

# **Medium to Long term results following open intra-abdominal repair of large incisional hernias with a new composite polypropylene and silicone mesh, without components separation.**

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## Introduction

The abdominal incisional hernia is a common complication of abdominal surgery reported up 11% of patients, and consequently is an important source of morbidity. As such, it is a frequent problem encountered by general surgeons. Recurrence rates after incisional hernia repair have been reported to range from 10-50% with associated morbidity and mortality. Reconstruction of large abdominal hernias is still a major problem in general surgery with reherniation rates being high without the use of a prosthetic material. Effective treatment of these hernias can be complex and even more challenging when managing high risk profile patients who suffer from obesity, previous recurrence, diabetes and a large hernial defect.

In 1990 Ramirez and colleagues[1] developed a technique for reconstruction of large abdominal wall defects using prosthetic material. The technique involved enlarging the abdominal wall by translating the muscular layers of the abdominal wall medially. The skin is first mobilised, and the external oblique muscle is transected laterally from its insertion into the rectus sheath and separated from the internal oblique. The rectus abdomens sheath is then advanced medially to aid in closure of larger defects. In our series we discuss managing large abdominal wall, incisional hernias (with and without abdominoplasty) without using component separation-with the aid of a new bifacial mesh. This mesh is composed of a non woven polypropylene layer that is colonisable by fibroblasts to ensure adherence, and non adherent (visceral side) made of multi-perforated and non woven silicone (Surgimesh Tintra). Surgimesh Tintra is a non woven microfibre (0.02mm), low weight (43g/m<sup>2</sup>) bifacial silicone and polypropylene mesh consolidated by heat sealing. The silicone layer is designed to resist both adhesion formation to bowel, and shrinkage.

Randomised trials have shown that mesh repair of incisional hernias reduces recurrence rates. However the type of mesh used may further influence the recurrence rate and postoperative pain and overall patient satisfaction. The majority of widely used meshes are the traditional polypropylene (PP) or polytetrafluoroethylene (PTFE) based. New generation meshes include not only biological meshes that may be used when there may be a risk of sepsis, but also newer synthetic materials- such as the silicone mesh used in this series.

We present our experience of using a non-adherent synthetic mesh (give description) a new type mesh of mesh ?? pilot study. In a variety of clinical settings ie obesity and intraabdominal contamination (limited). Also concomitant abdominoplasty.

### *Objectives and Aims*

#### *Primary Outcomes*

This project aims to evaluate the effectiveness and outcomes following open incisional hernia repair using a next generation, bifacial silicone and polypropylene mesh in the repair of complex hernia in an overweight and obese patient subgroup.

Primary outcomes include:

- Early and late post operative complications.
- Patient reported outcomes, including pain assessment, physical activity and quality of life assessments.

### *Secondary Outcomes*

This study also aims to develop an assessment tool for patients undergoing this surgery, and evaluating its reliability and validity. The areas for assessment included:

1. Cosmetic results and satisfaction with procedure
2. Pain
3. Functional performance
4. Quality of life

Other secondary outcomes included patient satisfaction with surgery and length of stay.

## **Methods**

### *Patients*

All patient who underwent elective open incisional hernia between 2005 – 2010 at the Melbourne Hernia Clinic (Victoria, Australia) using bifacial silicone and polypropylene mesh (Surgimesh Tintra) were enrolled into this trial. 33 cases were identified. The majority of patients were overweight (mean BMI 35.5 SD 6.7), with some patients undergoing abdominoplasty simultaneously.

For each patient, a single researcher retrospectively collected demographic, perioperative and postoperative data from all the medical documentation. Standardisation of the operative procedure was accomplished by a single surgeon performing all the operations using a text book mesh sublay technique under general anaesthetic. An additional patient interview was also conducted by the same researcher regarding recurrence (presence or absence), overall patient satisfaction and postoperative pain, using a standardised questionnaire.

### *Methods*

Retrospective data collection was used to determine patient characteristics such as age, sex, body mass index, ASA score, surgical technique (including mesh placement and technique used) and intraoperative hernia size. In the majority of cases the hernia was diagnosed clinically with computed tomography or ultrasound scan being used to clarify uncertain findings. Early post-operative complications were detected during the patients hospital stay and were recorded by reviewing the patients medical history following discharge.

### *Patient Assessment*

Patient outcomes following incisional hernia repair were divided across several domains identified from the proposed tools by Kehlet et al and Franneby et al. Similarly our experience with treating patients with this surgical condition enabled us to ensure content validity by covering important domains of patient outcomes. These included:

- Physical impairment as a consequence of pain or discomfort.
- Cosmetic result.
- Quality of life assessment.

Quality of life was adopted by relevant features of the SF (short form) 36 questionnaire. It determine whether in the previous month whether or not the patient had any impairment in social activity, daily activities (including regular tasks as dressing and washing) and work related duties.

Pain was assessed using a visual analogues scale (VAS). Pain was defined as “an unpleasant sensory experience associated with potential or actual tissue damage”. Patients were first asked to rate the intensity of pain felt (if present), or if no pain was felt whether or not there was discomfort present. Patients were also asked to determine when the pain was present ie at rest or only associated with certain types of physical activity.

#### *Mesh*

Three types of meshes were used, round of diameter (12.5cm), medium diameter (10cm) and large 15cm diameter. They were bifacial, double layer meshes. The adherent surface was made of non woven polypropylene that was colonisable by fibroblasts to ensure adherence. The non adherent (visceral side) was made of multi-perforated silicone.

#### *Statistics*

Continuous variables were expressed as means with their respective standard deviations. The Chi-Square test was used to determine differences between groups. A type 1 error rate of 5% was used to indicate the level of statistical significance. For reliability assessment of the survey, Cronbach’s alpha was calculate. All statistics were calculated using SPSS 20 for Mac OSX (IBM, Chicago, Illinois, USA).

## Questionnaire

### Cosmetic Result and Satisfaction procedure

*In general how would you rate the overall cosmetic results?*

Excellent  
Very good  
Good  
Fair  
Poor

*If you could go back to the time before your hernia was repaired, would you still choose to have surgery?*

Yes  
No  
Unsure

*In general, how would rate your satisfaction with your hernia repair?*

Excellent  
Very good  
Good  
Fair  
Poor

### Pain Assessment

*As a result of your hernia repair, do you have...*

Pain or discomfort out of ten at rest now?

Pain or discomfort with normal activities?

Pain or discomfort with moderate activities?

Pain or discomfort with strenuous activity?

### Quality of life Assessment

*Has your hernia repair impacted upon your ability to..*

Walk more than a kilometre?  
A lot  
A little  
None

Walk a short distances?  
A lot  
A little  
None

Bathe or dress yourself?  
A lot  
A little  
None

To perform household work?  
A lot  
A little  
None

Physical recreation such as walking or swimming?  
A lot  
A little  
None

Partake in entertainment activities such as going to the movies, concerts, etc?  
A lot  
A little  
None

Perform your normal occupational work?  
A lot  
A little  
None

Partake in social activities?  
A lot  
A little  
None

### Functional Assessment

*Does your hernia repair impair...*

Vigorous activities such as running or lifting heavy objects?

A lot  
A little  
None

Moderate activities such as moving a table, playing golf or vacuuming?

A lot  
A little  
None

Lifting or carrying groceries?

A lot  
A little  
None

Climbing several flights of stairs?

A lot  
A little  
None

Climbing one flight of stairs?

A lot  
A little  
None

Bending, kneeling or tying shoe laces?

A lot  
A little  
None

## Results

### *Patient Characteristics*

33 patients, 14 male and 19 female underwent incisional hernia repair between 2005 and 2010. 14 underwent abdominoplasty (42.4%) at the same time. Table 1 shows the characteristics of all patients divided into whether or not they had an abdominoplasty.

Patient Characteristics	Abdominoplasty (14)	No-abdominoplasty (19)
Males (n)	3	11
Age (mean)	52.8	57.9
BMI (mean)	34.5	35.9
Diabetic (n)	5 (15.1%)	1 (3.0%)
Smoker (n)	4 (28.6%)	3 (9.1%)

### *Surgery and Post-Operative Outcome*

The average operating was 3.12 hours (SD 0.87), and patients were hospitalised for a mean of 6.79 days (SD 3.05). The early post operative complications are shown in table 2. The only major complications was an episode of acute pulmonary. This was treated with diuresis and the patient recovered. The instance of thrombo-embolic disease was a superficial vein thrombosis that was associated with only minor morbidity. Overall the complication rate was low and did not differ significantly between the groups.

Complication	Abdominoplasty (14)	No-abdominoplasty (19)
Wound infection	2	1
Haematoma	0	1
Seroma	1	1
Respiratory tract infection	0	0
Thrombo-embolic disease	0	1

### *Patient Response Rate*

#### *Post - Operative Pain*

#### *Quality of Life Assessment*

#### *Cosmetic result and satisfaction with surgery*

## Discussion

*Some notes for inclusion  
little shrinkage  
effective in preventing recurrence properties of the mesh and technique aid in that  
none of the patients needed component separation  
it was always used*

Repair of large incisional hernias is a complex procedure, often performed in overweight patient subgroups- and in our study sometimes with and without abdominoplasty. Effective treatment requires not only effective surgical technique, but careful consideration as to the mesh used. We found that the Tintera prosthesis provided excellent long term results in our cohort with minimal long term complications and recurrences. Similarly the technique which we employed allowed good cosmeses to be achieved without requiring component separation.

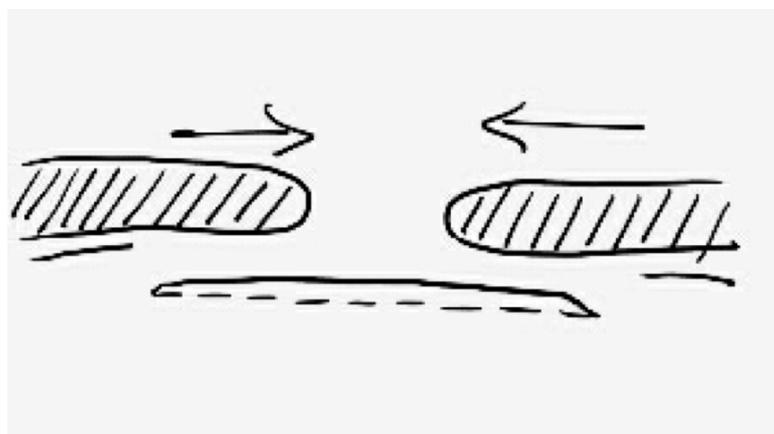
TinteraP is a bifacial composite hernia patch, with one side being composed of silicone and the other being polypropylene. The non-adherent silicone layer, permits contact with viscera with minimal adhesion formation and a reported reduction in bowel erosion.

### *Surgical Technique*

The operative technique is an open mesh repair using a bifacial mesh, one side being adherent (polypropylene) and the other side being non-adherent (silicone). The previous incision is reopened, and it is usually a longitudinal midline scar. The skin flaps are raised to the muscle wall. The margins of the hernial sac are then clearly defined. The sac is opened and all of the adhesions within the sac are divided, and also those adhesions that are attached to the anterior abdominal wall are cleared completely. The sac is then excised. The mesh is placed intraperitoneally and sutured with interrupted transmucular sutures (0 nylon), spaced approximately 5cm apart. During insertion of the mesh the edges of the rectus muscles are pulled to the midline. We then close the rectus sheath by using 1 nylon. This results in a taut intraperitoneal mesh which has virtually approximated the margins of the rectus muscles. The effect of this type of mesh placement does result in considerable tension of the abdominal wall, but in our opinion is necessary for normal function and appearance. None of our patients have required component separation to be added.

Redundant skin and subcutaneous fat is often then excised on both sides of the longitudinal incision. In about a third of cases the operation has been incorporated with an abdominoplasty, and in these cases the approach is via a long transverse suprapubic incision, where we raise the skin flaps up to the costal margins.

Computed tomography was used in the preoperative evaluation of the patients within the series, to determine the size and extent of the hernial defect.



**Figure 1: Mesh Placement**

Mesh is placed in the intraperitoneal space, below the rectus muscles after the hernia has been reduced

The mesh is secured with transmucular sutures, and the rectus muscles have been pulled taut during closure.

## *Components Separation*

Despite the advantages reported by using components separation, there are some associated risks with this technique that have been reported. These include ischaemia of the midline skin edges, wound dehiscence, infection and seroma. The use of mesh has allowed for a trend of minimally invasive components separation to occur, and to reinforce the fascia with mesh. Using the technique described in this paper and the Tintera mesh, we were able to repair several large hernial defects (sometimes with and without abdominoplasty) without the need for components separation.

Reasons for this may include

- Preferentially opting to repair the hernia under tension to aid in both structural integrity of the repair and cosmetic appearance.
- Minimal mesh shrinkage after repair (?source for this statement)

The validity of these statements are reinforced by not experiencing any episodes of reoccurrence in the medium to long term.

## *Assessment Tool*

## Conclusion

Large incisional hernia repair using intra-peritoneal placement of this mesh produce favourable medium and long term outcomes in terms of morbidity, quality of life, pain and activities of daily living and rate of recurrence. The technique described produces good results in large incisional hernias without the need components separation.

Our assessment tool provides a reliable analysis of outcomes for medium and long term follow up.

## Bibliography

1. Ramirez, O.M., E. Ruas, and A.L. Dellon, "Components separation" method for closure of abdominal-wall defects: an anatomic and clinical study. *Plast Reconstr Surg*, 1990. 86(3): p. 519-26.