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Novel Solutions for Wound Closure after Caesarean Section

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About the Experts

Olivia Smart
MBBS(London), Dip Obs, FRANZCOG

Dr Olivia Smart is an O&G specialist working in Christchurch. She completed her undergraduate training at University College London and postgraduate studies through RANZCOG. She holds a position at Christchurch Womens Hospital as well as working in private practice at Oxford Womens Health. She is a senior clinical Lecturer for the department of O&G at the University of Otago.

Her special interests are in advanced laparoscopic surgery and management of endometriosis, surgical education, colposcopy and the managment of vulvo-vaginal disorders.

Michael Stitely
MD (Pittsburgh), FACOG, FRANZCOG

Dr Mike Stitely is an Obstetrician and Gynaecologist at Dunedin Hospital where he is Associate Professor and Head of Department of The Department of Women's and Children's Health at the Dunedin School of Medicine, University of Otago.

Prior to coming to New Zealand, Mike was on the faculty at the West Virginia University School of Medicine in the USA. He initially worked as a consultant in Obstetrics and Gynaecology for the Southern District Health Board before being appointed as Associate Professor. He maintains research interests in medication use inpregnancy, prevention of surgical site infections,and developing surgical instrumentation, having published over 40 peer-reviewed articles. His team has recently developed a device to insert IUDs post-partum after vaginal delivery

Against a background of increasing rates of Caesarean delivery and the potentially high burden of the procedure, this review discusses two new approaches to wound closure for Caesarean section that may help to reduce the associated clinical and cost burden.

Caesarean delivery demand and healthcare burden

Although many women would prefer a vaginal birth,[1] rates of Caesarean section (CS) have increased globally over past decades.[2,3] Between 1990 and 2014, average CS rates increased by about 2.5% per year in more developed countries and by about 5% per year in less developed countries.[2]

A total of 16,423 NZ women had a CS in 2017, accounting for 27.9% of all births (58,959 women with a known type of birth) and an increase from 23.6% in 2008.[4] Between 2008 and 2017, the 2.3% increase in the proportion of elective CS performed in NZ (from 10.3% to 12.6% of known birth types) was slightly greater than the 1.8% increase in the proportion of emergency CS performed (from 13.4% to 15.2%).[4]

The increasing rate of CS is of concern because of the health risks to both mother and infant as well as the economic burden incurred by the healthcare system.[5,6] In 2017, there was alarm that ADHB would not have sufficient resources to provide for the number of CS if the trend of increasing numbers of elective CS continued.[7] The WHO has suggested in the global context that CS should only be undertaken when medically necessary and that only 10–15% of births warrant this form of medical intervention.[6]

Expert commentary (Mike Stitely): The healthcare system-related costs related to post-surgical wound complications are significant. Wloch et al. modelled these costs for an NHS hospital in the UK performing 800 Caesarean deliveries per year.[8] They found total healthcare system-related costs to be approximately $26,000 NZD per 800 cases in 2010, with inflation pushing this to $43,000 NZD in 2019. These costs will vary based on location. This cost excludes measures of inconvenience and short- and long-term disability related-costs to the affected woman and additional societal costs and impacts. Clearly, any investment in reducing Caesarean-related surgical-site infection has significant monetary and societal return on this investment.

Surgery: hospital inpatient	
Procedure duration	1 hour (10 min before delivery + 50 min to complete surgery[9]
Average ward-stay	3 nights[10]
Medical ward-stay	$1,000 per day[11]
Specialist	$130 per hour[11]
Nurse	$45 per hour[11]
Pharmaceutical supplies	Anaesthesia and pain control[12]
Blood loss (500–1,000 mL)	Potential need for transfusions and resources to control bleeding
Post-surgery: primary care	
Midwife follow-up	Soon after birth[10]
Obstetrician follow-up	At 6 weeks (if needed)[10]
GP practice visit	$75 per consult[11]
GP home visit	$150 per consult[11]
Practice nurse visit	$30 per consult[11]

Examples of some of the healthcare system resources consumed for CS surgery and post-surgical care, including costs for certain items (2015 values).
Management of post-surgical wound infection would require additional use of many of these resources.

Burden of wound complications: infection

Surgical site infection (SSI) is the most common wound complication that occurs after CS,[13,14] with infection rates quoted as high as 9–12%.[12,15] A UK study found a 9.6% rate of SSI and a Norwegian study an 8.9% rate.[16,17]

SSI after CS is associated with substantial patient morbidity and mortality and leads to increased costs for the healthcare system and out-of-pocket costs for the patient.[12,18,19] SSI is a major cause of prolonged hospital stay and hospital re-admission.[15]

With the rising incidence of CS deliveries, the occurrence of SSI is expected to increase in parallel and hence also the associated burden and cost.[20] Against this background, there is need for novel surgical therapies to minimise the risk of SSI and hence help reduce post-CS morbidity and mortality and resource use.[19]

Risk factors for infection

Operating time ≥38 min,[17] and body mass index (BMI) >25 Kg/m^2 have been shown to be significant and independent risk factors for post-Caesarean SSI (**Figure 1**).[16,17]

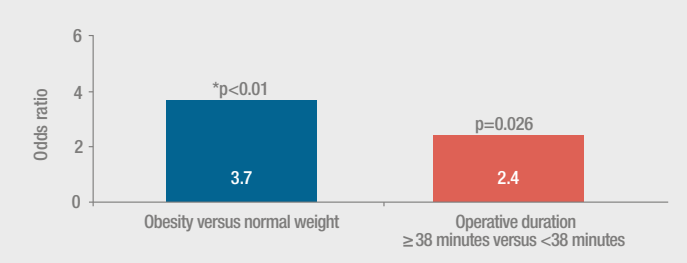

Figure 1. Risk factors for SSI occurring post-CS. Odds ratio = likelihood that a wound complication will occur in patients with the risk factor versus those without the risk factor.[16,17] *Unadjusted odds ratio (adjusted odds ratio not reported)

Obesity is strongly associated with an increased risk of CS,[21] and is the most important risk factor for the post-CS maternal complications,[22,23] especially wound infection and wound separation.

- In a retrospective cohort study that assessed all women who underwent CS at Wellington Hospital in 2014–2015, 5.2% developed an SSI and BMI ≥30 kg/m^2 was associated with significant SSI risk (OR 4.1, p<0.001).[23]
- The likelihood of CS wound separation has been shown to be 6-fold higher (p=0.01) in obese patients with a BMI ≥50 kg/m^2 compared with those with lower levels of obesity.[24]
- In a large multicentre cohort study, BMI >45 kg/m^2 was associated with substantial increase in a maternal post-CS wound complication composite endpoint (infection, endometritis, wound opening, seroma/hematoma, and hospital readmission) versus non-obese women.[22]

In addition to SSI often requiring re-admission, surgical repair of separated wounds sometimes requires readmission and re-operation, which are also associated with an additional cost of care.[25]

Wound closure guidelines

1. Surgical techniques

The UK's National Institute for Health and Care Excellence (NICE) guidelines recommend the following:[26]

- Neither the visceral nor the parietal peritoneum should be sutured as this reduces operating time and the need for postoperative analgesia and improves maternal satisfaction.
- If a midline abdominal incision is used, mass closure with slowly absorbable continuous sutures should be used because this results in fewer incisional hernias and wound separations than layered closure. This would be rarely undertaken for CS delivery but supra umbilical for the Class IV super obese should be considered.
- Routine closure of the subcutaneous tissue space should be used, as most cases will have >2 cm subcutaneous adipose tissue.

2. Use of staples versus sutures

The NICE guidelines recommend the following:[26]

- Use of staples for wound closure in CS increases the number of women who experience wound separation in comparison to the use of sutures.
- Consider using sutures rather than staples to close the skin after CS to reduce the risk of superficial wound separation.

Although staple closure is faster to perform than suture closure,[27] wound complications are statistically significantly less likely to occur in women whose incisions are closed with suture than closed with staples.[13,14] In a meta-analysis of randomised controlled trials (RCT) comparing absorbable suture with metal staples for CS wound closure, women whose incisions were closed with suture had a 51% lower risk of developing a post-surgery wound complication (RR 0.49; 95% CI: 0.28–0.87).[14]

In addition, patient satisfaction with the closure method, satisfaction with the scar's appearance, and patient and physician assessments of scar cosmesis have been shown to be superior for wounds closed with suture in a RCT that evaluated sutures and staples for skin closure after CS.[28]

3. Use of antibacterial sutures:

The NICE guidelines recommend the following:[26]

- When using sutures, consider using antimicrobial triclosan-coated sutures to reduce the risk of surgical site infection.
- Use of triclosan-coated sutures for wound closure reduces the number of people who experience SSIs and the number of people who require post-operative antimicrobials in comparison with the use of standard sutures.

The NICE guidelines note that because the treatment of SSIs can result in considerable costs, a reduction in SSIs could help to reduce costs as well as improve patient outcomes after surgery.[29] Although the costs of triclosan-coated sutures are higher than traditional sutures, this difference in cost is less than the cost of treating an SSI.

Guidelines from the US Centers for Disease Control (CDC),[30] World Health Organisation (WHO),[31] and American College of Surgeons and Surgical Infection Society (ACS & SIS)[32] also advocate the use of triclosan-coated sutures for the prevention of SSI.

Expert commentary (Olivia Smart): Many surgeons will elect to close the parietal peritoneum particularly in a primary caesarean where closure will avoid the formation of sub rectus omental adhesions, which can cause trouble at the time of emergency repeat CS. The evidence around this is inconsistent in the literature,[33] and further research is required.

Expert commentary (Mike Stitely): Usual surgical care in NZ includes the use of absorbable or delayed absorbable sutures for closure of the rectus sheath. Absorbable sutures are typically used to close the subcutaneous adipose layer when indicated and running subcuticular closure of the skin is performed with absorbable suture.

Wound dressings and bandages tend to be variable both between and within maternity units across the country. Uptake of the use of negative pressure wound dressings has slowed as the clinical evidence is not entirely convincing of their efficacy, even in high-risk patients.

Wound closure solutions

1. Stratafix Knotless Tissue Control Devices

Stratafix™ Knotless Tissue Control Devices are absorbable, antibacterial, monofilament sutures that have multiple small barbs on the string surface.[34] The need to tie surgical knots is eliminated and suturing difficulty is reduced. A triclosan coating helps to prevent SSI.

Anti-microbial properties

Triclosan-coated sutures have been demonstrated to exhibit anti-bacterial efficacy *in vitro* against a wide range of clinically-relevant gram-positive and gram-negative bacterial species with durable inhibition of colonisation by pathogenic bacteria.

- An *in vitro* and *in vivo* study evaluated Stratafix Symmetric triclosan-coated sutures in comparison with standard sutures lacking triclosan.[35] Stratafix Symmetric sutures demonstrated *in vitro* anti-bacterial activity against *Staphylococcus aureus*, methicillin-resistant *S. aureus* (MRSA), *Staphylococcus epidermidis*, methicillin-resistant *S. epidermidis* (MRSE), *Klebsiella pneumoniae*, and *Escherichia coli*. Antibacterial activity was maintained for 11 days against *E. coli* and 23 days against *S. aureus*. In animal models, the Stratafix sutures demonstrated significant reductions in *S. aureus* and *E. coli* relative to the standard sutures ($p<0.05$).
- In a RCT, use of Stratafix Symmetric triclosan-coated sutures was associated with a significantly lower risk of incisional SSI ($p=0.009$) compared with standard suture lacking triclosan for fascial closure in patients undergoing emergent surgery.[36]

Tissue-holding properties

In pre-clinical studies, cutting Stratafix Spiral Knotless and Stratafix Symmetric Knotless sutures did not result in tissue separation or unravelling of the device and, in tissue-holding performance tests, Stratafix Symmetric sutures demonstrated fascia-holding strength that was 32% stronger than interrupted sutures and 22% stronger than continuous sutures ($p=0.009$ in a 3-way comparison).[37]

Key advantages of knotless barbed suture in gynaecology surgery:[38,39]

- Elimination of knot-related complications
- Even distribution of tension across the wound
- Potentially reduced closure time
- Secure approximation of tissues
- Reduced suturing difficulty in open procedures
- Can easily be learnt
- Potential to reduce utilisation of surgical resources

Surgical outcomes and efficiency

The effectiveness and safety of the Stratafix Knotless Tissue Control Device have been demonstrated in a variety of gynaecological surgical procedures.[39] By eliminating the need to tie surgical knots, barbed suture provides certain advantages over conventional suture including:

- Reduced suturing difficulty and elimination of knot-related complications, potentially resulting in reduced operating room time.
- Increased tensile and wound-holding strength, especially for high-tension areas such as fascial closure, which is relevant for many gynaecological procedures.

In RCTs comparing with Stratafix knotless barbed sutures with conventional smooth suture for closure of uterine incision during CS, barbed suture demonstrated the following outcomes versus conventional suture (**Table 2**):

- Uterine closure time was significantly reduced.[40-42]
- Significantly less need for haemostatic sutures.[40-42]
- Significantly less need for haemostatic agents.[42]
- Blood loss was significantly or non-significantly reduced.[40,41]
- Blood loss was non-significantly increased.[42]

	Knotless barbed	Conventional	Difference	P-value
Peleg et al.[41]				
No. of patients	51	51		
Closure time	3 min 37 sec	5 min 20 sec	1 min 43 sec	<0.001
Additional haemostatic sutures	16 patients (31%)	41 patients (80%)	25 patients	<0.001
Estimated total blood loss	500 mL	600 ml	100 mL	=0.002
Grin et al.[42]				
No. of patients	35	35		
Closure time	5 min 8 sec	6 min 51 sec	1 min 43 sec	<0.001
Additional haemostatic sutures	11 patients (31%)	25 patients (71%)	14 patients	=0.002
Use of haemostatic agents	4 patients (11%)	12 patients (34%)	8 patients	=0.03
Estimated total blood loss	735 mL	704 mL	31 mL	=0.54
Zayed et al.[40]				
No. of patients	50	50		
Closure time	3 min 44 sec	5 min 43 sec	2 min 1 sec	<0.001
Additional haemostatic sutures	2 patients (4%)	12 patients (24%)	10 patients	=0.009
Estimated blood loss	116g	158g	42g	=0.086

Table 2. Outcomes with Stratafix knotless barbed suture compared with conventional suture in CS.[40-42]

Utilisation of surgical services

Use of Stratafix barbed suture may reduce utilisation and costs of surgical services based on data from:

- Two RCTs and one retrospective cohort study in which barbed sutures significantly reduced use of surgical materials (32%; $p<0.01$) and overall surgery costs (16–35%; $p<0.001$) versus traditional sutures in several surgical specialties (gastric bypass, hysterectomy, and prostatectomy).[43-45]

2. Dermabond/Dermabond Prineo

Dermabond™ Prineo™ is a non-invasive skin closure system that consists of a liquid topical tissue adhesive 2-octyl cyanoacrylate (Dermabond) and a self-adhering mesh.[34] It avoids the need for sutures or staples and no post-surgical dressings are required. Dermabond Prineo provides a flexible barrier to microbial penetration, which may help to reduce SSI.

Anti-microbial properties

Cyanoacrylate-based tissue adhesives, including Dermabond, provided a superior microbial barrier compared with common pressure-sensitive adhesives in an *in vitro* study.[46] Testing showed no penetration of bacterial pathogens into any of the cyanoacrylate adhesive samples at 72 hours compared with 99% bacterial penetration of the pressure-sensitive adhesive samples.

Two other *in vitro* studies have demonstrated that Dermabond adhesive inhibits growth of gram-positive organisms, including methicillin-resistant *S. aureus* and *S. epidermidis*, and gram-negative organisms, including *E. coli* and vancomycin-resistant *Enterococcus faecium*.[47,48] Data from one of these studies indicated that Dermabond provided a barrier to bacterial penetration for ≥72 hrs.[47]

Tissue-holding properties

In a pre-clinical study, incisions closed with Dermabond Prineo were shown to be 33% stronger compared with staples ($p<0.01$) and 40% stronger compared with sutures ($p<0.01$).[49]

Surgical outcomes and efficiency

A RCT that assessed clinical outcomes with Dermabond adhesive and sutures for skin closure after CS found no significant differences in blood loss, SSI, duration of post-partum hospitalisation, or wound disruption and that both methods can be used interchangeably based on surgeon and patient preferences.[50]

In a retrospective cohort study in women who received either Dermabond adhesive or Steri-strips for skin closure after CS, use of Dermabond adhesive was associated with a significant reduction in the frequency of wound separation ($p=0.03$) and a composite wound complications endpoint ($p=0.006$). There was a non-significant reduction in SSI ($p=0.057$), which requires further investigation.[51]

A subsequent large retrospective observational study comparing outcomes of CS with skin closure using skin staples plus waterproof wound dressings versus Dermabond Prineo found significantly lower rates of SSI ($p=0.011$) and wound complication ($p=0.036$) with Dermabond Prineo.[52]

In a RCT, Hollander Cosmesis Scale scores indicated a significantly ($p<0.001$) more favourable overall result with Dermabond Prineo versus sutures at 2 weeks after surgery in women and men who underwent abdominoplasty.[53] At 12 months after surgery, the Vancouver Scar Scale demonstrated a significantly ($p<0.001$) better cosmetic outcome with Dermabond Prineo and Patient Scar Assessment Scale scores indicated significantly ($p<0.05$) less pain, thickness, and irregularity with Dermabond Prineo.

Utilisation of surgical resources

Because Dermabond Prineo avoids the need for wound dressings or suture removal at a follow-up appointment, medical supplies and labour time spent on wound management are potentially reduced:

- In a RCT, use of Dermabond Prineo for skin closure following abdominoplasty resulted in a 13 min reduction in operating time ($p<0.05$) and 5% ($135 USD) saving in overall operating costs compared with resorbable sutures.[53]
- In a RCT, laparoscopic port-site skin closure with Dermabond was found to be effective and was associated with a 10 min reduction in operative time ($p<0.00001$) and 60% ($304 USD) cost saving per closure ($p<0.00001$) versus absorbable sutures.[54]
- In the large retrospective observational study that compared Dermabond Prineo with skin staples plus wound dressings for skin closure after CS, use of Dermabond Prineo was associated with a 5-hour reduction in length of hospital stay ($p=0.007$) and 5% ($434 USD) saving in mean total hospital costs ($p=0.025$).[52]

EXPERT'S CONCLUDING COMMENTS (OLIVIA SMART)

The need to address SSI as a priority for women undergoing CS delivery requires evaluation of any strategy that will reduce risk. Triclosan-coated sutures and the favourable surgical times and blood loss suggest that barbed sutures may well be beneficial.

Currently, there is limited data for use of Dermabond Prineo following CS delivery and further research should be undertaken to evaluate this. It is this expert's experience that post CS, the rates of dressing removal within the first 72 hours are relatively high due to ooze and I would therefore caution obstetricians to consider use of Dermabond Prineo in addition to subcuticular Stratafix rather than instead of.

EXPERT'S CONCLUDING COMMENTS (MIKE STITELY)

Recent product developments in wound and tissue closure offer clinical and service-level benefits. I have adopted the use of the delayed absorbable Stratafix Symmetric sutures for rectus sheath closure and absorbable barbed sutures for subcuticular skin closure. I find these products to be simple to use and to teach to trainees, and that they save time in our time-pressured clinical environment. Our unit has recently started a trial of using the Dermabond Prineo barrier dressings for high-risk Caesarean delivery cases (such as diabetes or Class 3 obesity). I have not seen any of these wounds back in clinic to assess properties such as cosmesis. I do find the dressing quick and easy to apply. One tip for its use is to ensure the surrounding area is clean and dry prior to application, and to ensure that the adhesive has dried prior to allowing contact with clothing or other textiles.

TAKE-HOME MESSAGES

- Rates of CS have increased significantly in NZ over the past 10 years, reaching one in four women giving birth in 2017.
- Increasing rates of CS suggest an increasing burden of CS-related wound complications.
- Obesity is strongly associated with increased rates of CS and is the most important risk factor for SSI and wound separation after CS.
- Increased operating time is associated with higher rates of SSI.
- Wound-closure devices that reduce the risk of post-CS wound complications have the potential to reduce the associated clinical and economic burden.
- Use of knotless sutures can shorten surgical time and potentially reduce intraoperative blood loss.
- Based on pre-clinical, clinical, and observational studies, Stratafix Knotless Tissue Control Devices and the Dermabond/Dermabond Prineo:
  - Provide secure tissue-holding, which may reduce the risk of wound separation.
  - Reduce the risk for SSI via a triclosan coating or formation of a flexible antibacterial barrier.
  - Improve surgical efficiency via reduced wound closure time.
  - Potentially reduce the utilisation of surgical resources.

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