Cost-Utility Analysis: Sartorius Flap versus Negative Pressure Therapy for Infected Vascular Groin Graft Management

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Background: Sartorius flap coverage and adjunctive negative pressure wound therapy (NPWT) have been described in managing infected vascular groin grafts with varying cost and clinical success. We performed a cost–utility analysis comparing sartorius flap with NPWT in managing an infected vascular groin graft.

Methods: A literature review compiling outcomes for sartorius flap and NPWT interventions was conducted from peer-reviewed journals in MEDLINE (PubMed) and EMBASE. Utility scores were derived from expert opinion and used to estimate quality-adjusted life years (QALYs). Medicare current procedure terminology and diagnosis-related groups codes were used to assess the costs for successful graft salvage with the associated complications. Incremental cost-effectiveness was assessed at $50,000/QALY, and both univariate and probabilistic sensitivity analyses were conducted to assess robustness of the conclusions.

Results: Thirty-two studies were used pooling 384 patients (234 sartorius flaps and 150 NPWT). NPWT had better clinical outcomes (86.7% success rate, 0.9% minor complication rate, and 13.3% major complication rate) than sartorius flap (81.6% success rate, 8.0% minor complication rate, and 18.4% major complication rate). NPWT was less costly ($12,366 versus $23,516) and slightly more effective (12.06 QALY versus 12.05 QALY) compared with sartorius flap. Sensitivity analyses confirmed the robustness of the base case findings; NPWT was either cost-effective at $50,000/QALY or dominated sartorius flap in 81.6% of all probabilistic sensitivity analyses.

Conclusion: In our cost–utility analysis, use of adjunctive NPWT, along with debridement and antibiotic treatment, for managing infected vascular groin graft wounds was found to be a more cost-effective option when compared with sartorius flaps. (Plast Reconstr Surg Glob Open 2015;3:e566; doi: 10.1097/GOX.0000000000000551; Published online 20 November 2015.)

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and surgical wound revision) has also been suggested for managing infected vascular groin grafts.4,6 Although NPWT is a relatively newer management option for this type of wound, there is substantial literature that supports its use in this scenario.4,6,7

Both the sartorius flap and NPWT have variability in their clinical outcomes and costs. Although clinical outcomes have been evaluated separately for these 2 choices in past clinical case series, costs for outcomes, including major and minor complications, have not. This unknown invites for the study of cost–utility in comparing each management option. A cost–utility analysis is composed of costs, probabilities, and quality-adjusted life years (QALY) of various health states that are used to evaluate competing interventions.8–17 For this reason, our goal was to perform a cost–utility analysis of sartorius flap versus NPWT for salvage of an infected vascular groin graft.

MATERIALS AND METHODS

Literature Review and Health States

A systematic review, using MEDLINE (PubMed) and EMBASE, identified publications on treatments intended to salvage infected vascular grafts confined to the groin (Fig. 1). Search terms included “infected groin wound and negative pressure wound therapy”; “infected groin wound and wound VAC” (V.A.C. Negative Pressure Wound Therapy, KCI, an Acelity company, San Antonio, Tex.); “infected groin wound and sartorius flap”; and “infected groin wound and reconstruction”. We also replaced “infected groin wound” with “infected vascular groin graft” and combined them with all the phrases above to perform an additional search. Each identified article was examined by 2 reviewers (A.C. and T.K.) for adherence to inclusion and exclusion criteria. Disagreements were resolved by consensus. Inclusion criteria included patients treated with flaps for vascular groin grafts whose bodies or anastomotic sites were infected but did not show signs of bleeding and had no associated septicemia. We included patients who fit Szilagyi III and Samson II and III classifications for infected vascular grafts.18,19 Exclusion criteria included patients younger than 18 years, non-human patients, and non-English citations.

Data collected included rates of successful wound healing and complications between the treatment modalities. Any treatment with partial or total excision of the graft material was deemed a failure of salvage. The complications evaluated were defined as distinct “health states” with associated probabilities, costs, and utilities for use in the decision model. Major complications included graft failure requiring axillary-femoral bypass and amputation or death. Minor complications included grafts with reinfection, seroma/hematoma, and wound dehiscence that were salvaged. Vascular graft success and complication rates from the literature review were utilized to calculate the cost-effectiveness of the procedure.

Probabilities

The probabilities associated with treatmentspecific health states/complications were derived from a comprehensive review of the literature previously described. Data were extracted from the
relevant publications, pooled, and weighted by the size of each study (Tables 1, 2). Meta-analyses for both NPWT and sartorius flap were conducted to estimate the pooled probabilities for the minor, major, and total complications. Studies were only included if they reported the outcome of interest. For each outcome measure, number of patients with an event and total number of patients were used to determine effect sizes for individual studies. A value of 0.1 was used for studies in which there were 0 events for a particular complication for the purposes of the meta-analysis. The sample size of a study not reporting a particular complication, denoted by “—,” was not included for the purposes of calculating a probability.

### Health State Value and Quality-Adjusted Life Years

Health state values were obtained using a 10-cm visual analog scale (VAS). The VAS had a minimum anchor of 0, representing death and a maximum anchor of 1 representing perfect health. Fifteen surgical experts familiar with infected vascular groin graft reconstruction and management of complications were provided identical health state scenarios and asked to rank each scenario on the VAS scale. An example question posed to the surgical experts was “Consider a patient with an infected groin graft that goes on to have a successful salvage with a muscle flap. Place a mark on the VAS that in your opinion would represent this particular health state for the patients on a scale between 0 indicating death and 1 indicating perfect health.” A nonparametric bootstrap was then applied on the 15 VAS values for each health state separately; 1000 samples with replacement were used to characterize the mean and standard deviation for each health state. The health state values were assumed to represent health state utility for the purposes of deriving QALYs (Tables 3, 4).

### Table 1. Probabilities of Complications Using Sartorius Flap Alone

| References          | Total No. of Cases | Minor Complications | Major Complications | Total Complications |
|---------------------|--------------------|---------------------|---------------------|---------------------|
| Töpel et al\textsuperscript{30} | 34                 | 1                   | 4                   | 1                   | 0                   | 0                   | 6                   |
| Herrera et al\textsuperscript{21} | 5                 | —                   | 2                   | 0                   | 0                   | 0                   | 2                   |
| Cyrochristos et al\textsuperscript{32} | 1               | —                   | —                   | 0                   | 0                   | 0                   | 0                   |
| Armstrong et al\textsuperscript{23} | 3                | —                   | 2                   | —                   | —                   | 2                   |
| Wu et al\textsuperscript{34} | 10                | 1                   | —                   | 0                   | 0                   | 1                   |
| Scify et al\textsuperscript{25} | 5                | —                   | 0                   | 2                   | 2                   |
| Schutzer et al\textsuperscript{36} | 50             | —                   | 1                   | 2                   | 6                   | 9                   |
| Colwell et al\textsuperscript{37} | 4                 | 1                   | —                   | —                   | —                   | 1                   |
| Graham et al\textsuperscript{27} | 18               | —                   | —                   | 5                   | 0                   | 5                   |
| Zelsman et al\textsuperscript{38} | 18               | 4                   | —                   | 0                   | 0                   | 4                   |
| Sladen et al\textsuperscript{39} | 25               | 4                   | 3                   | 0                   | 0                   | 7                   |
| Masur et al\textsuperscript{40} | 15               | 3                   | —                   | 0                   | 0                   | 3                   |
| Taylor et al\textsuperscript{39} | 5                | 4                   | —                   | —                   | —                   | 4                   |
| Perez-Burkhardt et al\textsuperscript{31} | 1            | —                   | 1                   | 0                   | 0                   | 1                   |
| Thomas et al\textsuperscript{42} | 4                 | 1                   | —                   | 0                   | 0                   | 1                   |
| Kimmel et al\textsuperscript{33} | 2                | 1                   | —                   | 0                   | 0                   | 1                   |
| Calligaro et al\textsuperscript{44} | 4               | 2                   | 1                   | 0                   | 0                   | 3                   |
| Sladen et al\textsuperscript{35} | 10              | —                   | 0                   | 0                   | 0                   | 0                   |
| Evans et al\textsuperscript{45} | 1                | —                   | —                   | 0                   | 0                   | 0                   |
| Calligaro et al\textsuperscript{37} | 1               | —                   | —                   | 0                   | 1                   | 1                   |
| Petrasek et al\textsuperscript{36} | 11              | 2                   | —                   | —                   | —                   | 2                   |
| Mahoney\textsuperscript{39} | 5                | 1                   | —                   | 0                   | 0                   | 1                   |
| Kaufman et al\textsuperscript{2} | 2                | —                   | —                   | 0                   | 0                   | 1                   |
| Total            | 25               | 14                  | 9                   | 9                   | 57                  |

Probability (SE)\textsuperscript{a} = 0.080 (0.024) 0.032 (0.015) 0.014 (0.009) 0.007 (0.006) 0.184 (0.036)

\textsuperscript{a}Probability and standard error (SE) were derived from a meta-analysis. A value of 0.1 was used for studies reporting 0 events for a particular complication for the purposes of the meta-analysis. The sample size of a study not reporting a particular complication, denoted by “—,” was not included for the purposes of calculating a probability.
The health state values were converted to QALYs by multiplying the values of a specific health state by the duration of that health state and adding that to the product of remaining life years and the value of a successful operation.

\[
QALY = (\text{value of health state}) \times (\text{duration of health state}) + (\text{value of successful procedure}) \times (\text{remaining life years})
\]

Duration of health state = Number weeks for recovery from complication ÷ Number of weeks in a year

Remaining life years = Average life expectancy – average age of patient

The remaining life years were derived from the assumption that a hypothetical cardiovascular patient undergoing salvage reconstruction is 50 years old and has a life expectancy of 73.7 years (based on the results of the Whitehall study). Assumptions were made regarding the appropriate follow-up for health states based on the current practice of surgeons at our institutions. Patients suffering minor complications underwent surgical debridement with antibiotics and were assumed to recover within 4 weeks. Major complications assumed a longer recovery; graft failure requiring axillary-femoral bypass and amputation assumed a recovery period of 12 weeks. However, after amputation, patients were not assumed to receive the full health state value for their remaining years of life. For example, the “graft excision and axillary-femoral bypass” health state assumes that the patient would recover in a 12-week period; thereafter, the patient returned to the value of successful surgery for the remaining years of life, whereas for amputation, the

### Table 2. Probabilities of Complications Using Negative Pressure Wound Therapy Alone

| References          | Total No. of Cases | Debridement | Graft Reconstruction, Excision or Ligation | Amputation | Death | Total Complications |
|---------------------|--------------------|-------------|-------------------------------------------|------------|-------|---------------------|
| Berger et al        | 17                 | 3           | 0                                         | 0          | 0     | 3                   |
| Acosta and Monsen   | 28                 | 0           | 4                                         | 2          | 1     | 7                   |
| Mayer et al         | 32                 | 1           | 1                                         | 0          | 1     | 3                   |
| Beno et al          | 2                  | 0           | 2                                         | 0          | 0     | 2                   |
| Doshuoglu et al     | 12                 | 0           | 2                                         | 0          | 0     | 2                   |
| Svensson et al      | 24                 | 4           | 4                                         | 2          | 0     | 10                  |
| Kotsis and Lioupis   | 7                  | 1           | 0                                         | 0          | 0     | 1                   |
| Doshuoglu et al     | 4                  | 0           | 0                                         | 0          | 0     | 0                   |
| Pinocy et al        | 24                 | 0           | 0                                         | 0          | 0     | 0                   |
| Total               | 9                  | 13          | 4                                         | 2          | 28    |                     |

Probability (SE)* 0.009 (0.008) 0.0140 (0.01) 0.007 (0.007) 0.008 (0.007) 0.133 (0.047)

*Probability and standard error (SE) were derived from a meta-analysis. A value of 0.1 was used for studies reporting 0 events for a particular complication for the purposes of deriving a probability.

### Table 3. Utilities, Costs, and QALYs for Graft Infections: Infected Graft Repair with Flap

| Health States                      | Value (SD) | QALY (SD) | Cost ($) | Codes |
|------------------------------------|------------|-----------|----------|-------|
| Successful reconstruction          | 0.706 (0.039) | 12.22 (0.14) | 12,134  | 15,738 | 908 |
| Wound complications requiring     | 0.572 (0.019) | 12.19 (0.14) | 20,444  | 10,140 | 908 |
| debridement                        |            |           | 15,333  | 908    | 920 |
| Graft excision with axillary-femoral bypass | 0.386 (0.031) | 12.14 (0.14) | 35,486  | 15,738 | 908 |
| Amputation                         | 0.386 (0.031) | 6.68 (0.11)  | 34,912  | 15,738 | 908 |
| Death                              | 0          | 0         | 12,134  | 15,738 | 908 |

Mean and SD utility values based on 1000 bootstrapped estimates from 15 individual physicians surveys. Amputation and graft excision assumed to have the same utility. QALY discounted at 3%. Likely baseline cost is derived from Medicare CPT reimbursement, minimum (Min) is 75% of Likely cost and maximum (Max) is 150% of Likely cost.
value of the health state remained unchanged after recovery. A graft excision example calculation can be found below:

Remaining health years: 73.7 years – 50 years = 23.7 years

Duration of health state: 12 weeks + 52 weeks = 0.23 years

QALY : 0.385 × 0.23 + 0.706 × (23.7 – 0.23) = 16.66 years (undiscounted)

Given that QALYs accrue over a period of 23.7 years, the value was discounted at a rate of 3% per year (Tables 3, 4).47

Perspective and Cost

The perspective of Medicare was adopted for the decision analysis. Given the advent of bundled payments and accountable health organizations as a potentially foreseeable eventuality, the authors felt this perspective was most pertinent for such a cost–utility analysis.

Medicare current procedure terminology (CPT) codes and diagnosis-related groups (DRG) codes were used to assess the costs for successful graft salvage with the particular flap and associated major and minor complications. Costs for a complication included the cost of a successful surgery plus the cost of a specific complication. All payment data were based on 2012 Medicare CPT and DRG reimbursement national averages (Tables 3, 4).48,49 Medicare payments were used as a surrogate for cost, which would be particularly applicable if the hospital were an accountable care organization responsible for payment when managing a patient with an infected vascular groin graft.

The cost of death was conservatively assumed to be the same cost as a successful procedure because at minimum the same procedures would have been performed as those for a successful case. NPWT was assumed to be applied for 6 weeks. Costs were not discounted, as all costs were assumed to occur within a year of the surgical procedure.

Decision Analysis

A decision analytic model (Fig. 2) evaluated 2 clinical strategies: sartorius flap coverage versus NPWT for managing an infected vascular groin graft. Probabilities, costs, and QALYs for each health state were incorporated into the model for all the health states relevant to the reconstruction. Expected values for costs and outcomes were derived by multiplying the probability of a health state by its cost and QALY. Expected values were summed for each clinical strategy to derive the overall expected cost and utility (QALY). The incremental cost–utility ratio (ICUR) was then calculated using the formula below:

\[
\text{ICUR} = \frac{-\text{(Expected cost of NPWT)}}{-\text{(Expected QALY of NPWT)}}
\]

This represented the added cost to prolong a patient’s life by 1 year of perfect health.50 A novel intervention is “cost effective” if the ICUR is greater than 0 and less than the “willingness to pay (WTP)” for an added year of perfect health, which we defined as $50,000.51,52 If one clinical strategy is more clinically effective and costs less, then this strategy, by definition, dominates the alternative strategy, and the ICUR is not calculated.53

Sensitivity Analysis

To identify important areas of uncertainty for future research, 1-way and selected 2-way sensitivity

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Table 4. Utilities, Costs, and QALYs for Graft Infections: Infected Graft Repair with Adjunctive NPWT

| Health States | Value(SD) | QALY(SD) | Cost ($) | Codes |
|---------------|-----------|----------|----------|-------|
|               | Base Case | Min | Max | CPT | DRG |
| Successful reconstruction | 0.709 (0.04) | 12.27 (0.14) | 9904 | 7428 | 14,856 | 920 |
| Wound complications requiring debridement | 0.585 (0.025) | 12.27 (0.14) | 18,214 | 13,661 | 27,321 | 11,046 |
| Graft excision with axillary-femoral bypass | 0.389 (0.031) | 12.19 (0.14) | 32,301 | 24,226 | 48,451 | 97,597 |
| Amputation | 0.389 (0.031) | 6.74 (0.11) | 31,727 | 23,795 | 47,590 | 97,597 |
| Death | 0 | 0 | 9904 | 7428 | 14,856 | 920 |

Mean and SD utility values based on 1000 bootstrapped estimates from 15 individual physicians surveys. Amputation and graft excision assumed to have the same utility. QALYs discounted at 3%. Likely baseline cost is derived from Medicare CPT reimbursement, minimum (Min) is 75% of Likely cost and maximum (Max) is 150% of Likely.
analyses were conducted based on a WTP of $50,000/QALY by changing base case values as follows: QALY (±15%), probabilities (±25%), and costs (±50%). In addition, a probabilistic sensitivity analysis (PSA) was conducted using all parameter estimates: (a) probabilities used beta distributions and were parameterized based on the mean and SE derived from the meta-analysis; (b) QALYs used normal distributions and the mean and SE from the bootstrap estimates; (c) costs used triangular distributions based on the base case costs and −25% (minimum value) to +50% (maximum value), to address regional variation in Medicare payments (Tables 3, 4). PSA was conducted using 10,000 random samples; essentially, the expected value calculation was repeated 10,000 times using simultaneous random draws from each distribution for costs, QALYs, and probabilities to characterize the uncertainty of the ICUR. The WTP value was assessed up to $100,000 cost/QALY. All of the above statistical calculations were performed using TreeAge Pro 2014 (Williamstown, Mass.) and Microsoft Excel 2007 (Redmond, Wash.).

This study was done in accordance with the principles outlined in the Declaration of Helsinki.

RESULTS

Literature Review

The literature review pooled 32 studies totaling 384 patients who had their infected vascular groin grafts managed with sartorius flaps or NPWT (234 sartorius flaps, 150 NPWT; Fig. 1; Tables 1, 2).

Complication and Clinical Success Rates

The overall complication rate was higher for the sartorius group at 18.4% (SE = 3.6) compared with the NPWT group at 13.3% (SE = 4.7). Subsequently, the clinical success rate without complication was higher for the NPWT group at 86.7% (SE=3.6) versus 81.6% (SE=4.7) for the sartorius group. Major complications were higher for the sartorius group versus NPWT: graft excision requiring axillary-femoral bypass 3.2% (SE = 1.5) versus 1.4% (SE = 1.0), respectively, and amputation 1.4% (SE = 0.9) versus 0.7% (SE = 0.7).
respectively. Death was similar in the sartorius group versus the NPWT group: 0.7% (SE = 0.6) versus 0.8% (SE = 0.7), respectively. Minor complications (ie, wound complication requiring debridement) were higher for the sartorius group at 8% (SE = 2.4) versus 0.9% (SE = 0.8) for the NPWT group (Tables 1, 2).

Quality-Adjusted Life Years and Incremental Cost–Utility Ratio

Health state value scores with subsequent QALYs and associated costs for each health state are shown in Table 3 and 4. From a clinical effectiveness standpoint, the decision tree analysis showed a slight clinical benefit favoring NPWT (QALY: 12.06) versus the sartorius flap (QALY: 12.05). Conversely, costs were substantially lower for the NPWT group at $12,366 versus $23,516 for sartorius flap group (Table 5). As a result, NPWT dominated the sartorius flap (dominance = lower costs and greater effectiveness).

Sensitivity Analysis

One-way deterministic sensitivity analysis demonstrated that the model was sensitive to QALYs associated with successful management for both NPWT and sartorius flaps (data not shown), although all other variables did not change the conclusion across the ranges tested. As a result, a 2-way sensitivity analysis was performed to elucidate the cost-effectiveness based on changes in the 2 variables (Fig. 3).

PSA results are shown as an ICUR scatter plot and a cost-effectiveness acceptability curve and demonstrate that NPWT is the dominant strategy in 49.4% of the cases, and cost-effective in an additional 32.2% of the cases (Fig. 4) at a WTP of $50,000/QALY. Sartorius flaps are considered to be cost-effective in 18.4% of the cases at the base case WTP. The cost-effectiveness acceptability curve shows the impact of change by the WTP (base case represented by the vertical line at $50,000/QALY). Under a range of WTPs, NPWT remains the preferred option (Fig. 5).

DISCUSSION

A cost–utility analysis is most useful in answering which surgical approach to use when a surgical disease has several competing approaches to choose from, each of which has its own clinical success rates, complication rates, and costs. This type of

| Table 5. Comparison of Cost and Clinical Quality and the Calculation of ICUR |
|-----------------|-----------------|---------|---------|
| Sartorius flap  | Cost ($)        | ΔC ($)  | QALY    | ΔQ     |
|                 | 23,350.76       | -11,150 | 12.05   | 0.01   |
| NPWT            | 12,366          |         | 12.06   |        |

ΔC, difference in cost; ΔQ, difference in QALY.

Fig. 3. Two-way sensitivity analysis of QALYs for successful therapy of NPWT versus sartorius flap. The blue line is the threshold line for WTP at $50,000/QALY or a line of indifference between the 2 therapies. The area above the line favors NPWT, whereas combinations of QALYs below the line favor sartorius flap.
analysis affords the surgeon the ability to argue clinical benefit while weighing costs when advocating the appropriate treatment for the patient.

Adjunctive NPWT, along with appropriate wound care (eg, wound debridement, antibiotics, and surgical wound revision), has been reported to be an excellent option for managing the infected vascular groin graft wound. Once a wound has been debrided, NPWT is relatively easy to apply and does not require the technical fortitude of flap harvesting that a sartorius flap requires. Management of the infected vascular groin graft wound with adjunctive NPWT was initially introduced in Europe in the early 2000s, where the controversial placement of foam close to a large vessel was justified as a last resort effort to salvage the wound when the patient was too ill for additional flap or extra-anatomic bypass surgery. Given the initial success of this treatment in a critically ill patient population, this treatment scheme gained popularity, especially in the European vascular realm. The choice of using NPWT versus the sartorius flap can also be limited by patient characteristics. In general, NPWT is contraindicated in fully anticoagulated patients, many of whom are those receiving vascular surgery. Additionally, the sartorius flap should not be used if there is substantial disease in or total occlusion of the superficial femoral artery, from which segmental perforators supply the flap with blood.

It is important to note that cost-utility analysis addresses a question from a global viewpoint that generalizes results with the goal of providing suggestions, not policy dictum. We caution against a blanket interpretation of our results, as it is very likely that a high-volume flap surgeon who is very comfortable using a sartorius flap for covering infected vascular groin graft wounds can obtain clinical outcomes that are comparable with or supersede those for NPWT. A second limitation inherent in cost-utility analysis is its dependence on the reliability of the literature in the literature review, although we attempted to address this through sensitivity analyses. Additionally, there is an assumption that the data gathered with regards to surgical technique and outcomes when performing flaps or placing NPWT devices are uniform with little variability. In reality, there are different NPWT companies that supply devices and recommend different negative wound pressure settings. Additionally, the literature varies in what negative pressure setting should be used when placing a NPWT device over a vascular structure. Clearly, inherent flaws are present when pooling data from a literature review, given the variability of data collection, patients, and surgeons.

The sensitivity to the QALY estimates for successful treatment is notable; our estimates were derived using a VAS instrument using surgeon estimates. Other
methods, such as standard gamble and time trade-off, can yield different values. A review of these 3 methods indicated that the VAS can produce the lowest health value among the 3 instruments for the same health state. The implications on our findings are unclear because both strategies presumably would suffer from the same lower health values. Nevertheless, this is an area for further research.

Furthermore, the reliance on the literature review in determining outcome probabilities inherits the confounding variable limitation present when using retrospective data. For example, it is difficult to assess how much impact flap or NPWT choice had in the death outcome. Certainly, there was a greater rate of minor and major complications in the sartorius flap group, and one may state that such complications may have contributed to an increased death rate given that the studied population of vascular patients has such little reserve. Nevertheless, there could be other confounding variables other than flap choice contributing to the death rate. A future, prospective study comparing the sartorius flap versus NPWT in this vascular population would address this limitation. A hospital perspective was not performed and thus may have underestimated costs and resources consumed; extrapolating conclusions to individual hospitals, as such, would be outside the scope of our analysis. A broader societal perspective was also not considered and would have to incorporate the total costs to the patient.

**CONCLUSIONS**

In our cost–utility analysis, the use of adjunctive NPWT, along with appropriate wound care (eg, wound debridement, antibiotics, and surgical wound revision), for managing infected vascular groin graft was found to be cost-effective under a wide range of assumptions, when compared with using a sartorius flap and when considered from the Medicare perspective.

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