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A randomized 'N-of-1' single blinded clinical trial of barbed dermal sutures vs. smooth sutures in elective plastic surgery shows differences in scar appearance two-years post-operatively

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Summary *Background:* Barbed sutures have unidirectional circumferential shallow barbs, which distribute tension throughout the wound and close wound securely without the need to tie knots.
Objectives: We compare two different methods of wound closure in elective plastic surgical cases: barbed 3/0 V-Loc™180 suture and smooth 3/0 Maxon™ sutures, both polyglyconate monofilament synthetic absorbable sutures. We assessed the aesthetic long-term results with a minimum two year follow up.
Methods: This is a prospective, randomized controlled study with internal control. A single surgeon performed all cases. Patients who underwent elective operations that involved long wound closure were enrolled in the study. Each patient acted as their own internal control with half their wound being sutured with 3/0 V-Loc™180 barbed suture and the other half with smooth 3/0 Maxon™ deep dermal sutures and then a subcuticular skin closure. In both groups, the superficial fascial system was closed with 1 Vicryl interrupted sutures on both sides. Long-term cosmesis was evaluated using the modified Hollander cosmesis score by review of standardized postoperative photographs by 9 blinded plastic surgeons and specialist registrars.

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Results: The study reports on 33 female patients. The time taken for wound closure was significantly reduced using the barbed suture ($p < 0.001$). There was no difference in the complication ratio in either group. Two-year aesthetic outcome was significantly superior when using the barbed suture ($p = 0.0075$).
Conclusion: Barbed sutures closure of long wounds is faster and produces a better long-term aesthetic outcome than smooth sutures.

Introduction

The need for rapid, effective and aesthetic wound closure in plastic surgery practice has only increased over the past 3 decades. Worldwide, obesity rates have nearly doubled since 1980 with corresponding increases in bariatric and body contouring surgeries.[1] Aesthetic closure of long excisional wounds is a major part of plastic surgery and is a significant contributor to prolonged operative times in many procedures. Unidirectional barbed sutures were developed in an effort to shorten operative times. They have been applied in post-bariatric and body contouring surgeries due to their proposed benefits of reduced operative time and suture burden, avoidance of surgical knots and reduced deep suture use.[2–7] Their unidirectional barbs may offer an additional benefit by limiting shear stress at the wound edges, thereby maximizing scar aesthetics through improved soft tissue mechano-transduction during wound healing.[8] The available literature, including a multicenter clinical trial[9] and a systematic review and meta-analysis,[10] have demonstrated a significant reduction in time to wound closure and total operative time with their use when compared with conventional smooth suture closure. Furthermore, the complication profiles for both approaches are comparable in most studies.[5,6,9,10] Only one study reported a higher rate of wound complications in the closure of knee arthroplasties.[4] While time to wound closure, total operative time and complication profiles are important, the long-term appearance of the scar is arguably one of the most important variables for the patient. Scars take upwards of two years to fully mature,[11] therefore although good, independent short-term studies have been performed,[9] there is a lack of independent, prospective, randomized, controlled trials that encapsulate all of these metrics, especially blinded assessment of long-term scar outcomes. We undertook an independent, randomized controlled (n-of-1) clinical trial with a minimum two year follow up to examine whether the reported intra-operative benefits of barbed sutures are matched with aesthetic long-term results when compared with smooth suture use.

Methods

Study design

This is a single center, prospective "n-of-1" randomized controlled study. Each patient received both the treatment and control sutures in the same operation, by a single surgeon. The study took place at the Peninsula Health Care Network in Victoria, Australia. A single surgeon, specialist in Plastic and Reconstructive Surgery, operated on all enrolled patients. Peninsula Health ethics committee approved this study and patients gave written informed consent. This study was registered on 09/28/2011 with the ANZCTR number ACTRN12611001030965. All authors have read and complied with the CONSORT guidelines.

Patients

Patients were recruited from March to October 2010 according to the eligibility criteria (Table 1) at their preoperative consultations in a single surgeon's private office. All patients were over 18 years of age and undergoing elective plastic surgery involving the closure of a long wound (Table 2).

Interventions

Randomization of the patients' right or left wound side was assigned by the surgeon by the toss of a coin, so that half of their wound was closed with 3/0 Maxon™ smooth sutures (Polyglyconate, Monofilament Synthetic Absorbable Sutures) and the other half with barbed sutures (3/0 V-Loc™180 Polyglyconate Monofilament Synthetic Absorbable Sutures, Covidien). In both sides of the wound, the superficial fascial system (SFS) was closed using interrupted 1 Vicryl sutures. The control side was closed using interrupted 3/0 Maxon™ deep dermal sutures and then Maxon™ 3/0 was used for skin closure (subcuticular method). This suture protocol was chosen for comparison with barbed suture because it is the most common technique used in our unit (18 out of 20 surgeons). The intervention side was closed using un-interrupted barbed 3/0 V-Loc™180 suture (subcuticular) after the closure of SFS, eliminating the deep dermal suture. Maxon™ and V-Loc™180 consisted of the same 180 day-absorbable material. Closure time was determined with a stop watch starting at the first needle puncture and ending at the cut of the thread.

Follow up schedule

Follow up was scheduled at one-week and 6 weeks post discharge from hospital. Patients who had developed a complication had more regular follow-up as required. The