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ORIGINAL ARTICLE
Reconstructive

Real-world Use of AlloDerm Acellular Dermal Matrix in Head and Neck Procedures in the United States

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Background: Real-world literature evaluating the use of AlloDerm SELECT Regenerative Tissue Matrix in head- and neck-related procedures is limited. To inform patient care decisions, this study evaluated healthcare resource utilization (HCRU) in US adults undergoing head- and neck-related procedures using AlloDerm.

Methods: A retrospective claims analysis was conducted using MarketScan Commercial and Medicare Supplemental Databases (study period: October 1, 2015, to March 31, 2022; index period: November 1, 2015, to March 1, 2022). Adults aged 18 years or older with (1) medical claims for AlloDerm and a skin substitute on the same day during the index period, (2) a head/neck procedure diagnostic code, and (3) 30 or more days of continuous enrollment before and after first AlloDerm use index date. Descriptive statistics were used to describe surgery types and 30-day follow-up reoperations, graft complications, and all-cause HCRU.

Results: Among 431 patients (51.7% women), mean (SD) age was 52.2 (15.8) years. AlloDerm was most used with oral cavity reconstruction (35.3%), septal perforation repair/rhinoplasty (16.5%), and parotidectomy (13.0%). Most procedures were performed in outpatient settings (hospital, 90.0%; ambulatory surgical center, 8.6%). Over 30 days, less than 1% of patients (4 of 431) required reoperation with AlloDerm; 0.5% (2 of 431) had graft-related complications. Most (75.6%) patients had an outpatient visit; few had an emergency room visit (7.9%) or inpatient claim (3.0%).

Conclusions: Real-world evidence indicates that AlloDerm is used in head- and neck-related procedures in US adults, particularly oral reconstruction. Postprocedure complications and reoperations are uncommon during the follow-up period.
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INTRODUCTION

The natural healing of damaged or injured skin architecture is a dynamic process involving complex interactions between cells, extracellular matrix, and growth factors, resulting in connective tissue scarring.[1] Pure regeneration is uncommon, and scar tissue is considered a pathological state due to it lacking the native structure, function, and physiology of the original, uninjured tissue.[1,2] When normal repair processes are not effective or damage is too extensive, patients may require reconstructive procedures such as autologous tissue grafting, which can cause scarring, seroma (fluid accumulation), or wound dehiscence at the donor site.[3] To reduce donor site morbidity and minimize the need for autologous tissue grafts, regenerative medicine for tissue repair and surgical reconstruction may be necessary, including the use of acellular dermal matrices.

Disclosure statements are at the end of this article, following the correspondence information.

Related Digital Media are available in the full-text version of the article on www.PRSGlobalOpen.com.

AlloDerm SELECT Regenerative Tissue Matrix is an acellular allograft of donated dermal tissue, processed to remove cells while preserving the biologic components and structure of the dermal matrix.[4] AlloDerm is approved for use in the repair or replacement of damaged or inadequate integumental tissue, or for other homologous uses of human integument.[4] The early use of AlloDerm also included dermal replacement grafts in patients with burn injury.[3] Since then, the application of AlloDerm has expanded to include tissue augmentation and reinforcement in dental, breast, hernia, and a range of head and neck procedures.[3]

Soft tissue reconstruction in head and neck procedures demands innovative solutions, and existing literature has reported on the effective, successful, and safe use of AlloDerm in parotidectomy[5–8]; nasal reconstruction (including septal perforation repair)[9–18]; tympanoplasty and mastoidectomy[19–26]; and eyelid,[27–36] burn,[29,36,37] and oral reconstruction.[38–43] These studies have reported no or only minor clinical complications, such as infection, inflammation, overcorrection, partial resorption, perforation, and seroma.[3,5–8,11,14,16,22]

Although AlloDerm use has been studied in a variety of clinical applications, including head and neck surgery,[5–45] there is a paucity of published literature evaluating its use and application in real-world settings, including claims analyses. Further, published literature evaluating AlloDerm-specific clinical outcomes and healthcare resource use in head and neck procedures in US adults is limited. The objective of this retrospective, observational claims analysis was to characterize AlloDerm use and healthcare resource utilization (HCRU) outcomes in US adults who underwent head- and neck-related procedures, with the goal of providing evidence-based insights to inform clinical decision-making and enhance patient care.

Takeaways

Question: How is AlloDerm SELECT Regenerative Tissue Matrix used in the real world for head- and neck-related procedures in the United States?

Findings: From the 431 patients identified in this retrospective analysis using Merative MarketScan Commercial and Medicare Supplemental Databases, AlloDerm was most used with oral cavity reconstruction. In the 30 days postprocedure, graft-related complications were rare, and few patients required reoperation (<1%, respectively).

Meaning: This real-world study shows that in the United States, AlloDerm is routinely used in head and neck procedures, most commonly for oral reconstruction procedures; complications or reoperations related to AlloDerm were rare 30 days postsurgery.

MATERIALS AND METHODS

Study Design and Data Source

A retrospective observational study was conducted using administrative claims from the Merative MarketScan Commercial and Medicare Supplemental Databases, with a study period from October 1, 2015, to March 31, 2022 (Fig. 1). The MarketScan database provides deidentified, longitudinal, comprehensive, fully adjudicated claims data for more than 293 million unique patients.[46] All variables used to identify outcomes and subgroups were based on inpatient and outpatient medical claims data that included enrollment details, service dates, *International Classification of Disease, 10th Revision, Clinical Modification* (*ICD-10-CM*) codes, Current Procedural Terminology (CPT) codes, and Healthcare Common Procedure Coding System codes.

Study Population

The timeframe during which patients were identified for study inclusion (index period) was from November 1, 2015, to March 1, 2022 (Fig. 1). The first use of AlloDerm identified during the study period is referred to as the index date. Eligible patients were aged 18 years or older with (1) presence of a medical claim for AlloDerm (Healthcare Common Procedure Coding System Q product code) and a skin substitute procedure (CPT codes of 15275, 15276, 15277, or 15278; on the same day [index date]), and (2) an *ICD-10-CM* diagnostic claim for a head and neck procedure (ie, parotidectomy, rhinoplasty, septal perforation repair, tympanoplasty, mastoidectomy, eyelid reconstruction, or oral cavity reconstruction). (**See table, Supplemental Digital Content 1,** which displays procedure inclusion and exclusion codes and descriptions,

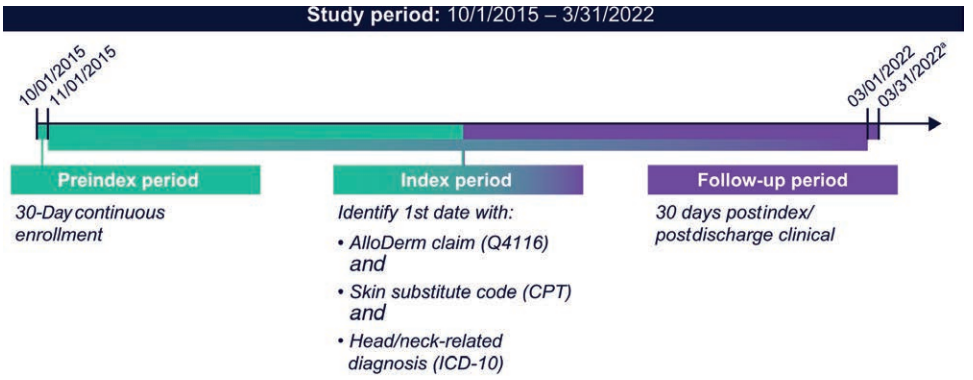

Fig. 1. Study design. [a]Data end for MarketScan at the time of analysis.

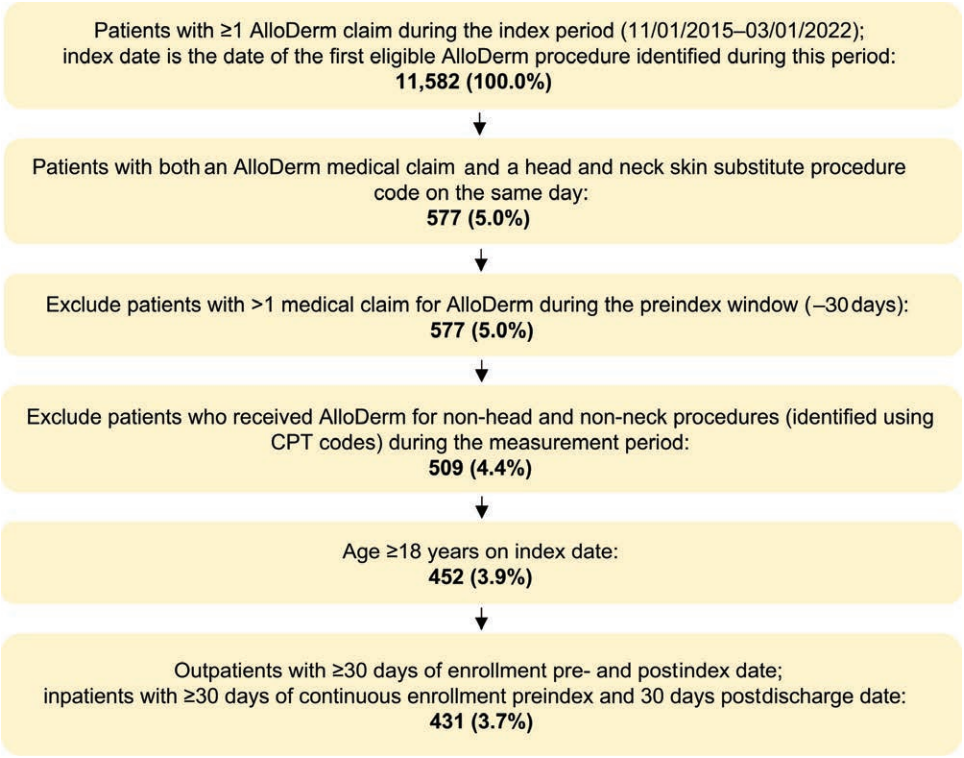

Fig. 2. Patient attrition.

http://links.lww.com/PRSGO/D651.) In addition, all patients were required to have 30 or more days of continuous medical plan enrollment before and after the index date, also referred to as pre- and postindex, respectively. Patients were excluded if they had either (1) 1 or more medical claim for AlloDerm during the preindex window (30 days before the index date) or (2) received AlloDerm for non-head and non-neck procedures identified through CPT exclusion codes (**Supplemental Digital Content 1,** http://links.lww.com/PRSGO/D651).

The follow-up period for outpatient procedures was 30 days after the procedure date. For procedures with inpatient admissions, follow-up was 30 days after the discharge date.

Outcomes

Demographic and Clinical Characteristics

Demographic characteristics reported were age, sex, geographic region, and insurance plan type; they were taken from the index procedure date. Clinical characteristics included head and neck procedure type using AlloDerm (eg, parotidectomy, septal perforation repair/rhinoplasty, tympanoplasty); procedure setting (eg, inpatient hospital, outpatient hospital, emergency room [ER]); and provider specialty/setting for skin substitute procedure (eg, acute care hospital, otolaryngology, ophthalmology).

Thirty-Day Postdischarge Follow-up and HCRU

During the 30-day period after the index procedure, clinical outcomes, including reoperation (classified as any visit[s] with an AlloDerm code [Q4116] for same-procedure indication), graft-related complications identified through predefined *ICD-10-CM* codes, and associated all-cause medical follow-up visits (ie, visits for any health-related concern, including outpatient, ER, and inpatient visit and inpatient length of stay), were assessed. (**See table, Supplemental Digital Content 2,** which displays *ICD-10* codes and descriptions for graft-related complications, http://links.lww.com/PRSGO/D652.)

Statistical Analyses

All outcomes were summarized using descriptive statistics (ie, frequencies, percentages, means, medians, SD, and interquartile range). No statistical comparisons or tests were conducted.

RESULTS

Demographic and Clinical Characteristics

Of 11,582 patients with 1 or more AlloDerm claim(s) during the index period, 431 adult patients had head or neck procedures with AlloDerm and met all other eligibility criteria for inclusion in the analysis population (Fig. 2). Baseline demographic characteristics for all patients are presented in Table 1. Mean (SD) age was 52.2 (15.8) years, most (68.2%) patients were aged 35–64 years, and approximately one-half (51.7%) were women. The largest proportion of patients resided in the geographic South (28.5%) and were insured by a preferred provider organization (51.7%). Clinical characteristics assessed on the date of

Table 1. Baseline Patient Demographic Characteristics

Variable	All Patients (N = 431)
Age, mean (SD), y	52.2 (15.8)
Age group, n (%)	
<65 y	363 (84.2)
≥65 y	68 (15.8)
Female sex, n (%)	223 (51.7)
US geographic region, n (%)	
Northeast	57 (13.2)
North central	97 (22.5)
South	123 (28.5)
West	47 (10.9)
Unknown	107 (24.8)
Insurance plan type, n (%)	
Comprehensive	45 (10.4)
EPO	5 (1.2)
PPO	223 (51.7)
HMO	39 (9.0)
Noncapitated POS	38 (8.8)
Capitated POS	3 (0.7)
CDHP/HDHP	72 (16.7)
Unknown	6 (1.4)

CDHP, consumer-directed health plan; EPO, exclusive provider organization; HDHP, high-deductible health plan; HMO, health maintenance organization; POS, point of service; PPO, preferred provider organization.

Table 2. Patient Clinical Characteristics at Index Procedure

Variable	All Patients (N = 431)
Head/neck procedures using AlloDerm, n (%)	
Parotidectomy	56 (13.0)
Septal perforation repair/rhinoplasty	71 (16.5)
Tympanoplasty	15 (3.5)
Mastoidectomy	29 (6.7)
Cleft palate/lip reconstruction	4 (0.9)
Burns to head and neck	1 (0.2)
Eyelid reconstruction	42 (9.7)
Oral cavity reconstruction	152 (35.3)
Other head/neck procedures	101 (23.4)
Procedure setting, n (%)	
Outpatient hospital	388 (90.0)
Emergency room: hospital	3 (0.7)
Ambulatory surgical center	37 (8.6)
Inpatient hospital	2 (0.5)
Unknown	1 (0.2)
Provider specialty/setting for skin substitute procedure, n (%)	
Acute care hospital: nonspecified	191 (44.3)
Otolaryngology	115 (26.7)
Ophthalmology	23 (5.3)
Plastic/maxillofacial surgery	15 (3.5)
Dental specialist	10 (2.3)
Other (<2%)	49 (11.4)

the index procedure are presented in Table 2. AlloDerm was used in a variety of head and neck procedures, most commonly in oral cavity reconstruction (35.3%), septal perforation repair/rhinoplasty (16.5%), parotidectomy (13.0%), and eyelid reconstruction (9.7%). The majority of AlloDerm procedures were performed at an outpatient setting, either at a hospital (90.0%) or an ambulatory surgical center (8.6%). The most commonly reported provider specialties/settings for skin substitute procedures were acute care hospitals (44.3%), otolaryngology (26.7%), and ophthalmology (5.3%) practices.

Table 3. 30 Days Postdischarge Follow-up: Clinical Outcomes and All-cause HCRU

	All Patients (N = 431)
AlloDerm reoperation, n (%)	
Outpatient	4 (0.9)
Inpatient	0 (0)
All-cause outpatient visit, n (%)	
Total	326 (75.6)
1	96 (22.3)
2	73 (16.9)
≥3	157 (36.4)
All-cause ER visit, n (%)	
Total	34 (7.9)
1	28 (6.5)
2	4 (0.9)
≥3	2 (0.5)
All-cause inpatient admission, n (%)	
Total	13 (3.0)
1	12 (2.8)
2	1 (0.2)
≥3	0 (0.0)
LOS per admission,* mean (SD), d	6.4 (5.7)

LOS, length of stay.
*LOS was calculated only for patients who had ≥1 inpatient admission.

Thirty-Day Postdischarge Follow-up

Table 3 and Figure 3 show 30-day postdischarge follow-up data for clinical outcomes and all-cause HCRU. In the 30-day follow-up period, 4 (0.9%) patients required a reoperation with AlloDerm. Two (0.5%) graft-related complications were reported. One of these complications was attributed to "eyelid reconstruction" surgery, whereas the other was nonclassifiable based on procedure codes present at the index date. In terms of HCRU, the mean (SD) per-patient frequency of medical visits was 2.6 (3.1) for all-cause outpatient, 0.1 (0.4) for ER, and 0.3 (0.2) for inpatient. During follow-up, 75.6% of patients had an outpatient visit and 7.9% had an ER visit for any health concern. In addition, 3.0% (n = 13) had an inpatient admission (attributed to any cause) with a mean (SD) length of stay of 6.4 (5.7) days.

DISCUSSION

This retrospective observational study using claims from MarketScan confirms the use of AlloDerm in head and neck reconstructive surgery in real-world settings. In this context, AlloDerm was used primarily for oral cavity reconstruction (in more than one-third of patients); other common uses were for septal perforation repair/rhinoplasty, parotidectomy, and eyelid reconstruction. Nearly all (99%) of these procedures were conducted in an outpatient setting. Graft-related complications were rare, and few patients required reoperation (<1% for both). Whereas more than 75% of patients had all-cause outpatient visits during the follow-up period, fewer than 8% of patients had an all-cause ER visit, and even fewer (3%) had an all-cause inpatient hospitalization.

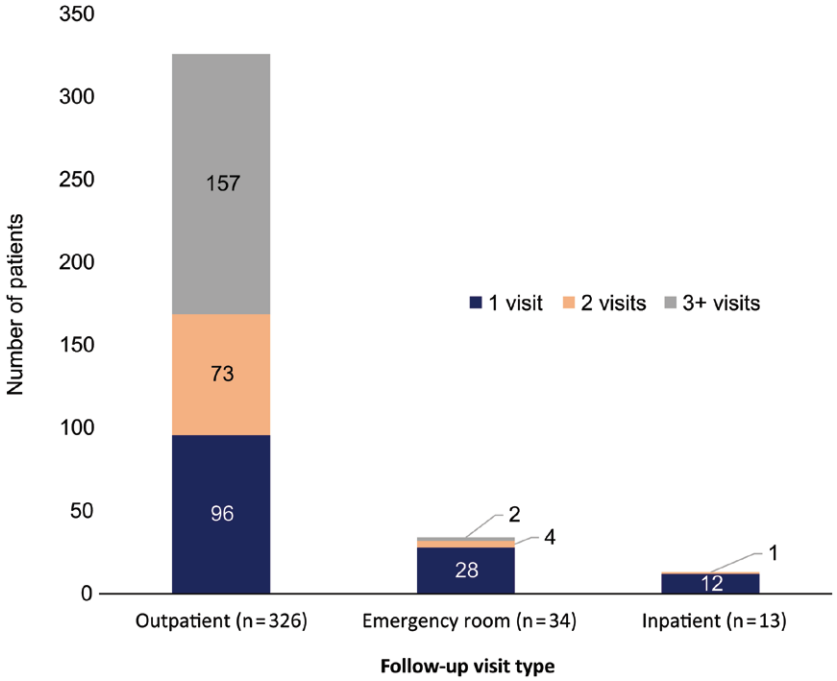

Fig. 3. Thirty-day follow-up all-cause medical visits postdischarge.

This low rate of observed complications in the 30 days after AlloDerm application is consistent with prior studies of its use in head and neck reconstructive procedures, where few to no complications were observed.[5–16,18–26,29–38,40–43] When complications before research have been noted, they typically included over- or undercorrection of reconstruction procedures, seroma, erythema, or graft displacement, infection, or resorption.[3,5–8,11,14,16,22] Nearly all of these complications resolved with nonoperative intervention.[5–7,11,14,22]

Strengths and Limitations

Specific to AlloDerm used for head and neck procedures, this is the first study to quantify its use and describe patient characteristics, clinical outcomes, and associated HCRU using a geographically representative US patient population. The use of a claims database allowed for a large sample size of real-world data reflecting the use of AlloDerm in routine practice. An evaluation comparing MarketScan data and data from the Medical Expenditure Panel Survey has shown MarketScan data to be generally representative of commercially insured patients.[47] The ability to longitudinally track patient data from all sources of care via unique patient identifiers also allowed for a robust analysis.

MarketScan claims data are primarily obtained from large employers; therefore, the current results might not be generalizable to other populations, including those self-insured or insured through public insurance, such as Veterans Affairs healthcare, Tricare, Medicaid, or Medicare. Further, uninsured patients were not captured in the data. In addition, clinical details and treatment outcome information are limited in claims data.

Due to the heterogeneity of *ICD* codes attributed to the head and neck indications of interest, results are subject to misclassification because the codes captured may not be representative of the diagnosis code to which they are linked. Similarly, given that graft complication *ICD* codes are not specific for AlloDerm and may apply to other prosthetic devices or implants, it is possible that complications captured within the follow-up window were incorrectly associated with AlloDerm. To mitigate the risk of misclassification, efforts were made to ensure an AlloDerm medical code was present on the same day as diagnosis codes for head and neck indications or any graft-related complications. In addition, other AlloDerm patients without head/neck procedures were excluded from the analysis population.

The list of *ICD* codes used to link AlloDerm with specific head and neck indications was derived from published literature and may not be inclusive of all related procedures. This is mostly reflected in patients who were categorized as having "other head/neck procedures" that were nonclassifiable from the list of predetermined indications due to the heterogeneity of data. Finally, this study captured a 30-day follow-up window after the index procedure, which is a common research practice due to the challenges of attributing longer-term clinical outcomes to the initial index surgery. It is possible, however, that this 30-day window excluded longer-term complications attributable to AlloDerm.

CONCLUSIONS

This analysis of the real-world usage of AlloDerm demonstrates its common use in head and neck procedures in the United States, mostly with oral reconstruction procedures.

The majority of skin substitute procedures involving AlloDerm are outpatient procedures. Complications and reoperations related to AlloDerm were extremely rare (<1%) in the 30-day period after these procedures.

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DISCLOSURES

Dr. Dominguez is a full-time employee with AbbVie. Dr. Liang was a former contractor with AbbVie. Dr. Abbed is a full-time employee of Allergan Aesthetics, an AbbVie Company. Dr. Mukhatyar is a former employee of AbbVie. Dr. Shimoga is a full-time employee of AbbVie. AbbVie funded this study and participated in the study design, research, analysis, data collection, interpretation of data, reviewing, and approval of the publication. All authors had access to relevant data and participated in the drafting, review, and approval of this publication. No honoraria or payments were made for authorship.

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