.3%)
Trauma	1 (20.0%)	2 (20.0%)		3 (20.0%)
Surgical wound or pressure ulcer	1 (20.0%)	2 (20.0%)		3 (20.0%)
Skin cancer	1 (20.0%)	0 (0.0%)		1 (6.7%)
Specialty of attending provider			.044	
Plastic surgery	5 (100%)	4 (40.0%)		9 (60%)
Burn surgery	0 (0.0%)	6 (60.0%)		6 (40%)
Infected wound prior to surgery	3 (60.0%)	0 (0.0%)	.022	3 (20%)
Median template size, in cm <sup>2</sup> (IQR)	225 (200-365)	238 (147-479)	.951	225 (160-478)
At least one template reapplication	2 (40.0%)	3 (30.0%)	1.0	5 (33.3%)
Use of STSG after template	3 (60.0%)	8 (80.0%)	0.670	11 (73.3%)
Template complication				
Cellulitis or infection	1 (20.0%)	1 (10.0%)	1.0	2 (13.3%)
Skin graft complication				
Cellulitis or infection	1 (33.3%)	1 (12.5%)	1.0	2 (18.2%)
Skin graft failure	0 (0.0%)	3 (37.5%)	.506	3 (27.3%)
Other	0 (0.0%)	1 (12.5%)	1.0	2 (7.1%)
Mean number of secondary procedures ± SD	0.9 ± 0.8	1.9 ± 2.2	.090	1.3 ± 1.6
Closure achieved (excluding lost to follow-up)	4 (100%)	6 (75.0%)	1.0	10 (66.7%)
Median time from operation to closure in months	19.5	6.1 (2.2-11.8)	.571	9.3 (2.4-16)

STSG, split-thickness skin graft.

limited donor site availability,<sup>17,18</sup> poor matching of skin tone or texture, or lengthy complex procedures and associated donor site morbidity.<sup>19</sup> Therefore, dermal templates that can create a wound bed acceptable for skin grafting and achieve acceptable results in matching patient skin characteristics and positive outcomes

can limit the disadvantages after other alternative reconstructive options.<sup>5</sup> The Integra CCS bilayer is the current standard dermal substitute and has demonstrated well-established reliable outcomes for head and neck reconstructive surgeries.<sup>5-7</sup> However, high cost and infection rates are known disadvantages of CCS.

We compared CCS with a newly developed dermal substitute, Novosorb BTM. This is the first report to compare CCS with an alternate dermal substitute in the reconstruction of soft tissue head and neck wounds.

Compared with CCS, BTM is a completely synthetic skin substitute comprised of polyurethane that is ready for application directly from packaging and is easier to handle and secure to the surrounding soft tissue secondary to the tensile strength of the polyurethane component. In a preclinical burn model by Cheshire et al,<sup>20</sup> BTM achieved superior vascularization and host cell infiltration than CCS. Early clinical studies of BTM have reported its successful outcomes in small case series for a variety of wound locations and indications, including burns, lower extremity trauma, necrotizing fasciitis, and surgical wounds.<sup>10,14-16</sup> The potential advantages of BTM include its wider time window allowable for skin grafting<sup>15</sup> and ability to salvage template infections without surgery.

This study comparing BTM treatment in 5 patients and CCS treatment in 10 patients demonstrates similar rates of complications and complete closure in head and neck wounds. The complication encountered most often was skin graft failure in the CCS group and skin graft infection in the BTM group. Furthermore, the number of patients needing at least 1 template reapplication were similar between groups. However, whereas 8 patients (80%) in the CCS group required a second surgery for skin grafting, only 3 patients (60%) in the BTM group required this. This discrepancy indicates an increased likelihood of requiring a secondary skin grafting procedure for patients receiving CCS treatment. Not only are the patients exposed to routine risks of a second surgery, but they are also exposed to a potential source for additional morbidities such as postoperative pain, infection, bleeding, and delayed healing.<sup>21-23</sup> Although this study contains a relatively low number of patients, reducing the need for secondary surgery can reduce costs associated with use of one dermal template compared with another. Furthermore, surgeon specialty may reflect underlying differences in wound status as all BTM cases were applied by plastic surgeons, whereas CCS was applied by both plastic surgeons and burn surgeons.

## Limitations

One primary study limitation is the small sample size of patients with head and neck injuries treated with either BTM or CCS dermal templates. This rendered the study underpowered to detect quantitative differences in characteristics and outcomes between the BTM and CCS groups. Furthermore, because the study examined outcomes retrospectively, it was not possible to minimize the impact of potential confounders through randomization. Therefore, a large-scale, prospective, randomized study is needed. Another limitation of this study is that outcomes such as the rate of complete healing were acquired through review of the electronic medical record. This likely resulted in an

underestimation of the rate of complete healing in both groups as many patients who had healed wounds followed up by telephone visit or forewent their in-person visit. Finally, the lack of evaluation of important outcomes including patient satisfaction, scar appearance, mobility, and secondary contracture were not measured. Given the aesthetic and functional demands of the head and neck region, this information would provide insight into the relative benefits or drawbacks to using the BTM dermal template compared with the CCS dermal template.

## Conclusions

Head and neck wounds treated with BTM demonstrated comparable closure rates; time to healing; and complication rates for infection, dehiscence, hematoma, and seroma compared with CCS bilayer. Wounds treated with BTM required fewer secondary procedures including skin grafting. These findings suggest that BTM is a safe and efficacious alternative dermal template for head and neck wound reconstruction.

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**Ethics:** All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008 (5). This study received Institutional Review Board approval. For a retrospective study, formal consent is not required. Patient consent for photographs was obtained.

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