Our Experience with Wisebands: A New Skin and Soft-Tissue Stretch Device

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Complex wounds that involve skin and soft-tissue defects that are unsuitable for primary closure by conventional suturing are common in the field of surgery. Among the many surgical options available to overcome these problems are various mechanical devices that have recently been proposed for delayed primary closure of such wounds. The authors present their experience with a new complex wound closure device, Wisebands, a device uniquely designed for skin and soft-tissue stretching. During the last 2 years, the authors have treated 20 patients with 22 skin and soft-tissue wounds for which primary closure was not feasible. The Wisebands devices were applied to the wounds, stretching the skin and underlying soft tissue, gradually closing the defects until the edges were sufficiently approximated for primary closure. Successful wound closure was achieved in 18 patients (90 percent). The Wisebands devices were removed in two patients (10 percent) because of major wound complications. In two other patients (10 percent), minor wound complications had occurred that did not necessitate removal of the device. At a mean follow-up of 1 year (range, 10 months to 2 years), stable scarring with no functional or significant aesthetic deficit was achieved. The authors conclude that the Wisebands device facilitates closure of complex skin and soft-tissue wounds, with low morbidity and complication rates, and can provide the surgeon with another important tool for closing complex wounds. Nevertheless, appropriate patient selection, intraoperative judgment, and close postoperative care are essential to ensure closure and avoid undue complications. (*Plast. Reconstr. Surg.* 113: 862, 2004.)

The skin has distinctive viscoelastic properties and therefore can be stretched by applying mechanical forces. It does so by its creep and stress-relaxation properties. Human skin under tension can be permanently stretched, provided the force applied is limited and does not cause blanching or breakage of the collagen fibers in the dermis.[1–3]

Surgeons of all specialties are often faced with skin and soft-tissue defects that cannot be closed primarily by conventional suturing. This problem is a common finding after trauma, tumor ablation, fasciotomy skin incisions, and dehisced surgical wounds. Over the years, numerous surgical techniques have been described in an attempt to address this problem, including secondary healing, split-thickness skin grafts, local flaps, tissue expansion, and revascularized flaps. Various mechanical devices have been proposed recently for delayed primary closure of these wounds.[1,4–15]

We present our experience with the Wisebands wound closure device, a new skin and soft-tissue stretching apparatus for closing complex wounds. This device permits delicate controlled stretching and approximation of the wound edges and of the underlying tissue (subcutaneous fat, fascia, and muscle). The Wisebands device consists of a tension feedback control mechanism, a flat plastic band, and a metal surgical needle (Fig. 1). The needle and its band are brought through the wound edges, down to the severed soft tissue under the skin defect (Fig. 2). A feedback tension control device holds the band. By rotating a knob on the unit, a controlled load is transferred to the wound edges. When the tension exceeds 1 kg/cm^2, the feedback control mechanism releases and stays in the last safe posi-

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tion. After completion of the approximation, the device is removed from the tissue.

The operating principle is based on harnessing the viscoelastic properties of the skin and the stretching abilities of the soft tissue which, under controlled mechanical load, can be stretched to a considerable degree within a short period of time. The controlled load applied to the suture band causes gradual traction and tension to the skin, so that a complete closure of large skin and soft-tissue deficits is achieved in a continual process of intermittent tension and relaxation.

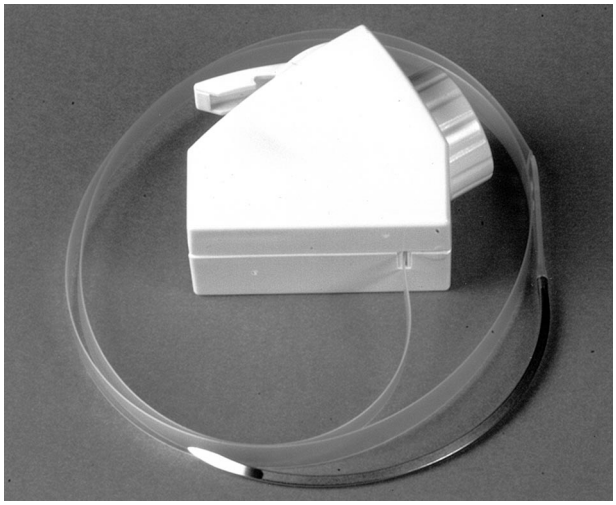

FIG. 1. The Wisebands wound closure device with the attached needle.

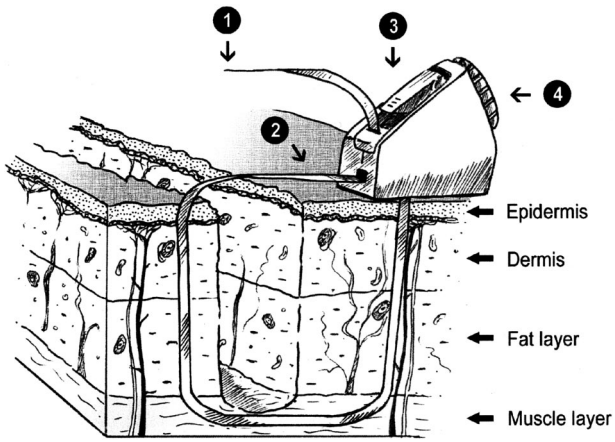

FIG. 2. Schematic drawing of the Wisebands wound closure device: *1*, A 5-mm-wide polypropylene band; *2*, the "in port" at the base of the device; *3*, safety catch; *4*, rotating knob. Rotating the knob (*4*) on the device applies controlled load to the band (*1*), causing gradual traction and tension on the tissue. The band exits from the device through an exit port on the top of the device.

PATIENTS AND METHODS

Between January of 2000 and January of 2002, we conducted a prospective, open-label, nonrandomized study that included 20 patients with 22 skin and soft-tissue deficit wounds. Primary closure was not appropriate, and other techniques were required for closing all these wounds. Informed consent was obtained from each patient to participate in this study, which was approved by the institutional review board in full accordance with the Declaration of Helsinki.

Inclusion criteria for participating in the study were an open, clean skin deficit wound in which primary closure was not deemed as being achievable; feasibility of closing the wound by skin grafting or flaps; and patient compliance to sign the informed consent form. Exclusion criteria consisted of the following: any medical illness or limitation that could impede the candidate from complying with the protocol or confound the data interpretation (e.g., likelihood of later treatment by radiation or chemotherapy); primary closure of the wound could be successfully carried out; and wound area exposure to irradiation. For all patients, information including age, sex, medical history, and the anatomic location and cause of the wound was recorded.

The original dimensions of the wound were measured using a plastic ruler, and the number of Wisebands devices used was documented. Data on the total time of treatment with the devices and the number of stretching cycles for each wound were also recorded.

All wounds were considered contaminated and a routine bacteria profile was performed. All patients received preoperative prophylactic intravenous antibiotic treatment during the application of the Wisebands devices. Routine cultures were taken from the wound at that time. When indicated, the wounds were debrided of all devitalized skin and soft tissue around the lesion before applying the Wisebands device. Antiseptic solutions were applied at this time, until the wound was cleaned and the edges allowed approximating. In cases where immediate postoperative stretching would be needed, the open wound was dressed with wet saline gauzes until complete closure of the wound was accomplished.

Technique

The Wisebands wound closure device is composed of a polypropylene band that is 5 mm wide, 0.3 mm thick, and 50 cm long. It is attached at one end to a stretching device and to a surgical needle at the other end (Fig. 1). The surgical needle is passed through the skin and underlying soft tissue (fat, fascia, and muscle) at the wound margins. Once it has emerged from the wound edges at the opposite side, the needle is cut off and the attached band is introduced into the device through a slit at its base (Fig. 2). The device is equipped with a safety catch—when it is in the upward position, the catch is "open" and allows free passage of the band; when it is in the downward position, it is "locked," holding the band in position.

Rotating the knob located on the device applies a controlled load to the band (Fig. 2). This causes gradual traction and tension on the tissue. The band exits through an exit port at the top of the device. The stretching force applied to wound margins is limited to 1 kg/cm^2 by a safety catch designed into the device. Should any attempt be made to exceed this stretching limit, the device shifts to neutral position and the tension gauge is disengaged.

The characteristic function of the device is a gradual and cyclical force application. It consists of skin stretching (mechanical creep) followed by stress relaxation. The process of tissue stretching consists of tightening the band, pausing until the tension has eliminated, and then retightening the band using the knob to apply an appropriate tension. Should any compromise sign in skin viability appear (e.g., skin pallor, tautness of skin, persistent local pain), the stretching cycle is terminated. Implementing a cyclical procedure ultimately allows the reduction of the tissue deficit until full approximation has been achieved. Similarly, wound complications are another cause for the cessation of the stretching cycle (e.g., local infection or neurovascular compromise).

After the skin edges have been completely approximated, they are either stapled or sutured and the Wisebands device is removed. The removal involves cutting the band at the skin level on the opposite side of the device, which is then pulled out together with the band. In some of the wounds, tension sutures are inserted, without tightening them at the time of surgery, and tied later after the device has approximated the wound edges.

Follow-Up and Outcome

A successful wound closure procedure was defined as a complete approximation of the wound margins that allowed the skin to undergo primary suturing or be stapled. A failed wound closure was defined as failure of the approximation of the wound edges, requiring an alternative technique for wound closure, such as secondary healing, skin graft, tissue expansion, or a flap.

The patients were examined at least twice daily until wound closure was achieved. All wounds were inspected for viability of the skin and soft tissue and for the development of any signs or symptoms of wound complication. Minor wound complications or adverse effects such as tolerable pain, skin irritation, skin blanching, hematoma, or neurapraxia were noted and treated accordingly. Major wound complications that dictated the removal of the Wisebands device included intractable pain, severe infection, large hematoma (i.e., >5 cm), and overt neurovascular compromise or tissue breakdown.

Once the wound edges were sutured, patient follow-up took place at 7, 14, and 21 days after wound closure and once per month subsequently for 6 months. The final follow-up was performed at 1 year after the operation. Serial standardized photographs of all the wounds were obtained.

Case Reports

Case 1

A 47-year-old man was admitted for excision of a basal cell carcinoma from his forehead. Under local anesthesia, a multiple frozen-section–guided excision was made, resulting in a skin defect measuring 4 × 7 cm (Fig. 3, *above*, *left*).

During the operation, one Wisebands device was applied, and intraoperative tightening of the band over a period of 1 hour reduced the size of the defect by half (Fig. 3, *right*). On the second day after surgery, tightening of the band continued at a rate of 0.5 cm every 5 hours. On the third postoperative day, the wound edges were approximated and sutured and the Wisebands device was removed. The patient was discharged on the same day and the sutures were removed 2 weeks later. He was followed-up for 1 year after surgery. At 1-year follow-up, the scar was soft, pliable, and with no eyebrow or eyelid pull (Fig. 3, *below*, *left*).

Case 2

A 48-year-old man had suffered multiple injuries in a road accident with a complicated open fracture of his right

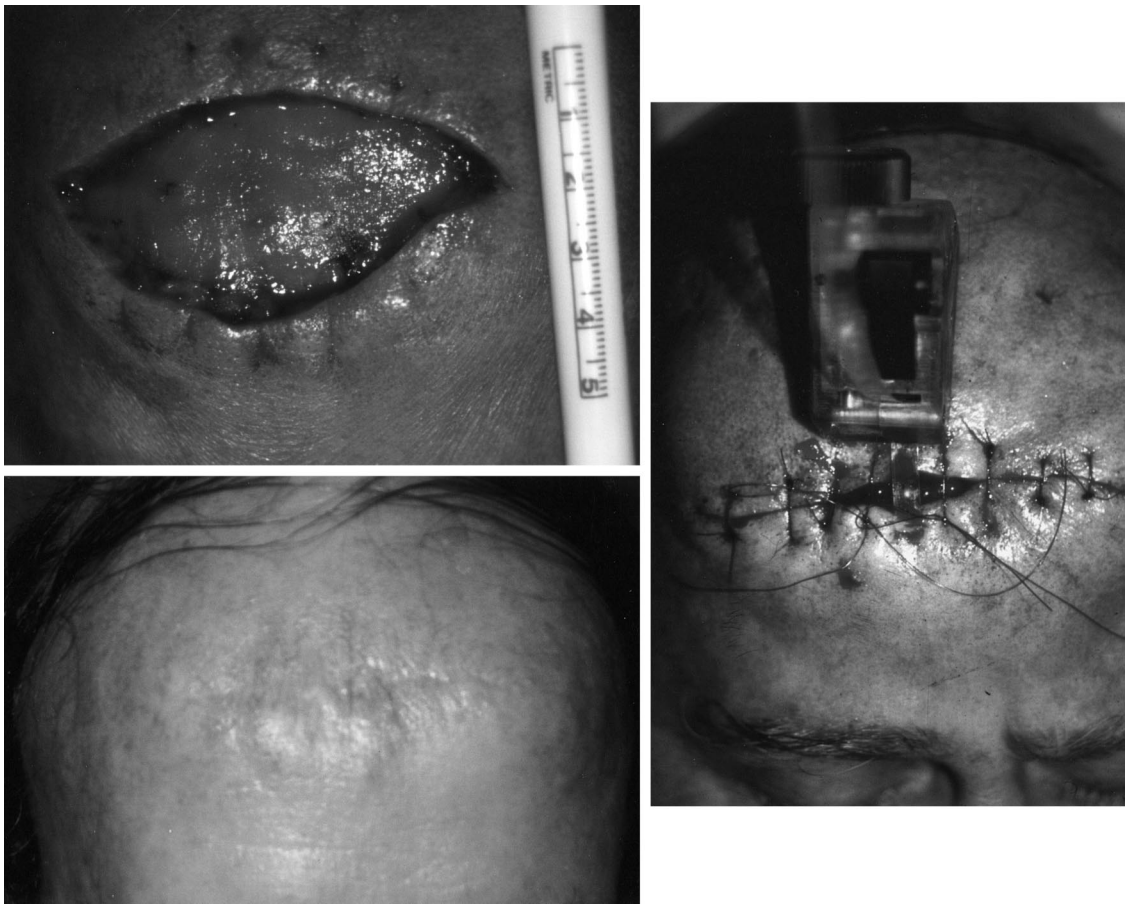

FIG. 3. The patient in case 1 after excision of the basal cell carcinoma from his forehead. (*Above*, *left*) Open wound at the forehead. (*Right*) Approximation of wound edges with one Wisebands device. (*Below*, *left*) Final scarring at 1-year follow-up.

distal humerus involving the brachial vessels. At admission, the patient was hemodynamically unstable and underwent operation urgently. A temporary arterial bypass and a forearm fasciotomy were performed to reperfuse the upper limb. The next day, he was returned to the operating room, and the brachial artery was repaired with a vein graft. The retracted fasciotomy incision had produced a 21 × 7-cm skin defect, with the neurovascular bundle and vein graft exposed at its base (Figs. 4 and 5, *above*). Tension sutures were inserted loosely and two Wisebands devices were applied, and intraoperative tightening of the bands over a period of 1 hour reduced the width of the defect by three quarters (Fig. 5, *center*). The defect was closed during the following 2 days at a rate of 1 cm/day, with 8-hour intervals between the procedures. Once the wound edges were approximated, the tension sutures were tightened and skin staples were applied under local anesthesia at the bedside. Three weeks later, all sutures were removed (Fig. 5, *below*). At 1-year follow-up, the arm had good functional outcome, with acceptable scarring.

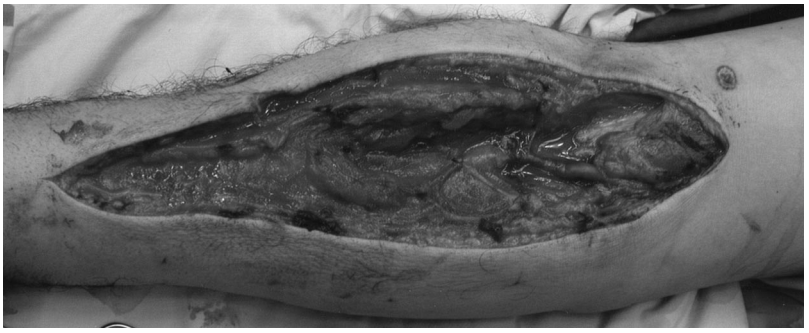

FIG. 4. The patient in case 2 with an open fracture of the humerus and forearm compartment syndrome, revealing injured brachial vessels. Forearm after fasciotomy and vein graft of brachial artery.

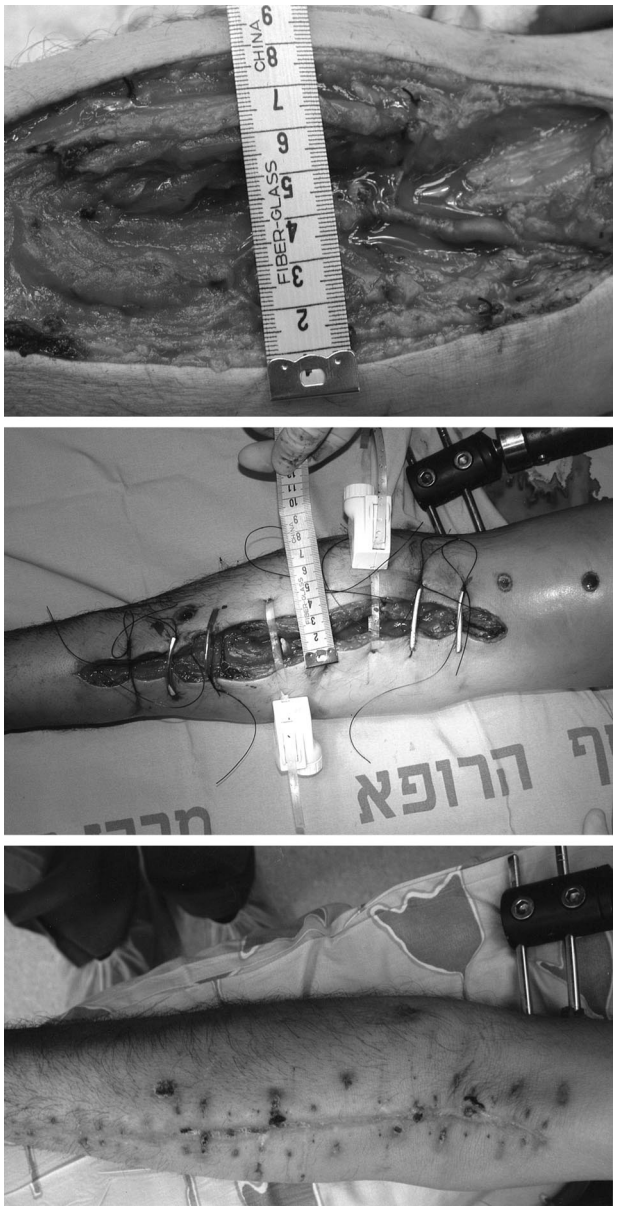

FIG. 5. (*Above*) Close-up view of the wound and vein graft. (*Center*) Insertion of two Wisebands devices and tension sutures. (*Below*) Scar after 3-week follow-up.

Case 3

A 40-year-old woman who had undergone wide excision of a malignant melanoma lesion on her right posterior calf was left with a skin and soft-tissue defect reaching the fascia and measuring 8 × 4 cm, which could not be treated by primary closure (Fig. 6, *left*). The proximal and distal ends of the wound were closed with tension sutures, and one Wisebands device was applied at the center of the wound (Fig. 6, *right*). The device was tightened two times per day for 2 days until the approximation of the wound edges and primary closure of the wound could be achieved. The sutures were removed 3 weeks later (Fig. 7, *left*). Follow-up revealed a soft and pliable scar, with no functional loss or conspicuous scarring (Fig. 7, *right*).

RESULTS

Twenty patients [14 men and 6 women, with an average age of 37 years (range, 18 to 61 years)] with a total of 22 open wounds were treated with the Wisebands device. The calf (59 percent) and forearm (18 percent) were the most common locations for the wounds treated in this series (Table I). Trauma and surgery were the most common causes, constituting 35 percent of the patients for each, followed by tumors (25 percent) and burns (5 percent). The size of the skin deficit (length × width) ranged from 31 × 20 cm to 6 × 4 cm (mean, 12.5 × 5.5 cm). The number of Wisebands devices that were applied ranged from one to four, with an average of two Wisebands devices per skin deficit (Table I). In 16 patients (80 percent), the wound included a combination of skin and soft-tissue deficits (fat, fascia, and muscle); in four patients, the wound had only a skin deficit.

Treatment time (i.e., the time from application of the Wisebands device until its removal) ranged from 1 hour to 7 days (mean, 61 hours). Wounds were approximated within 24 hours after surgery in seven cases (Table I).

Successful wound closure, defined as complete approximation of the skin edges, was achieved in 18 patients (90 percent). The Wisebands devices were removed in two patients (10 percent) because of major wound complications. In the first case, the wound became infected while closing, showing marked erythema, purulent discharge, and peripheral systemic temperature of 38°C. The skin-stretching devices were removed and the patient was treated with intravenous antibiotics and frequent local dressing changes soaked with antibacterial solutions. After the wound infection had subsided, the wound was covered by a split-thickness skin graft. In the second case (forearm), the patient complained of intense pain while the devices were being tightened. After the second stretching cycle, the devices had to be removed because of the provoked intractable pain. The wound was later covered by a split-thickness skin graft. In both cases, these major wound complications were reversible, with no permanent damage once the devices were removed. No other major wound complications, such as skin necrosis, large hematoma, neurovascular compromise, or tissue breakdown, were observed among the patients.

Minor wound complications or adverse ef-

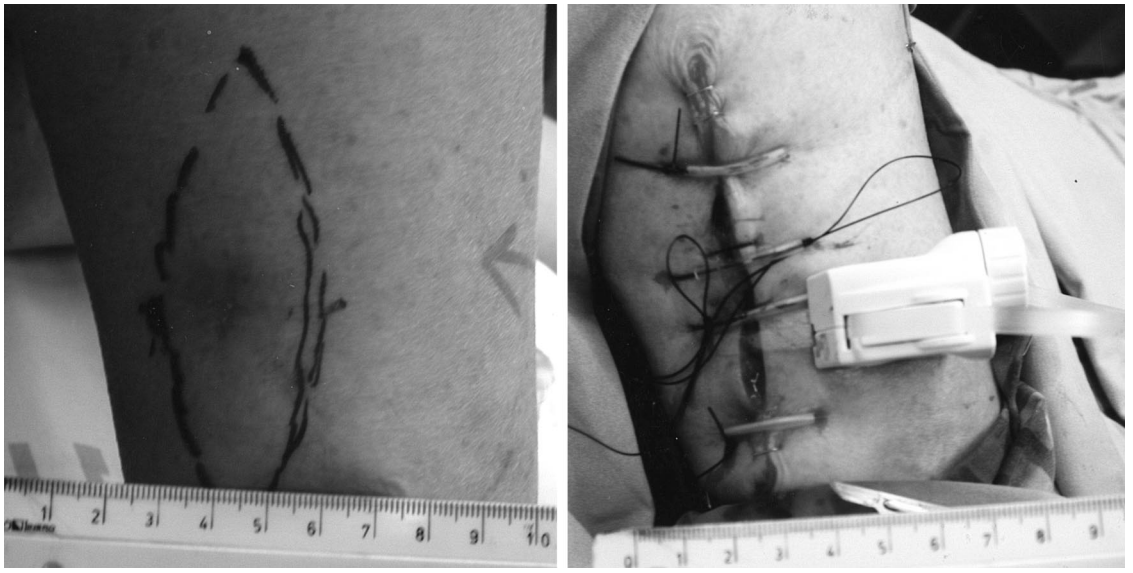

FIG. 6. The patient in case 3 with malignant melanoma of the posterior calf. (*Left*) Marking of the planned wide excision. (*Right*) Approximation of wound edges with one Wisebands device and tension sutures.

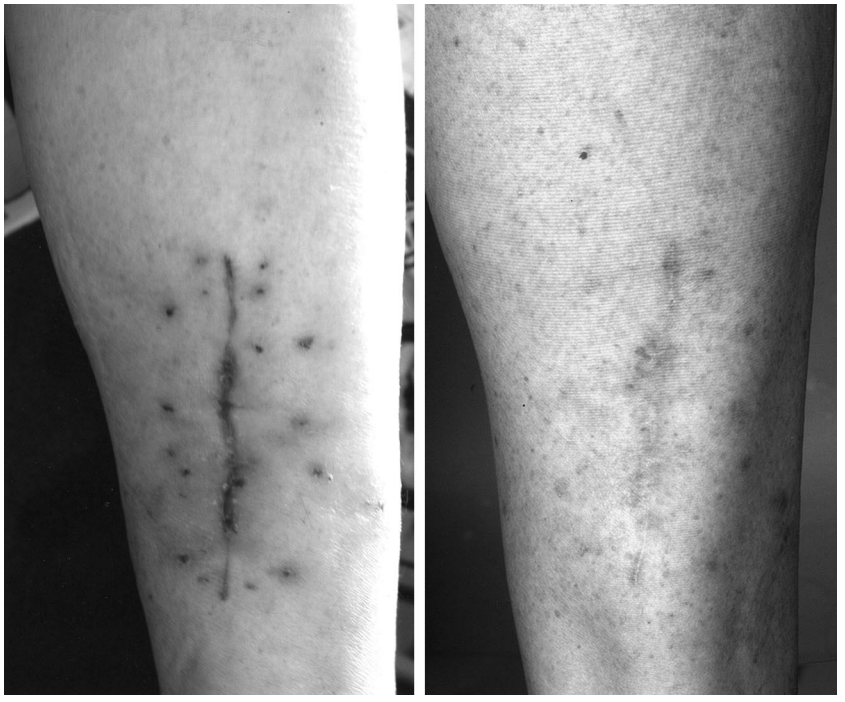

FIG. 7. (*Left*) Scar after suture removal. (*Right*) Final scarring at 1-year follow-up.

fects were noted in two patients (10 percent): one had local pain and skin irritation, and one with a wound on his shin had temporary regional neurapraxia. None of these minor wound complications interfered with completion of wound closure and did not necessitate removal of the Wisebands device.

Final scarring of the wounds after 1 year of follow-up was found to be acceptable, with only three patients (15 percent) having wide (>2 mm) or hypertrophic scars. There was no need for scar revision for cosmetic reasons in any of the patients.

DISCUSSION

Closure of wounds with skin and soft-tissue deficits poses a challenge to surgeons of all specialties. Various methods are suitable for wound closure, among them presuturing, surgical skin undermining, skin stretching de-

TABLE I
Summary of Surgical Data on 20 Patients Treated with the Wisebands Device

Body Area	Wounds (%)	Wisebands Devices	Intraoperative Stretching	Postoperative Stretching	Treatment Time	Major Complications
Forehead	1 (4.5)	1		1	3 days	
Forearm	4 (18)	1–3		4	1–6 days	Intractable pain
Abdomen	1 (4.5)	3	1		75 min	
Back	1 (4.5)	2		1	7 days	
Thigh	2 (9)	2	1	1	80 min–2 days	
Lower leg	13 (59)	1–4	4	9	100 min–7 days	Wound infection
Total	22	44	6	16	Mean, 2.54 days	

vices, skin grafts, skin flaps, free flaps, and tissue expansion.[4–15]

Choosing the most appropriate method for wound closure in each case depends on many factors, primarily wound width and depth, exposed vital structures, thickness of the skin, location of the wound, and the presence of infection. Other considerations include expected healing time and hospital stay, complexity of the procedure, convenience, the patient's will, and treatment costs.

Mechanically assisted delayed primary closure was recently introduced as an approach for surgical wound closure,[1] followed by many reports on numerous techniques and a variety of devices.[4–15] Unlike skin grafts or flaps, mechanically assisted delayed primary closure stretches local tissue, thereby providing the ideal color and skin texture match. Another advantage of this method over tissue expanders is that it spares the need for a second operation and general anesthesia.

This method was developed as a consequence of enhanced understanding of the mechanical creep properties of skin, which enable it and the underlying tissues to be stretched considerably beyond its intrinsic extensibility and within a relatively short period of time. Moreover, when tension is applied in cycles, with relaxation periods between loads, one can achieve far greater elongation beyond intrinsic extensibility capabilities.[1–3]

The amount of stretching force that can be safely exerted depends on various factors, including the patient's age, sex, and general health status; the anatomical location of the wound and skin; and the subcutaneous thickness at the site. When both skin and subcutaneous tissue are normal, rapid stretching within a short time span (20 to 30 minutes) is the general rule.[1] However, when chronic edema and fibrosis have replaced the normal ground substance, stretching will need to be carried out at a much slower rate and with longer intervals between stretching cycles. Therefore, appropriate patient selection, intraoperative judgment, and postoperative care are critical for achieving success with this approach. As a generalized rule, wounds in the extremities and forehead area can be closed at a rate of 1 cm/day, whereas wounds in the torso area can be closed at a faster rate.

All previous stretch and expansion methods and devices have focused on skin closure as a goal and thereby have managed to produce a two-dimensional action only. An open wound should be regarded as a three-dimensional structure and, occasionally, except for skin, deeper soft-tissue elements such as fat, fascia, or muscle are involved. These soft tissues are part of the wound and need to be approximated to minimize the "dead space" under the skin. Because these structures also have stretch properties,[16–19] the Wisebands device was originally designed to relate to those (Fig. 2).

In our study, we found that the Wisebands device offered some advantages over other methods and devices for wound closure. Surgical preparation for wound closure included minimal wound dissection, with no skin undermining, allowing maximal preservation of the neurovascular supply to the skin. This in effect shortened the operating time and in many cases the hospital stay, consequently reducing treatment costs.[1,2] Moreover, the device is compact and lightweight, making it convenient for use on an outpatient basis.

Another advantage found was the versatility and flexibility of the device in accommodating different wound sizes and shapes in different anatomical body areas. Its application was technically simple and demanded a short learning curve when introduced to other surgeons.

Skin stretching with the Wisebands device was found to be safe and reliable. The device is designed with a safety catch, which limits the

stretching force to 1 kg/cm^2. This limit is lower than the maximal safe tension documented in the literature for skin stretching (reaching up to 3 kg/cm^2)[1,2] because of the different stretching properties of the soft tissue compared with skin.[16–19] No wound necrosis or breakdown occurred in this series; however, if wound infection is suspected, the safety catch mechanism allows loosening of the band, with better exposure for local treatment of the wound. In cases where the band has to be removed, as in the two cases of major wound complication in our series, full resolution with no permanent damage is expected.

Patient compliance with the device was good despite some degree of pain and discomfort during the process. In only one case (5 percent) did we have to remove the Wisebands device because of intractable pain. Pain reported by two other patients during the stretching process was relieved with oral analgesics, and we were able to resume stretching to successful wound closure.

CONCLUSIONS

In this article, we introduce our experience using the Wisebands wound closure device, which facilitated the closure of complex wounds with skin and soft-tissue deficits of different sizes and causes and at various anatomical locations. The Wisebands device was technically simple to apply and permitted controlled approximation of the wound edges. The final scarring was found to be cosmetically acceptable, and no functional deficit or adverse sequelae were noted at the end of the process. We believe that this device can provide the surgeon with another important tool for closing complex wounds. Nevertheless, appropriate patient selection, intraoperative judgment, and close postoperative care are essential to ensure closure and avoid undue complications.

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