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Clobetasol's Influence on the Management and Cost of Skin Overgrowth Associated with the Bone-Anchored Hearing Aid

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Background: Management of the skin/abutment interface in patients with bone-anchored hearing aids (BAHAs) can occasionally be a challenge. Even with the most compliant patients and the most intensive home/office treatment regimens, painful triamcinolone injections and revision surgery can become necessary. Such treatments can be associated with an inordinate cost burden. To our knowledge this research provides the first objective comparison of cost and patient outcomes after the introduction of topical 0.05% clobetasol cream for the care of the skin/abutment interface in patients with BAHAs.

Methods: Thirty-three patients were managed with the traditional algorithm (local wound care, triamcinolone injection, and revision surgery). Nineteen patients were managed with the contemporary algorithm in which 0.05% topical clobetasol cream was added to the traditional treatment regimen.

Results: Common postoperative skin reactions were comparable in the traditional vs contemporary treatment groups: granulation tissue (53.8% vs 56.3%), soft-tissue overgrowth (30.8% vs 18.8%), and both granulation tissue and soft-tissue overgrowth (15.4% vs 25.0%). The addition of clobetasol cream was associated with a marked decrease in the invasive treatment endpoints in the contemporary vs traditional treatment groups: triamcinolone injections (0.0% vs 12.1%) and surgical revision (0.0% vs 9.1%). The difference in cost for managing soft-tissue overgrowth at the abutment site was substantial, with the traditional treatment group averaging $2,773.25 per patient and the contemporary treatment group averaging $47.94 per patient ($P<0.021$) according to 2013 estimates and values.

Conclusion: Clobetasol use during early postoperative care of a BAHA implant dramatically decreases cost and improves treatment outcomes by reducing the need for invasive postoperative procedures to treat common postoperative skin reactions.

Keywords: *Clobetasol, health care costs, hearing aids, hearing loss, postoperative complications, prostheses and implants*

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INTRODUCTION

Bone-anchored hearing aids (BAHAs) have been commercially available since 1987. BAHAs were originally approved only for select patients with unilateral conductive hearing loss, but indications have expanded to include patients with bilateral conductive or mixed hearing loss and unilateral sensorineural hearing loss. As a result, current estimates indicate that >90,000 patients use BAHAs worldwide.[1]

Significant surgical and technologic advances in BAHA design, function, and implantation have occurred during the past 35 years, but success for each patient has always been influenced by a few factors: device technology, proper patient selection, surgical technique, robust osseointegration, and maintenance of a healthy skin/abutment interface. To address these factors, several changes have been implemented over time. While technologic advances, patient selection criteria, and operative techniques have adapted, the postoperative care of the skin/abutment interface has only recently undergone a transformation.[2-4]

The postoperative complication profile of BAHA implants includes skin irritation, hematoma, infection, pain, bleeding, fixture dislodgement, and failure of osseointegration, but local inflammatory skin reactions at the skin/abutment interface have emerged as the most common offenders.[3,5-7] With reported rates of abutment-associated soft-tissue overgrowth and granulation of 7.1%-39.6%, considering local inflammatory skin reactions as an expected response to the insertion of the foreign body that is the BAHA abutment is not unreasonable.[4,5,7] Unless the

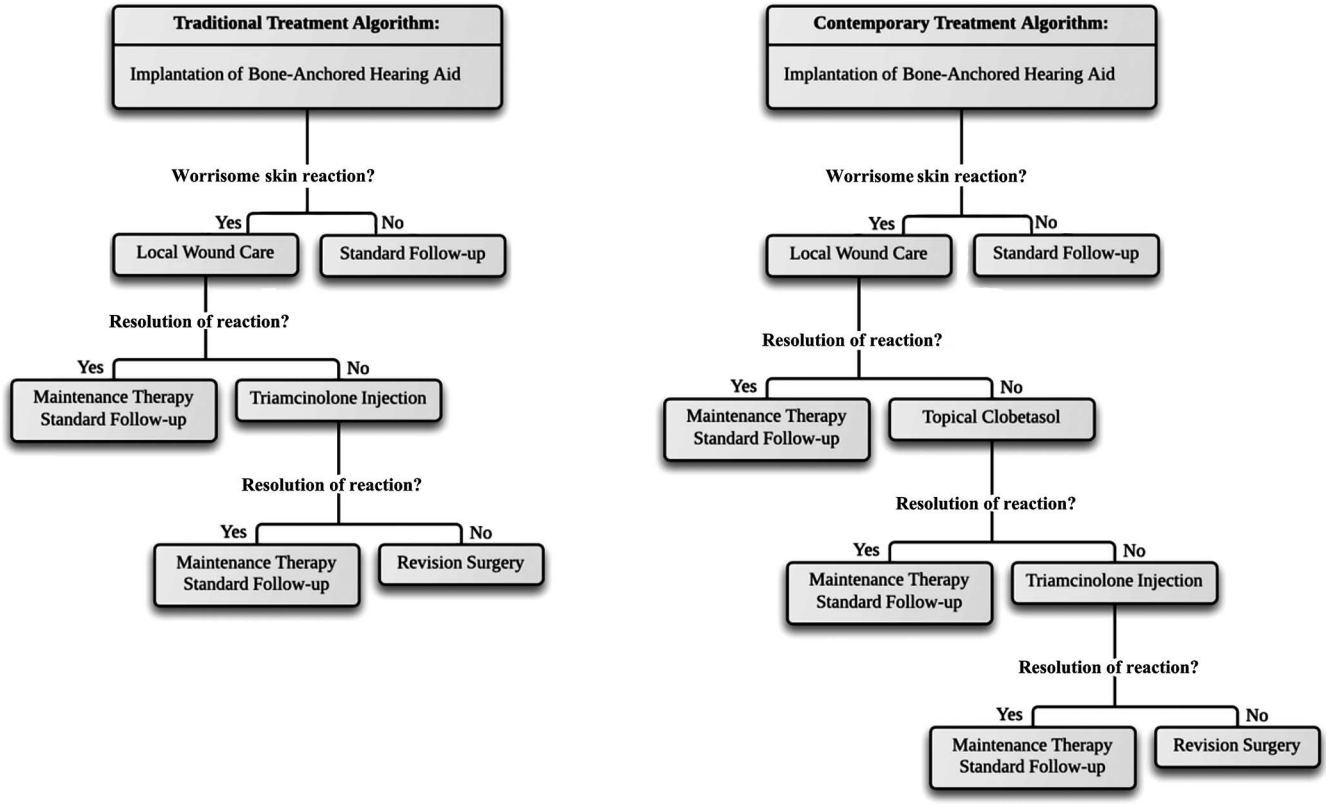

Figure 1. Therapeutic algorithms in the traditional vs contemporary treatment groups.

abutment site is managed by frequent and attentive cleaning, epidermal heaping and overgrowth at the site will ensue. This buildup of tissue leads to an inability to affix the hearing aid on the abutment post, and the tissue can eventually overgrow the abutment entirely.

In the past, such soft-tissue reactions were abated with a traditional treatment algorithm consisting of a progressive stepwise implementation of the following treatment options: local wound care (including general cleaning, topical antibiotics, and in-office silver nitrate cautery of granulation tissue), localized triamcinolone injections, and revision surgery.[5,7] In a 2008 study, the traditional algorithm was augmented with the addition of topical clobetasol cream and demonstrated encouraging results.[2] The augmented stepwise contemporary treatment algorithm consists of the following: local wound care, topical clobetasol cream, localized triamcinolone injections, and revision surgery (Figure 1). This study quantifies the cost and treatment outcomes for the management of common postoperative soft-tissue inflammatory conditions at the BAHA skin/abutment interface before and after topical 0.05% clobetasol cream was added to the treatment algorithm.

METHODS

This research study was reviewed and approved by the Ochsner Clinic Foundation Institutional Review Board. We reviewed the cases of all patients referred to Ochsner Medical Center who received a BAHA during the 11-year period of July 1, 2000 to June 30, 2011 and created a retrospective database using surgeons' operative case logs and a combination of paper and electronic medical records.

Inclusion criteria required patients to be recipients of a BAHA and have a history of at least 1 year of adherence to a standard postsurgical follow-up protocol. No patients in this study underwent any simultaneous neurosurgical procedures. Fifty-two patients met these inclusion criteria. BAHA implantation was performed in standard fashion with either the inferior-based skin flap or single vertical incision technique, already described elsewhere in great detail.[6,8] The standard 1-year follow-up protocol consisted of 5 visits with the following postsurgical intervals: 1 day, 1 week, 1 month, 4 months, and 7 months. Postoperative health of the skin/abutment interface was managed on an individual basis by adjusting the frequency of clinic visits and progression through the treatment algorithms described below.

Medical records were reviewed for skin reactions at the abutment site and resolving therapy during the first year of postoperative care. Skin reactions were classified as no reaction, presence of granulation tissue, soft-tissue overgrowth at the abutment site, and both the presence of granulation tissue and soft-tissue overgrowth at the abutment site. For patients who experienced a skin reaction, treatment endpoints were recorded and defined as the therapy that successfully resolved the reaction. Demographics, skin reaction type, and treatment endpoints were compiled by cohort and statistically compared using SAS v.9.3 (SAS Institute Inc.). Pearson chi-square and Fisher exact tests were employed to assess the association between binary variables and the two treatment algorithms.

Treatment endpoints were used to determine the average cost per patient of the two algorithms using a weighted

Table 1. Average Cost of Intervention Per Patient

Intervention	Cost Per Patient
Local wound care	$13.90
Topical clobetasol	$40.23
Triamcinolone injection	$7.08
Revision surgery	$14,700.00

average of direct medical costs obtained from United States Department of Health and Human Services and Medicare/Medicaid data in 2013 US dollars. The costs of each treatment were gathered using publicly available data and calculated using established norms of dosing and frequency. When possible, national cost estimates are given in contrast to costs from singular entities.

Wound care at our institution consists of general cleaning, topical bacitracin ointment, and silver nitrate cautery of granulation tissue. The average cost for bacitracin 500 U/g ointment is $3.59 for a 28 g tube.[9] We found an average of 33 days of topical bacitracin treatment time in our study. One application of bacitracin is measured as 0.5 g of ointment.[10] Factoring 0.5 g of ointment with twice-daily dosing for 33 days results in an average total of 33 g of bacitracin ointment per patient, so each patient needed 2 separate 28 g tubes. Two tubes at $3.59 each cost $7.18. The cost for silver nitrate was estimated to be $6.72 ($0.56 per stick $\times$ 2 sticks per visit $\times$ 6 visits).[11] The average total local wound care cost was therefore $7.18 (bacitracin) plus $6.72 (silver nitrate), a total of $13.90 per patient.

For clobetasol 0.5%, the average cost for a 30 g tube is $13.41.[9] Average clobetasol treatment time in our study was 88 days. One application of ointment is 0.5 g.[10] Factoring 0.5 g of ointment with twice-daily dosing for 88 days results in an average of 88 g of clobetasol cream per patient, so each patient needed three 30 g tubes. Three tubes at $13.41 each cost $40.23.

Triamcinolone acetonide therapy was used infrequently. When indicated, use averaged 1 injection per patient before reaching the treatment endpoint. With each injection estimated to deliver 40 mg of triamcinolone acetonide, the cost was $7.08 per injection.[12]

Finally, the national average for total hospital cost of outpatient otologic surgery is estimated to be $14,700 (range, $12,889-$17,165; SD, $1,058).[13]

Table 1 provides the average intervention costs on which our cost analysis is based. The Mann-Whitney U test was used to compare costs between the traditional and contemporary treatment groups.

RESULTS

Patients in the two cohorts were similar; their demographics are detailed in Table 2. Of the 33 patients treated using the traditional algorithm, 51.5% had no documented skin reactions during their first postoperative year, 27.3% developed granulation tissue, 9.1% developed soft-tissue overgrowth at the abutment site, and 12.1% developed a combination of granulation tissue and soft-tissue overgrowth at the abutment site (Table 3). We calculated the skin reaction type and treatment endpoint percentages only for the 16 patients who had reactions, excluding the 17 patients with no adverse postoperative reactions. In the reaction group, granulation tissue emerged as the most common soft-tissue reaction, constituting 56.3% of the reactions observed. Soft-tissue overgrowth at the abutment site accounted for 18.8% of the reactions observed, while 25.0% of the skin reactions observed contained a combination of both granulation tissue and soft-tissue overgrowth.

Among the 19 patients treated according to the contemporary algorithm, 31.6% had no documented skin reactions during their first postoperative year, while 36.8% developed granulation tissue, 21.1% developed soft-tissue overgrowth at the abutment site, and 10.5% developed a combination of

Table 2. Demographics of Study Participants (n=52)

Variable	Traditional Algorithm n=33	Contemporary Algorithm n=19	*P* Value
Age at time of implantation, years			
Mean (SD)	48.3 (19.1)	46.1 (21.7)	0.70
Median	52	46	
Sex			
Male	14 (42.4%)	6 (31.6%)	0.55
Female	19 (57.6)%	13 (68.4%)	
Implanted ear			
Right	19 (57.6%)	7 (36.8%)	0.24
Left	14 (42.4%)	12 (63.2%)	
Cause of hearing loss			
Conductive	14 (42.4%)	7 (36.8%)	0.97
Sensorineural	7 (21.2%)	4 (21.1%)	
Sudden sensorineural	8 (24.2%)	5 (26.3%)	
Mixed	4 (12.1%)	3 (15.8%)	

Table 3. Traditional Algorithm Treatment Data

Skin Reaction Type	Number of Patients	Percentage of Patients n=33	Percentage of Reaction Group n=16
None	17	51.5	
Granulation tissue	9	27.3	56.3
Soft-tissue overgrowth	3	9.1	18.8
Both granulation tissue and soft-tissue overgrowth	4	12.1	25.0

Treatment Endpoint	Number of Patients	Percentage of Patients n=33	Percentage of Treatment Group n=16
No reaction	17	51.5	
Local wound care	9	27.3	56.2
Triamcinolone injection	4	12.1	25.0
Revision surgery	3	9.1	18.8

both granulation tissue and soft-tissue overgrowth (Table 4). We calculated the skin reaction type and treatment endpoint percentages only for the 13 patients who had reactions, excluding the 6 patients with no adverse postoperative reactions. As in the traditional algorithm cohort, granulation tissue was the most common soft-tissue reaction observed in the contemporary treatment cohort, accounting for 53.8% of reactions observed. Soft-tissue overgrowth at the abutment site was the second most common reaction, accounting for 30.8% of reactions observed, while 15.4% of skin reactions observed were a combination of both granulation tissue and soft-tissue overgrowth. Figure 2 shows postoperative reactions by cohort.

Analysis of the surgical techniques employed during this study demonstrated that the first 77% of the patients received implants by means of an inferior-based skin flap technique, while the last 23% received implants by means of a single vertical incision. When the two surgical groups were separated in terms of common inflammatory vs all other types of complications, 23 of the 40 patients (57.5%) with the inferior-based skin flap approach had at least one documented occurrence of granulation tissue or soft-tissue overgrowth, whereas 6 of the 12 patients (50%) with the single vertical incision had at least one documented occurrence of granulation tissue or soft-tissue overgrowth (Pearson chi-square test, P=0.65). With regard to management of the common postoperative skin reactions, local wound care successfully resolved 56.2% of all skin reactions for patients in the traditional treatment group, while 25.0% of patients required at least 1 triamcinolone injection and 18.8% of patients required revision surgery. Patients in the traditional group had an average of 5.9 clinic visits (median of 7) during the first postoperative year.

Analysis of patients in the contemporary treatment group revealed very different results, as 15.4% of all worrisome skin reactions were successfully resolved with local wound care alone, and the remaining 84.6% were successfully resolved with the addition of clobetasol cream (associated mean resolution time was 2.5 months). None of the patients in the contemporary treatment group required the invasive

Table 4. Contemporary Algorithm Treatment Data

Skin Reaction Type	Number of Patients	Percentage of Patients n=19	Percentage of Reaction Group n=13
None	6	31.6	
Granulation tissue	7	36.8	53.8
Soft-tissue overgrowth	4	21.1	30.8
Both granulation tissue and soft-tissue overgrowth	2	10.5	15.4

Treatment Endpoint	Number of Patients	Percentage of Patients n=19	Percentage of Treatment Group n=13
No reaction	6	31.6	
Local wound care	2	10.5	15.4
Clobetasol	11	57.9	84.6
Triamcinolone injection	0	0.0	0.0
Revision surgery	0	0.0	0.0

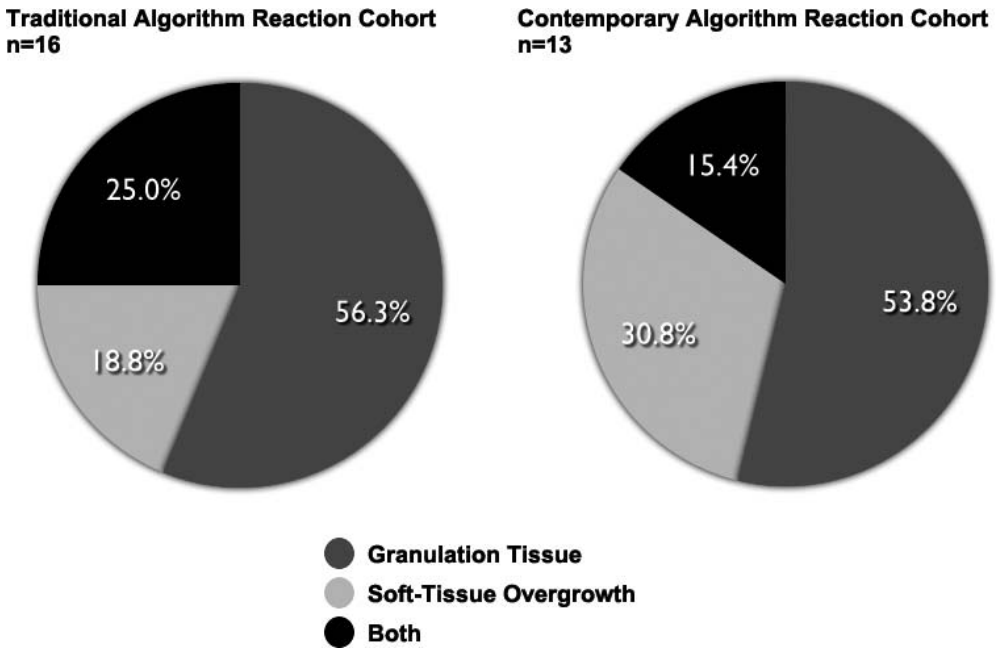

Figure 2. Postoperative skin reactions by cohort.

treatment modalities of triamcinolone and/or revision surgery. Patients in the contemporary treatment group had an average of 6.5 clinic visits (median of 6), so the group was not associated with an increased burden of visits compared to the traditional treatment group (Wilcoxon rank sum test, P=0.12). Figure 3 shows a comparison of treatment endpoints in the two cohorts.

Applying the cost of each therapy to the treatment endpoints of the 2 cohorts yielded a weighted average cost for each algorithm. The total cost for managing 16 patients in the first postoperative year with the traditional treatment algorithm was $44,371.96, an average of $2,773.25 per patient. This cost is significantly higher than the cost of managing[13] patients in the postoperative period with the contemporary treatment algorithm, which totaled $623.23 and represented an average of $47.94 per patient ($P<0.021$). The difference in cost savings was largely realized by the avoidance of revision surgery.

DISCUSSION

While the implantation techniques and technology of BAHAs have evolved, the standard postoperative care has remained largely unchanged.[3-5,7] Since the introduction of BAHAs to the market, otologists and implant recipients alike have been challenged by the substantial workload associated with maintenance of the skin/abutment interface and avoidance of common soft-tissue inflammatory reactions.[7] This workload is particularly high during the first postoperative year, after which a decline in the occurrence of inflammatory reactions is seen.[5,7]

The overall rate of common postoperative soft-tissue inflammatory reactions in our study (55.8% of patients were affected) is higher than the rate in previously published studies. More specifically, granulation tissue was diagnosed in 30.8% of all patients, soft-tissue overgrowth in 13.5%, and a combination of both granulation tissue and soft-tissue overgrowth in 11.5%. These data represent a much higher

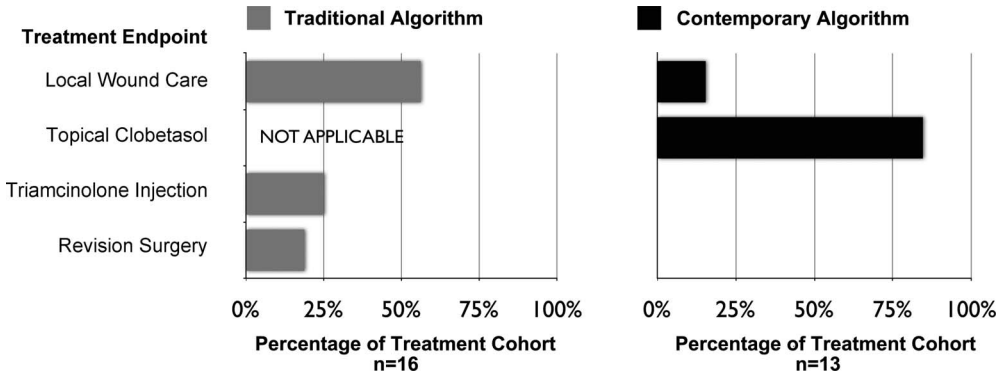

Figure 3. One-year comparison of treatment endpoints in the traditional vs contemporary algorithms.

number of patients affected than previously reported in the literature, where inflammatory reactions are stated to occur in 7.1%-39.6% of BAHA recipients.[4,5,7] The variations between our data and previously published data can most likely be attributed to low institutional thresholds for documentation. One would expect that if such discrepancies were purely the result of operative technique, inadequate postsurgical management, and/or a noncompliant patient niche, the remainder of the complications profile would also be elevated above the average, a finding that was not present in the data analysis.

Several factors in surgical technique have previously been identified as promoting inflammatory skin reactions, and this study includes such techniques as a potential confounder.[5,6] Because the single vertical incision technique has been associated with less postoperative burden of soft-tissue inflammation, the preponderance of skin flap technique surgeries might help explain the higher-than-average rate of soft-tissue reactions in our study.[6] With this hypothesis in mind, 63.2% of the patients in the contemporary treatment algorithm received a theoretical benefit from having the single vertical incision. Despite this factor, no statistical significance was found in the number of patients who experienced postoperative complications in the two treatment groups. In our case series, the severity and types of inflammatory reactions were seen to be equivalent between the 2 operative approaches.

Implant extrusion and loss of implant were not observed in our patient population, and compared to rates published by other authors (2.5%-18%), the absence of these complications was quite an achievement.[3,5,7] No patients in our study had any intraoperative complication resulting in either an aborted procedure or an inpatient hospitalization. Likewise, no patients needed inpatient hospitalization and/or intravenous antibiotics during postoperative management.

The overall rate of postoperative skin infections significant enough to merit oral antibiotics was 7.7%, a rate similar to rates published by other authors (1%-5% of all patients).[3,5] While we observed wound dehiscence and/or distal-tip necrosis of the skin flap in 7.7% of all patients, other authors have described similar findings in 0.7%-12% of all patients.[2,5] Of the 29 patients who had one of the common postoperative soft-tissue skin reactions, only 3 needed revision surgery. All 3 instances were a result of soft-tissue overgrowth at the abutment site, and all 3 patients were members of the traditional treatment group. The combined institutional surgical revision rate was 5.8% (3 of 52 patients) compared to the 12.1%-18.8% reported by other authors.[3,5]

Our data reveal the full benefit of topical clobetasol. While the relative proportion of each type of inflammatory skin reaction was similar in the traditional and contemporary treatment groups (granulation tissue, 56.3% vs 53.8%; soft-tissue overgrowth, 18.8% vs 30.8%; and a combination of granulation tissue and soft-tissue overgrowth 25.0% vs 15.4%), large variations were observed in treatment outcomes and cost. The addition of topical clobetasol cream was associated with a marked decrease in cost and invasive treatment endpoints in the contemporary vs traditional treatment groups: triamcinolone injections (0.0% vs 12.1%) and surgical revision (0.0% vs 9.1%). The average cost for postoperative management for the traditional treatment group was $2,773.25 per patient, while the cost for the contemporary treatment group was only $47.94 per patient ($P<0.021$).

CONCLUSION

This study shows that the addition of clobetasol to early goal-directed management of the skin/abutment interface decreases the need for painful/invasive postoperative treatment options such as triamcinolone injections and revision surgery in patients with BAHA implants. The cost of topical clobetasol is relatively low and does not differ much from the cost of local wound care or corticosteroid injections. In contrast, the relative cost of outpatient otologic surgery is substantial. We found that the group of patients who utilized clobetasol avoided the need for surgical revision, and thus we realized a significant cost savings in the contemporary treatment group.

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