Cost-effectiveness of a topically applied pre-operative tissue expansion device for radial forearm free flaps: a cohort study

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Objectives: The objective of this study is to test the hypothesis that using a non-invasive and inexpensive pre-operative tissue expansion device (DynaClose) for radial forearm free-flap donor sites will result in a significant reduction in the cost of both in-hospital and out-of-hospital wound care compared with that of unexpanded radial forearm free-flap donor sites.

Design: A cohort study consisting of patients previously randomised in a randomised controlled trial. An intention to treat design was utilised.

Setting: A large tertiary care centre in eastern Ontario, Canada.

Patients: Thirty-four patients presenting to Otolaryngology Head and Neck clinic were enrolled. Of these patients, 29 were previously enrolled in a randomised controlled trial, while an additional five patients were enrolled and randomised for the purpose of this study.

Interventions: Patients were randomised to either the treatment (pre-operative tissue expansion, DynaClose Expansion System) or control group.

Main outcome measures: Wound care costs (in US dollars) were calculated for all patients for both in-hospital care and for patients requiring home care. Non-parametric data analysis was utilised for statistical assessment.

Results: There was a 93% reduction in the use of split-thickness skin grafts in the treatment group. There was a significant reduction in total wound care cost for patients in the treatment group versus the control group (P < 0.0001). Patients in the treatment group required a mean (SD) total of $36.00 (23.50) per patient, while the control group required $277.00 (325.00) of wound care. After excluding the cost of home care, the treatment group continued to have a significant reduction in total and in-hospital wound care costs compared with the control group (P < 0.001).

Conclusions: Using a simple, inexpensive and non-invasive method of pre-operative tissue expansion results in a significant reduction in the costs of wound care for both in-hospital and out-of-hospital treatment. The DynaClose dynamic skin expansion system results in a cost-effective method to reduce the need of a split-thickness skin graft for coverage of a radial forearm free-flap donor site.

Surgical closure of a radial forearm free-flap (RFFF) donor site traditionally requires a split-thickness skin graft.1 Post-operatively, both the split-thickness skin graft donor and recipient sites require considerable wound care. Additionally, the split-thickness skin graft recipient site requires a period of immobilisation to allow for an adequate blood supply to develop into the graft.2–6 Even with high levels of care, complications often occur at the recipient site resulting in extended periods of wound care.7–9

Recently, our team published two randomised controlled trials10,11 and a case series12 demonstrating a new dynamic wound closure technique. This method utilises an inexpensive and non-traumatic elastic adhesive tape (DynaClose®; Canica Design Inc. Almonte, Ontario, Canada) to pre-expand the forearm skin overlying the free-flap donor site prior to surgery. Patients who have the DynaClose system applied demonstrate significant reductions in healing time and post-operative pain compared with patients without
pre-operative tissue expansion. Long-term outcomes are equally promising as there are improvements in cosmetic outcomes of the forearm defect without any associated functional deficits. Many of these outcomes are likely a direct result of the DynaClose reducing the requirement of a split-thickness skin graft for coverage of the free-flap donor site. Of the 31 patients who were treated with the Dynaclose®, 29% achieved full primary closure, 52% achieved closure utilising a locally harvested full-thickness skin graft from redundant skin at the proximal graft site with only 14% requiring a distant split-thickness skin graft.

Given the benefits associated with this technique, an assessment of cost-effectiveness may provide further evidence supporting the use of this device. Given the low cost of the DynaClose, it seems reasonable to speculate that its use may result in reduced overall wound care costs.

Therefore, the purpose of this study is to test the hypothesis that using a simple skin stretching device placed on the forearm 2 weeks prior to harvesting a radial forearm free flap will result in reduced costs of wound care both in hospital and after discharge compared with patients who do not have the skin pre-expanded.

Methods

Study design

We conducted a prospective study of patients previously randomised to a clinical trial between June 2008 and November 2009 at a large Tertiary Care Centre in Eastern Ontario, Canada. All patients were prospectively followed for 1 year after randomisation to assess the total in-hospital and out of hospital wound care. One Reconstructive Plastic Surgeon and two Head and Neck Oncology Surgeons were responsible for screening and enrolling patients. An intention to treat design was utilised. Additional subjects were recruited and randomised prospectively to achieve our desired sample size.

Ethical considerations

The ethics review board of The Ottawa Hospital reviewed and approved the study. Written consent was obtained from all patients. Given the experimental nature of this treatment, all patients were provided information regarding the potential benefits of this new method of tissue expansion as well as the known risks. After this discussion, any patient asking specifically to have the intervention applied was not randomised and was excluded from the study. The use of DynaClose did not delay surgery for patients.

Patients

All patients presenting to an adult tertiary care centre requiring a radial forearm free flap for repair of a defect left after a resection of a head and neck cancer were asked to participate in the study. Patients were excluded if they were not willing to be randomised to one of the treatment groups or any patient diagnosed with a chronic pain syndrome or connective tissue disease.

Interventions

Using computer-generated random numbers, enrolled patients were randomly assigned to either the treatment or control group. Patients in the control group did not have the DynaClose skin-expansion tapes applied. Those in the treatment group had the DynaClose® skin-expansion tapes applied 2-weeks prior to harvesting the free flap. The DynaClose is a topically applied skin-expansion device consisting of an adhesive tape with a central elastic component. The adhesive is attached to the forearm skin while the elastic pulls the skin thereby placing tension on the surrounding skin. This device was placed over on the volar aspect of the patients forearm overlying the future RFFF flap donor site (Fig. 1). We continued to randomise patients until both groups achieved our required sample size (see sample size calculation below).

Procedure

Details with respect to the specifics of the surgical procedure are available in a previous clinical trial. All patients were assessed by the surgical team 2 weeks prior to their operative procedure. Basic demographic data collection and initial randomisation were completed at this visit. Patients randomised to the DynaClose® (treatment group) had the device placed on their forearm at this visit. The DynaClose® was removed on the day of surgery.

Dressings and wound care

Specific wound care techniques were developed with the assistance of a wound care team at our hospital. Wound care methods were dependent on whether the wound was closed primarily, using a full-thickness skin graft or a split-thickness skin graft.

For all wounds, regardless of closure method, a layer of Jelonet (Jelonet®; Smith & Nephew Inc. St. Laurent, Quebec, Canada) covered with sterile dry gauze was utilised. Dressing changes began on post-operative day two and continued daily until healing was achieved.
A forearm splint was utilised for patients requiring a split-thickness skin graft. The splint was placed over the recipient limb to provide immobilisation for a total of 5 days post-operatively. The initial wound assessment and dressing change for both full-thickness skin grafts and split-thickness skin grafts occurred on post-operative day 5. Any skin graft not achieving the definition of completion of wound healing continued daily dressing changes consisting of Jelonet covered with sterile gauze.

The split-thickness donor site on the lateral thigh was covered with an Allevyn (Smith & Nephew Inc. St. Laurent, Quebec, Canada) dressing followed by overlying an OpSite (OpSite®; Smith and Nephew) dressing. The lateral thigh donor site dressing was changed every 5 days.

Any failures or breakdown of a full or split-thickness skin graft were treated with an application of Allevyn®; Smith and Nephew) dressings, which were changed every 3 days. Any patient in which wounds were not healed at the time of discharge had a home care nurse assess and dress the wound on a daily basis. If a home care nurse believed that the wound was healed, dressing changes were discontinued and the patient was reassessed by the treating surgeon the following week. Cost of wound care supplies is noted in Table 1.

### Wound healing

The definition of wound healing utilised in a prior publication was utilised for this study. An unhealed wound was defined as a wound in which any of the following were present: (i) wound cellulitis associated with pain, (ii) discharge of serous or purulent exudates, (iii) separation of wound edges resulting in granulation tissue exposure, (iv) dehiscence of a surgical wound closure requiring healing by secondary intention, (v) failure of split-thickness skin grafts/full-thickness skin grafts over the free-flap donor site, (vi) evidence of tendon exposure, (vii) oedema of the split-thickness skin grafts or full-thickness skin grafts or (viii) any other complication of the split-thickness skin grafts or full-thickness skin grafts (i.e. haematoma or seroma). Any wound demonstrating one or more of these features was considered to be in the process of healing. Wounds were assessed daily by the reconstructive surgical team.

### Outcomes

**In-hospital wound care cost.** Cost for all wound care supplies was calculated based on current pricing (in US dol-
lars) for all supplies used at our hospital. Nursing care and physician costs are not included as nurses are paid per shift and not number of dressing changes. Any additional dressings required for graft failure or wound dehiscence were included in the wound care cost.

Home care wound care costs. Any patient requiring extended wound care after discharge from the hospital was recorded. The cost of nursing and dressing supplies was included in the assessment.

Total wound care cost. Total wound care cost includes the cost of the DynaClose, in-hospital wound care cost and home care cost. The sum of this data was used as the primary outcome measure.

Statistical analysis
All outcomes were assessed using an intention to treat analysis. After assessing for the normality of the data using the Anderson–Darling test, outcome data were noted to be skewed to the right; therefore, non-parametric testing was utilised for all statistical analysis. To assess the three primary outcome measures, Total Wound Care Cost, Home Care Cost and In-Hospital Wound Care Cost, a Mann–Whitney Test was utilised. After a Bonferroni adjustment for three outcome variables, significance was defined as $P < 0.016$. Demographic data were compared using the Kruskall–Wallis test. Categorical data were analysed using the Fisher’s exact test.

Sample size calculation
Based on our case series as well as on our clinical experience using the alternate method of RFFF skin closure, the mean (SD) total difference in wound care cost between treatment and control was estimated to be $100.00 (SD $75.00). Therefore, a minimum of 14 patients per group were required to achieve a power ($\beta$) >80% with an $\alpha$ of 0.016. Patients were continuously enrolled until both groups had a minimum of 15 patients.

Results
Twenty-nine patients enrolled in a previous randomised controlled trial were followed prospectively. An additional five patients were prospectively enrolled and randomised to achieve the desired statistical power of this current study. A total of 34 patients completed follow-up. There were 15 patients in the control group and nineteen in the treatment group (Table 2). Five (35%) patients in the control group and none of the patients in the treatment group required home care (wound care) for their forearm donor site. One patient in the treatment group requested removal of the DynaClose owing to discomfort. This patient remained in the treatment group as per the intention to treat analysis. Two patients were noted to have a loss of adhesion of the DynaClose and required a second application. The cost of the reapplication was included in the final analysis.

With respect to closure methods, two patients in the treatment group required a split-thickness skin graft while all 15 patients in the control group required a split-thickness skin graft. Five patients in the treatment group were closed primarily with the remainder of patients achieving closure using a small locally harvested full-thickness skin graft from redundant forearm tissue.

There was a significant reduction in both in-hospital ($P < 0.0001$) and total wound care ($P < 0.0001$) cost in the treatment group compared with that of the control group. Cost data are presented in Table 3. Primary closure was associated with the lowest cost followed by full-thickness skin graft closure and then split-thickness skin graft closure ($P < 0.0001$).

Patients who had a graft complication had a significantly higher total wound care cost compared with those without a complication ($P < 0.0001$). There were significantly more patients in the control group with complications ($P = 0.002$). In the control group, three patients had a minor loss (<20% of split-thickness skin grafts), one patient had a moderate loss (up to 50% loss of split-thickness skin grafts) and two patients had tendon exposure. There were no failures of the full-thickness skin grafts or primary closure in the treatment group.

After excluding patients with greater than half of the total graft area failure or tendon exposure ($n = 3$), both total wound care costs ($P < 0.0001$) and in-hospital costs ($P < 0.0001$) remained significantly reduced in the treatment group.

Table 2. Demographics for treatment and control groups

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Control group</th>
<th>Treatment group</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female sex %</td>
<td>15.9</td>
<td>45.5</td>
<td>0.17</td>
</tr>
<tr>
<td>Age (year)</td>
<td>64.4 (7.39)</td>
<td>61.09 (9.1)</td>
<td>0.31</td>
</tr>
<tr>
<td>Arm surface area (cm$^2$)</td>
<td>539.3 (70.6)</td>
<td>516.0 (78.0)</td>
<td>0.33</td>
</tr>
<tr>
<td>Skin graft area (cm$^2$)</td>
<td>31.9 (7.6)</td>
<td>28.9 (11.1)</td>
<td>0.27</td>
</tr>
<tr>
<td>Skin graft as % of forearm surface area</td>
<td>5.9 (1.2)</td>
<td>5.8 (3.0)</td>
<td>0.15</td>
</tr>
<tr>
<td>Days in hospital</td>
<td>18.3 (21.8)</td>
<td>13.9 (4.1)</td>
<td>0.475</td>
</tr>
</tbody>
</table>

Values reported as mean (SD) unless otherwise noted.
Discussion

Synopsis of key findings

The development of a new technology requires evidence of efficacy, safety and cost-effectiveness. Recently conducted randomised controlled trials have demonstrated considerable efficacy when using this method of pre-operative skin expansion. With respect to safety, complications have been mild and infrequent.10,11 This current study has demonstrated the cost-effectiveness of this method, thus providing further evidence supporting its usefulness in reconstructive surgery.

Reduction in the cost of wound care when using this method of pre-operative tissue expansion likely relates to three factors, the reduction in healing time, the lack of a split-thickness skin graft donor site as well as the low rate of complications when using tissue expansion. Any patient with a significant complication, such as tendon exposure, required an extended period of wound care to allow the RFFF donor sites to heal by secondary intention. This extended wound care time contributed a significant amount of wound care costs to their associated intervention group. After excluding these patients with significant complications (greater than half of the graft failure or tendon exposure, n = 3), the reduction in wound care costs remained both statistically and clinically significant in the treatment group. Even with these major complications excluded, the use of pre-operative tissue expansion device reduces total wound care cost.

As noted, there were significantly more complications associated with a split-thickness skin graft compared with both primary closure and full-thickness skin graft closure. The increased rate of graft complications in the control group further contributes to the increase in healing time, thus increasing costs. The reported incidence of complication rates associated with split-thickness skin graft coverage varies in the literature.5,7,9,13,14 Although the incidence of complications of split-thickness skin grafts in our population was consistent with other published studies,7,9 complication rates associated with the full-thickness skin graft in this current study were considerably lower.4,5,15 Basic science research has demonstrated that tissue expansion results in an increase in vascular neogenesis into the tissue undergoing expansion.16 Tissue subjected to constant expansion over the course of 2 weeks likely develops increased neovascularization. One may hypothesise that the increase in neovascularisation may allow for higher rates of graft survival in locally harvested full-thickness skin graft tissue. In fact, our experience in over 70 patients using this method has yielded strikingly reduced rates of graft failure when using a locally harvested full-thickness skin graft. Thus, the lack of complications in the treatment group highlights an additional benefit of pre-operative tissue expansion.

Generally speaking, a reduction in healing time correlates with a reduced cost. Uncomplicated wounds closed primarily heal relatively quickly; thus, wound dressings are typically not required after 2–5 days. With respect to primary closure of free-flap donor sites, one initial concern was the possibility of wound dehiscence owing to tension across the opposing edges. Both short-term and long-term functional results have failed to demonstrate any significant complications associated with primary closure in our population.10 There have been no episodes of wound dehiscence in this assessment or in any patient published in our prior studies. Both the lack of complications and the brief healing time associated with primary closure directly reduce the costs of wound care.

In addition to the complication rates and wound healing time, harvesting a split-thickness skin graft from the lateral thigh results in another wound requiring care, thus increasing the total cost in the patient. Using the DynaClose reduced the need for a split-thickness skin graft, thereby removing any contribution to the lateral thigh donor site on wound care costs in the treatment group.

Table 3. Summery of data for cost analysis comparing treatment with control groups

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Treatment</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Median</td>
</tr>
<tr>
<td>Total home care days required</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>In hospital dressing cost (US dollars)</td>
<td>$27.2 (36.0)</td>
<td>$17.20</td>
</tr>
<tr>
<td>Home care cost (US dollars)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total dressing cost with complications</td>
<td>$36.0 (23.5)</td>
<td>$33.20</td>
</tr>
<tr>
<td>Total dressing cost no complications</td>
<td>$36.0 (23.5)</td>
<td>$33.20</td>
</tr>
</tbody>
</table>

Cost-effectiveness of a topically applied pre-operative tissue

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Limitations

One must consider that the study was unblinded with all surgeons being aware of group assignment. However, on comparing the results of primary closure to other published research, as well as the evidence from our previous research,10–12 it is reasonable to conclude that this method of pre-operative tissue expansion influences closure rates thereby reducing the costs of wound care. In addition to this, the use of the DynaClose results in visible evidence of stretching and tension on the skin. Given that the DynaClose tapes were removed at the time of surgery, surgeons are able to easily identify patients in whom the tapes were applied. Thus, true blinding is not possible.

With respect to our wound care protocol, the wound care team at our institution developed the protocol for treating post-operative RFFF donor sites and split-thickness skin graft donor sites. It is likely that the majority of reconstructive services utilise a variety of wound care protocols; thus, our particular protocol represents one of many. Nevertheless, it would be unlikely, regardless of the wound management protocol, that wounds closed primarily would require more dressing changes and supplies than a wound closed using a split-thickness skin graft. Furthermore, using a locally harvested full-thickness skin graft negates the requirement of a second donor site, thus further reducing wound care costs. Given that the DynaClose System has demonstrated a large reduction in the need for split-thickness skin graft, reduced wound care costs are expected regardless of wound care protocol.

Another important consideration is the determination of healing time. Given that healing time directly influences dressing costs, a clinically valid definition of healing time is required. Our team recently published a RCT11 assessing healing time and discussed the difficulty using a subjective definition. Most studies assessing the healing time of radial forearm free flaps have relied on dressing changes as a proxy for healing time. This is not an ideal measurement; thus, our attempt to standardise the definition of healing time likely improved the validity of the outcome. Although varying the definition of healing time may influence overall costs of wound care, it would not likely influence the relative cost of each intervention group.

Conclusion

The use of the DynaClose pre-operative skin expansion device represents a significant advancement in our management of radial forearm free flaps. Given the clinical efficacy of the DynaClose, the demonstrated cost-effectiveness further supports the use of this technique in reconstructive surgery.

Keypoint

- The use of the DynaClose tissue expansion device results in a significant reduction in the cost of wound care for patients undergoing a radial forearm free flap.

Conflict of interest

None of the authors included in this study have any financial interests or disclosures associated with any product used in this study. No conflicts of interest declared.

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References


