

ABRA Surgical Skin Closure Clinical and Economic Highlights

Highlights

1. Fasciotomies were closed primarily in an average of 2.6 days using ABRA Surgical Skin Closure, several times faster than standard techniques and instead of covering with grafts.
2. ABRA Surgical Skin Closure eliminates the need for skin grafting and provides excellent cosmetic result. Adjustment at bedside minimizes the need for multiple operations.
3. Early results with ABRA Surgical Skin Closure demonstrated cosmetically acceptable, delayed primary closure of difficult fasciotomy wounds.
4. In a chart review at The Ottawa Hospital (TOH), **fasciotomy wounds were closed in an average of 5.6 days saving an average of \$8,062 per patient over other methods.**
5. From TOH review, the US analysis shows an **estimated cost savings of up to \$28,000 per patient (\$5,000 - \$28,000 for various age groups), when ABRA is used for fasciotomies.**

Many of the published articles and posters make reference to the challenges of primarily closing fasciotomies and the traditional approaches to managing them. Traditional methods include the use of skin grafts, NPWT and vessel loops & staples, which do not consistently achieve a primary closure.

ABRA Surgical Skin Closure is an advancement that achieves a low-tension primary closure of full thickness skin, eliminating skin grafts and their associated complications, and directly resulting in significant patient benefits and cost savings.

Singh, N., Bluman, E., Starnes, B., & Andersen, C. (2008). Dynamic Wound Closure for Decompressive Leg Fasciotomy Wounds. American Surgeon, 74 (3), 219.

- "One observation we have noted is that in these young trauma patients is the profound granulation tissue that occurs in the span of 48 hours. The wound VAC is excellent for preparing a patient for an STSG, but we have found that it "freezes" the edges and does not promote delayed primary closure (DPC) unless there is some sort of traction on the wound..."
- "We have found that our initial wound size, which was 8.1 cm, decreased to 2.7 after placement of this device and that this equal distribution of force brought the skin edges closer without causing the medial side to open further."
- "Our average closure days were 2.6 days, which was shorter than that described by Taylor."

Taylor, R.C., Reitsma, B.J., Sarazin, S., & Bell, M.G. (2003). Early Results Using a Dynamic Method for Delayed Primary Closure of Fasciotomy Wounds. American College of Surgeons, 197(5), 874-877.

- "The average time from fasciotomy to application of the dynamic wound closure method was 9.8 days"
- "The average number of days from application to wound approximation was 11.5 days (range 6 to 14 days) with a rate of closure of 1 cm per day."
- "All six fasciotomy incisions were successfully closed with no need for a split-thickness skin graft and no complications of wound infection or skin edge necrosis."
- "Delayed primary closure is preferred over split thickness skin grafting for fasciotomy wounds because it is cosmetically and functionally superior."
- "When a constant load is applied to an area of skin, that skin increases in length over time and subsequently the force required to keep it at this length decreases over time...this increase in length occurs within minutes and is explained by the predictable arrangement of collagen fibers in the skin. In the relaxed state, the collagen fibers are arranged in a randomly oriented pattern. As a load is applied to skin, the collagen fibers straighten longitudinally, aligning in the direction of the stretching force, until the fibers are parallel and resist further extension."

- “The term biological creep denotes a physiologic property of skin that results in the generation of new tissue secondary to a persistent chronic stretching force, such as that which occurs in the gravid abdomen during pregnancy or during conventional tissue expansion. Microscopically, there is a net gain of tissue that results from mitosis of fibroblasts, new collagen synthesis, and angiogenesis. It is speculated that tensile factors stimulate this biosynthetic and mitotic activity of fibroblasts.
- “The property of biological creep allows skin to expand to almost limitless proportions. The dynamic wound closure method described here and the vessel loop shoelace technique both take advantage not only of the biomechanical properties of inherent extensibility and mechanical creep, but also of the physiologic property of biological creep.”
- “In contrast to vessel loops, which are difficult to tighten, this dynamic closure method is simple to use and can be adjusted daily. Dressing changes, which can be cumbersome with vessel loops, are not hindered by this method. The wound can be cared for with the system in place and the apparatus is durable enough to allow full range of motion and weight bearing.”
- “One of our patients went home with the system in place and was followed by a homecare nurse.”
- “...vessel loop technique also exhibits point loading at the staple insertion sites because of excessive pull force, which can result in marginal ischemia on either side of the wound.”
- “Taken as a whole, the vessel loop technique applies the correct concept but with the wrong apparatus.”
- “The apparatus should ideally be applied at the time of fasciotomy and tightened as the swelling resolves. This will shorten the time between fasciotomy, wound closure, and discharge.”

References and Details

1. *Dynamic Wound Closure for Decompressive Leg Fasciotomy Wounds*. Singh N, Bluman E, Starnes B, Andersen C. *The American Surgeon*. 2008 Mar;74:217- 220.

This publication about ABRA Surgical Skin Closure is an 11 patient case series of young, healthy patients treated in Iraq at a US Combat Support Hospital for lower leg decompressive fasciotomy wounds. Ten of the 11 patients (91%) were closed in a delayed primary fashion after application of the device. Primary closure was achieved in an average of 2.6 days. The one patient not closed had bilateral above the knee amputations. “In addition to primary closure, we avoided the need for creating additional wounds in patients subject to multiple injuries.”

2. *Delayed Dynamic Abdominal Wall closure Using Abdominal Re-approximation Anchor (ABRA Device After An Initial Damage Control Laparotomy*. Win TS, Huget EL, Praseedom R, Jah A. Department of Surgery, Addenbrooke's Hospital, University of Cambridge, United Kingdom. Poster Presentation: 4th World Conference Abdominal Compartment Syndrome, Dublin, Ireland, June 25-27, 2009

This poster is an ABRA Surgical Skin Closure case summary of a delayed abdominal closure following an initial damage control laparotomy. “Delayed abdominal closure using dynamic continuous traction results in gradual approximation of the tissues. It eliminates the need of prosthetic mesh, skin grafting and provides excellent cosmetic result. Adjustment of tissue traction at bedside minimizes the need for multiple operations.”

3. *Early Results Using a Dynamic Method for Delayed Primary Closure of Fasciotomy Wounds*. Taylor RC, Reitsma BJ, Sarazin S, Bell MSG. *Journal of the American College of Surgeons*. 2003 Nov;197:872 – 878.

The first published study summarizing the early results of using dynamic wound closure was a five case (six incision) series at The Ottawa Hospital (TOH), Ontario, Canada. This study outlined how dynamic wound closure uses the biomechanical properties of human skin including biological and mechanical creep to close the skin. “...early results with the dynamic wound closure method have demonstrated cosmetically acceptable, delayed primary closure of difficult fasciotomy wounds in a timely matter.”

4. Canica Datasheet #1

The study referenced in #3 was followed by an economic study, also done at The Ottawa Hospital (TOH) where the hospital and homecare costs of primarily closing an extremity fasciotomy with ABRA Surgical Skin Closure were compared against closing with a skin graft or a secondary closure with skin graft. From TOH chart review, fasciotomy wounds were closed in an average of 5.6 days and ABRA Surgical Skin Closure saved an average of \$8,062 per patient over the standard treatment methods for fasciotomy closures.

2. *Fascial Closure Following Severe Abdominal Compartment Syndrome: A Case Report Regarding an Efficient Combination of Dynamic Abdominal Closure and Negative Pressure Wound Therapy.* Ferreira F, Barbosa E, Guerreiro E, Santos F, Soares G, Grade P, Fleming J. Department of Surgery, Hospital Pedro Hispano - ULS Matosinhos, Porto, Portugal. Poster: 4th World Conference Abdominal Compartment Syndrome, Dublin, Ireland, June 25-27, 2009.

There is increasing awareness of Abdominal Compartment Syndrome (ACS) and the need to manage it. In this published poster illustrating an experience using ABRA Abdominal Wall Closure in combination with EZCARE™ (trademark of Smith + Nephew), ABRA and negative pressure wound therapy was concluded to be an easy and reproducible option for primary fascial closure following severe Abdominal Compartment Syndrome (ACS). Of note are the morbidity and mortality rates (and their associated costs) associated with ACS, and the superior outcomes that are obtainable when ABRA is used.

3. *Case Discussion: Secondary ACS Due to Tight Abdominal Closure. Abdominal Compartment Syndrome (WSACS) Newsletter, December 2008, Volume 2, Issue 4, Pages 10 – 11*

A discussion on the published poster presented at the World Society of the Abdominal Compartment Syndrome (#2 above), is presented in the World Society of Abdominal Compartment Syndrome (WSACS) Newsletter and notes the ability to achieve primary fascial closure following a decompressive laparotomy using ABRA Abdominal Wall Closure.

4. *Management of Open Abdominal Wounds using a Dynamic Fascial Closure System.* Reimer MW, Yelle YD, Reitsma B, Doumit G, Allen MA, Bell MSG. *Canadian Journal of Surgery.* 2008 Jun;51(3):209-214.

This is an early study of 23 patients with open abdomens that could not be primarily closed, where an overall reduction in wound area of 95% was achieved using ABRA Abdominal Wall Closure. This study involved an early version of the ABRA Abdominal Wall Closure System and late management of open abdomens, where ABRA was placed an average of 18 days after the beginning of treatment for the open abdomen wound. In this early experience with ABRA, primary closure was achieved in 61% of these complex cases.

Today's results with ABRA are far superior to those shown in this study, due to updates in the ABRA system design, including the addition of a perforated silicone sheet to protect the bowel and to prevent granulation and adhesions, advances in procedural methods with ABRA, results of combined therapies (ABRA + NPWT) and the earlier placement of ABRA.

5. *Closure of Massive Abdominal Wall Defects - A Case Report Using the Abdominal Reapproximation Anchor (ABRA) System.* Urbaniak RM, Khuthaila DK, Khalil AJ, Hammond DC. *Annals of Plastic Surgery.* 2006 Nov;57:573-577.

A published case report using ABRA Abdominal Wall Closure System recommends ABRA as an effective instrument to accomplish closure of difficult wounds. This study describes the use of ABRA to restore lost abdominal domain and achieve a complete repair of the musculofascial support of the abdominal wall, achieving primary closure.

6. *ABRA Abdominal Wall Closure System with V.A.C.® Therapy Compared to V.A.C.® Alone in Management of Open Abdomen.* Hamilton D, Simpson M, Sonka B, Kearney P, Boulanger B, Bernard A, Chang P. University of Kentucky, Department of Surgery, Division of General Surgery, Lexington, KY. Poster Presentation: Abdominal Wall Reconstruction Conference, Washington, DC, June 17-19, 2010

Poster presentation of interim data for 11 of 30 patients enrolled in the study. "Early data clearly demonstrates decreased resource utilization of the study group in terms of operating room use. Additionally, the study group avoids the known risks associated with transportation of a critically ill patient such as loss of intravenous access, a need for additional ventilatory support, and cardiopulmonary arrest."

Copies of these and other supporting references are available from Southmedic on request.