THE USE OF PAPER TAPE APPLICATION IN SKIN TISSUE EXPANSION AND ABNORMAL SCAR MODULATION

By

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As the candidate’s supervisor I have/have not approved this thesis for submission.

Signed: _____ Name: _____ Date: ____

Prologue

I am a tailor by heritage, an engineer at heart and a plastic and reconstructive surgeon by trade.

My forefathers arrived in South Africa as traders in early 1900's. Back in India, the father to son passage of the tailoring trade spanned centuries. My grandfathers on both paternal and maternal sides set up tailoring shops on landing in SA. As expected their sons were shown the art of tailoring and entrained into the business at the time. This was not peculiar to the male counterparts only. My mother and some of her sisters also took to the trade of tailoring in traditional ladies garments. This art was passed on to them by their mothers.

The facets of the trade included knowledge of the fabric, designing of the garments, cutting the fabric to design. A multistaged production of the garment with trial body fitting, specifically for intricate work was not uncommon. This eventually culminated in the sewing of the garment by machine and by hand. Perfection was the goal in the hope of appeasing the patron and cultivating personal pride.

In their newly adopted country of South Africa, families maintained developing and propagating their society of tailors. The association was further strengthened by the parents arranging marriages of their sons and daughters from unrelated or distantly related families. This was generally from another town. Here in lies my beginning as my father and mother were matched. The rest is history.

I grew up in this society. My exposure to tailoring was constant. At home where my mother worked churning out her products and at the workshop were my uncles and father continued their tailoring trade. It was customary for all the boys in the families to go to their family shop to work after school on a Friday and on weekends. I started at the age of eight.

As factory made garments made their way onto the shelves and counters of the tailoring shops, and customised tailoring was beginning to slow down, the need for performing neat alterations was increasing. I learnt in my teens to perform some of these alterations using both machine and hands. I continued to work on weekends and in holidays in this way until I finished medical school.

Medical school was never my idea. I had my heart set on mechanical engineering in the latter years of my high schooling. I liked fixing things and took on every opportunity at home indulging in painting, carpentry, electrical repairs etc. My fascination with cars also started at an early age and my elder 1st cousin brother allowed me to drive his car from an age of 13. The mechanical side of the car was a constant wonder in my mind. I would have been become a mechanic if it had not been for my good grades in school. Mechanical engineering was the dream and fast sports cars the product. The independent variable that I was not able to manipulate was the man in-charge, my father of course.

I applied in my matriculation year for registration in medicine and mechanical engineering. Hopeful that I would not get accepted to medical school at the University of KwaZulu-Natal (UKZN). But I was.

My two most valued outcomes of my medical studies are my qualification and my wife. We were class mates. Whilst she was serving the community in her own practice she provided me with support in every respect. She was and remains the pillar of strength and to her I owe my success. She took on most family responsibilities whilst remaining dedicated to her practice.

A day before the commencement of a rotation in cardiothoracic surgery, my first choice of an elective rotations associated with my specialising in surgery, I was contacted by Prof Bhugwan Singh (general surgeon in charge of the rotation), to go to Plastic and Reconstructive Surgery for one week because the assigned registrar

had taken ill. I complained but accepted the interim measure. I did not have the foggiest idea what plastic and reconstructive surgery was about. A few days at work and it felt like I was a duck taking to water. I was fascinated by the hands on nature of the discipline. I negotiated to stay on for the full three months and decided that this was going to be my career. I felt at home with this trade.

Skin was the material. Design, cut and sew was the execution. The results were there to be seen. Little alterations immediately or later could easily be done to achieve perfection and make patrons happy. It was tailoring after all.

My career continued to evolve. The unique aspect of plastic and reconstructive surgery was that one can express ones personality in ones work. Books and colleagues are a guide. An artist with an empty canvass, paint brush in the hand and all the colours to express your passion to the benefit of the patient was the game.

It was not uncommon for my clinics to be frequented by patients with scar related functional problems, hypertrophic scars and keloids. In the management of abnormal scars, as a plastic and reconstructive surgeon I felt powerless. High failure rates in control, symptomatic relief and treatment was a commonplace. I found it almost impossible to provide any good assistance to patients with large keloids and/or multiple keloids in our resource constrained setting. Cosmesis other than facial keloids were not an important factor for these patients. The pain and itch was intolerable to many. There was no magic potion for this especially if the intralesional injection of steroids was not an option. Silicone sheeting was expensive and not available. Pressure garments and lanolin cream was the default treatment.

Scar revisional surgery was more rewarding to deal with. Simple ones being managed by options of simple excision, serial excision, skin grafts, little flaps and Z plasties. Replacing like with like tissue, made local tissue the first choice. The

concept of using tissue expanders for skin creation was a brilliant one using nature's biological and physiological processes in fast forward.

One of my earlier experiences in my residency with tissue expansion in 1997 was a patient that was struck by lightning in an open field. He arrived for treatment in our clinic as a delayed presentation with exposed necrotic bone on the vertex of the skull. The debridement included the full thickness removal of the bone to an already granulating dura. A skin graft to this was performed at the second operation. My final plan was to reconstruct the traumatic alopecia of the scalp by tissue expansion. Six months later I placed a tissue expander under the normal scalp adjacent to the defect. The expansion resulted in extrusion at one of the corners. I continued to expand rapidly on a daily basis for maximum tissue gain before surgery. I was forced to remove the expander without any preplanning. With carefully considered design I was able to remove the perforated portion of the skin at the site of extrusion, transpose a flap and recreate the defect and get tension free closure. This case became a turning point for me.

My use of tissue expansion as reconstructive technique rapidly increased, with attention to detail in preplanning, and to effective and efficient expanded flap use in the reconstruction. I was however discouraged from using tissue expansion in limbs because of their failure rate.

The largest drawback of tissue expansion devices were that of its invasive nature, non-uniform distribution of the tension and pain. The most important contribution was its use in open existing wounds. This was not the domain of the traditional tissue expander. The common characteristic of these devices was tension application to generate skin. This was the birth place for my first attempt in 2003 for tape dermatogenesis in a lower limb pretibial scar.

Changes seen in scars of patients during the tape dermatogenesis gave support to my idea that the taping technique would improve abnormal scars.

At the inception of my new work using tape to create skin, the concept of PhD thesis did not come to my mind. My first original paper titled “Traction-Assisted Dermatogenesis by Serial Intermittent Skin Tape Application” was submitted to the Plastic and Reconstruction Surgery in Dec 2007. It was the encouragement and the positive comments from the reviewer for the journal, Prof Dennis Orgill that prompted my correspondence to the Chairman of the postgraduate committee to have the paper reviewed for a PhD.

Eventually with the support Prof Bhugwan Singh, the PhD looked like it would materialise. Prof Singh was the very one that was responsible for my unplanned exposure to Plastic and Reconstructive Surgery as a resident in 1993.

Prof Dennis Orgill on my approach, immediately agreed to be my co-supervisor. With Prof Colleen Aldous as my supervisor by my side, I started writing my thesis in April of 2016 and within the next few days of writing this prologue, it will be complete.

It was a journey, and my heartfelt gratitude need to be extended to Colleen and Dennis for their support.

It is hoped that you the examiner will enjoy reading the thesis. I will like to thank you in advance for taking time off from your busy schedules and families to do this.

11th January 2016

Dedication

I dedicate this PhD and my career as a plastic and reconstruction surgeon

to my beautiful wife Dr Kavitha Bisnath. Without her understanding and support this work may not have been achievable.

A great big thank you

to my parents for their guidance in my childhood, for being given no choice other than a career in medicine and for the tailoring heritage.

Declaration

I...Mahendra Daya.....declare that

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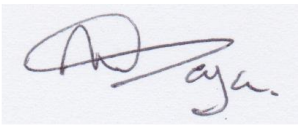
Signed:  Date: 16/01/2017

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Abstract

Background

The basic application of constant tension within limits of tolerance on the skin will cause the lengthening in the skin in the direction of the force over time. This is the fundamental basis for achieving skin tissue expansion. On the other hand, the treatment and prevention of abnormal scars are dependent on, amongst many other factors, on tension reduction, occlusion and compression. The technique of application of paper tape was devised in our setting to manipulate tension in these applications.

The technique was tested in a clinical setting. The objective below formalizes the approach for both the published and still to be published component of this PhD by manuscript. The study is required because the literature is deficient in covering the use of paper tape in reconstructive surgery and abnormal scar management.

Tissue expansion for the purposes of beautifying the body, has been part of human culture for centuries. Simple devices and garments have been or are used for lengthening necks, elongating penises, narrowing waistlines and expanding pierced ear lobes and lips etc. Medical use of tissue expansion is achieved by surgically implanting tissue expanders or attaching external tissue stretching devices. The major drawback of internal devices is the risk of complications, failure in reaching reconstructive goals, pain and temporary disfigurement, the need for multiple surgeries, cost of devices and procedures and that surgical expertise and supervision is essential. In the local community that our institution serves it is not uncommon for patients to seek medical attention for keloids and various conditions requiring reconstruction for which tissue expansion may be considered as primary management choice. In developing countries like South Africa the economic burden of scar management is not seen as priority in the public health service. Costs

associated with conventional tissue expansion techniques are also high, especially if the procedure fails. The anatomic region of the lower leg, which in particular has high failure rate for tissue expansion, provided the impetus for devising this technique and was applied in two cases of lower leg scar resurfacing. It is the success here that created foundation for further research into its application in other plastic and reconstructive surgery cases.

The paper tape is used as a device to hold dressings on to skin in wound care management. Prophylaxis in hypertrophic scarring following skin incisions and closure is described. No studies have been reported on the use of paper tape application to the scars, skin lesions and surrounding skin to produce skin tissue expansion or abnormal scar modulation.

In the context of finding a cost effective solution serving the local health needs of the patient population we serve, and against the background of the lack of literature on the topic, it will be beneficial to answer the research question “Is the use of paper tape in skin tissue expansion and abnormal scar modulation effective?”

We therefore set out to explore the therapeutic effects and reconstructive value of paper tape application. These case reports, case series and cohort studies would result in introducing a novel technique of skin tissue expansion and abnormal scar modulation. This would supplement existing techniques in the literature with a major advantage of low cost and potentially wide ranging clinical applicability. It should also be noted that because of the heterogeneous nature of the patient population a control component was not be feasible. Despite this limitation the discipline of plastic surgery will benefit from the work. The study was undertaken with the following aims and objectives.

Aim

To explore the use of paper tape application in skin tissue expansion and abnormal scar modulation, provide a theoretical framework and practical guidelines for its use.

Objectives

1. To identify a suitable tape and application method for skin tissue expansion and abnormal scar modulation.
2. To explore in scar management the therapeutic effect of the paper tape application in skin tissue expansion.
3. To explore in scar management the therapeutic effect of the paper tape application in abnormal scar modulation.
4. To describe the use of paper tape application in other reconstructive clinical settings.
5. To determine the effect on the symptoms of pain and itch associated with abnormal scars.
6. To determine the effect on size of the abnormal scar.
7. To determine the effect on scar quality of the abnormal scar.
8. To determine by independent expert review the change in abnormal scar.
9. To provide, based on a literature review, a theoretical framework in the use of paper tape in skin tissue expansion and scar modulation.
10. To develop practical guidelines for the use of paper tape.

Methods

The above objectives were fulfilled in the following manner by preparing manuscripts for publication, summarizing methodology of the studies performed.

Objectives 1 and 2 (published article; featured in a manuscript format in Chapter 3)

Daya, M. and V. Nair, *Traction-assisted dermatogenesis by serial intermittent skin tape application.* Plastic and Reconstructive Surgery, 2008. **122**(4): p. 1047-1054
A clinical case study of achieving skin tissue expansion with the use of paper tape in lower legs, was followed by a cohort study recruiting consecutive patients presenting to our clinic for scar resurfacing in any area of the body in whom our choice of reconstruction to be offered was tissue expansion. Instead of the conventional offer of internal tissue expansion, the patients were consented for tissue expansion by a novel technique of paper tape application to the skin and scar. Experiences in the study served to refine the taping technique which is described and successful outcome was measured by completion of scar resurfacing by surgery.

Objectives 3, 6, 7, 8 and 9 (published article; featured in a manuscript format in Chapter 11)

Daya, M., *Abnormal scar modulation with the use of micropore tape.* European Journal of Plastic Surgery, 2011. **34**(1): p. 45-51.
Consecutive patients presenting to the general plastic clinic with hypertrophic scars or keloids that were deemed to be suitable for scar modulation by taping were offered paper tape application technique. The purpose of the study was to measure the effect of tension elimination and pressure application by taping the abnormal scar. This required the covering of the entire scar instead of dividing it into two for the purpose of having a control arm. The subjects were a heterogeneous group with abnormal scars in various anatomical sites and varying scar age. Several objective and subjective parameters of scarring were measured and scored to determine outcomes.

Objective 4 (manuscripts in Chapters 5-10 to be submitted for consideration to journal editors)

A retrospective chart review was performed with a view to determining and reviewing the clinical conditions for which paper tape application was utilized as therapeutic or reconstructive modalities for skin tissue expansion. This took the form of case reports, case series and cohort studies. The purpose was to report on the clinical experience, patient and reconstructive outcome, and refinements in terms of technique, taping intervals and duration to reach these goals.

Objective 9

A review of the literature on the mechanical forces which were the conceptual basis for the studies in objective 1 to 8 was performed to provide a theoretical framework for the observed changes. An appropriate database search was conducted on each of these.

Objective 10

Practical guidance is offered based on the learning curve and clinical experience associated with the conducted studies over a 10 year period of use of paper tape application for skin tissue expansion and scar modulation. Specific value and attention was assigned to technique, clinical applications and procedural protocols. Photographic pre-test and post-test records are demonstrated.

Results

Objective1 and 2

3M™ Micropore™ Surgical Tape was used as a tape and 3M™Cavilon™ Durable Barrier Cream was used as a skin barrier cream. Serial applications of the tape to the skin produced traction assisted tissue expansion (TATE) (previously referred to as traction assisted dermatogenesis) for scar resurfacing. Of the 26 patients entered into the study, 14 (53%) patients completed the surgical management and

four patients were in the midst of treatment. Four patients defaulted on treatment, and in four patients the expansion failed to progress.

Objectives 3,5,6,7 and 8

3M™ Micropore™ Surgical Tape was used as a tape and 3M™Cavilon™ Durable Barrier Cream was used as a skin barrier cream. Twenty-nine patients with a total of 42 abnormal scars were included in the trial. Serial applications of the tape to the skin and scar produced tension reduction, pressure and occlusion of the scar. [This type of taping is now referred to as tension reduction taping (TRT)] Twenty-nine (69%) scars demonstrated reduction in scar thickness. On a number analogue scale measured in 32 patients, 28 (88%) scars and 27 (84%) scars showed a score reduction in response to taping for pain and itch respectively. Scar quality improvement was seen in 28 scars (n=40). Photographic scoring demonstrated a high rate of decrease in scar redness, flattening and a decrease in the surface shine.

Objective 4

Single case studies of patients presenting with a giant congenital melanocytic nevus, recurrent myelomenigocoele and fasciotomy wound of the forearm were managed successfully with TATE to achieve surgical wound closure. A series of four consecutive lower limb amputations at critical length were managed by TATE to achieve surgical wound closure. A cohort study of 11 patients with 14 skin and soft tissue lesions were managed successfully by pretaping (a shortened period of application of TATE) to affect closure of large elliptical excisions of tumour bearing skin. A case study of larger groin and thigh wound resulting from failed flap surgery for a sarcoma healed without surgery by traction assisted closure (TAC) producing accelerated wound closure with minimal residual scarring or contracture formation.

Objective 9

Traction causing stretch of the skin by TATE produces a mechanobiological cellular and humeral response by the living substrate that promotes dermatogenesis/tissue

expansion. Scar modulation is produced by the biological response of the abnormal scar to TRT. Similar value is derived from the use of taping in scar management as prophylaxis against abnormal scar production following aesthetic surgery.

Objective 10

Practical guidelines are offered to the reader on the clinical use of 3M™ Micropore™ Surgical Tape in various clinical settings to achieve tissue expansion of skin, accelerated and effective wound closure, prophylactic scar management in aesthetic surgery and abnormal scar modulation. A physiological and biological basis is also provided to support the use of the devised technique of taping.

Conclusion

In a clinical setting paper tape can be used to achieve tissue expansion of skin, closure of wounds, prophylactic and therapeutic scar modulation. Our concept of use of 3M™ Micropore™ Surgical Tape (in an application for which it is not designed), opens new avenues for further research and development in this area of plastic and reconstructive surgery. Its use is however, not confined to the discipline of plastic surgery because of its simplicity in clinical application. The practical guidelines on the use of 3M™ Micropore™ Surgical Tape will provide other surgical specialists and general practitioners with medical education to consider this option in appropriate clinical settings.

Key words

Mechanobiology, tissue expansion, external tissue expansion, cutaneous wound healing, cutaneous scarring, hypertrophic scars, keloids, traction assisted tissue expansion, tension reduction taping, traction assisted closure, mechanotherapy, microdeformational wound therapy

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Chapter 1: Introduction

The human body is composed of multiple organ systems. The fundamental building blocks of these systems are the different types of cells in an extracellular matrix (ECM) that make up the various tissue types. The cells themselves are a constellation of biochemical, molecular and electrical reaction chambers. The cells with their cytoskeletal structures are interlinked to each other in the ECM.(1) The human body and the cells that makes it up are exposed to a multitude of mechanical forces in daily life. This includes tension, compression, pressure, shear, gravity, osmotic pressure and hydrostatic pressure etc. Even the influence of microgravity on cellular biology is recognized as important in this era of space travel.(2-4)

Mechanobiology is the study of the influence of mechanical forces on molecular, cellular and tissue levels. Cells responds to the mechanical forces applied to tissues by a process which is referred to as mechanotransduction.(5) The extracellular matrix is an integral part of the tissue which transmits the applied forces to the cells.(6) The mechanosignaling pathways in the cells trigger various biological reactions in response to the cellular deformation.(7-9) At the molecular level this may include an alteration in the configuration of cell membrane channels or receptor sensitivity, enzymatic and protein synthesis in the cytoplasm and gene expression in the nucleus.(10-13) The cells, in response to the molecular and biochemical reactions, react by differentiation, proliferation, migration and apoptosis.(14) Cells are physiologically programmed to respond to mechanical forces e.g. pregnancy, tumour growth, improved muscle strength and endurance to mechanical loading and cyclical strain, and bone strengthening to the impact of running.(15, 16)

Medical science uses mechanical forces to influence cellular and tissue responses for tissue generation, wound healing and scar modulation. Various surgical disciplines have harnessed the potential of mechanobiology for tissue growth or expansion.

In orthopaedic surgery, the Illizirov technique of lengthening bones using an external metal device, uses the forces of tension and controlled distraction following long bone corticotomy for limb lengthening.(17) The distracting forces are applied directly to the bone by transfixing intraosseous wires and pins. The soft tissue envelope also responds by growth to the artificially growing bone. This technique of distraction osteogenesis has been applied for bone reconstruction of bone defects, soft tissue contracture release and craniofacial surgery.(18-21) A significant advantage of this technique is that it is minimally invasive, low cost with innovative techniques and that once the device has been attached, it requires minimal training and skill. Invariably the patient or a caregiver is responsible for the bone distraction by following very simple guidelines or protocols.

In plastic and reconstructive surgery, tissue expanders are used for skin 'creation'.(22) By means of multistaged surgical procedures, a selected size and shaped silicone chamber is buried subcutaneously during the first operation. Using either a remote or an integrated port, this chamber is inflated with saline over the ensuing weeks to months. Strain is applied to the overlying skin with each inflation harnessing the biomechanical properties of skin.(23) By a process of mechanical and biological creep, skin is created in three dimensions.(24) The purpose in general for tissue expansion is to avoid donor site morbidity and use the created skin as a vascularized flap to reconstruct soft tissue defects with appropriately matching skin during a second operation. Some of the shortcomings of the procedure include failures, complications and a need for training and skills development in planning and execution of tissue expansion.(25, 26) The biggest drawback is that the technique is not applicable with already existing open wounds.(27)

In surgery, skin stretching devices and techniques are useful for open wounds.(28, 29) They are classified as external tissue expanders. They generally rely on engaging into the skin with aid of hooks, sutures, wires and loops to apply a mechanical force of tension to bring about approximation of the wound edges by

mechanical creep over period of time. The approximated skin edges are then allowed to unite to each other by spontaneously healing during a period of consolidation as the stretching device remains engaged. In most cases though, the mechanically stretched skin is surgically freshened at the edges and closed after removal of the stretching device. Dermatogenesis by direct application of 3M Steri-Strip™ or DynaClose® tape to the surface has been demonstrated in isolated case reports.(30, 31) A traction force was applied in these cases directly to the skin. The tolerance of the epidermis of the skin to this direct traction force and the dissipation of the force to other tissues was not understood. The influence of mechanical skin stretching devices or techniques on healing wound is gaining interest.(32)

Many cell types are associated with wound healing. Keratinocytes, fibroblasts, myofibroblasts and endothelial cells play a central role in cutaneous healing. They all respond to mechanical forces by a cascade of events or pathways at the cellular and molecular level against the backdrop of the homeostatic structural milieu of tensegrity, cytoskeletal framework anchored in an extracellular matrix.(33, 34) The cells being structurally connected to each other, respond to the mechanical stimuli. Mechanotherapies in wound healing are therapies that are able to generate mechanical forces in various forms that are able to modulate healing of normal, complex and complicated wounds. Some of these therapies include:

1. Microdeformational wound therapy (MWT) e.g. Negative pressure wound therapy (NPWT)(35, 36)
2. Shock wave therapy(37, 38)
3. Ultrasound(39)
4. Electrotherapy(40)

Negative pressure wound therapy has been extensively studied.(41) The collapse of the sponge associated with the application of suctions results in an immediate shrinkage of the wound. The wound undergoes macro deformation elicited by the sponge shrinkage and at the wound-sponge interface the negative pressure

subjects the cells and wound matrix to microdeformation.(42) These forces of deformation are then responsible for the mechanosignaling in closed wound healing environment. Some of the biological effects include elevation in gene expression of leucocyte chemoattractants, proliferation and migration of epithelial cells and dermal fibroblasts, decrease in matrix metalloproteinases activity and elevation in the micro-vessel density.(43-46) The net result is that it facilitates moist wound healing, enhances angiogenesis, facilitates collagen synthesis and increases the breakdown of dead tissue and fibrin.(47) At present NPWT is widely used to accelerate the healing of various types of wounds in variety of anatomical sites.

Cutaneous scarring is a significant aesthetic and functional burden following injury to the skin.(48) Foetal wound healing appears to follow a regenerative process as opposed to a repair process by fibrosis in extra-uterine life.(49-51) This biological conversion from tissue regeneration to tissue replacement by scar has generated a lot of research interest. The long term aim of this research is to achieve scarless wound healing. Meanwhile, interest in mechanobiology and cutaneous scarring research is expanding with the aim of delivering mechanotherapy to scars for prevention and abnormal scar treatment. Mechanotherapy can be defined as therapeutic interventions that reduce and reverse injury to the damaged tissues or promote the homeostasis of healthy tissues by mechanical means at the molecular, cellular and tissue levels.(52)

There is a relationship between scar growth and tension.(53-56) Clinically, keloid formation shows an association by anatomic site. They present in different shapes and configurations e.g. “crab” like, “butterfly” like etc. A long standing keloid shows a central regression zone and peripheral proliferative zone. Tension seems to be the common thread in this pattern of presentation. Animal models have demonstrated that mechanosignaling is responsible for the biochemical and molecular response favoring fibroproliferation. Mechanotherapy is directed to alter the stimuli, processing or the reception.(52) Some of the strategies in dealing with

the tension forces are skin stabilization by paper and silicone tape, multilayered suturing and plication, flaps and z-plasty.(57) The addition of adding radiotherapy is also an important strategy in curative multimodality interventions. The ultimate aim is to reduce the continuous skin inflammation by reducing skin tension which is the source of cyclically applied mechanical forces in daily locomotion.

The use of paper tape application in skin tissue expansion and abnormal scar modulation has not been explored.

In this thesis paper tape (3M™ Micropore™ Surgical Tape) was used to generate mechanical forces of tension by traction, compression, pressure and shear. Micropore tape is a surgical tape designed for holding down dressings on wounds. The concept of using paper tape to achieve tissue expansion, wound healing and scar modulation is novel. The technique in essence can be understood using a simulation model. The target zone of the therapy can be a scar, a lesion or a wound surrounded by normal skin. The purpose and specifically the technique of paper tape application was to impart a tension force on the surrounding normal skin with pulling force by traction being directed toward the target zone of the therapy. The secondary effect of the taping produced by normal intrinsic elasticity of the skin was compression, pressure on the target zone and shear forces at tape-skin interphase.

The thesis then is a presentation of clinical series and case reports of administering traction assisted tissue expansion (TATE) (formerly referred to as traction assisted dermatogenesis), traction assisted closure (TAC) and tension reduction taping (TRT). These studies are supported at the beginning of the thesis by a review of the literature to establish a basic understanding of mechanobiology in tissue expansion, wound healing and scarring to establish a theoretical framework for the practice of taping. The thesis ends by providing the reader with a study that reviews all the clinical materials on taping and an overview of the physiology of wound healing and scarring, and the biomechanics of skin.

The study was carried out in the city of Durban, the largest city in the province of KwaZulu-Natal, South Africa. Patients were recruited for the prospective studies from our cities academic quaternary state hospital, Inkhosi Albert Luthuli Central Hospital. The retrospective medical records reviewed were sourced from the medical records database at the same hospital as well as my private practice medical records of patients presenting for management at a private hospital, Umhlanga Hospital.

Trauma and burn injury is a major disease burden in South Africa. In the state sector in particular we see a large number of patients presenting for scar revision and abnormal scar management as a result of trauma or burn injury. The majority of patients seen in the state sector are Black African, an ethnic group which carries a predisposition for abnormal scars formation.(58, 59) The state sector is resource constrained and the management of these patient must be medically effective, as well as cost effective. Since we envisaged the taping technique to be very low risk for complication because of its non-invasive nature, and that the administration of the taping was projected to be cost effective, the studies undertaken were deemed to be beneficial to the local population and the medical fraternity by research to be undertaken.

The research was undertaken with the following aim and objectives

Aim

To explore the use of paper tape application in skin tissue expansion and abnormal scar modulation, provide a theoretical framework and practical guidelines for its use.

The study hopes to establish whether there is role for paper taping in the phenomena of skin tissue expansion and abnormal scar modulation. Since the proposed technique is novel, yet totally non-invasive and simple in physical application, providing theoretical support for its use will improve its scientific

appropriateness. The clinical materials supported by an understanding of the mechanobiology of forces on tissues, the ultimate objective will be to develop practical guidelines for its use.

Objectives

1. To identify a suitable tape and application method for skin tissue expansion and abnormal scar modulation.
2. To explore in scar management the therapeutic effect of the paper tape application in skin tissue expansion.
3. To explore in scar management the therapeutic effect of the paper tape application in abnormal scar modulation.
4. To describe the use of paper tape application in other reconstructive clinical settings.
5. To determine the effect on the symptoms of pain and itch associated with abnormal scars.
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8. To determine by independent expert review the change in abnormal scar.
9. To provide, based on a literature review, a theoretical framework in the use of paper tape in skin tissue expansion and scar modulation.
10. To develop practical guidelines for the use of paper tape.

Structure of this Thesis

This is a thesis by manuscripts and consists of five parts. Each part contains chapters that conform to the theme of each part. The chapters in each part corresponds to manuscripts which are either published or are to be submitted for consideration to appropriate editors of medical journals.

- Part 1 consists of a single chapter, Chapter 2, which reviews the literature on the mechanobiology for the entities of tissue expansion, wound healing and scarring to provide scientific support and a theoretical basis for our technique of mechanotherapy by taping to achieve tissue expansion, wound healing and scar modulation.
- Part two consists of nine chapters numbered as Chapters 3 to 10. Chapter 3 prospectively explored the use of paper tape in patients presenting to Inkhosi Albert Luthuli Central Hospital, Durban, KwaZulu-Natal, South Africa for scar revisions that were amenable for resurfacing by tissue expansion. The patients, with their consent, were offered our devised technique of traction assisted dermatogenesis (now referred to as traction assisted tissue expansion). The clinical series describes the technique and reports on our results. Chapter 4 is manuscript of a letter to the editor on external tissue expansion and my response to commentary contained therein. Chapters 5 to 10 retrospectively reviews medical patient records from Inkhosi Albert Luthuli central Hospital (academic government hospital) and Umhlanga Hospital (private practice hospital), Durban, KwaZulu-Natal, South Africa and reports only unique single cases or series. These studies represents 10 years of work with the use of paper tape for tissue expansion and wound healing in different reconstructive clinical settings.
- Part three consists of a single chapter, Chapter 11 which prospectively explored the role of paper tape in patients presenting to Inkhosi Albert Luthuli Central Hospital, Durban, KwaZulu-Natal, South Africa for abnormal scar management. The patients, with their consent, were offered our devised technique of tension reduction taping (newly introduced terminology for the description of the taping. This term does not feature in the manuscript). The clinical series describes the technique and reports on our results.
- Part four consist of a single chapter, Chapter 12 which produces a collective review of our techniques of paper taping for tissue expansion, wound healing and scar management. Its mains purpose is to provide the reader with

practical guidance for the use of 3M™ Micropore™ Surgical Tape and an understanding of the technique by summarizing wound healing and biomechanics of skin.

- Part five consists of a single chapter, Chapter 13 which is a synthesis of the entire thesis, laying the foundation for a critical appraisal including limitations of the studies, future perspectives and directions in research, and a conclusion.

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Part 1: Cellular and Biochemical response of Skin, Wounds and Scars to Mechanics of Traction Assisted Tissue Expansion, Traction Assisted Closure and Tension Reduction Taping

In Chapter 2 of Part 1 you are introduced to the science of mechanobiology. Fundamentally the changes influenced by the technique are driven by the exertion of mechanical forces on skin, scars and wounds.

Chapter 2: Mechanobiolology of Traction Assisted Tissue Expansion, Traction Assisted Closure and Tension Reduction Taping

Keywords

Mechanobiology, mechanotransduction, mechanosignaling, tensegrity,

Summary

Traction assisted tissue expansion, traction assisted closure and tension reduction taping is an innovative technique of using paper tape to exert mechanical forces to skin, for surgical reconstruction and to scars for modulation. The use of mechanical forces in medicine extends to many specialties. Cells respond to mechanical forces. This may include differentiation, proliferation, migration and apoptosis. The extracellular matrix and the cytoskeletal structure of the cells is integral to the mechanotransduction. The skin is a tensegrity structure that responds to deformation and in concert with the mechanotransduction at the cell to cell and cell to extracellular interfaces, triggers signaling pathways in the cells down to molecular levels of influencing gene expression in its nucleus. The aim of this review article is to provide a theoretical framework for tissue, cellular and molecular level response to the technique of paper taping to achieve tissue expansion, wound healing and mechanotherapy for scars.

1. Background

In the last decade significant growth in our understanding of the effect of forces on skin has occurred. The dermis endure external forces by direct or indirect means. Some of these forces include gravity, musculoskeletal mobility, tension, compression and shear.(1) Skin, an organ that is exposed to the external environment, is a complex structure consisting of epidermis and dermis. The

epidermis is predominantly composed of keratinocytes. Its cytoskeletal network of structural proteins provide the cohesion between the cells in all planes. Forces applied to the epidermis is transmitted via this network as it deforms in response to it.(2) The underling dermis is composed predominantly of the structural protein collagen in an extracellular matrix. Interspersed within this protein mesh are a multitude of cell types and vascular networks. The epidermis is adherent to the dermis by the means of anchor proteins called integrins.(3)

Skin is intrinsically under tension in its natural state covering the body. The tension will vary in different anatomical regions. The tension felt at any one point on the skin will also vary in different directions. It is this quality of skin, and the mechanical issues related to it in covering the body, that is exploited to generate mechanical forces with the application of paper tape to the skin for tissue expansion, wound closure and scar modulation.

Clinical research into the use of paper tape commenced in our surgical unit in 2003. The use of paper tape to achieve each of these end results has been termed traction assisted tissue expansion (TATE, formerly called traction assisted dermatogenesis), traction assisted closure (TAC) and tension reduction taping (TRT). The purpose of the tape in a described technique was to induce a skin response to the force being subjected to it.(4, 5) Studies emanating from its use have demonstrated its success.(4, 5) These studies were a test of the concept that the application of tape can be used to impart forces to produce a response in skin, wounds and scars.

The purpose of this article is to review the mechanobiology of force application to skin and the underlying tissues to determine a theoretical framework for the use of paper tape in plastic and reconstructive surgery.

2. Mechanics of TATE, TAC and TRT

The basic fundamental mechanics of taping is common to the outcome for TATE, TAC AND TRT. The taping process using a simulation model is explained below.

In the simulation model (Figure1), Zone 1 is representative of a suture line, scar, abnormal scar, skin lesion or wound. Zone 1 is the area of primary influence by taping. Zone 2 is the section of normal skin on either side of zone 1. The skin from zone 2 from either side of zone 1 is manually migrated towards it. When skin is pinched or manually migrated, tension being applied produces stretch of the skin in zone 3. The section being stretched experiences greater immediate intrinsic tension produced by the viscoelastic property of skin. Zone 1, toward which the skin is migrated, is relieved of tension and depending on the extent of tissue migration it is subjected to forces of lateral compression. Following the migration of the tissue the zones 1 and 2 are held in position by the application of the tape. The skin has a natural tendency to recoil towards its original position but the non-stretch tape prevents it from doing so. The skin outside the tape zone 3 remains under stretch creating tension in the system created by the application of the tape. Zone 1, which is already under lateral compression by the migration of tissue towards it, will now be subjected to vertical compression by the tensioned tape pressing down on it.

In TRT the tissue tension created in zone 3 is controlled with the main aim of neutralizing the tension at the zone 1. Because of the normal state of the intrinsic skin tension in zone 3 some degree of tension is produced in the tape to cause some vertical compression at zone 1. TRT is used in managing abnormal scars and in prophylaxis against poor quality scarring after cosmetic procedures and scar revision. In managing abnormal scars, greater tension is created in the tape by increasing the degree of migration of zone 2 to produce greater vertical compression in zone 1. In TATE and TAC the tension is maximized by controlled maximum stretch of zone 3.

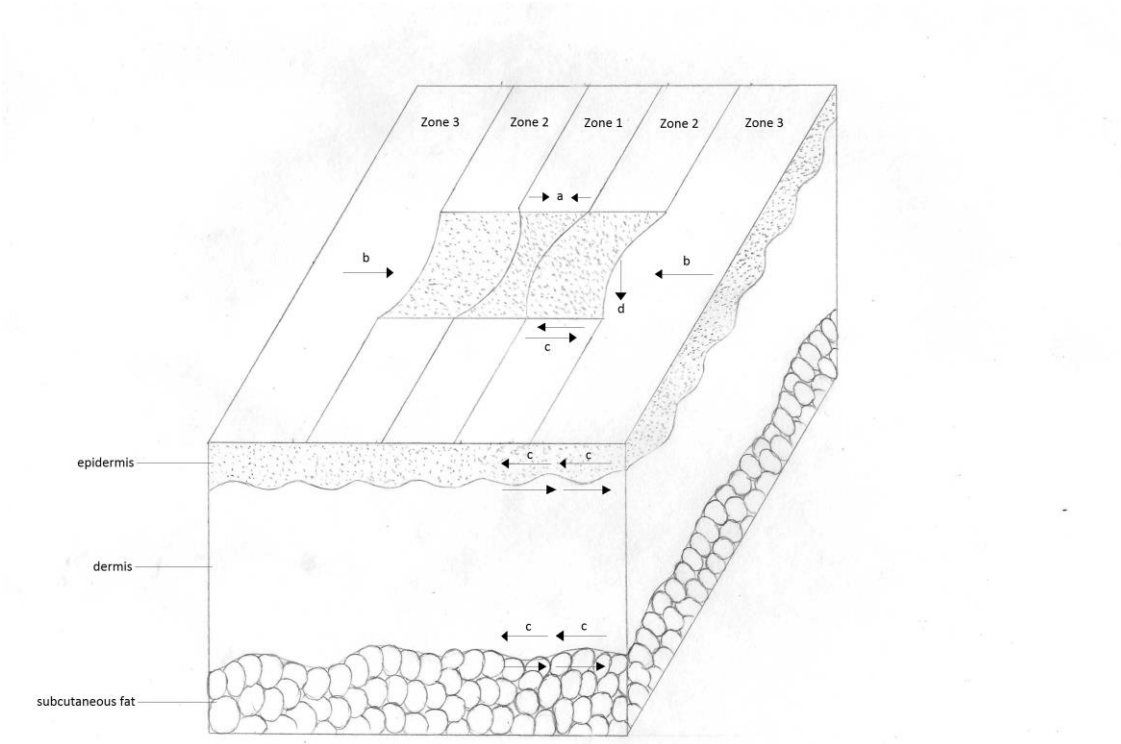

Figure 1: Mechanics of skin taping for TATE, TAC and TRT.

a = compression

b = tension

c = shear

d = downward pressure from tape

The tape application under tension will produce shear forces at the tape-skin interface, epidermis-dermis interface and at the deeper interfaces of different tissue types and gliding planes. The tolerance of various tissues to these diverse forces has not been studied, but the introduction of a barrier cream* to the skin has been an essential ingredient in the application technique. On clinical observation it would seem to have prevented the blistering of the skin. Blistering of the skin is the separation of the epidermis from the dermis. It therefore appears that the barrier cream seems to improve the tolerance for traction producing shearing forces at the epidermis-dermis interface.

^ 3M™ Micropore™ Surgical Tape

* 3M™Cavilon™ Durable Barrier Cream

3. Mechanobiology of TATE, TAC and TRT

Irrespective of the goal of taping to achieve a clinical endpoint, traction taping of the skin results in the generation of mechanical forces. The cellular and biochemical response of the tissue to these forces has not been studied specifically for taping. A simple application of laws of physics to the technique of taping seems to indicate that these forces generate tension, compression, pressure and shear. A theoretical framework for the mechanobiology of taping of skin is postulated by reviewing the literature that examines the biological response of tissue to the application of mechanical forces on skin.

4. Mechanical forces in medicine

The effects of mechanical forces may be appreciated in many physiological and pathophysiological processes in the body.(1) These include growth, pregnancy, obesity and tumour growth. The tissue response is obvious but the mechanical forces at a cellular level in an extracellular matrix produces cellular change. Cells respond to a wide variety of different mechanical forces as follows:

- Compression – intermittently loaded bone with an unnatural strain distribution can be associated with a substantial increase in bone mass, whereas static load has no effect on bone remodeling.(6) Compressive stress shrinks the lateral intercellular space surrounding bronchial epithelial cells and by mechanotransduction signals triggers binding of epidermal growth factor family ligands to epidermal growth factor receptor.(7) Compressive forces applied during orthodontic tooth movement increases fibroblast growth factor-2 production by human periodontal ligament cells.(8)
- Tension – mechanical tension contributed to the formation of hyperplastic scar formation on the back of rats, in conjunction with increase in both nerve density and nerve growth factor expression in scar tissue.(9) Hinz demonstrated in a rat model that increased mechanical tension enhances the contractility of wound granulation tissue and results in early expression of

myofibroblast markers.(10) The loss of mechanical tension decreases tissue contractility and expression of myofibroblast markers.

- Shear – shear stress affects mechano-sensing and intracellular signaling by the activation of a number of mechano-sensors in endothelial cells. These include membrane proteins such as receptor tyrosine kinase, integrins, G proteins and G protein-coupled receptors, calcium channels and intercellular junction proteins.(11)
- Osmosis – experimental work has shown that wound oedema resolution enhances local blood flow and promotes granulation tissue. Vacuum-assisted closure effectively reduces oedema in wounds. In a controlled study, vacuum-assisted closure use reduced oedema in fasciotomy wounds and produced surgical closure in the test group of 34 patients in 6,7 days as opposed to 16,1 days in the control group of 34 patients. The difference was statistically significant.(12)
- Gravity – cellular and molecular studies in space medicine is an essential component of rapidly developing space engineering.

  Wound healing is a response to traumatic stimuli, the dynamics of which can be altered by microgravity.(13) This includes the degranulation of platelets, release of transforming growth factor (TGFb), platelet derived growth factor (PDGF) and epidermal growth factor (EGF). Micro-gravitational status has been shown to influence the expression of EGF receptors, and impairs EGF-induced signal transduction.(14, 15) Micro-gravity down regulates TGFb production and PDGF receptor.(16) In rats, the response of wounds to PDGF was attenuated compared to control wounds on the ground.(17)

  Stem cells are considered to be a key source of regenerative medicine. Although the studies performed are ground based microgravity simulations, findings do suggest that the morphology, proliferation, migration and differentiation of stem cells are influenced by microgravity.(18)
- Pressure – Pressure is a uniformly distributed force applied perpendicular the skin surface.(19) In daily life the human body in locomotion is exposed to

epidermal loading. The skin and deeper tissue will undergo deformation, microcirculatory, cellular and molecular responses.(20) Pressure on skin is a major pathophysiologic factor in the development of pressure ulcers. Tissue necrosis is a function of pressure-time relationship and is mainly as a consequence of ischemia. Tissue changes include venous, venous thrombosis, oedema, cellular extravasation, and neutrophil and macrophage activity. Beyond a certain level of force or duration, catabolic processes overcome reparative mechanisms resulting in tissue breakdown. The pressure-duration relationship is affected by a multitude of intrinsic and extrinsic factors. Moisture reduces load bearing capacity of the stratum corneum and the glycosaminoglycans in the dermis. This results in a greater elongation of skin, the collagen is under greater strain and possibly putting cells and vasculature interspersed among the collagen fibers under greater stress and risk of trauma. Skin adapts to pressure by increases in hyaluronic acid and chondroitin sulfate content. The effect of surface forces on the morphologic pattern of skin capillaries showed potentially damaging effects of surface forces on the integrity of the skin vasculature.(21)

The consequence of hypertension on the cardiovascular and other organ systems are deleterious. In hypertension, pressure-induced mechanical stretch on vascular wall leads to differential gene expression.(22) Aortic valve interstitial cells can exhibit phenotypic characteristics of fibroblasts and myofibroblasts. Using a ex vivo bioreactor, myofibroblast markers alpha SMA and Vimentin proteins were down regulated by cyclic stretch and pressure, suggestive of inhibition of contractile activity and possibly myofibroblast phenotype.(23)

5. Mechanobiology of cells

Sensitivity to a variety of mitotic stimulators and growth factors may be modulated by cell conformation.(24) Glowacki showed that flattening spherical chondrocytes

altered phenotypic expression to fibroblast type cells which then showed more rapid growth than the spherical counterparts.(25) Tucker showed that sensitivity of non-neoplastic fibroblasts to humoral factors is governed by cell spreading. Changes in cell shape may be more important than cell to cell contact in regulating growth of fibroblasts.(26) The three dimensional shape of the population eventually limits growth, most likely because of limitation imposed by nutrient diffusion. Tumor growth is a useful example. Tumourigenesis escapes the growth restriction imposed upon three-dimensional cell population by geometry through stimulating angiogenesis, resulting in vessels penetrating the tumour and permitting further rapid growth. It is reasonable to hypothesise that the stretching cell and flattening of it shape will change its proliferation and phenotypic expression.

5.1 Cell shape and function

Endothelial cell

The endothelial cell can be stimulated to sprout and tubularise in response to angiogenesis factors.(27) In wound healing, macrophages stimulated by hypoxia and phagocytosis, is a major source of angiogenesis activity. Resting endothelial cells are kept quiescent by the cell to cell contact with the pericytes. Endothelial cell in vitro when confluent is refractory to growth factors. The in vivo response is likely to be similar. Endothelial cells, when elongating or spreading, increase sensitivity to growth factors especially bFGF. Vasodilatation of a parent venule maybe a trigger for the first capillary sprout. Stretch on the endothelial cell may be the sensitizing event to angiogenesis growth factors. Stretching of the skin may be responsible for sending similar signals for angiogenesis.

5.2 Theory of Tensegrity

Cells use tensegrity architecture constituted by tensile and compressive cellular components, and by its interconnections creating a tensile prestress for its mechanical stability, enabling cells to respond to mechanical signals.(28) These

physical forces, by a process called mechanotransduction, influence the intracellular biochemistry and gene expression.(29) Mechanobiology is then the organization of the living cells at molecular level to exhibit their characteristic shape, structure and mechanical properties in response to physical forces. This cellular biological response can escalate to influence tissues and organisms as a whole. Using the theory of tensegrity, living cell behavior can be explained and this in turn can be used to help design mechanical techniques and/or devices to modify molecular, cellular and tissue behavior.

In terms of the cytoskeleton of cells, tensile forces will drive the assembly of filamentous biopolymers as opposed to relaxation or compression that promotes depolymerisation. The cellular tensegrity model describes the force balance between tension-supporting contractile actin filaments, compressive-supporting microtubules and traction- supporting focal adhesions through molecular clusters.(30) Any change in any one of the three forces will impact on the other two in turn. Cells respond to the change in balance by remodeling and/or rearranging supporting cytoskeletal biopolymeric structures. The extracellular matrix (ECM), a polymer network, may be viewed as an extended cytoskeleton that connect cells. Cell to cell contact and interactions maintain cytoskeletal tension. Focal adhesions between cells are upregulated under influence of traction forces.(31) ECM tension may also regulate release of growth factors that are trapped in the ECM.

There are several tensegrity models.(28) The cable and strut model on application of a force explains strain hardening, prestress-dependent stiffness and the effect of cell shape on mechanics. Tensegrity at the subcellular level includes molecules of RNA and DNA as the applied forces to the cell via the cell membrane and supporting cortical cytoskeleton produce structural changes in nuclei and nucleoli.(2)

6. Mechanobiology in skin

6.1 Scar

Tension on the scar is a major predisposing factor in abnormal scar formation. In mechanotransduction it is the process by which physical forces are sensed and converted into biochemical signals that result in cellular responses. (See figure 2

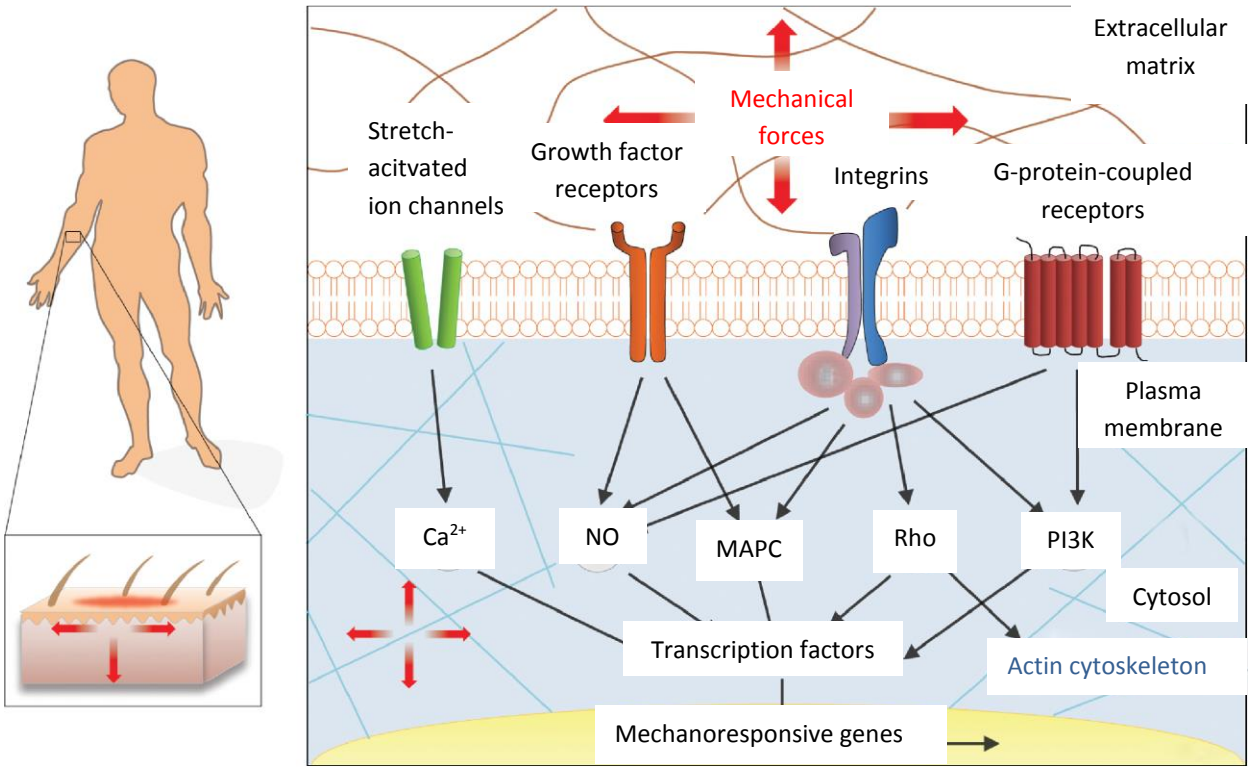

Figure 2. Intracellular mechanisms of mechanotransduction. Mechanical force is sensed by the integumentary system and activates multiple intracellular signaling pathways. Several membrane-bound mechanosensory complexes have been described and include stretch-activated ion channels, growth factor receptors, integrins, and G-protein-coupled receptors. Of primary significance in fibroblasts and keratinocytes is matrix–integrin activation of focal adhesion complexes that contain focal adhesion kinase (FAK). Mechanical force is transmitted across the cell membrane to activate downstream biochemical pathways including but not limited to calcium-dependent targets, nitric oxide (NO) signaling, mitogen-associated protein kinases (MAPKs), Rho GTPases, and phosphoinositol-3-kinase (PI3K). The convergence of these signals results in the activation of transcription factors that translocate to the nucleus and activate mechanoresponsive genes (copied from Journal of Investigative Dermatology 2011,131(11) 2186-96, adapted by Wong et al from Jaalouk and Lammerding, 2009).

Mechano-responsiveness of complexes on the cell membrane has been proven for TGF-b/Smad, integrin and calcium ion pathways.(32) Signaling is transmitted into the cell ending in the nucleus. In vitro models show that mechanical strain upregulates matrix remodeling genes and down regulates normal cellular apoptosis through an Akt-dependent mechanism resulting in cells producing more extracellular matrix which underlies the pathophysiology of hypertrophic scarring.(33, 34) However, in vivo inhibition of Akt increased apoptosis did not significantly reduce hypertrophic scar formation.(35)

Mechanical force prolongs acute inflammation via T-cell-dependent pathways during scar formation. Wong *et al* found that scar formation in T-cell deficient mice was reduced 9 fold ($P < 001$).(36) T-cell deficient mice failed to recruit systemic inflammatory cells such as macrophages and monocytic fibroblast precursors in response to mechanical loading. Focal adhesion kinase (FAK) links mechanical force to skin fibrosis via inflammatory signaling.(37) Molecular strategies targeting FAK can potentially uncouple mechanical force from pathologic scar formation. Blockade of mammalian target of rapamycin with rapamycin specifically impaired fibroblast expression of collagen biosynthesis genes, thus blocking fibroproliferation.(38) In fibroblasts the focal adhesion complex plays an integral role in the propagation of the mechanical cue into an extensive network of biochemical signals leading to widespread downstream effects including the influx of inflammatory cells, stimulation of angiogenesis, keratinocyte migration, fibroblast proliferation and collagen synthesis.(39)

The role of endothelial cell dysfunction may be promoted by mechanobiology of the dermis and blood vessels along with genetic and systemic factors.(40) Fibroblasts derived from hypertrophic scars and keloids show a decreased level of gap junctional intercellular communication and connexin 43 (Cx43) protein expression.(41) In keloids the cell-surface Fas receptor induced apoptosis is abnormal.(42) Both findings by Lu *et al* may account for the break in the proliferation

and apoptosis balance. Peripheral zones of the keloid demonstrate aggressive growth as compared to the central zone. Differences in fibroblast cell-cycle distribution and P53 protein expression may account for this.(43) Akaishi, using a visualized finite element study showed that stretching tension is an important factor associated with peripheral keloid growth.(44)

Dermal fibroblasts represent a heterogenous population of cells. In murine skin, a single fibroblast lineage is responsible for the bulk of the connective tissue deposition.(45) One such lineage has been identified with CD26/DPP4 surface marker. Blocking of its enzymatic activity with small molecule could result in diminished cutaneous scarring during wound healing. Biological effects of cellular stretch on human fibroblasts using mechanotransduction pathways showed increased migration, reorienting themselves perpendicular to the direction of the stretch.(46) Aoki *et al* proposed that siRNA knockdown of tissue inhibitor of metalloproteinase-1 in keloid fibroblast leads to degradation of the collagen type 1 contained in the thick collagen bundles of the keloid.(47)

Akaishi hypothesized that neurogenic inflammation triggered by mechanical stress stimulating mechanosensitive nociceptors on sensory fibers would activate fibroblasts through various signals.(48) Neuropeptides will also affect scarring by influencing cell proliferation, cytokine production, antigen presentation, sensory neurotransmission, mast cell degradation, vasodilation and increased vascular permeability.(49) Surgical denervation in an animal model study showed that denervation reduced dermal scarring.(50) Dermal cells themselves through mechanoreceptors may display an excessive responsiveness to the mechanical stress.(51) Input to the spinal cord could induce central sensitization for pain and itch. The analysis of neuropeptides in stretched skin showed that neuropeptides are released not only from peripheral terminals of nerve fibers but also resident skin cells.(52)

Lipids which are integral component of the cells of the skin, serving as secondary messengers to actively participate in the chronic inflammation processes driven by mechanotransduction pathways associated with keloid formation.(53)

Targeting these mechanisms as part of a physical scar management strategy could be useful in controlling fibro-proliferative diseases. Many of the existing physical treatments such as compression therapy, silicone therapy, adhesive tape and occlusive dressing therapy are related to mechanotransduction mechanisms.(54) Akaishi reported on the tension reduction of effects of silicone gel sheeting.(55) Mechanical manipulation of wound environment with a dynamic stress-shielding polymer device can significantly reduce scar formation.(56, 57) The embrace device significantly improves scar appearance following revision surgery.(58)

In a large animal study, mechanical loading of incisional wounds upregulated expression of genes associated with inflammatory and fibrotic pathways. Device-mediated offloading of these wounds reversed these effects.(59) Increased amounts of TGFb are found in wounds that heal by scar formation as opposed to regenerative process in human fetal skin transplanted in a mouse model.(60). Surgical strategies for reduction of tension including the use of flaps in combination of postoperative radiotherapy, large keloids can be successfully treated.(61) Gene expression in fetal murine keratinocytes and fibroblasts showed 546 differently expressed genes between scarless and scarring transition.(62) In a study performed in 204 Japanese cases it was shown that genetic factors, specifically the rs8032158 single nucleotide polymorphism, may include keloid severity.(63) Fibroproliferative disorders are not the only skin condition related to mechanobiological processes. Others like Ehlers-Danlos syndrome, cutix laxa, scleroderma, neurofibromatosis and ageing also seem to be associated.(64)

The effect of mechanobiology on stem cells is being explored. The bulge of the hair follicle in adult wound repair maybe a potential source of the regenerative capacity

derived from multipotent stem cells.(65). Human mesenchymal stem cells may be involved in keloid pathogenesis.(66)

6.2 Tissue expansion

Stretch is applied to skin under normal physiological conditions, for example pregnancy or by artificial means. Mechanical forces applied artificially may be applied during tissue expansion due to implantation of soft tissue expanders or by external skin stretching devices and also by distraction osteogenesis in hard tissue using external devices.

6.2.1 Tissue expanders

Since the first description of tissue expanders by Austad and Radovan in 1980's, they remain a very important tool for creating skin for various reconstructive purposes.(67, 68) The procedure of tissue expansion is invasive, multistaged and can be associated with complications and failure. The expansion process is three dimensional as the inflation of the expander mimics a growing soft tissue mass. The expanders come in various shapes and sizes but rely on geometric planning and placement for maximal utilization of created skin.(69, 70) The greatest benefit is creation of "like" tissue and avoidance of a donor site morbidity. The major drawback is that tissue expanders cannot be used with open wounds.

6.2.2 Skin stretching devices

Many different types of devices have been used for the purposes of achieving tissue expansion by an external means.(71-74) The most significant benefit being they use in open wounds of the skin. These devices harness the viscoelastic properties of skin using incremental traction to stretch skin over period of time.(71) The skin stretching is two dimensional, relying on an invasive technique to purchase the skin using hooks or suture loops to transmit the mechanical force. The disadvantage then may be the cost, need for anaesthesia for the application of device and the

experience of pain during administration of skin stretch. But the complication rate is low and for open wounds, skin grafting and flaps can be avoided.(72)

6.2.3 Ilizarov technique

Rigid fixation and mechanical factors being considered in bone fracture management, is vital for achieving consolidation with minimal amount of new bone formation and without the cartilaginous phase.(75) Achieving longitudinal compression at the contact site of the bones does not suppress the reparative process and does not cause resorption of the bone tissues. To achieve this, isolating bone from the periosseous muscle has deleterious effects on fracture healing by compromising blood supply. The role of distraction in formation of new bone is controversial. But it can be agreed that distraction applied to bone with stable fixation generate connective tissue between the bone ends, goes on to form bone under the influence of tension-stress.

This process of the distraction osteogenesis is dependent upon the force, rate and rhythm, and cross-sectional area of the bone. Compression without adequate blood supply retards osteogenesis and may encourage resorption. Mechanically loading the bone against the background of good blood supply and dynamic muscle activity surrounding the fracture site, encourages osteogenesis. Therefore immobilizing joints and muscle as part of fracture management has a negative influence on neo bone formation. Internal transosseous osteosynthesis techniques assist in maintaining mobility, but harmonic combination of mechanical and biological factors could be compromised. External fixation systems can potentially offer advantages of maintaining compression over the entire treatment period, and are less traumatic than implantation of internal fixation device. But most external fixation devices cannot stabilize fragments against loads applied from any direction.

Osteogenesis in limb lengthening using the Ilizarov technique to create tension-stress relies on increased fixation stability and maximum preservation of the periosseous and intraosseous soft tissues enhanced bone formation.(76) Bone marrow preservation is important. Bone lengthening clearly is accompanied by soft tissue lengthening including fascia, skeletal muscle, smooth muscle, blood vessels, nerves and skin.(77) One mm of distraction per day in four steps leads to optimum bone formation. A slower rate of 0,5mm per day leads to premature consolidation and faster rate of 2mm per day to undesirable changes in elongating tissues. The growth plate that forms under the influence of tension-stress has features of both physeal bone and intramembranous ossification.

6.2.4 Static vs cyclic mechanical loading

In vitro high frequency cyclic strain was more effective at inducing Akt phosphorylation than low frequency or static strain.(35) Analysis of neuropeptides in stretched skin showed that cyclical stimulation by mechanical force resulted in a significant increase in expression of neuropeptides and growth factors than continuous force.(52) When dermal fibroblasts are subjected to cyclic axial stretching, they migrate faster and for a longer distance than unstretched cells.(46) Wen showed that in response to cyclic stretch by deformation at 10 cycles per minute, dermal fibroblasts needed a minimum of 15% cell stretch to stimulate fibroblast orientation response. Fibroblast orientation is mediated at least in part by integrin beta 1 through phosphorylation focal adhesion kinase, p38 and activation of Rho.(78)

7. Rationale for developing system of using paper tape in tissue expansion, scar modulation and wound closure

The first opportunity to use tissue expansion was for scar removal in the lower limbs of two patients. The success in these cases prompted the design of a prospective study for scar revision to test its use in other areas of the body, which were

traditionally treated with tissue expanders. The concept was born out of necessity because of a high failure and complication rate associated with tissue expanders in limbs in clinical practice in our setting. The economic costs and morbidity associated with failure is always of concern to a MLIC like South Africa. 3M micropore tape is surgical tape used for holding dressings on skin. The cost is low and could be considered as a ubiquitous consumable in the medical domain. The greater than 50% success rate of this technique in our study provided support in adding this technique to the other strategies of tissue expansion already in use.

An early observation during the tissue expansion study was that the scars decreased in volume and improved in quality and texture. Therefore it was logical to test the hypothesis of scar modulation by taping for abnormal scars. A high success rate in this study made way for use of the technique for scar prophylaxis in cosmetic and scar revisional surgery.

Presuturing was described as a technique for preparation for skin lesion excision.(79) The main purpose being to simplify wound closure. But it had many shortcomings which could be overcome by the use 3M micropore tape to achieve the same results. The biggest advantage of our system of taping was that it was non-invasive and could be applied multiple times to incrementally bring about skin stretch over a period of hours to days. We termed this technique of taping pretaping.

There have been many other cases of tissue expansion treated for indications other than scars. Our confidence, the expertise gained and the non-traumatic nature of the developed system significantly lowered our threshold to use taping for tissue expansion. Knowing full well that failure to progress could be easily changed over to other techniques of reconstruction.

Referral of patients with critical level lower limb amputations with open large stump wounds to us for reconstruction presented a challenge. The use of external

stretching devices was the main technique applied. The handicap being cost and some of them can be cumbersome in applying. The taping technique was tried with 100% success which proved to be rapid and effective.

The use of taping in the amputation scenario resulted in the application of the tape directly onto the wound. The tape appeared to be behave like an occlusive dressing, unlike other known occlusive dressings on the market to which a mechanical force could not be applied. Open fasciotomies of the limb could then be closed and we extended its use to other situations of open wounds in various parts of the body. We were able to avoid skin grafting and in many cases flap reconstructions.

The indications we believe will continue to grow and refinements will continue. There is now a need for a sterile low cost kit to be developed for the purpose of taping especially with use with open wounds.

8. Conclusion

Cells and the extracellular matrix respond to mechanical forces signaling along biochemical and molecular pathways, inducing alteration of gene expression, structural and functional protein production and their receptor complex activity. Skin is a complex structure in tensile prestress balance which when exposed to mechanical forces applied by the system of taping responds by deformation triggering mechanotransduction. There are many well-known techniques of creating skin for reconstruction and closure, and scar management. Although cyclical application of force is responsible for a larger magnitude of cellular signaling most of the techniques including taping are non-cyclical in nature. The clinical experience with the use of taping for tissue expansion, scar modulation and wound closure has been encouraging and is worthy of research into its direct impact on cellular and molecular biology.

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Part 2: Clinical Application of Taping of the Skin in Plastic and Reconstructive Surgery to Achieve Wound Cover or Closure

In Part 1 it can be appreciated that through the application of a stretching force to the skin, by a process of mechanotransduction, tissues respond at the cellular and molecular level. The mechanobiological response is driven by cellular mechanoreceptors and mechanosignaling pathways in the cell. Viscoelastic properties of skin are not the focus of this part. Viscoelastic properties of skin and mechanobiology in skin provides a basic understanding of the skins response to stretch, that collagen responds by reorientation first, followed by a net increase in its production to the ongoing application of a force. In the second part of the thesis the technique of taping with paper tape to produce tissue expansion of local skin in preparation for reconstructing or closing defects arising from a multitude of clinical conditions at various anatomical sites of the body is described. Part 2 is about the several studies performed introducing the concept of traction assisted tissue expansion (TATE). TATE was formerly referred to as traction assisted dermatogenesis. The first study in Chapter 3, is about a cohort of patients in whom scars were excised and resurfaced with expanded skin. The techniques use are expanded to other clinical applications in the chapters that follow, ending in a study in which the concept is used for assisted wound healing which we have called traction assisted closure (TAC).

Chapter 3 was published in PRS in 2007.

Chapter 3: Traction Assisted Dermatogenesis by Serial Intermittent Skin Tape application. Daya M, Nair V. Plast Reconstr Surg. 2008 Oct;122(4):1047-54. doi: 10.1097/PRS.0b013e3181858c68

Abstract

Background

The use of tissue expanders and skin stretching devices are both a commonplace in reconstructive surgery. We like to describe a non-invasive technique of tissue expansion.

Methods

A Prospective study in which twenty six consecutive patients made up of 8 males and 18 females were recruited for expanding the skin by our devised technique of intermittent serial traction micropore taping of skin at a weekly interval. Once the skin was expanded the scar revision was performed in 1 or 2 stages by excision and flap advancement. The age range was 8 to 48 years. The anatomical regions scar revision were scalp=6, face=9, upper limb=6, and lower limb=9.

Results

The size of the scars to be resurfaced ranged from 35 mm by 50 mm on the temple to 280 mm by 130 mm on the scalp. The average follow up following surgical correction was 11 months. The number of taping sessions ranged from 2-15 sessions with an average of 6.9. Fourteen patients had successfully completed the surgical management, 4 patients are in midst of their management. Four patients defaulted treatment and four patients the expansion failed to progress. Illustrative samples of some of the cases are described. .

Conclusion

Traction assisted dermatogenesis is an additional method of tissue expansion that is easy and cost effective in our reconstructive armamentarium.

Introduction

Tissue expansion with use of internal tissue expanders is a reputable and reliable method of creating skin in many forms of reconstruction.[1] Other techniques like presuturing,[2,3] towel clips[4] and skin stretching devices[5] and are also useful but are mainly applicable intra operatively or a few days running up to the definitive reconstruction. All the above procedures have the disadvantage of being invasive. We describe a technique in which micropore is used to serially expand the skin for resurfacing of healed defects in several areas of the body. Its biggest advantage is the low cost, non-invasiveness, and can be very easily performed by the patient.

Method and Material

A Prospective study beginning in April 2005 and ending in April 2007 was done in all patients presenting with functional or cosmetic scar deformity for surgical improvement. The chosen method of reconstruction for these patients was tissue expansion. The patients were managed by our new technique instead of placement of a tissue expander.

Twenty six consecutive patients made up of 8 males and 18 females were recruited for the study. The age range was 8 to 48 years. The anatomical regions expanded were scalp=6, face=9, upper limb=6, and lower limb=9. The area to be resurfaced followed trauma in 13 patients, burn injury in 9 patients, hairy nevus in 1 patient, skin grafted defects following surgery in 3 patients

New Technique

The area of the scar to be resurfaced with surrounding normal skin is delineated (figure 1a). The surrounding skin if hair-bearing is shaved. The skin is then moisturised with a sparse application of cavilon cream. The surrounding normal skin is then stretched to its maximum in the direction which is appropriate for obtaining the final closure by the flap advancement. A 1 inch micropore 3M tape is then applied to hold this position of stretch of the normal skin (figure 1b). Further tape is applied for the rest or the scar and the surrounding skin in the same manner. The patient is allowed to bath normally. The tape is retained for a full period of one week (figure 1c). It is then removed and the skin is washed and prepared with the cavilon cream. A new application of tape is performed once the skin is stretched further recruiting the developed laxity following the last application. In the initial part of the study the patients were prepared and taped by the doctor. In the latter part of the study or once the patients were confident to do so they performed the taping on their own at home according to our given instructions. The process was repeated weekly. When the expansion was deemed to be adequate or the latter 3 taping episodes did not generate additional laxity the patient was taken to theatre. At surgery area to be resurfaced was managed in one of 2 ways. The one method was to incise in the border between the scar and the normal skin on either side. The normal skin was then advanced over the scar. If direct closure could be obtained with or without undermining then the entire scar was excised. Incomplete scar excision was often predictable preoperatively. The skin was then sutured to the residual scar edge where the lateral flap comes to lie without undermining. Alternatively as in the demonstration case the created excess in the scar was excised and then closed directly (figure 1d). Once healed the tissue expansion was resumed at 6 weeks to obtain further skin laxity thereby achieving final closure in a second operation (figure 1e). Application of the micropore tape was continued for a period of 3 months to support the healing wound and scar.

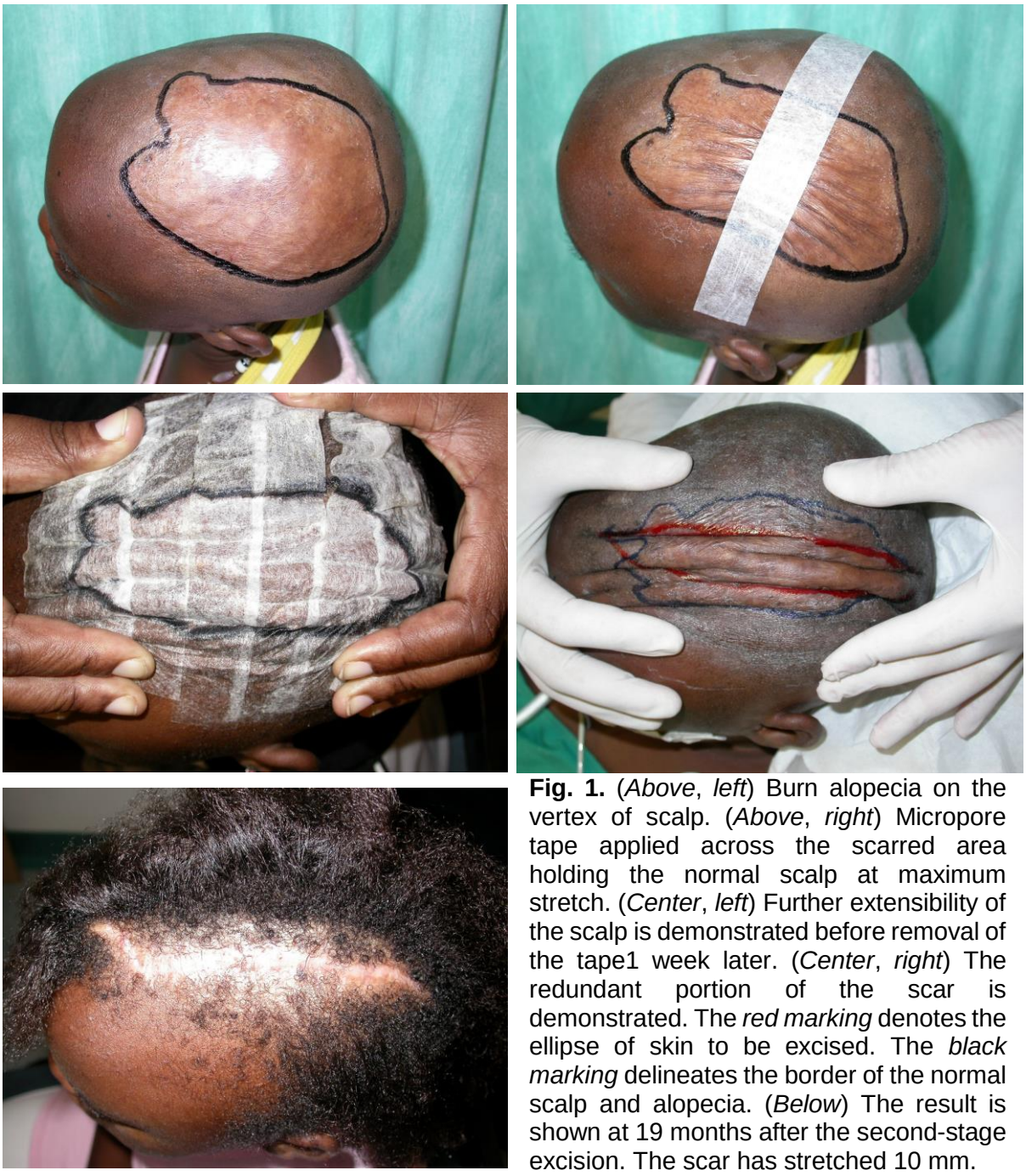


Fig. 1. (*Above*, *left*) Burn alopecia on the vertex of scalp. (*Above*, *right*) Micropore tape applied across the scarred area holding the normal scalp at maximum stretch. (*Center*, *left*) Further extensibility of the scalp is demonstrated before removal of the tape1 week later. (*Center*, *right*) The redundant portion of the scar is demonstrated. The *red marking* denotes the ellipse of skin to be excised. The *black marking* delineates the border of the normal scalp and alopecia. (*Below*) The result is shown at 19 months after the second-stage excision. The scar has stretched 10 mm.

Results

The size of the scars to be resurfaced ranged from 35 mm by 50 mm on the temple to 280 mm by 130 mm on the scalp. Four patients had more than 1 (range 2-3) site

expanded simultaneously. In 3 of them the scars were in separate anatomical regions. In 1 patients there were 2 scars at the lower leg which were longitudinal and adjacent with a 3 cm bridge of skin between them. This allowed for a taping across both scars simultaneously. The average follow up for the patients following completion of surgical correction was 11 months. The number of taping sessions ranged from 2-15 sessions with an average of 6.9. At the time of preparation of the paper 14 patients had successfully completed the surgical management, 4 patients are in midst of their management and the process of expansion was suspended in 8 patients. Four patients from the latter group defaulted treatment after the first application of the tape, 1 patient a child with hairy cell nevus on the cheek did not tolerate the application and 3 patients with defects greater than 140 mm by 80 mm on the scalp showed a failure to progress after 3-10 sessions of tissue expansion. The following are samples of some of the cases that were managed by the method described in our technique.

Case1

This patient a twelve year old girl sustained a full thickness burn of the scalp at the age of 1 (figure 2a). The size of the burn alopecia was 125 mm by 95 mm. she underwent a 2 stage excision of the burn scar and hairbearing scalp flap advancement. Eight session of expansion were performed in the 1st stage. Four months later in the 2nd stage following 4 sessions of expansion the balance of the burn scar excised and closed. The post operative management included supportive taping with micropore for 3 months. The final result (figure 2b) was good.

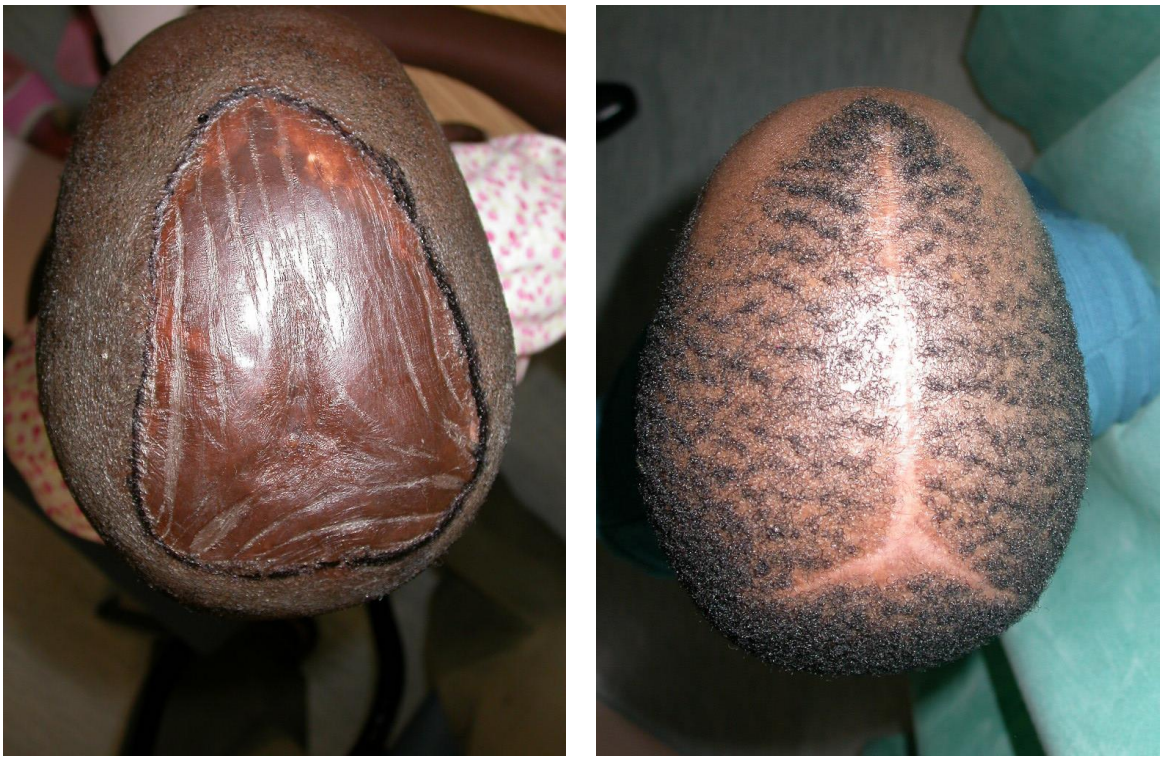
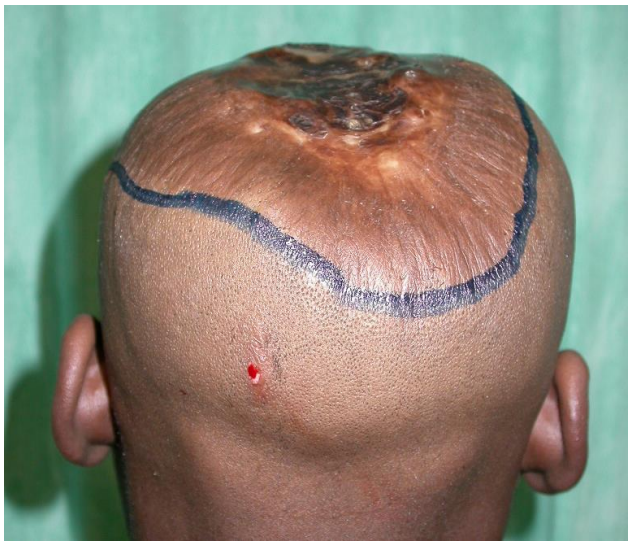


Fig. 2. (*Left*) The area of burn alopecia demonstrated at 1 week after the first application of tape. (*Right*) The final result at 4 months after second-stage scar excision.

Case 2

This patient a twenty year old patient sustained a full thickness burn to the scalp under the age of 1. He had a large cranial defect due to the initial necrosis and the dura had epithelised with the rest of the wound by secondary intention. The area of burn alopecia measured 230 mm by 140 mm (figure 3a). He was initially managed by the medical staff and later he performed the taping himself. His compliance and attendance to the hospital was erratic and therefore the no of taping sessions difficult to measure. Other problem experienced in this patient was the slow progress in the latter stages due to the scar immobility centrally (figure 3b). He underwent the first stage excision 7 months later. The dura was de-epithelised with the CO2 laser. Complete advancement of the scalp could not be achieved over the exposed



dura after freeing the flap attachment to the bony edge. Closure of the residual defect with the width of 15 mm was achieved with VAC therapy. At the 4 months post surgery the wounds are well healed (figure 3c) and the patient is awaiting the second stage which I predict to be uncomplicated.

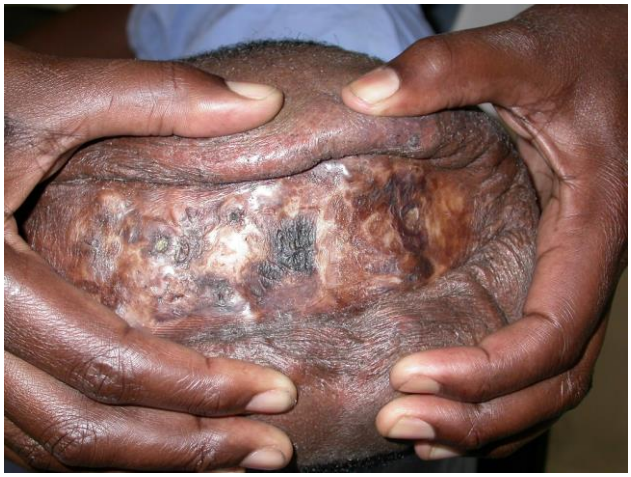
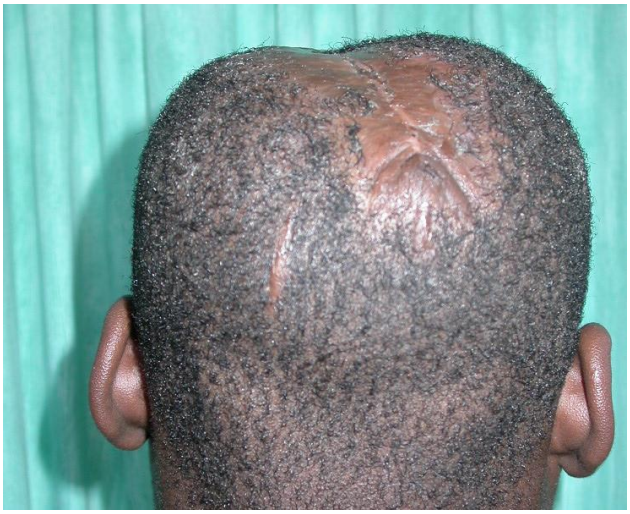


Fig. 3. (*Above*) Posterior view showing the scar centrally adherent to the dura and at its periphery, and then the cranial bone edge.(*Center*) An interval view of the vertex of the cranium showing the scalp riding over the central scar; however ,further extension is hampered by tethering of the flap to the bone edge. (*Below*) Posterior view at 4months after the first stage with the adherent scar successfully removed; a significantly narrower burn alopecia on the scalp remains.



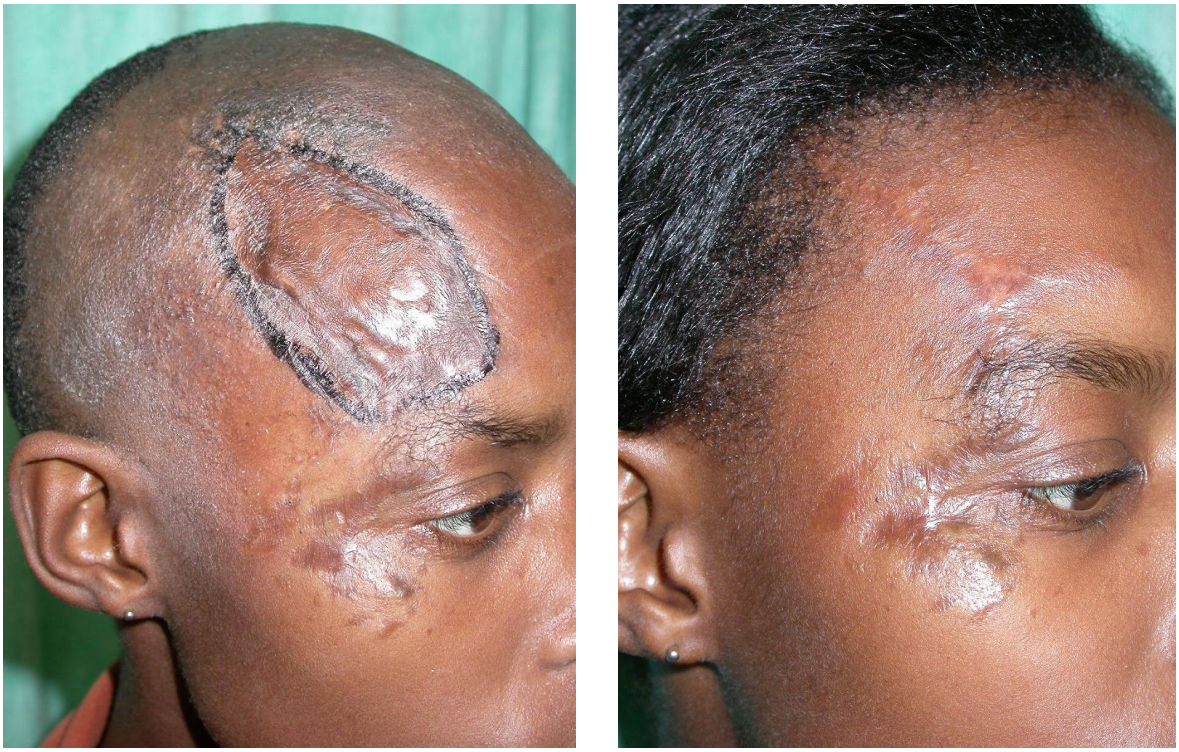


Fig. 4. (*Left*)An oblique view of the adherent scar on the forehead and scalp. (*Right*)An oblique view showing a good, mature scar 10 months after excision.

Case 3

This patient a 20 year old female presented with degloving injury to the scalp and forehead (figure 4a). She had skin graft directly adherent to the bone centrally. The scar measuring 85 mm by 48 mm was resurfaced by flap advancement after 10 sessions of taping. In the latter sessions the progress of expansion was noted to be slow. The result 10 months later was satisfactory (figure 4b).

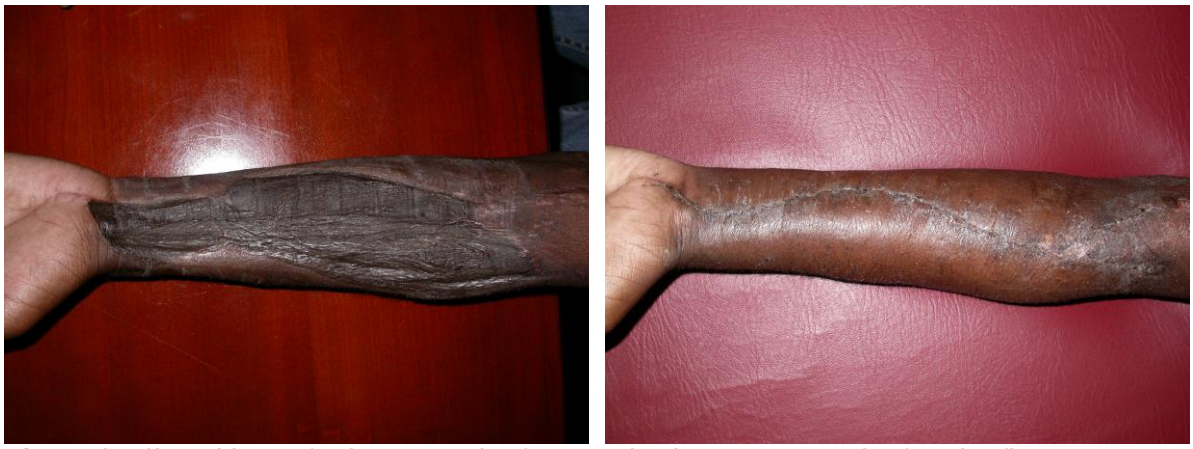


Fig. 5. (*Left*) A skin-grafted area on the forearm is shown at 1 week after the first application of the tape. (*Right*) Closure was obtained after single-stage excision.

Case 4

This patient a 25 year old male presented with wide skin grafted degloving injury and fasciotomy scar (figure 5a). He had sustained a crush injury to the forearm together with a brachial artery injury 9 months earlier. His hand function was good and he desired a cosmetic improvement. The scar size in the widest diameters were 280 mm by 80 mm. The scar was excised after 5 sessions of taping and closure obtained. A z plasty was performed over the cubital fossa. A good result is noted at 6 weeks (figure 5b).

Case 5

This patient developed a 6 mm thick hypertrophic scar following a burn to the thigh 2 years earlier (figure 6a). The scar measured 210 mm by 55 mm. The scar was excised and closed directly after 3 sessions of taping. No undermining was performed and no subcutaneous fat was excised. The result 1 year later showed a good result but a stretched scar measuring 15 mm in the greatest width (figure 6b).

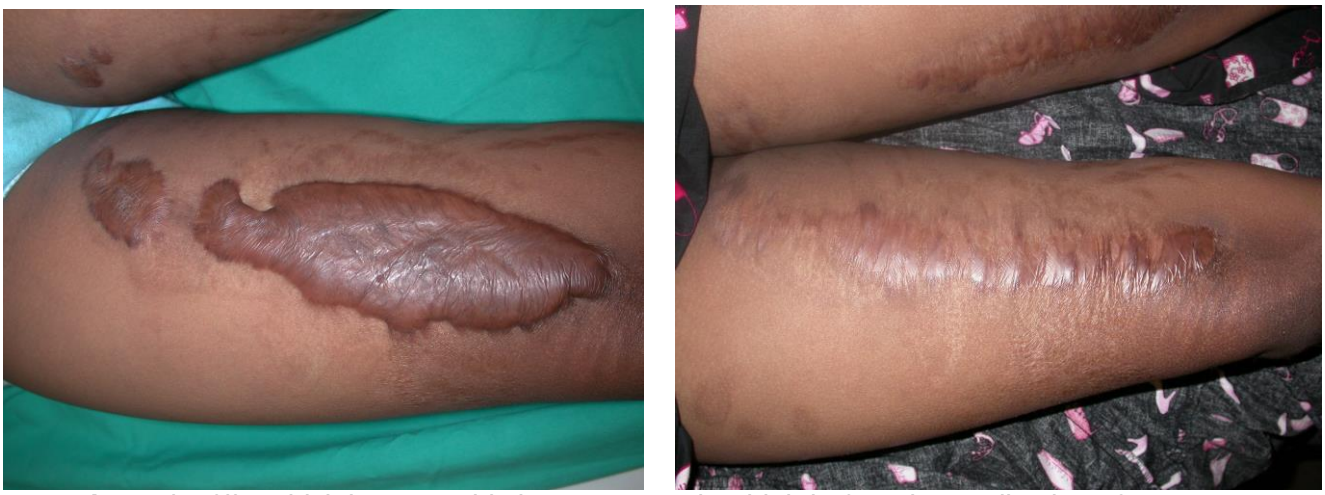


Fig. 6. (*Left)*) A thick hypertrophic burn scar on the thigh before the application of tape. (*Right*) The result at 1 year shows a stretched scar

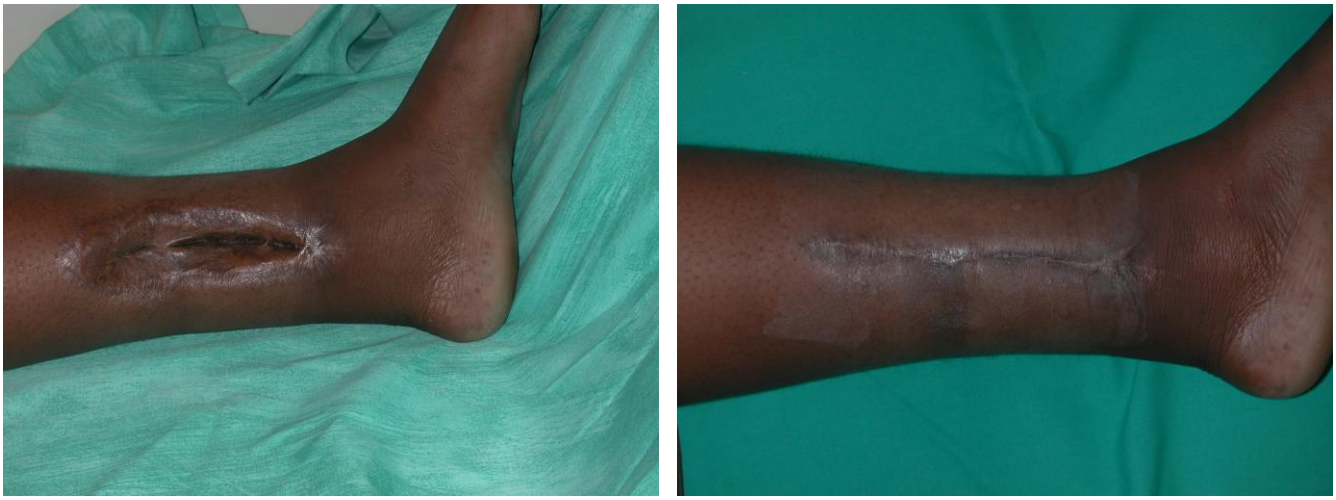


Fig. 7. (*Left)*) A contour deformity on the lower third on the medial aspect of the leg. (*Right*) A good correction of the deformity is noted at 3 months.

Case 6

This patient presented with a scar and contour deformity following trauma (figure 7a). Centrally the scar was adherent to the tibia. After 2 sessions of taping the scar was excised and the closed with lateral adjacent flaps. A good result is noted a 3 months (figure 7b).

Case 7

This patient represents one of the cases in which the taping was abandoned for placement of expander implants. The patient, a 26 year old female sustained a burn injury to the face and scalp (figure 8a). She desired an aesthetic improvement. The expansion failed to progress satisfactorily in the latter part of the 10 sessions of the taping (figure 8b).

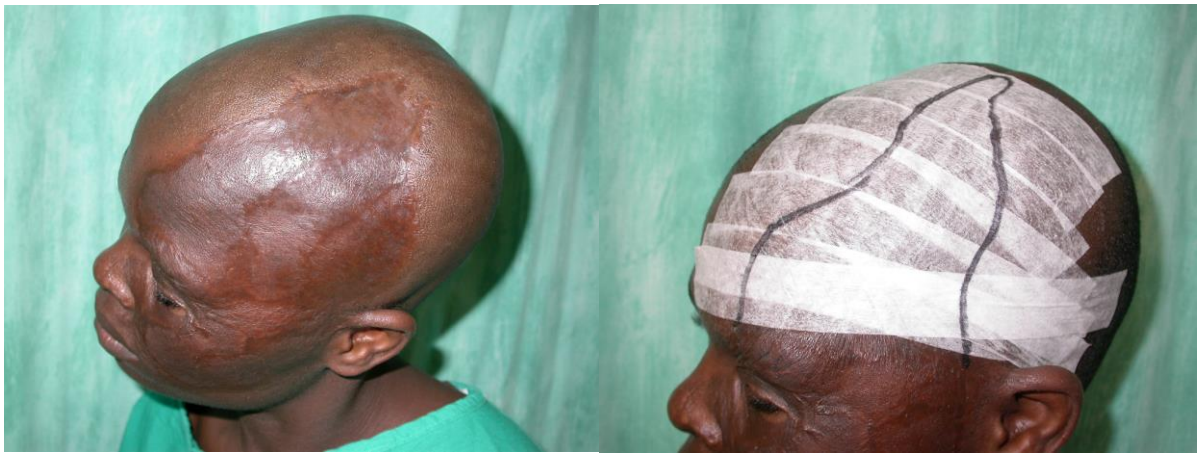


Fig. 8. (*Left)* The distribution and size of the burn scar on the scalp and forehead should be noted. (*Right)*) The apex of the scar demonstrates a better response than the base of the triangulated scar.

Clinical observation and interpretation of wound bed following scar excision

At operation in these cases I noted that the wound bed appeared to have higher density of punctuate bleeding for the tissue being operated on and the tissues seemed to be better hydrated with the tissue fluid. (Fig 9) It is my interpretation that this increased hydration is in keeping with the increase in the pliability and the suppleness of the scar which was observed with the onset of the taping.

Complications

There were 3 minor complications in the early part of the study. These were single cases of erythema of the skin, folliculitis of the scalp, skin blistering. It was our impression that the problem occurred because of mechanical factors and was

resolved by introduction of cavilon application a skin protectant, gentler less traumatic hair removal and controlling the traction that is exerted on the skin by the tape.

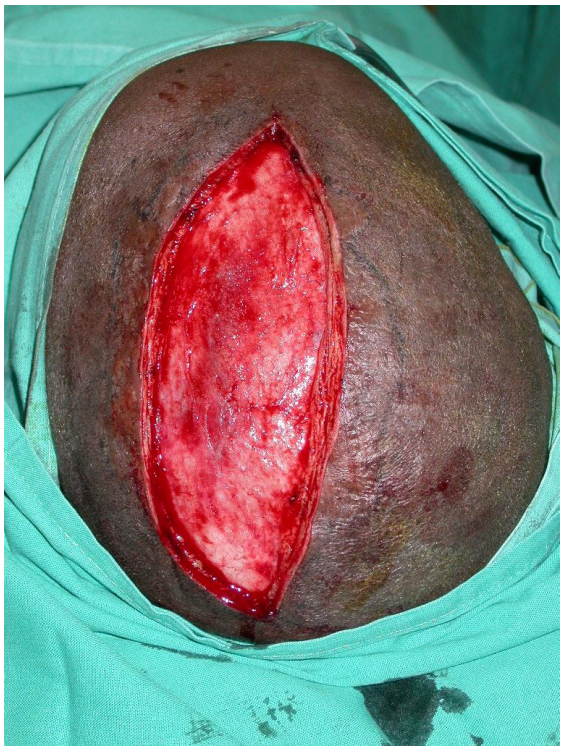


Fig. 9. The wound bed shows increased vascularity, with a higher density of punctuate bleeding and a very high photographic reflectance, probably depicting the increased tissue fluid hydration.

Discussion

Clearly this is a very useful technique that can be used for tissue expansion. This technique is a two dimensional tissue expansion as compared to 3 dimensional with the use of inflatable expander placement. It has all the potential to achieve the same applications as other 2 dimensional skin stretching devices. We have not tried the use of micropore taping to close open wounds. The wound exudate poses an obstacle giving skin stretching devices a distinct advantage in an open wound situation.[6,7] The greatest benefit though is the low cost, non invasive application and it is administrable by the patient.

Skin is viscoelastic .[8,9] The immediate extensibility of skin by the force applied is the product of its intrinsic elasticity. Mechanical creep is defined as the elongation of skin with a constant load over time beyond intrinsic extensibility. Stress relaxation with the passage time enables the additional loading of skin to recruit more tissue. This has been described as the vehicle harnessed for wound closure with presuturing, intraoperative tissue expansion, skin-stretching devices, and skin retraction with undermining. Unlike these methods the application of the tape is over much longer term with the intermittent tension loading of the skin and it approximates time duration of conventional tissue expansion. Biological creep plays a role in conventional tissue expansion resulting in the generation of new tissue due to a chronic stretching force. It is possible that traction taping with micropore may express an element of both. Pietramaggiori determined the response of normal perfused tissue in a rat ear model to tensile forces.[10] The skin demonstrated an increase in vascularity together with remodelling and epidermal cell proliferation. They concluded that as cell growth and vascular supply are critical to wound healing and tissue expansion, devices applying controlled mechanical loads to tissues may be a powerful therapy for to treat tissue defects. Our in intraoperative observations of the tissue blood supply maybe in congruence with their findings.

Four patients had more than 1 site taped simultaneously. Scars that are remote from each other does not pose a problem. Adjacent scars on the other hand are probably amenable to simultaneous tissue expansion if their spatial orientation allows for the lateral laxity to be sourced from the same direction for each scar.

Serial excision is not an unpopular method of revising scars.[11] It has a major disadvantage of multiple procedures to render the desired scar reduction. Combining this modality with taping significantly reduces then number of serial procedures. Our need for a 2 stage excision was performed due to poor progress in the skin creep resulting from the either hindrance from the development of central bulk (figure 1d) or the tethering of the normal skin edge to the deep underlying

tissue that did not allow for gliding and overriding of the scar (figure 3b). An elevated hypertrophic scars also hinders the migration of the surrounding skin over the scar (figure 6a). It is also our Impression that skin that has been previously undermined due to trauma or surgery (figure 4a) progresses poorly. Therefore if a second stage expansion was planned then during the first surgery the flaps were not undermined. In addition deep attachment of the soft tissues as in case 7 (figures 8a and b) at the base of the cranium is likely to be reason for the poor progress at this level as opposed to the vertex in this patient.

Tissue expansion with expanders has a significant major complication of about 25%.[12,13] This complication in limbs may increase to above 40% in limbs. Some of these complications include extrusion, sepsis and expander failure. Our technique is not a substitute for the use of tissue expander in the revisions of scars. But I believe that in a considerable number of patients the use of tissue expanders and its associated complications maybe avoided. It may prove to be especially useful in the limbs. Lasheen et al.[14] successfully used external tissue expansion using negative pressure to overcome this significant risk of complications. They method nevertheless does not overcome the need for a specialised device. In addition both internal and external expanders are managed by the doctor. Our described technique was easily learnt by the patient and the caregiver who were eager to perform the task on their own. Self administration did not appear to result in any compromise once the process was well understood.

In case no. 2 VAC™ therapy[15] was used as an adjunct to closure of the wound that could not be primarily be closed on the table. I also see potential value to the use of micropore tape applied over the polyurethane film dressing during the VAC™ therapy to further augment the movement of the flaps in closure of the open complex wounds.

In our initial experience we observed revised scar had a tendency to stretch. The reason for is not known. The postoperative support with micropore taping in part overcame this problem. This phenomenon deserves to be further investigated

Conclusion

This is novel technique to which we would like to assign the terminology traction assisted dermatogenesis. We believe it is an additional method of tissue expansion that is easy and cost effective in our reconstructive armamentarium. The ideal case for this technique is probably scar revisions where the both the scar and the surrounding soft tissues are readily mobile. Its use may easily be extended to achieving easy closure after skin lesion excision for which presuturing is generally advocated thereby avoiding small skin grafts and small local flaps. I believe that it also has the potential to diminish the donor site morbidity following flap harvest by primary closure with pre expanded local tissue.

Financial Disclosure and products page

No specific or external funding was received for this study. The patients were treated in a public hospital and the cost of the treatment was paid for by the state. The supplier for the Micropore and cavilon cream is 3M. I Mahendra Daya and Vaneshree Nair have no financial interest in this company.

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Introduction to Chapter 4

In Chapter 3 one of the complications noted was blistering. This was experienced early in the study when a skin barrier cream was not being applied. The introduction of the Cavilon™ cream prevented this from happening. The tolerance for shear forces imparted by the taping were better tolerated once the barrier cream was applied, preventing this complication. Canica Dynaclose® described in Chapter 4 does eliminate the blistering but probably does not generate sufficient tension in the elastomer of the band to produce efficient skin lengthening. This is evident in the long healing time reported by Dr Bell in his letter to the editor which follows on the next page. His point about the application of excessive tension in the application of the tape was an important one. Excessive tension could result in decreasing blood supply to the tissue. This could potentially lead to tissue necrosis. On the other hand, the hypoxia could stimulate angiogenesis and is worthy of further investigation in the post-doctorate phase of research.

Chapter 4: Letter to the Editor. External Skin Expansion. Plast Reconstr Surg. 2009 Jun;123(6):1895-6; author reply 1896. doi:10.1097/PRS.0b013e3181a3f4e7

Sir:

I was delighted to read the article by Daya and Nair confirming the concept of external skin expansion.[1] I have been working on this principle for 8 years with engineers from Canica Design, Inc. (Almonte, Ontario, Canada), developing products to accomplish wound closure and presurgical external skin expansion in a safe and reliable way.

There are two complications one may encounter in the skin with tape application under tension. The first is blistering from the shear forces at the skin adhesive junction.[2] These blisters are painful and can cause scarring. Reinforced strips do not stretch, which means that when they are adhered under tension, all of the force on the tape is transferred to the skin beneath the strip. The skin is no longer compliant, as it is bonded to the reinforced fabric. The skin right at the end of the strip suffers the highest load. The second problem is pain.

Dr. Dal Cin describes expanding the skin to close an 8-cm skin graft on a scalp with dynamic external forces over a period of 149 days. The patient lost enthusiasm at several points along the way because of discomfort. However, with the adjustable features of dynamic traction, gently stretching the scalp, the graft was excised and primary closure achieved.[2,3]

The Canica Design solution has been to simply use an elastomer between two strips of Micropore tape (3M, St. Paul, Minn.). This provides gentle relentless traction on the skin. The level of tension is set initially by a limiter controlling the stretch of the elastomer, which protects even the most easily damaged skin (e.g., leg ulcers in

diabetics and in irradiated skin). Similarly, this mechanism of controlled tensioning reduces pain. It is noninvasive, repeatable, and very easily applied. The product is called DynaClose. It is licensed for wound closure and is currently being reviewed by the U.S. Food and Drug Administration for surgical skin expansion. It is approved in Canada for both uses.

We believe this product offers benefits similar to the technique described by Daya and Nair in prestretching skin but will avoid the problems of skin irritation, breakdown, and pain. This is achieved by controlled elastic forces.

As Daya and Nair state, the use of the external traction principle has many potential applications[4–6]: prestretching skin before surgical reconstruction, pain relief, and scar reduction. The Canica DynaClose tape can also be used in open wounds, which can be viewed directly through the transparent silicone sheeting, so that any infectious process would be directly evident (Fig. 1). This principle of dynamic closure is invaluable in closing unclosable wounds nonsurgically. DynaClose is the latest and simplest of the Canica family of Dynamic Wound Closure devices, which are well documented in the literature.[7–10]

With my evident conflict of interest as a paid design consultant for Canica Design, I cannot participate in a valid study of these products, but I would encourage others to assess the benefits of this newly available technology in an objective fashion.

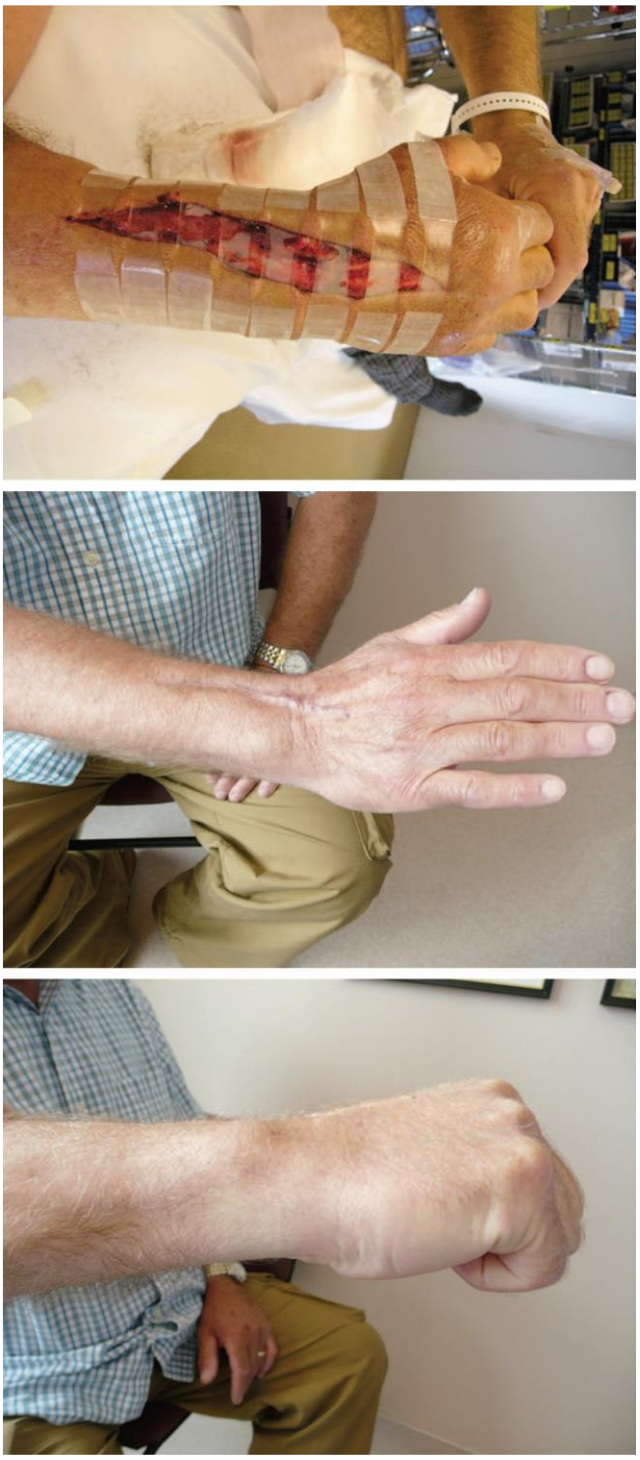

Fig. 1. This fasciotomy was primarily controlled by DynaClose tape to prevent excessive retraction. The tapes were changed weekly to achieve delayed primary closure by 5 weeks, with no secondary intervention required. (*Above*) Photograph obtained on July 9, 2007. (*Center* and *below*) Photographs obtained on April 23, 2008

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Reply

Sir:

I am most appreciative of the compliment extended to us by Dr. Bell. The technique that both of us describe has clear advantages. I have applied this technique only to scars and not open wounds. I am most encouraged by the described technique with the DynaClose product, with a clear advantage of its application in open wounds.

The complications of erythema, folliculitis, and blistering are noted in our article.[1] The use of the skin barrier cream may be invaluable because these complications were not seen after careful skin preparation and the use of skin protectant. We also thought that it was important to control the amount of traction on the skin on application of the tape to avoid the shearing forces, which are powerful enough to blister the skin. None of our patients experienced pain. Perhaps the experience of pain is related more to the use in open wounds and invasive external devices.

We find that the described Canica DynaClose technique has a long period of expansion: 149 days for the case report of the 8-cm skin graft scalp resurfacing[2] and 5 weeks for the open fasciotomy case as described in the letter. It is my opinion that the latter case is a combination of traction and open wound secondary healing, and the contribution of each cannot be clearly elucidated. The DynaClose device is demonstrated to be applied over a wide area of the adjacent skin. The attached skin directly under the device or the tape is rendered noncompliant and is not available for the process of expansion. Only the unattached skin outside the zone of attachment is available for both mechanical and biological creep. The relatively long interval of expansion may also be an indicator that the amount of traction generated by the DynaClose device is not optimized for the potential extensibility and creep in the surrounding skin. The controlled elastic forces achieved by this device may prevent the noted complications, but the limit of the skin to withstand the traction forces without sequelae needs to be further studied in the interest of decreasing tissue expansion time.

I would also like to encourage clinicians and researchers alike to further explore the potential of this technique of tissue expansion.

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Introduction to Chapter 5

In my reply to the editor (Chapter 4), one of the handicaps I mentioned was the slowness of the Canica Dynaclose® to affect healing by skin lengthening. One of my criticisms of the devices use in the case described was that instead of creating tissue expansion, the wound of the forearm appeared to be healing by secondary intention. In Chapter 5 we affect tissue expansion by TATE in a 48 hour period with a view to closing an excision width of 8cm on the back after two tape applications. This was for a giant congenital melanocytic nevus (GCMN) in a 1 month old baby. The laxity of the skin of the baby might have been a significant contributing factor to achieving rapid expansion. The application of the traction was not cyclical nevertheless there was no clinical evidence of hypoxic damage to the skin during the period of application. After pinching and holding the folded skin created, the tape was firmly applied to hold the position of the stretched skin on each occasion. No blistering was experienced. It would seem therefore that significant forces can be applied and that the inherent adhesiveness of the tape may be at the appropriate limit of tension before slippage of the tape occurs on application of the 3M Micropore™ tape on the skin.

Chapter 5: Excision and Reconstruction Following use of Paper Tape Application in Skin Tissue Expansion in a 6 Week old Child with a Giant Congenital Melanocytic Nevus of the Back

Key words

Giant congenital melanocytic nevus, melanoma, tissue expansion, traction assisted tissue expansion, 3M™ Micropore™ Surgical Tape

Summary

A giant congenital melanocytic nevus (GCMN) is a rare. The need to treat has to be balanced against the risk of melanoma and risks of surgery for cases treated for aesthetic improvement. There are multiple modalities for treatment many of which are advocated in the first few years of life. Tissue expansion technique for generating normal skin, avoiding donor site morbidity, is one of them. However the use of internal tissue expanders is not without its own risks. We present a 6 week old baby born with a GCMN on the back who had undergone an external form of tissue expansion referred to as traction assisted tissue expansion with the use of the paper tape. The process took 2 days to produce skin that was used to cover the defect that resulted from surgical excision of the GCMN. We describe the technique and surgery, producing a good patient outcome.

Background

A GCMN is a nevus that is extrapolated to be greater than 20cm in dimension into adulthood. In a new born this may equate to about 6cm. Its incidence is estimated to be < 1:20 000. Despite its rarity, this lesion presents both a medical and cosmetic problem. It carries a risk of melanoma at a young age, although this risk maybe a little as 2%.(1) Treatment by removal is directed predominantly at decreasing this risk. Many treatment options are available for intervention during childhood.(2)

Treatment in the neonatal period includes curettage, dermabrasion and laser resurfacing which aims to remove the pigmented portion of the skin. The rationale for this early management is to perform the excision of the nevus before the deeper penetration by the pigment laden melanocytes into dermis. The residual normal dermis provides for spontaneous epithelialisation of the wound with minimal to moderate scarring. The neonatal period presents the surgeon with this window of opportunity. However it remains debatable whether this diminishes the risk of malignancy. Many surgeons will choose to completely excise the nevus.(1) Failure to treat a lesion early leads to the growth of the nevus as the child grows. Therefore delaying excision results in a bigger defect for reconstruction with a higher degree of complexity.

Full thickness removal of nevus depending on the size is managed later in infancy or childhood by any one of several surgical options. These include staged serial excision, excision and grafting with autologous skin or skin substitutes and multi-staged tissue expansion with tissue expanders culminating in excision and reconstruction by flap surgery.(3, 4)

Traditional expander device associated tissue expansion is a recognised reconstructive tool for resurfacing GCMN. The technique is used in infancy and early childhood. Its drawbacks as a procedure is that it is multistaged, invasive, inflicts pain and carries significant risk of complications and failed outcomes. Duclert-Bompaire demonstrated in a 10 year experience of 45 children using 73 expanders a 26% complication rate. One quarter of the cases were GCMN and the trunk as an anatomic region showed the highest propensity to complicate.(5) The external tissue expansion technique that we are describing is unlikely to share this complication profile because it differs from the method of achieving tissue expansion by insertion of internal tissue expanders. Perhaps, even the overall physiology may differ in some aspects.

We present a novel technique in the following case study. It demonstrate the feasibility of achieving acute skin tissue expansion by the non-invasive, economical and pain free technique of traction assisted tissue expansion (TATE) in preparation for single stage excision and closure at a very early age of six weeks.(6) This would otherwise not have been possible using the traditional techniques reported in the literature.

Case Presentation

A case study of a 6 week old baby with a GCMN measuring 8 X 9cm and occupying more than 50% of the horizontal width of the thoracolumbar section of the back is presented (Figure 1). The TATE technique was utilised to create additional skin in a period of 48 hours followed by the complete surgical excision of the lesion and direct closure.

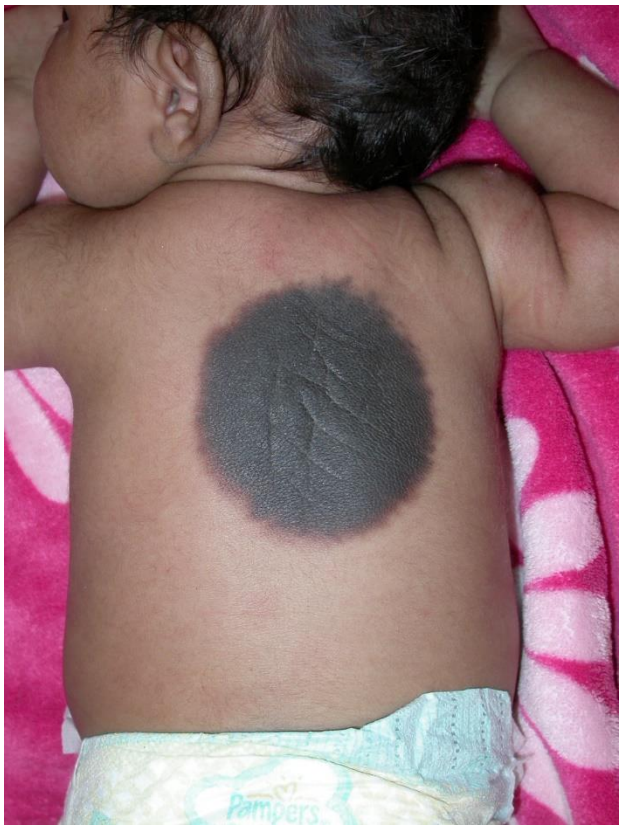


Figure 1: Six week old infant with a GCMN on the back

Traction Assisted Tissue Expansion

The infant was laid prone and skin barrier cream* was sparsely applied to the surrounding skin and the lesion. The skin was pinched vertically and folded in the midline of the back recruiting the immediate lateral laxity in the skin and held in place by the application of the paper tape^ (Figure 2). Twenty four hours later patient was reviewed. The pinch test with the tape still applied demonstrated skin tissue relaxation with now additional skin being available for harnessing by the paper tape application. The existing tape was removed and following a new application of skin barrier cream and paper tape was applied recruiting the additional laxity. The patient was scheduled for surgery on the next day.

* 3M^{TM}Cavilon^{TM} Durable Barrier Cream

^ 3M^{TM} Micropore^{TM} Surgical Tape

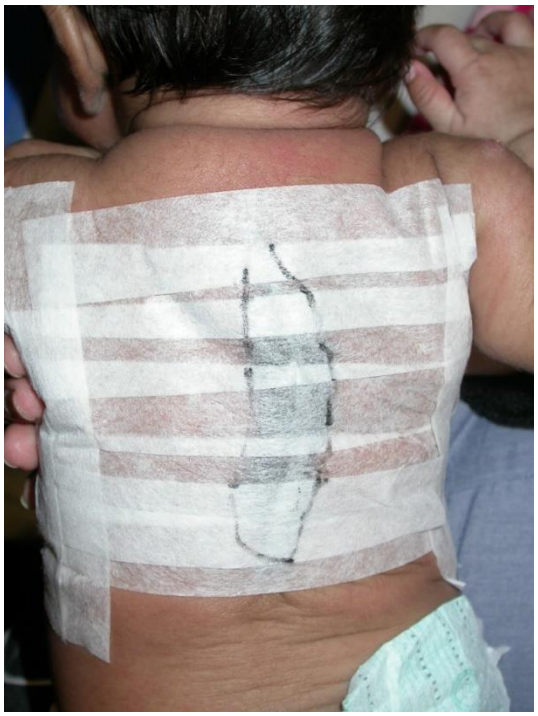


Figure 2: First application of Micropore tape. The outline in the reduction of the folded size of the nevus can be seen through the tape.

Surgery

Once anaesthetised the skin under the tape was tested for laxity. There was clearly additional laxity generated (Figure 3).The tape was removed and another

application of tape recruiting the additional laxity was performed. The tape was kept applied for the time it took for the scrub sister and anaesthetist to prepare. The application was in place for 15 minutes, with removal just prior the skin preparation with a disinfectant. The lesion was marked for removal as vertically orientated ellipse. The lesion was excised with the subcutaneous tissue down to deep fascia (Figure 4a and b). The elliptical defect measured 10 cm X 13 cm. The skin was closed without any undermining in three layers with 4/0 monocryl over a suction drain and adhesive dressing retention tape[+] was applied to the suture line for additional support. No tension in the closure was noted.

[+] Hypafix®

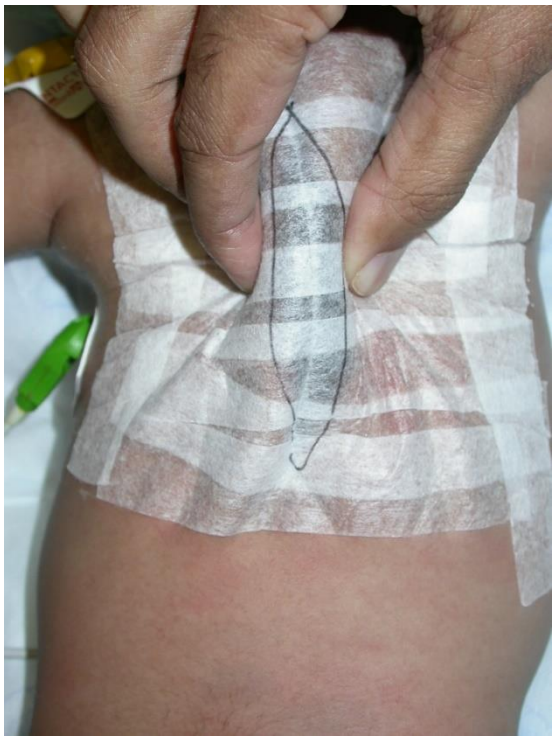
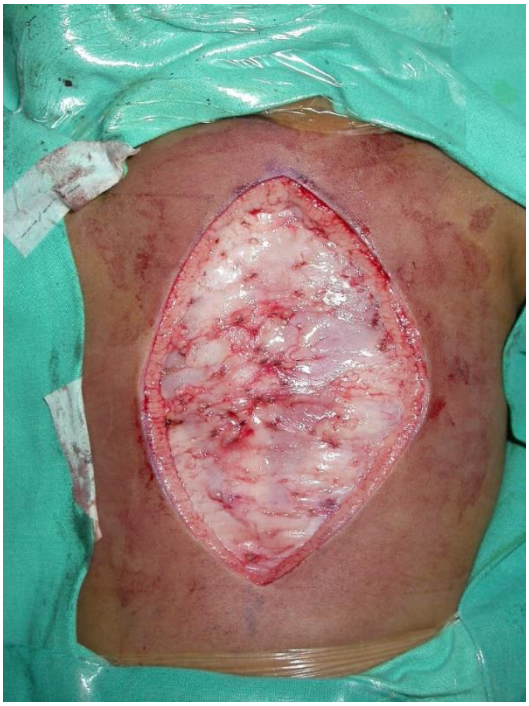


Figure 3: Pinch test on the day 3 (day of the surgery) showing the generated laxity following the second application of the tape on day 2

Outcome

At one week the child was reviewed and healing was noted to be uneventful. Histological assessment showed no malignancy and the nevus excision was reported as complete. The mother was advised to continue applying paper tape with skin barrier cream to support and modulate the healing scar. Review at three months

post-surgery showed a good quality minimally stretched scar on the back (Figure 5). There was no residual pigmentation in the skin noted



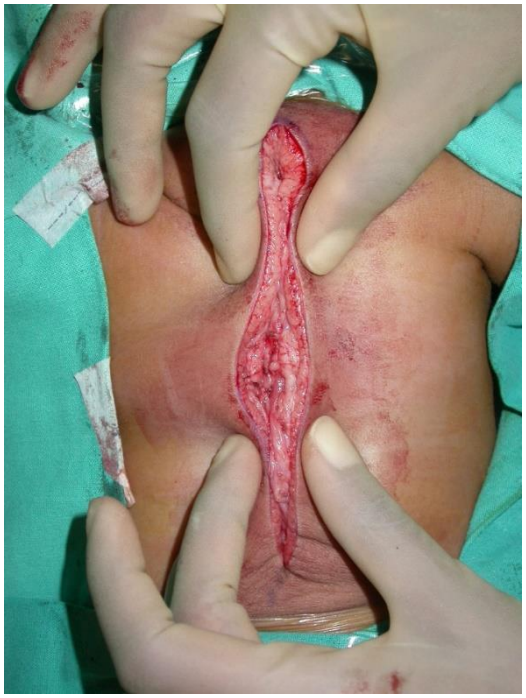


Figure 4a: The wound defect is shown on the back following excision of the nevus (Left)
Figure 4b: The laxity of the surrounding skin is demonstrated. Important to note that no undermining of the lateral flaps has been performed (Right).

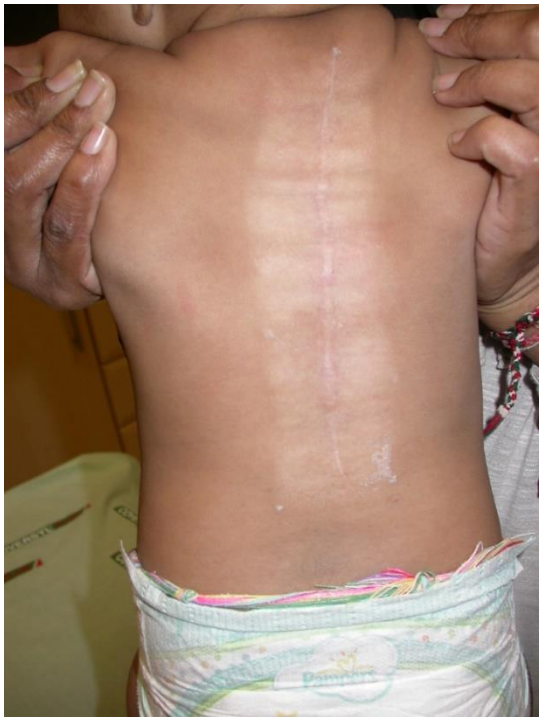


Figure 5: The outcome shown after 3 months of healing

Discussion

The described physiology of traditional skin of tissue expansion exploits the biomechanical properties of skin.(7-9) These include viscoelasticity, strain response, stress relaxation, tissue creep, and collagen realignment. The short time lapse in the production of additional skin by traction assisted tissue expansion by external means in this case report is likely to harness mainly these skin properties. These components are major contributors to the tissues acute response to the traction force and referred to as skin lengthening by mechanical creep. A two day application of strain is not likely to induce biological creep which includes amongst other changes collagen synthesis and rearrangement. This requires tension being maintained over period of time spanning days to weeks. Tissue expansion by tissue expander insertion relies significantly on this phenomenon, generating skin over a longer period of time.

On the other hand TATE may also induce gliding of the different tissue types between tissue planes to increase reach and is likely to be a significant contributor to the creation of the new skin for advancement. In addition effecting these biomechanical responses in the six week old infant may come with the of the added privileges of tissues and planes between them being more pliable due to higher elasticity, laxity and water content of the tissues. It is hypothesised that in rapid acute tissue expansion by TATE, pressure and tension displaces the water in the tissue, rendering them less turgid as deflation occurs to provide additional movement for harnessing in subsequent tape applications. These assumptions are worthy of further exploration.

This case report may represent the earliest age in a child in whom tissue expansion was used as well as the rate at which this was achieved. Clearly our technique cannot be applied universally to all presenting lesions because it relies on mechanical creep and the serial recruitment thereof. The relative size of the lesion to the surrounding normal skin of the various anatomical regions of the body is another important determinant. The pinch test in the region of the lesion is the surgeon's best tool in assessing the rate of tissue expansion and the laxity requirements to achieve the reconstructive goals.

Conclusion

The skin lengthening demonstrated in this case report over a period of two days has been remarkable. TATE is an important addition to the other many surgical strategies on offer in managing GCMN in early childhood. It is simple, easy to administer and can be combined with staged serial excision to enhance the tissue recruitment for larger lesions.

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Introduction to Chapter 6

In Chapter 5 the rate at which the expansion of the skin of the back in the 1 month child occurred was surprising. Tissue pliability and the fact that the lesion could be folded on itself to stretch the surrounding skin appeared to be an important contributing factor. In the following chapter, Chapter 6, TATE in used in a 1 year old child to expand the skin of the back to repair a recurrent myelomeningocele. In this child the inherent laxity of skin was limited, the subcutaneous fat was thick and the lesion itself could not be folded on itself to create space to stretch the surrounding skin from either side towards the midline. With the first application of the tape, there was some doubt as to whether TATE was going to be successful. With each application that followed thereafter the pliability of the tissue improved and the myelomeningocele appeared to decrease in size. The expansion progressed, taking a longer period of time than in the patient reported on in Chapter 5. Further, the pinch test before surgery was not able to demonstrate a simulated closure. But once the myelomeningocele was removed, the surrounding skin and underlying tissues advanced with ease. The simulation of the pinch test can therefore, especially in the presence of the thick layer of subcutaneous fat, be deceptive in predicting closure.

Chapter 6: Repair of a Recurrent Myelomeningocele associated with an Inclusion Epidermal Cyst Following Traction Assisted Tissue Expansion in a 15 month old Child

Key words

Myelomeningocele, recurrent myelomeningocele, tissue expansion, traction assisted tissue expansion, 3M™ Micropore™ Surgical Tape

Summary

The incidence of myelomeningocele (MMC) of the spine, with the lower back being the commonest site, is between 0.1 and 5 per 1000 birth. Recurrence after repair is very rare. The aim of the surgery is to release the neural placode and obtain a multi-layered soft tissue cover the central neural tissue. Defects reaching above 5cm cannot be closed primarily by direct advancement of tissues and would generally require plastic surgical reconstruction with a flap. The use of tissue expansion with the use of internal expanders to provide soft tissue flap cover is not common. It is nevertheless a useful strategy if conditions allow for its use. We present a 15 month baby who presented with a recurrent MMC measuring 9 X 10 cm who had undergone an external form of tissue expansion referred to as traction assisted tissue expansion with the use of the paper tape. The process took 3 weeks to produce soft tissues that was used to cover the defect that resulted from surgical excision of the MMC. We describe the technique and surgery, producing a good patient outcome.

Background

Recurrent MMC are relatively rare gauging from the lack of information on the entity in the literature. The management is dependent on the nature of previous treatment but in essence is best extrapolated from the management of the primary MMC. MMC

can present in various sizes. Surgical excision and direct closure is successful mainly for the smaller ones <5cm. Dural closure and adequate multi-layered soft tissue closure is essential for a successful outcome. The majority of MMC are required to be treated soon after birth. If repair can be delayed then tissue expanders in staged operations can provided adequate soft tissue cover.(1, 2) But, it is important to balance the risk and rewards. Larger MMC require some form of flap cover from a local or regional source.(3, 4) More than one flap maybe required to achieve durable closure.

Flap descriptions are numerous. These include:

- Direct closure with or without donor skin grafts.(5)
- Local fasciocutaneous flaps of different shapes, sizes and movements.(6-8)
- Paravertebral muscle and fascial flaps.(9)
- Regional muscle and musculocutaneous flaps and modifications thereof viz. latissimus dorsi and gluteus maximus flap.(4, 10, 11)
- Perforator flaps.(12, 13)

Many of these options could have been utilized in this case. There is certainly varying degrees of complexity in the execution of these flaps. To avoid such complexities it was decided, in the absence of urgency, to explore the feasibility of offering skin tissue expansion as a solution to achieving a durable repair.

Several authors have reported their experiences with the use of tissue expanders to provide good quality tissue for closure in cases where a delay in treatment by a staged procedure could be performed.(1, 2, 14, 15) These cases are few in numbers but in most instances it produced success. The use of tissue expanders despite its success is not without its risks.

Given the surgeon's clinical experience with TATE the parents were offered this option for achieving tissue expansion. The most significant benefit being that of no

donor site morbidity. Failure to have produced sufficient tissue for closure, traditional flap surgery was to be the default reconstructive strategy.

The management approach to this case report of a recurrent MMC was guided by principles of primary MMC management. The recurrent MMC was large and we chose to use a tissue expansion technique for its reconstruction. The case study aims to demonstrate the feasibility of achieving skin tissue expansion by the non-invasive, economical and pain free technique of traction assisted tissue expansion (TATE) in preparation for single stage excision and repair at age of 15 months. This would otherwise not have been possible without the use traditional flap reconstruction techniques reported in the literature.

Case Presentation

A Case study of a 15 month old child with a recurrent MMC is presented. He was a paraplegic with no associated central nervous system problems. He underwent the primary direct repair of the MMC at the age of four days. The healing was uneventful but a year later presented with tender swelling in the region of the previous repair. Of significance was minute amounts of occasional white discharge from a dimple in the scar for a few months. Magnetic resonance imaging showed a large recurrent MMC. He was referred to plastic surgery for assistance with providing for soft tissue cover during the planned revision repair of the MMC by the neurosurgeon.

On my clinical examination there was a 9 X 10 cm MMC at the lumbar region of the spine (Figure 1). The overlying skin had vascular staining in the superior portion and dimple in the skin was noted in the superior section of the scar. No discharge was noted. The child was 12 kg in weight. The local subcutaneous tissues surrounding the MMC was abundant and seemed to be fibro-fatty in consistency with very little laxity being generated on pinch testing of the skin. The overlying skin of the MMC also seemed to be adherent to its underlying sac. The plan was to generate skin laxity to enable removal all the overlying skin and soft tissues of the MMC and

provide primary closure by advancing the lateral soft tissue of the back. The parents were introduced to the concept of TATE to achieve this plan.

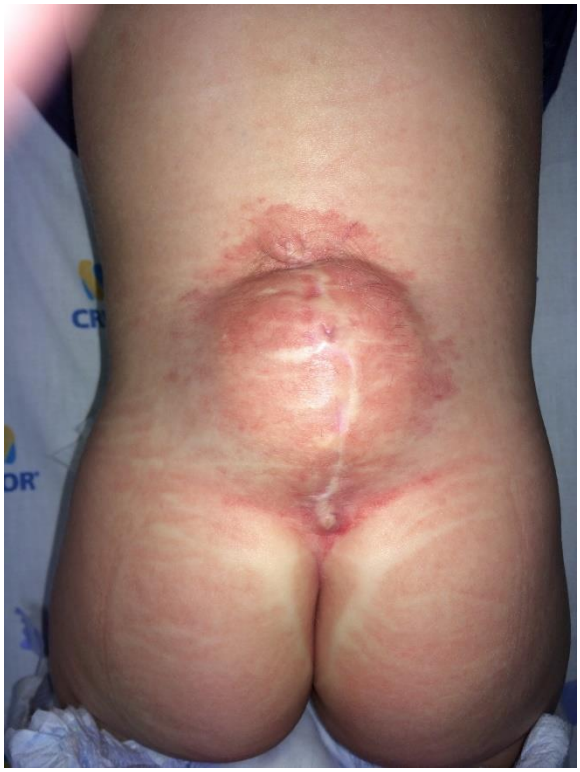

Figure 1: Fifteen month old infant with a recurrent lumbar MMC

Traction Assisted Tissue Expansion

The mother received instructions on how to perform the taping. For her to repeat several of the applications. The first and third application was performed by the treating reconstructive surgeon. During the procedure the child was to be laid prone. A skin barrier cream* was sparsely applied to the surrounding skin and the lesion. The skin was pinched vertically and folded in the midline of the back recruiting the immediate lateral laxity in the skin and held in place by the application of the paper tape^. The paper tape was removed at three day intervals repeating the procedure step above in order to recruit additional laxity. On assessment following two such applications to the back, the soft tissues showed good progress in tissue laxity. The patient was electively scheduled for surgery 2 weeks later, meanwhile the child's

mother was to continue with the taping. The child underwent a total of six episodes of paper tape application, of which four were performed by the mother.

* 3M™Cavilon™ Durable Barrier Cream

^ 3M™ Micropore™ Surgical Tape

Surgery

At surgery the MMC measured 5 x 11cm, demonstrating a shrinkage from the presenting size (Figure 2).

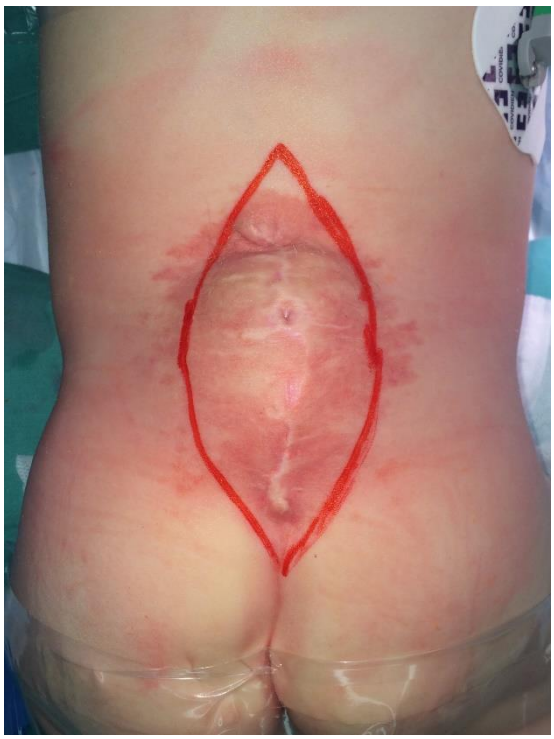

Figure 2: A reduced size of the MMC is noted on the day of the surgery

A sinus like opening was discernable on the skin surface in the superior section of the old scar. The overlying skin was excised exposing the subcutaneous tissue and the MMC sac. Pockets of keratin type debris in the subcutaneous tissue overlying the sac (Figure 3). The roof of the sac of the MMC with all its overlying tissue was then excised. The recreated defect measured 8 x 11 cm. The neural placode was released and the dura was mobilized from the lateral side walls of the open vertebral

canal and tubed centrally to achieve closure (Figures 4 and 5). Fibrin glue with a biologic dural patch was then laid over the suture line. The wound was closed in multiple layers after migrating without any release (explained later) the deep fascia surrounding the paravertebral muscles and finally the skin and subcutaneous tissue after minimal undermining (figure 6). The closure was relatively tension free. An adhesive dressing retention tape[+] was applied directly over the operation site for wound support.

[+] Hypafix®

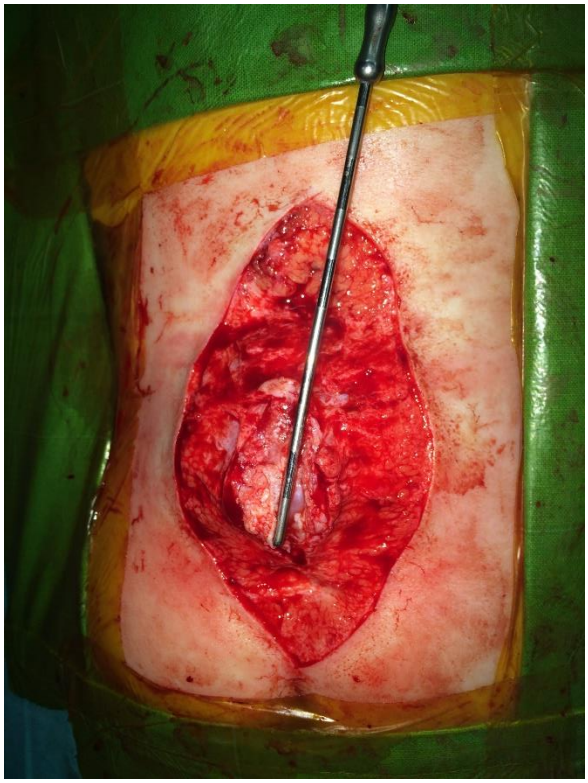

Figure 3: The wound defect is shown after removal of the skin. The probe shows the trajectory of excised sinus and white keratinous material is shown to lie in the subcutaneous tissue over the sac

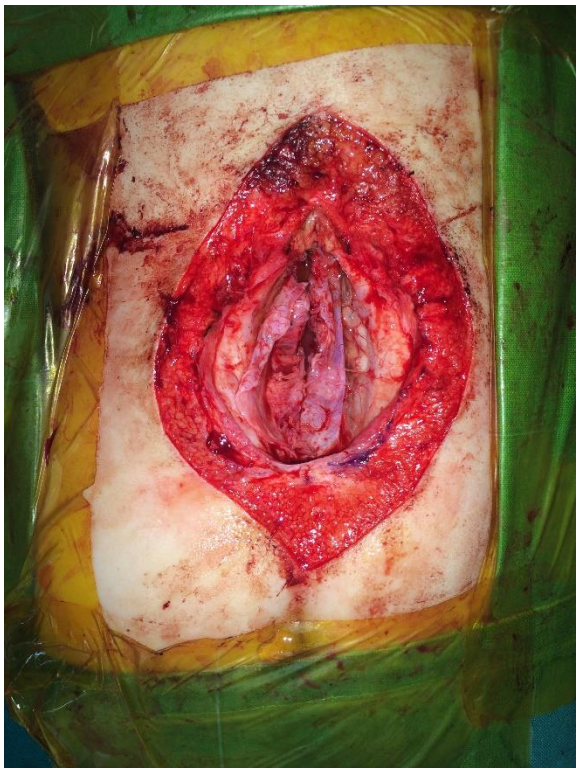

Figure 4: The dura is shown at a stage of the operation with it partially raised before completely mobilized to the midline

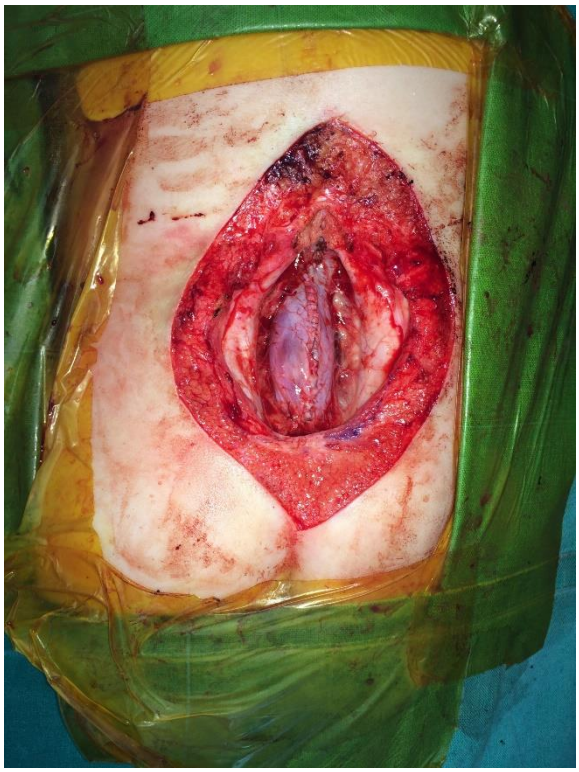

Figure 5: Complete central closure of good quality dura is shown

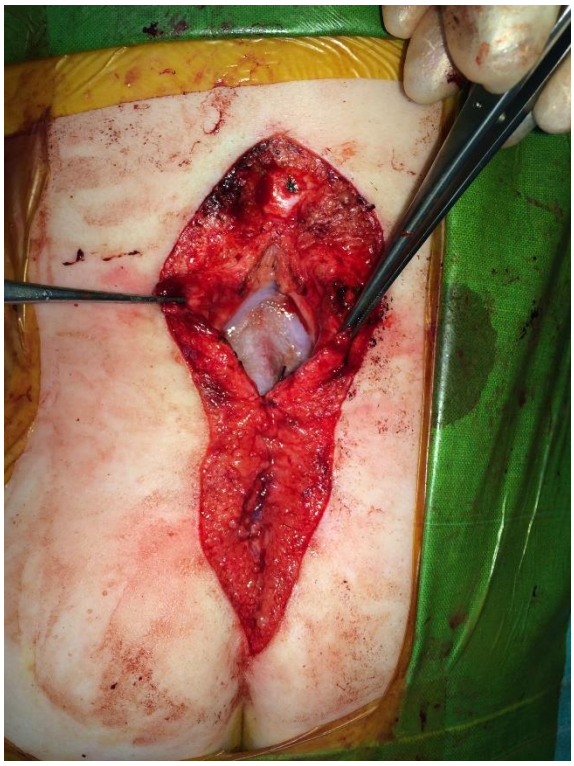

Figure 6: Partial closure of the fascial layer of the lateral flaps is shown

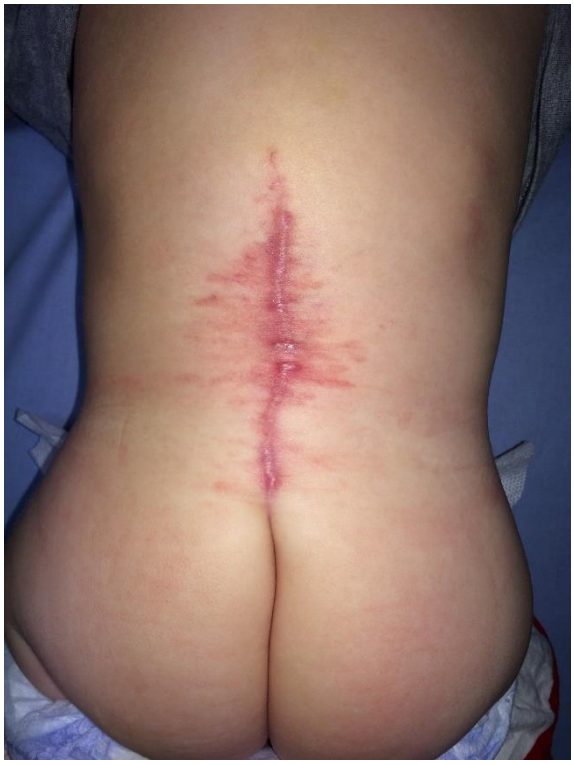

Figure 7: The surgical outcome is shown at 3 months

Outcome

The post-operative phase was complication free. At Three months follow up the suture line was well healed (Figure 7). The scar was hypertrophic. The histological report on tissue specimens taken at the operation confirmed a MMC with associated epidermal inclusion cysts. The latter was evident on microscopy as cystic inclusions with keratinized squamous epithelial lining. At 18 months follow up there was no evidence of any mass swelling at the operation site.

Discussion

Plastic surgeons are usually consulted for assistance with large MMC. In this case for a large recurrent one. The appropriate choice for soft tissue reconstruction is important to avoid complications of wound breakdown, tissue necrosis and cerebrospinal fluid leak. Many flaps have been described to provide cover for a spinal defect following the neural placode release and dural repair. Choosing the type and number of flaps will depend on multiple factors. Nevertheless a multilayered closure should be the aim.

Instead, an 8 X 11cm full thickness defect into the spinal canal was successfully closed by simple flap closure achieved by TATE. Surprisingly the deeper tissues including the dura lining the sides of the wide open vertebral arch and the deep fascia overlying the medial and posterior aspects of the paravertebral (erector spinae) muscle was easily mobilized without surgical release to achieve durable closure for the open spinal canal. The tissue expansion achieved gave the surgeon the freedom to remove all the soft tissues from the dorsal aspect of the MMC. At surgery the keratin debris was multiloculated within the subcutaneous tissues and the anterior portion of the sac was not separable from the dura. Aggressive resection was necessary to diminish a recurrence of the epidermoid cyst.

It cannot be generalized from this single report but it stands to reason that the traction assisted tissue expansion potentially transmits tension forces to the deeper lying fascial structures that were also conditioned to migrate.

Conclusion

The skin lengthening demonstrated in this case report over a period of three weeks has been remarkable. TATE is an important addition to the other many surgical strategies including traditional internal tissue expansion in managing this rare recurrent MMC associated with an inclusion epidermal cyst. It is simple and easy to administer. If the time line under appropriate conditions allow, then it may be applicable to managing a primary MMC in the neonatal period without the need for traditional flap surgery. A prospective cohort trial may be of value to further test this hypothesis.

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Introduction to Chapter 7

In Chapters 5 and 6 we observed two different type of responses to taping in the skin. In Chapter 5 we achieved rapid expansion which would support a postulate that the response was mainly as result of harnessing the viscoelastic properties of skin. Biological creep of tissue which we are used to seeing with tissue expansion with the use of tissue expander insertion, occurs over a longer period of time. In the next chapter, Chapter 7, the ability of TATE to stretch the surrounding skin in a period less than 24 hours to produce laxity for closure of skin ellipses created from removal of skin lesions, was tested. Sufficient skin laxity for closure in less than 24 hours was not reached in all patients. The period of taping had to be extended. It would seem that for larger lesions biological creep had to be stimulated to produce more skin. The viscoelastic properties of skin enabled acute laxity and as time passed with the tape applied stress relaxation occurred, producing ease of skin closure. The supply of skin for closure may be dependent on multiple factors such as age, anatomic region, thickness of skin and subcutaneous layer, and attachment of the skin to the underlying deep tissues. In Chapter 7, a cohort study of 11 patients with 14 lesions, the concept of pretaping to achieve easy direct closure of skin following elliptical excisions of skin and skin lesion is introduced. Pretaping is a shortened duration of TATE.

Chapter 7: Acute Tissue Expansion by Pretaping to Achieve Elliptical Excision and Closure for Skin Tumours and Soft Tissue Tumours

Key words

Skin tumuors, soft tissue tumours cutaneous squamous cell carcinoma, cutaneous basal cell carcinoma, melanoma, soft tissue sarcoma, tissue expansion, traction assisted tissue expansion, presuturing, pretaping, 3M™ Micropore™ Surgical Tape

Abstract

Introduction

An elliptical excision of skin and subcutaneous tissue for treating a tumour and closure represent the simplest form closure. For a good closure lateral laxity in the skin is essential. Other contributory factors are size of the lesion, orientation of the ellipse, anatomical area, age of patient. Insufficient lateral laxity will require flap closure and/or skin graft. Flap designs add complexity and requires plastic surgical training. Our objective was to stretch and precondition skin prior to surgical excision of tumour to increase the ability to simply close of relatively larger skin ellipses by harnessing the viscoelastic properties of skin. We introduce the concept of traction assisted tissue expansion (TATE) with paper tape naming it in this context as pretaping.

Patients and Methods

A retrospective cohort of all (11) patients presenting over a period of seven years that were eligible for this technique being used where the surgeon deemed the skin would not achieve simple closure following a direct elliptical excision of skin and soft tissue tumours was studied. TATE is a novel technique which uses application of paper tape to the skin and tumour to stretch the skin sufficiently to achieve surgical skin closure of an elliptical excision. Either a single or multiple tape application technique was used. Data collated and analyzed included patient demographic

profile, tumor profile, parameters associated with pretaping and clinical outcome. A descriptive account of eleven cases from categories differentiated by total time period for which expansion was used and nature of the tumour entity treated, will also be demonstrated.

Results

The pretaping was successful in all cases. A successful outcome was represented by a healed simple direct wound closure observed at 2 weeks following excision of the tumour. The average age of the sample was 48years. The sample represents 14 pretaping applications for 13 lesions. All applications were performed on limbs. The 13 lesions treated were made up of four melanomas, seven basal or squamous cell carcinoma and two soft tissue sarcomas. The total time period of each application varied from 30 minutes to 26 days. The cutaneous lesions average ellipse width was 25mm and soft tissue sarcomas average was 110mm.

Conclusion

Pretaping can within limits tissue expand skin to achieve simple skin closure following elliptical excision of skin and soft tissue tumours in patients that would have otherwise required skin grafting or skin flaps. Pretaping can be initiated days in advance to the day of surgery or for as little as 30 minutes prior to arriving in theatre for the procedure.

Background

An elliptical excision of skin and subcutaneous tissue for treating a tumour and closure represent the simplest form of bilateral flap closure and can be performed with relative ease. However, the amount of skin available to affect closure is important to consider. Skin grafts intended to cover a wound where there may be inadequate lateral skin coverage, are prone to failure. Therefore a technique for performing a wider ellipse with simple closure which would bel less dependent on

plastic surgical expertise as required for quality skin grafting and flap designing and use, would be welcome.

For a good closure lateral laxity in the skin is essential. Determining the lateral laxity is a skill that both medical practitioners and specialist acquire early in their training when removing small skin lesions and soft tissue lumps and bumps in patients presenting to them. The pinch test of the skin is the subjective method of assessing lateral laxity used by the surgeon to predict closure of a created ellipse.

The ability to affect a simple closure of an elliptical defect created by excision with a margin for skin tumours and deeper soft tissue tumours, is dependent on the size of the lesion, orientation of the ellipse, anatomical area, age of patient and the lateral laxity. In the absence of sufficient lateral laxity to the orientated ellipse and/or excision of relatively larger lesions, additional skill in the art of manipulating skin is required. Although not exclusive this art is mainly learnt in the practice of plastic and reconstructive surgery. If the surgeons feels that it will not close then he needs to design another approach for excision and flap closure and/or skin graft. Flap designs add complexity and requires plastic surgical training.

If simple closure is to be achieved for excision of lesions that fail the pinch test by a minimal extent, and rapid skin expansion for that lesion can be produced then complexity of flaps and skin grafting can be avoided. Liang was the first to describe presuturing both experimentally in pigs and in clinical cases to achieve wound closure.(1) The technique relies on the skin being sutured over the proposed ellipse of skin minutes prior to it being excised. It requires the area of the excision to be anaesthetised before placement of the sutures. The technique intends to harness the viscoelastic properties of skin by inducing stretch prior to the elliptical skin excision and closure. However, its practical value has been limited largely because it is invasive and requires administration of an anaesthetic for both the presuturing and the definitive procedure.(2)

We introduce the concept of traction assisted tissue expansion (TATE) with paper tape on similar principles of presuturing. We present a case series to illustrate the utility of pretaping the skin prior to skin tumour or deeper soft tissue tumour excision. The objective is to achieve a simple closure following an adequate elliptical skin excision thereby highlighting the novel use of traction assisted tissue expansion with paper tape as an equivalent procedure to presuturing but without its disadvantages. The concept of TATE for skin lesion management will be referred to as pretaping in this paper.

Patients and Methods

This retrospective cohort study based on medical records included all (11) patients presenting over a period of seven years that were eligible for this TATE technique being used where the surgeon deemed the skin would not achieve simple closure following a direct elliptical excision. If the skin deficit for closure was judged to be small to moderate in relative terms, taping was applied prior to the excision if the surgeon subjectively felt that tissue expansion could be achieved in a relatively short period of time without undue risk to the patient and delays. These cases would have otherwise required local flap surgery or skin grafting to achieve post excision wound closure.

Data collated and analyzed included:

- Patient demographic profile.
- Tumor profile including diagnosis, size of lesion with and without margins of excision and anatomic region involved.
- Attributes associated with pretaping including total time period of application, Time interval period between each episode of application, total number of applications per lesion treated.
- Clinical outcome.

A descriptive account of eleven cases from categories differentiated by total time period for which expansion was used and nature of the tumour entity treated, will also be demonstrated.

Description of Pretaping

Single Application Technique

Cutaneous lesions just failing to reach a simulated closure by pinching can be subjected to a single taping session of 30 to 60 minutes performed outside of theatre prior to the surgery. Case 4 from our case series is an example of this technique.

A border is marked with a pen around the lesion. To this an appropriate circumferential surgical margin guided by the tumour diagnosis is drawn. The marked outline is converted to an ellipse for excision and to facilitate easy closure (Figure 1a). On the limb the longitudinal axis of the ellipse is usually orientated along the long axis. If pinching the ellipse to test for closure fails to assure the surgeon of closure then the pretaping technique is applied.

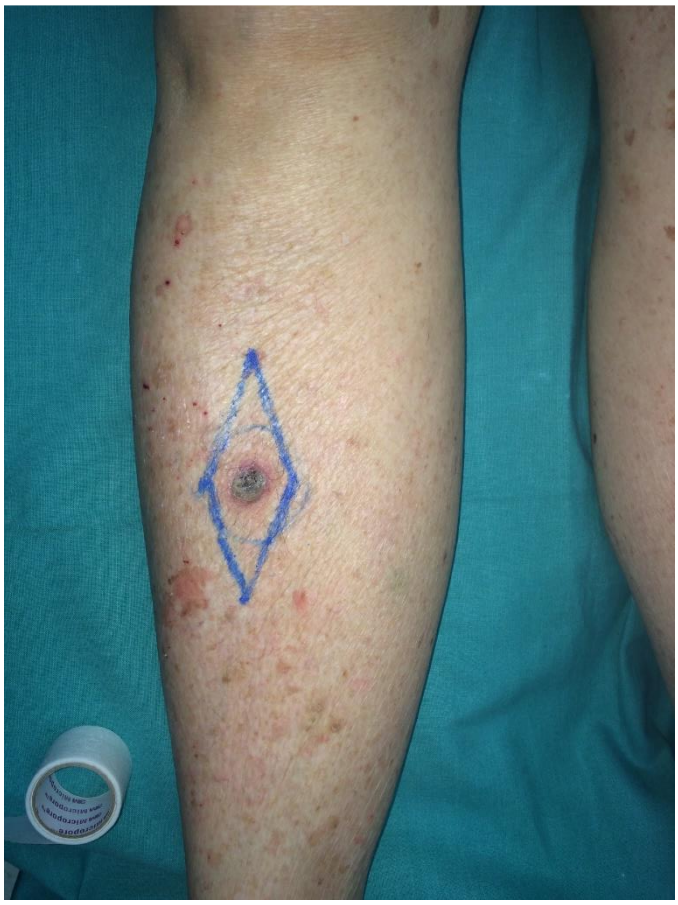


Figure1a: Case 4 shows a Bowenoid lesion on the anterior aspect of the leg which is marked as an ellipse of 27mm x 70mm

The process is initiated by first applying sparse amounts of skin barrier cream* to the skin around the lesion. Using the immediately available skin's lateral laxity, skin lateral to the longitudinally arranged ellipse is manipulated using fingers and migrated to its central axis. The ellipse is allowed to concertina and the paper tape^ is applied perpendicular in direction to the elliptical axis holding the migrated skin from each side in position (Figure1b). To optimise the splintage of the skin and the tapes adherence, the tape edge is overlapped slightly. The ends of the tape on either side of ellipse are taped down if required with another single strip of tape parallel to ellipse. The taping is best performed in the waiting ward prior to arriving in theatre or procedure room. After a 30 to 60 minutes, the surgeon can pinch the skin with the tape in place in order to test for the gain in skin laxity. If the pinch test

fails then the period can be extended a few more hours and may even have the tape reapplied for additional skin recruitment.

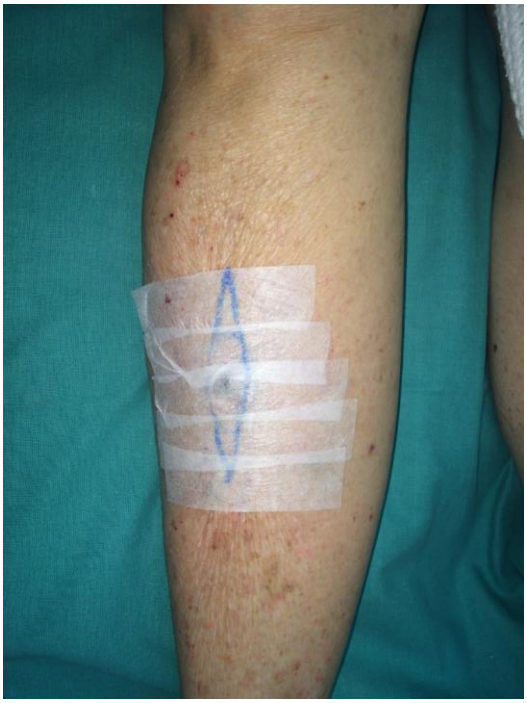


Figure 1b: The ellipse is pretaped for a period of 30 minutes recruiting the lateral laxity

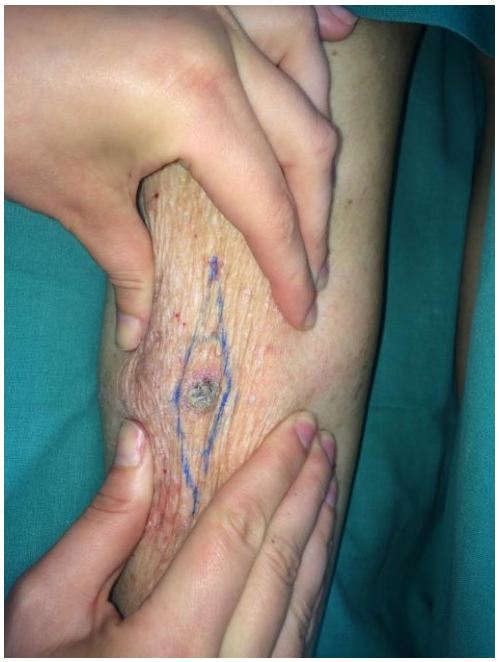


Figure 1c: The generated laxity is being demonstrated after the removal of the tap

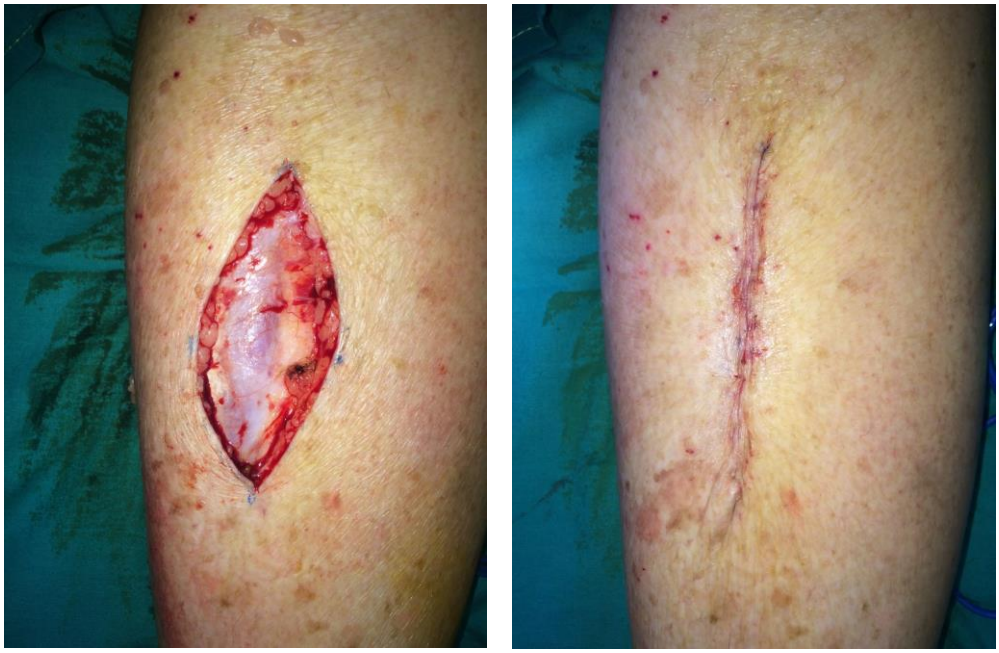


Figure 1d: A 33mm X 70 mm defect is shown before closure (Left)
Figure 1e: A straight line closure is obtained with a 2 layered repair (Right)

When adequate skin is obtained, the tape is removed just prior to cleaning the skin for surgery. The laxity generated can be checked (Figure 1c). After cleaning the ellipse is excised and closure is obtained in a multi-layered closure with final layer being subcuticular running suture (Figure 1d and e). The closure will, in most cases be tensionless.

* 3M™Cavilon™ Durable Barrier Cream

^ 3M™ Micropore™ Surgical Tape

Extended Multiple Application Technique

Larger lesions, lesions with significant underlying or overlying fat and/or tight skin and/or those cases anticipated not to generate sufficient skin with a once off short-term application, the taping is applied for a day or more prior to the surgery. Case 10 and 11 (See Figures 4 and 5) are examples of this type of technique.

In many instances scheduling the elective surgery produces a patient waiting time period lasting many days. This time can be used for pretaping in preparation for the surgical excision and skin closure. The interval between applications can be anything from one to seven days. Application interval is frequently a matter of convenience for both doctor and patient. However, a daily application is likely to produce a faster rate of tissue expansion reaching sufficient lateral skin laxity to affect closure of the post tumour excision defect. To maintain the tissue expansion of the skin taping must continue up to the time of the surgery. Even with limited experience with the technique, the surgeon will be able to estimate the length of time and the number of applications of paper tape required.

Aftercare

The suture line is then supported externally by application of adhesive dressing retention tape[+]. This tape can get wet during showering and is only removed five to seven days later upon follow up. Further ongoing self-administrated taping with skin barrier cream and micropore is usually recommended to the patient for a period of six weeks for additional support and scar management.

[+] Hypafix®

Results

The pretaping was successful in all cases. A successful outcome was represented by a healed by simple direct wound closure at 2 weeks following excision of the tumour. The first case where the pre-taping technique was used was performed in 2009 (Table 1 is summary of cases treated). The average age of the sample was 48years (range 33 to 68 years). Five cases were male. The sample represents 14 pretaping applications for 13 lesions. One patient (Case 9) had pretaping applications where a melanoma was treated by a second wider local excision following the first to achieve adequate margins of excision for the same lesion (Figure 2a-d). Another patient had three pretaping applications for 3 separate on the

opposite sides of the same leg, which were managed simultaneously (Figure 3a and b).

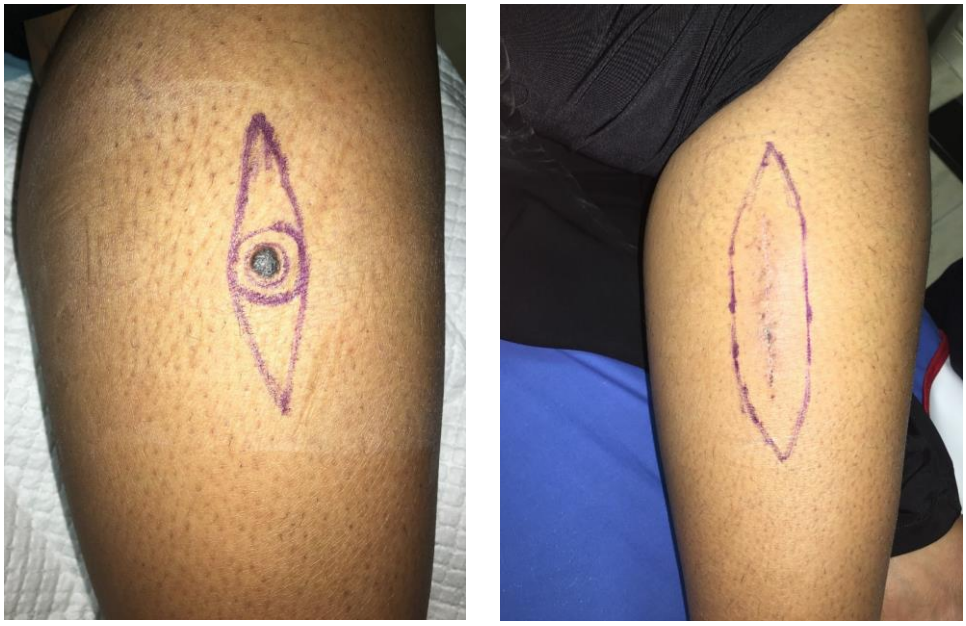
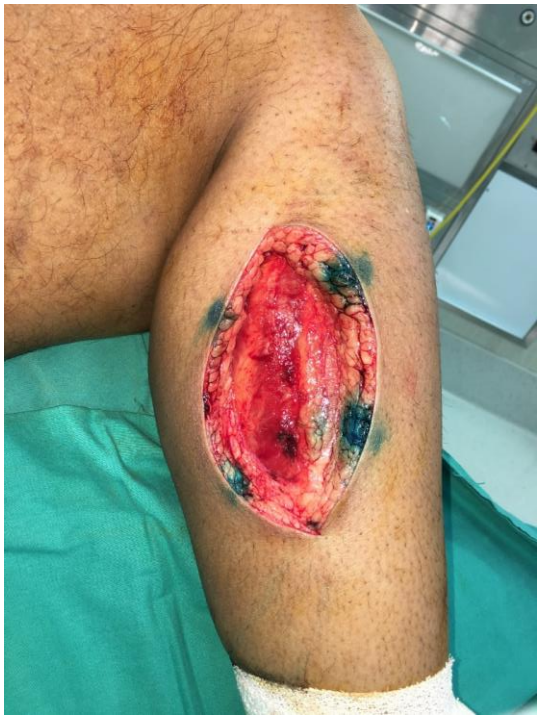


Figure 2a: Case No. 9 shows a melanotic lesion clinically suspected to be dysplastic nevus marked to be removed with a 5mm margin. The ellipse is shown measuring 20mm X 50mm prior to the application of pretaping for 30mins. N.B. the patient had significant amount of subcutaneous adiposity and limited laxity (Left)
Figure 2b: The same is leg is being shown 3 weeks later with a healed scar with a 15mm margin marked on either side with the ellipse measuring 30mm X 120mm to achieve a wide local excision for 1,6mm Breslow's thickness melanoma. A 2nd set of tape application for a period of 2 days before surgical excision, is to follow (Right)



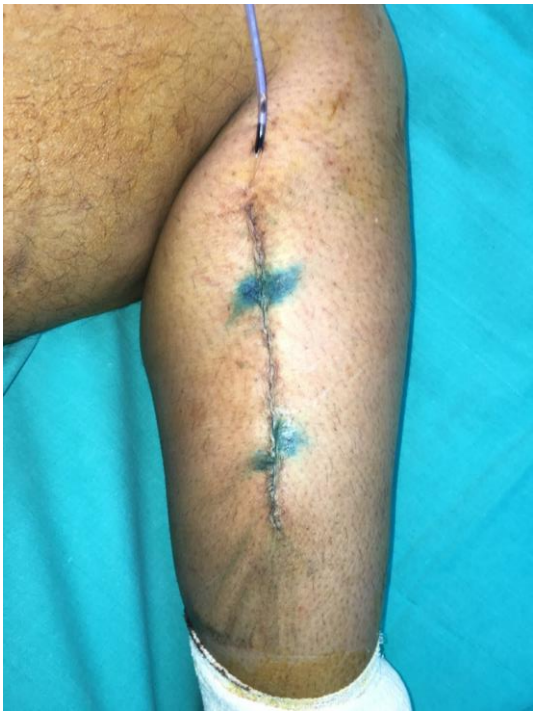
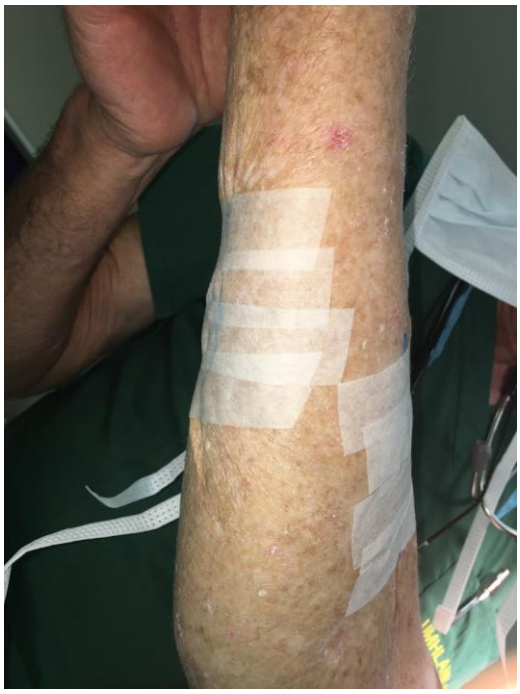


Figure 2c: The defect post excision measuring 80mm X 140mm is shown (Left)
Figure 2d: A straight line closure is obtained with a 2 layered repair (Right)

Table 1: Summary of cases treated

Case number	Application number by lesion	Treated condition	Ellipse size	Anatomical position of defect	Total period of application	Number of applications
1	1	Bcc and Scc	27mm X 75mm	anterior leg shin	60 minutes	1
1	2	Scc	80mm X 30mm	anterior leg shin	60 minutes	1
1	3	Scc	78mm X 27mm	calf	60 minutes	1
2	4	melanoma in situ	20mm X 55	volar forearm	30 minutes	1
3	5	melanoma 1 mm	35mm X 100mm	lower leg posterior	30 minutes	1
4	6	bowenoid lesion	27mm x 70mm	anterior leg shin	30 minutes	1
5	7	Bcc	16mm X 50mm	anterior lower leg shin	30 minutes	1
6	8	Bcc	47mm X 20mm	anterior leg shin	30 minutes	1
7	9	Bcc	25mm X 60mm	lateral lower leg	30 minutes	1
8	nil	lentigo maligna melanoma	66mm X 32mm	lateral arm	nil	nil
8	10	lentigo maligna melanoma	140mm X 44mm	lateral arm	18 days	4
9	11	dysplastic nevus	55mm X 20mm	posterolateral	30 minutes	1
9	12	melanoma 1.6mm re-excision	30mm X 120mm	posterolateral	2 days	3
10	13	sarcoma thigh	120mm X 180mm	anterior thigh	26 days	5
11	14	angiosarcoma	100mm X 350mm	anterior thigh	1 days	1

Scc Squamous cell carcinoma
Bcc Basal cell carcinoma



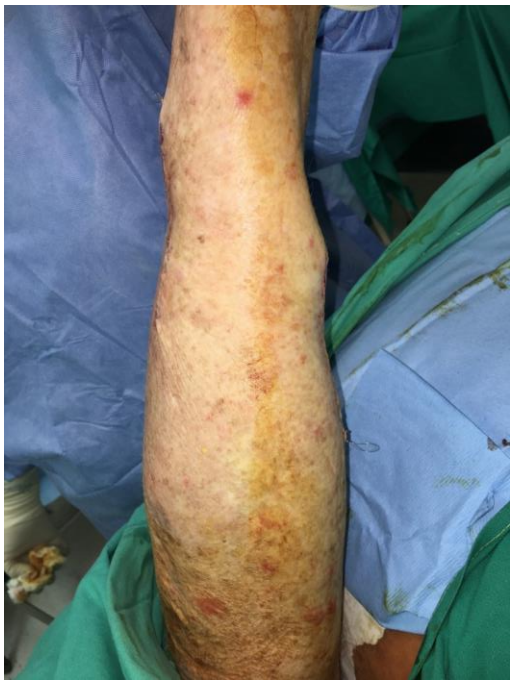


Figure 3a: Case No.1 is shown with 2 sections of the leg being pretaped for lesion on opposing sections of the leg (Left)
Figure 3b: The leg is shown in posterior view having obtained closure of a combined post excision defect measuring 75mm in the horizontal plane (Right)

All applications were performed on limbs. Of the 14, 12 applications were performed for cutaneous lesions with 10 in the legs and 1 each in the arm and forearm. Two cases 2 (No. 10 and 11) were on thighs for soft tissue sarcomas (Figures 4a-d and Figures 5a-d respectively). The 13 lesions treated were made up of four melanomas, seven basal or squamous cell carcinoma and two soft tissue sarcomas.

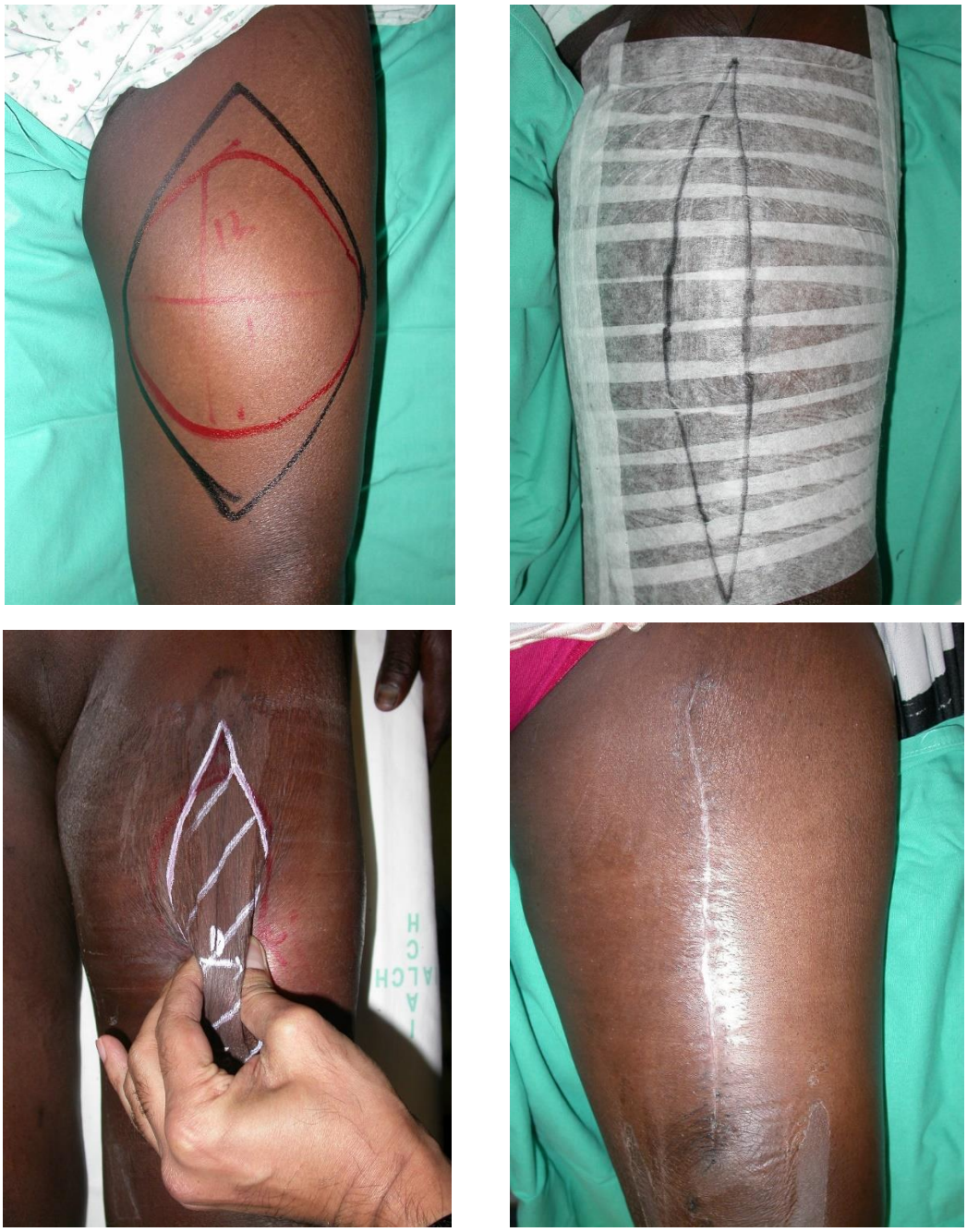


Figure 4a: Case No.10 shows a sarcoma originating from the deep anterior aspect of thigh which requires removal of the overlying skin for achieving a wide local excision. The initial ellipse size measured 120mm x 180mm (Upper left)
Figure 4b: The reduction in the ellipse as indicated by the black line seen through the tape is demonstrated on day 25 (day before surgery) with the 5th episode of pretaping (upper Right)
Figure 4c: Significant softening of the tissues with generation of laxity is shown by the pinch test on the day of the surgical excision (Lower left)
Figure 4d: A healed wound is demonstrated 1 month after surgery (Lower right)

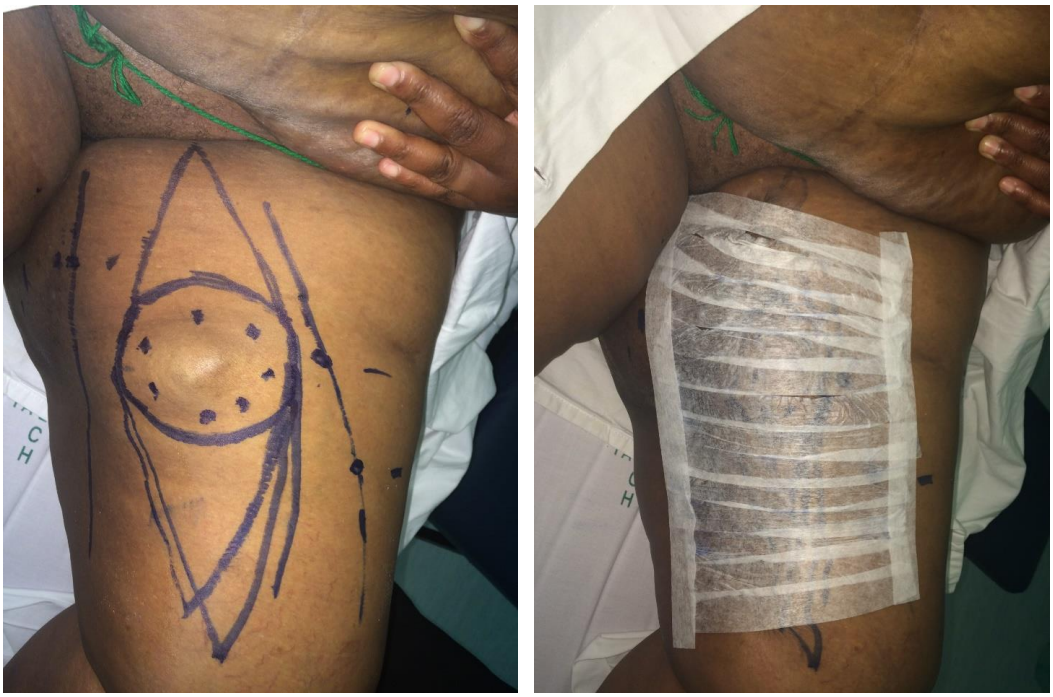


Figure 5a: Case No. 11 shows an angiosarcoma arising in the subcutaneous tissue requiring removal of overlying skin measuring 100mm x 350mm (Left)
Figure 5b: The patient undergoes an overnight single episode of pretaping (Right)

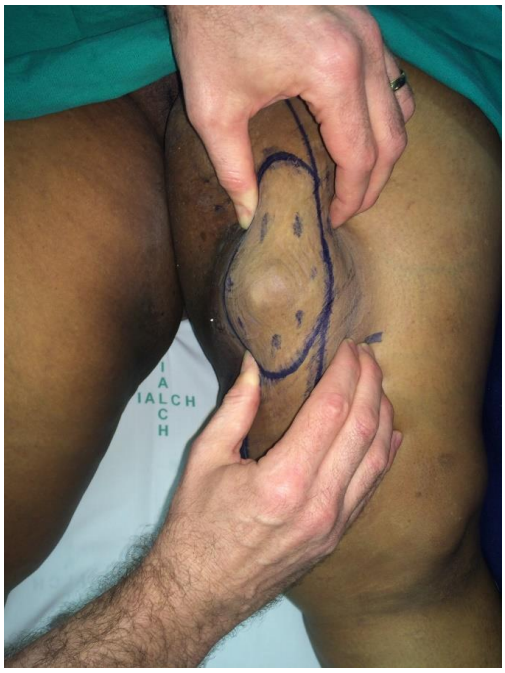


Figure 5c: In a significantly fat thigh the generated tissue laxity is demonstrated after removal of the tape just prior to surgery (Left)
Figure 5d: The thigh is shown with a hypertrophic scar 2 months post excision and closure (Right)

The total time period of each application varied from 30 minutes to 26 days. The total number of re-applications per set varied from 1 to 5 with a time period of each application varying from 15 minutes to 7 days. (See table 2 giving an expanded overview categorized for cutaneous vs soft tissue sarcoma lesions)

The cutaneous lesions average ellipse width was 25mm (range 16 to 44mm) and soft tissue sarcomas average was 110mm (range 100 to 120mm). (See Table 3)

Table 2: Parameters of pretaping measured for cutaneous and soft tissue sarcoma

		Cutaneous neoplasm	Soft tissue sarcoma
Total time period of each set of pretaping application	30 to 60 minutes	10	
	1 days		1
	2 days	1	
	18 days	1	
	26 days		1
Number of applications per set	1	10	1
	2	0	0
	3	1	0
	4	1	0
	5	0	1
Time period of each application	15 minutes	2	0
	30 to 60 minutes	10	0
	1 days	2	2
	2 days	0	0
	3 days	0	1
	6 days	3	0
	7 days	0	3

Table 3: Tumour size and excised tissue ellipse width for cutaneous and soft tissue sarcoma

	Cutaneous neoplasm		Soft tissue sarcoma	
	Size (mm)	Size with margin (mm)	Size (mm)	Size with margin (mm)
Range	7 to 16	16 to 44	80 to 100	100 - 120
Average	12	25	90	110

The cases

Case 1, a 68 year old male had 2 longitudinal elliptical excisions for 2 individual skin lesions on the leg preceded by taping performed simultaneously for each (Figures 3a and b). With pretaping a total of 57mm of horizontal width of the skin was removed and closed primarily. Case 9, a 37 year old female with a body mass index of 40 had melanoma removed by longitudinal elliptical excision and closure in 2 stages (Figures 2a-d). The first for diagnosis and the second for completion of treatment to obtain adequate margins. A total of horizontal width removed in the presence of significant adiposity was 50mm. A single application of pretaping was performed for the 30 minutes during the first stage followed by 3 weeks later 3 applications .during the second stage. The initial 2 application lasted a day each and the last 15 minutes just prior to surgery.

It is my opinion that in both these cases direct closure would not have been achievable without pretaping. Instead split skin grafting would have been necessary with its resultant contour defect. Although the use of a flap may avoid this, elaborate designs like the keystone flap are usually required which demands a higher level of complexity.(3, 4)

We foresee that cutaneous lesions will most likely be the main indication for pretaping. But its use for deeper soft tissue tumours that also requires excision of skin has the potential of having the complexity of the skin defect reconstruction downgraded. Significant size defects require flap surgery. Momeni et al showed in 9 cases of distal extremity, the use of the anterolateral thigh flap to achieve limb preservation.(5) The thigh on the other hand does have a greater abundance of tissue but large resection defects created not infrequently require free or regional flaps. In this series 2 cases presenting with a sarcoma of the thigh were treated with the described technique.

Case 10 (Figures 4a-d), a 59 year old female and case 1 (Figure 5a-d), a 33 old female was pretaped for a period of 26 and 1 day respectively. Case 10 showed demonstrable tissue expansion in the first 24 hours but the taping was continued until the day of the electively booked surgery. One day was not enough but it highly probable that if the taping continued as a daily new application, the required tissue expansion could have been achieved in a few days to a week. The patient was instead taped as an outpatient on a weekly basis for 3 weeks followed by 2 additional sessions 4 days before surgery. Case 10 and case 11 had 120mm and 110mm of horizontal width of skin excised respectively. Based on my longstanding clinical experience in excising and reconstructing defects of the thigh for soft tissue sarcomas the laxity generated by the pretaping for closure of the longitudinal defect was remarkable. Achieving direct primary closure decreases morbidity in comparison to the use of flap surgery for defect closure following soft tissue sarcoma excision. This was demonstrated by Kang et al who used the propensity score analysis in matched patients from each group from a cohort of 148 patients.(6)

Discussion

Orientation of lesion

Although elliptical excision and closure can be simple, the orientation of the ellipse is vital. Langer's line should be observed.(7) Orientation of ellipse along the relaxed tension lines (RTLS) is important for harnessing laxity and scar orientation for best possible functional and aesthetic outcome. Anatomical location determine the orientation of these lines. In limbs a vertical orientation of the ellipse does not coincide with RTLS. Nevertheless outside the zone of flexion creases the surgeons seems to default to this orientation especially for larger lesions. A longitudinal elliptical orientation may offer in theory oncological benefit. A wide field of excision can be achieved of the longitudinally arranged lymphatic drainage channels. This may be especially important when dealing with squamous cell carcinomas and melanomas. . Therefore, depending on the anatomic positon of the lesion on the limb, the size of the lesion, age of patient and adiposity of the tissue, the available

tissue for closure may be limited in supply. Pretaping may be a very useful adjunctive step to managing skin tumours.

The theoretical concept of orientating the ellipse in a specific direction from an oncological perspective is less relevant in the trunk region. Because in this region, lymphatic drainage patterns despite being anatomically mapped to drain to a particular nodal basin the direction cannot be predicted on a patient to patient basis without a direct mapping being performed. Orientating an ellipse along RTLS when possible will give best possible aesthetic outcome. Further the trunk region is a privileged site with a greater degree of multi-directional laxity and therefore relatively larger lesions can be managed by an elliptical excision and closure. Pretaping therefore may be of less value in this region.

The other important anatomic region with the highest incidence of skin tumour is the head and neck. This region has a high degree of sensitivity to aesthetics and therefore the best option may not be an ellipse. Small lesions certainly benefit from orientation along Langer's lines but ellipses for larger lesions result in longer scars. These may be some of the reasons why in my practice only limbs defaulted to use of the pretaping as an adjunct to elliptical excision and closure in our series. As a group the trunk and head and neck region was not specifically excluded from the technique of pretaping being used.

Study

All cases treated were adults mainly because of population bias arising from those patients presenting to the surgeon for management. The technique is easily applicable in children with no discomfort. Tissue laxity differs across the age groups. Older adult patients present with greater laxity giving the impression of greater apparent skin availability. In younger adults and children the skin appears to me more taught because of the better dermal quality and elasticity of skin but harnessing of mechanical creep to provide length in the skin by taping is likely to be

readily available as demonstrated in a previous series.(8) It is not possible to comment at this stage though which group will provide a better quality and rate of tissue expansion.

The leg region in clinical practice seems to provide a tighter envelope of skin in comparison to other regions of the body and is less amenable to direct skin advancement in closing defects. The leg is therefore likely to be a significant beneficiary of the pretaping technique. The following two cases from the series best validates this point.

In this series the 12 of the 14 paper tape applications for pretaping was applied for a period of 30 minutes to 2 days only. Hirshowitz demonstrated the value of skin stretching devices preoperatively (equivalent to presuturing) lasting 1 to 2 days and intraoperatively for 20 to 30 minutes.(9) In our other 2 cases, case 8 and case 10 the total period of application was 18 and 26 days respectively. As for case 8, case 10 was also given an elective booking date for surgery. In addition the taping as instructed was performed by the patient at home in preparation for the surgery. These 2 cases for the total time period of pretaping required for skin tissue expansion should be considered as potential outlies. .

One of the shortcomings in this study is that it provides only level 4 scientific evidence. Sceptics may argue that the surgeon may have been able to achieve in many of the cases undergoing less than 60 minutes of pretaping, closure. They may also argue that undermining of the lateral flaps to close is all that is required. In all lesions except case 10 with a sarcoma.no undermining of tissues was performed to close the defect. Even in case 10 undermining occurred by default as result of the tumour excision. Although undermining would result in more tissue recruitment this was not deemed necessary in most of this cohort of patients. Chandawark et al demonstrated the value of acute tissue expansion (ATE) in cohort of 21 consecutive patients that addition of ATE to skin undermining provides more skin than

undermining alone.(10) The addition of undermining can easily be performed following pretaping especially when treating larger lesions. Removing lesions by elliptical excision and closure in the absence of sufficient laxity, undermining may not overcome the problem of tension across the suture line. Tension generated across the suture line especially in the skin of the elderly patient who may not be able hold the sutures and the risk of immediate dehiscence is real.(11) As surgeons even if we commit tension in our suturing we do rely on stress relaxation time of the skin to allow for the decrease in the tension of closure.(12) This is unfortunately not a limitless property of skin. In the interim there is tissue ischaemia and potential inadequate tensile strength in skin closure predisposing to wound dehiscence. Therefore closing under tension is no assurance of complication free wound healing. In all 13 lesions there were no wound disruptions and healing was uneventful. At the very least tension reduction is achieved.

The only problem experienced was lymphedema in case 12. The cause for this is speculative but the skin excision was full thickness including the deep fascia over wide territory along the saphenous vein and its major associated lymphatic channels. The patient's body mass index was also > 40 but the lymphedema responded to conservative therapy.

The physiology of the skins response to pretaping specifically has not been elucidated. The conceptual framework based on theory for the observed tissue expansion is worthy of exploration. In pretaping tissue expansion is achieved by the predominance of 2 types of mechanical forces. They are traction on the skin surrounding the marked ellipse and compression of the ellipse. The compression is created by the downward pressure of the tape on the elliptical skin and the lateral side to side bunching arising from migration of tissue to the centre. Mechanical forces generated by this technique not only assist in stretching the surrounding skin but also reduces the size of the ellipse. Although not directly relevant in the context

of this study Morabito et al demonstrated the use of traction-compression as a mechanical agent of closure in treating major exomphalos in neonates.(13)
An alternate concept is that pretaping can be considered as preconditioning the skin to potentially closing the skin under tension. In fact in all our cases the stress relaxation in the skin occurred upfront to the skin elliptical excision and closure was tension free. Herein lies its major benefit for even borderline cases for elliptical excision and closure.

At a molecular level by recruiting mechanobiology by the upfront traction application, changes in growth factors induced by the strain may be of benefit in wound healing.(14) Erba et al demonstrated in his experimental study with the use of computer controlled stretch device on the back of mice that skin stretching is associated with dermal angiogenesis and the activities associated with vascular endothelial growth factor increased as early as 2 hours after starting of skin stretching.(15) Pretaping is likely to achieve the same and that the initiation of neovascularisation pre-empting the surgery is very likely to be of value in augmenting wound healing. Chin demonstrated experimentally in mice that application of tension induces hypoxia and with cyclical loading this was transient but post stretch analysis demonstrated well oxygenated tissue and that growth factor profile changes brought about by mechanotransduction accelerate tissue growth.(16) This may not be present with pretaping for short periods of once off pretaping but the potential for harnessing this property by pretaping for longer periods is probable. Chin also in a similar experimental model demonstrated the release of neuropeptides with skin stretching but its value in the context of pretaping remains speculative and worthy of exploration.

The practice of the intraoperative tissue expansion by load cycling is effective primarily for limited expansion for small defects.(12) Marrero demonstrated the success of a stretching device in 6 of 7 patient in achieving closure during Mohs surgery for basal cell carcinoma in extremities and face.(17) Machida demonstrated

in a guinea pig model its value, although less in length gain in comparison to chronic expansion.(18) Guida demonstrated in pigs that at the microscopic level dermal capillaries were dilated in intraoperative expansion group as opposed to the control group.(19) These findings may be relevant to pretaping.

It is important to note that as with any tissue expansion process gain in skin length is time dependent. Therein lies the handicap of the presuturing technique. From a practical point of view the performance of presuturing is confined to a short period of time during the same anaesthetic whilst the surgical team prepares for the completion surgical excision and closure. Presuturing as a separate procedure performed hours in advance to final procedure of skin lesion excision will deliver the advantage of tissue gain but adds to the cost, risks and inconvenience of an additional procedure. This maybe the reason why presuturing may not have stood the test of time. Although Anstad writes in his discussion without scientific backing that undermining extensively may achieve the same as presuturing without any untoward effects he remained sceptical on the need for presuturing.(20) We don't agree but with pretaping we have absolutely nothing to lose. Pretaping overcomes many of the issues associated with presuturing in that it is non-invasive and can be repeated as many times as required for weeks to reach the desired endpoint of appropriate skin tissue expansion. Its role in excising lesions can be considered as both prophylactic and therapeutic for tension reduction in closing created wounds. Its role in assisting wound healing by introducing a pre-emptive mechanical force to surgical excision remains of point of interest and research in progress will shed more light.(21) Pretaping is been considered in this study as an ideal substitute for presuturing and therefore its value in extending its application for procedures like rhytidectomy is worthy of exploration.(22)

Conclusion

Pretaping can within limits be offered to patients who require a significant sacrifice of tissue for skin and soft tissue tumours that will otherwise not qualify for tumour

removal by direct elliptical excision and simple skin closure. Pretaping can be initiated days in advance to the day of surgery or for as little as 30 minutes prior to arriving in theatre for the procedure.

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Introduction to Chapter 8

In Chapter 7 an acute form of tissue expansion was achieved with short term taping. By pretaping for less than one hour in many cases the skin stretch was achieved during admission, a few hours before surgery. In Chapter 3 the tape was applied to achieve TATE with the change of the tape occurring once a week. This was performed to emulate the tissue expansion with the use of tissue expanders which are usually inflated once a week. In Chapter 8 the tape change was made more frequently having prospered from the learning experiences of the study in Chapter 7. This strategy of changing the tape every 24 to 48 hours made sense because TATE was being used to close open wounds of open amputation stumps in three cases. Hypothetically speaking tissue expansion could be achieved at a faster rate to obtain surgical wound closure by a more frequent change following a shorter period of tape application. Wound size reduction and change in the shape of the wound observed whilst taping was an interesting phenomenon.

Chapter 8: The use of Paper Tape Application in Skin Tissue Expansion to Achieve Closure to Salvage Guillotine Amputation in the Lower Limb

Keywords

Limb amputations, guillotine amputation salvage, tissue expansion, traction assisted tissue expansion, 3M™ Micropore™ Surgical Tape

Abstract

Introduction

In a guillotine type lower limb amputation without local skin flaps for closure, rehabilitation of a critical length stump pose some reconstructive challenges. Many surgeons may default to a higher level amputation above the existing joint to achieve closure but not without sacrificing leverage with potentially negative consequences. This case series aims to investigate the novel use of rapid sequence serial traction assisted tissue expansion with paper tape to achieve closure of a presenting lower limb amputation stump at a critical length.

Patients and Methods

A retrospective chart review of cases treated by traction assisted tissue expansion (TATE) for lower limb amputation since its inception in 2014 was performed. Data collated and analysed included demographic profile, morbidity factors, level of amputation, defect type (open wound or healed scar), size of defect, Paper tape application parameters inclusive of time line to taping, number of applications and duration of application, size of surgical defect and duration of follow up. TATE is novel technique which uses the serial application of paper tape to the skin and wound or scar to stretch the skin sufficiently to achieve surgical skin closure of the amputation stump.

Results

Four cases were treated using the technique of TATE to achieve stump closure in lower limb amputations. The subjects were all males with an age range of 22 to 66 years old. All patients presented with a considerable size defect and required between 2 to 33 applications of tape per case with interval of one to three days between each application. The size of defect ranged from 110mm X 70mm to 160mm X 150mm. The length of time tape was applied per case ranged from 1 to 52 days. The only complication experienced was skin de-epithelialization.

Conclusion

TATE with paper taped offers an easy strategy to achieve tissue expansion for stump cover with relative ease and comfort without the need elaborate resources and expertise.

Introduction

Lower limb amputations may need to be performed for a multitude of reasons. Successful rehabilitation is dependent on multiple factors such as stump's length, number of preserved joints, proximal joint mobility and stability, and stable soft tissue cover. Amputations performed for situations like trauma, atherosclerotic vascular disease and sepsis may result in amputations at a critical length without the much needed provision for soft tissue and skin cover. In the guillotine type amputation without local skin flaps for closure, rehabilitation of a critical length stump pose some reconstructive challenges. Many surgeons may default to a higher level amputation above the existing joint to achieve closure but not without sacrificing leverage with potentially negative consequences.

This case series aims to investigate the novel use of rapid sequence serial traction assisted tissue expansion with paper tape to achieve closure of a presenting lower limb amputation stump at a critical length. Skin stretching devices have been used

under similar circumstances but there are invasive and painful, and comparatively more expensive and labour intensive than the primary author's devised technique of tape dermatogenesis that was provided to these patients.(1-3)

Patients and Methods

A retrospective chart review of cases treated by tape dermatogenesis for lower limb amputation since its inception in 2014 was performed. Data collated and analysed included demographic profile, morbidity factors, level of amputation, defect type (open wound or healed scar), size of defect, Paper tape application parameters inclusive of time line to taping, number of applications and duration of application, size of surgical defect and duration of follow up.

Traction assisted tissue expansion technique in open wounds

The wound is first cleaned (figure 1a). If the wound is noted to be exudating then gauze and adaptic roll is made to cover the central portion of the wound (Figure 1b). A sparse amount skin barrier cream* is applied to the surrounding skin. The paper tape^ is then applied migrating the skin flaps by traction from either side in the direction of the projected closure (Figure 1C). The line of the closure can be manipulated as the taping progresses with each application. In a low exudating wound or when the exudation decreases the roll dressing can be omitted and the paper tape is directly applied and remains in direct contact with the wound. The application is repeated everyday but can be individualized depending on the gain in laxity to three days. Clinical judgement is used to determine readiness for the excision and closure (Figure 1d).

* 3M^{TM}Cavilon^{TM} Durable Barrier Cream

^ 3M^{TM} Micropore^{TM} Surgical Tape

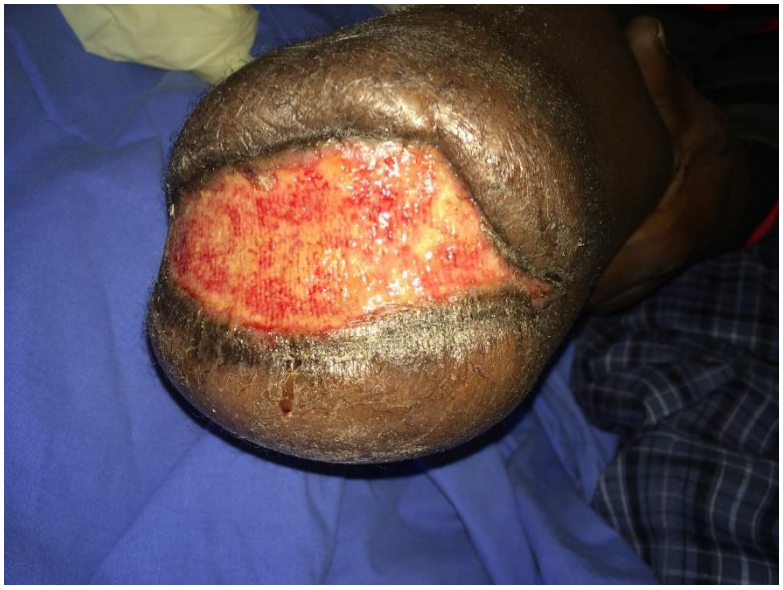


Figure 1a of case 1: A guillotine below knee amputation stump wound is demonstrated of case 1 measuring 140 X 65mm at 4 weeks

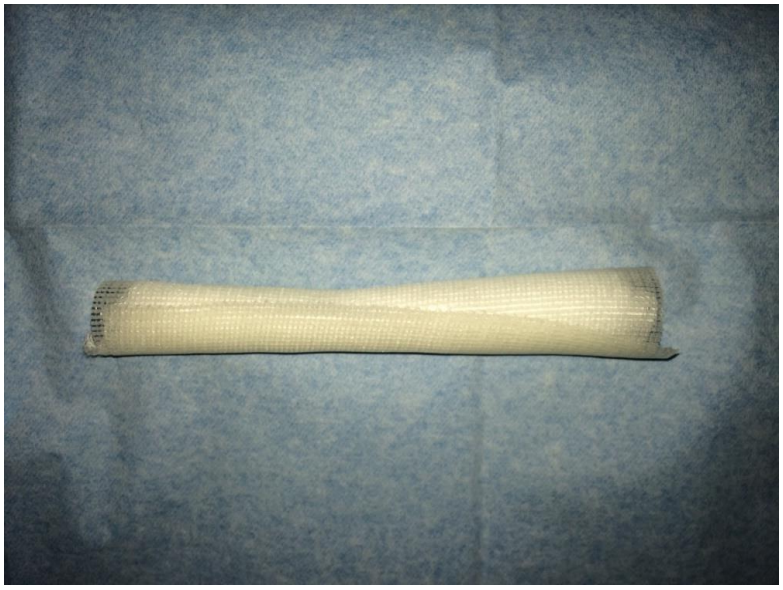


Figure 1b of case 1: An adaptic touch lining a small gauze role is shown. This will then be placed over the length of the wound

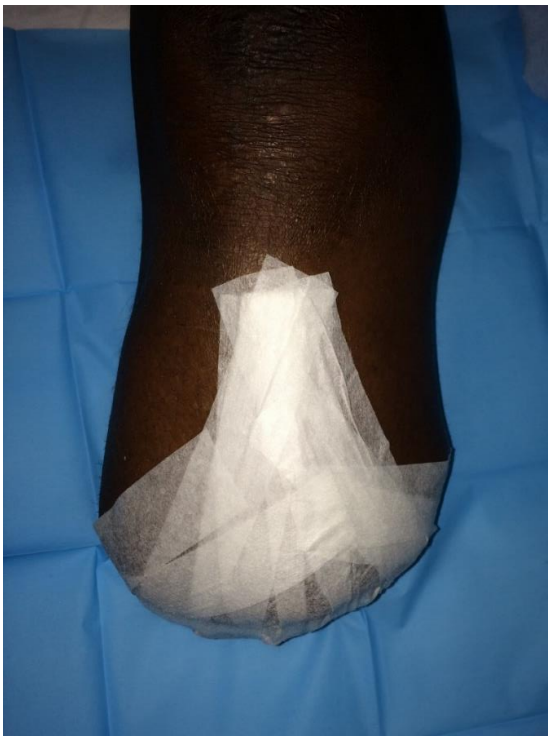


Figure 1c of case 1: The micropore tape is applied and direction of the migration of the skin flaps can be influenced by the configuration of the tape

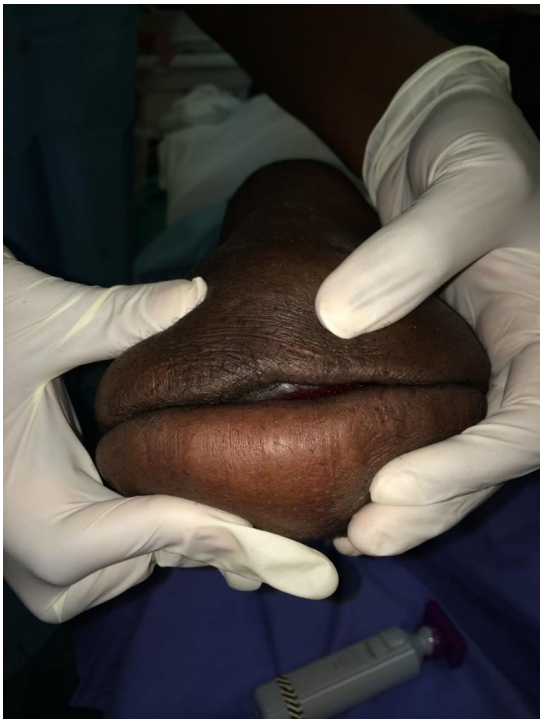


Figure 1d of case 1: Pinching the skin flaps to simulate closure is used in this case to gauze readiness of surgical excision and closure

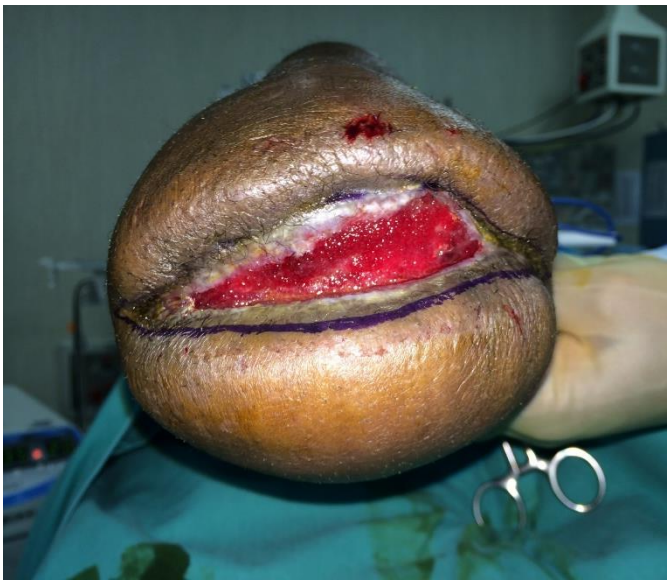


Figure 1e of case 1: On day 10 a reduced wound size can be appreciated. The area within the blue mark lines is for excision

Surgical technique and postoperative care

The wound and/or scarring is fully excised (Figure 1e & f). The wound edges are undermined as required to unfurl the internally rolled edges. The wound is closed in multiple layers over a suction drain if required (Figure 1g). The line of closure is supported immediately with an adhesive dressing retention tape[+] and later in the healing phase by paper tape^ application for a period of at least 6 weeks.

[+] Hypafix®

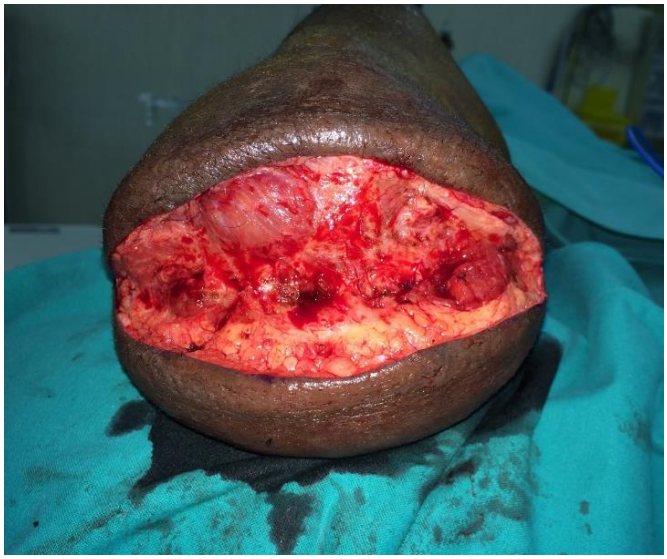


Figure 1f of case 1: A recreated defect is shown after excision of all the scarred tissues revealing good quality muscle, fat and fascia below. The surgical defect measured 140mm X 60mm

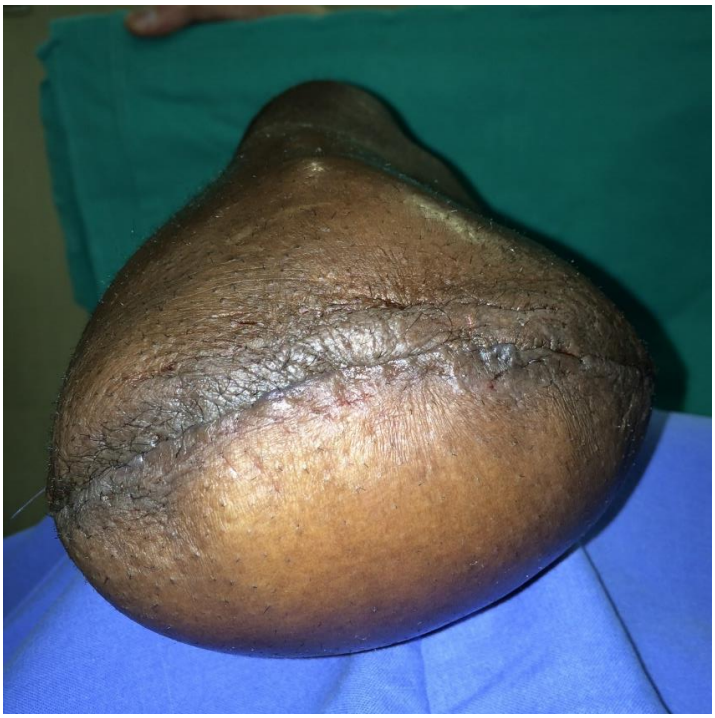


Figure 1g of case 1: The immediate postoperative result with the line of closure is shown

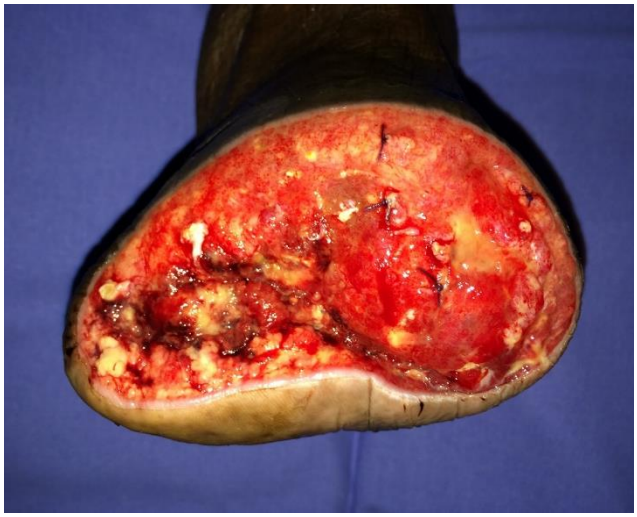
Results

Four cases were treated using the technique of TATE to achieve stump closure in lower limb amputations. (Table 1 summarizes these cases and associated figures). The subjects were all males with an age range of 22 to 66 years old. In two cases the reason for the amputation was tibio-peroneal disease complicated by sepsis and in the remaining cases trauma. In three of the cases the introduction of taping occurred in the acute and subacute phases of wound healing. In the fourth case the taping was introduced for a healed stump four years after amputation (high above knee) to improve the stump shape and scar stability which was a hindrance to prosthesis use. The stump was short and had been healed by skin graft application directly onto the bony end of the stump at the time of amputation.

Table1: Summary of cases managed in series. Case numbers correlate with numeric figure numbers when viewing cases

Case No.	Age	Morbidity	Treated condition	Time line to taping	Level of amputation	Defect type	Defect size (mm)	No. of applications	Duration of each	Time span to closure	Size of surgical defect (mm)	Duration of follow up
1	48	Pvd, Hpt, smoker	Tibio-peroneal dx,sepsis	4w	BKA	open	140 X 65	6	1 to 2d	10	140 X 60	12m
2	66	Pvd, Hpt, DM	Tibio-peroneal dx,sepsis	1 w	Trans-metatarsal	open	110 X 70	8	2d	14	100 X 65	15 m
3	22	Nil	Crush & degloving injury	3w	BKA	open	170 X 100	33	1 to 3d	52	100 X 55	7m
4	26	Nil	Crush & degloving injury	4y	High AKA	skin grafted	160 X150	2	1d, 10mins	1	150 X 110	9m

Pvd – peripheral vascular disease
Hpt – hypertension
DM – diabetes melliltus
Dx - disease
BKA – Below knee amputation
Mins - minutes
d - days
m - months
y - years
w - weeks
.



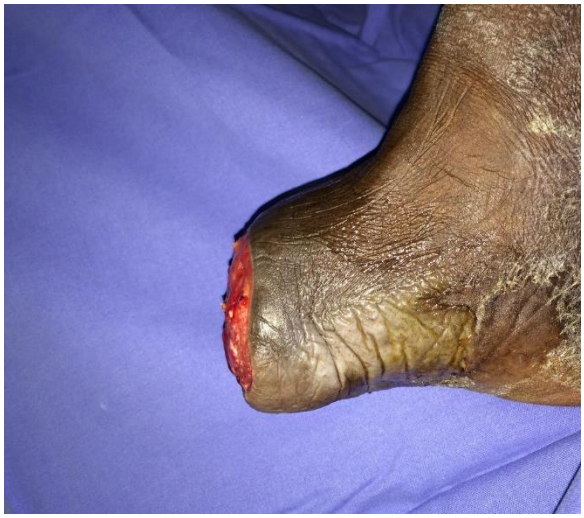


Figure 2a of case 2: The transmetatarsal amputation of the foot of case 2 is shown from an anterior view on day 8 post amputation with a wound measuring 110 X 70 mm before commencement of taping (Left)
Figure 2b of case 2: Lateral view of the amputation stump of the foot is shown (Right)

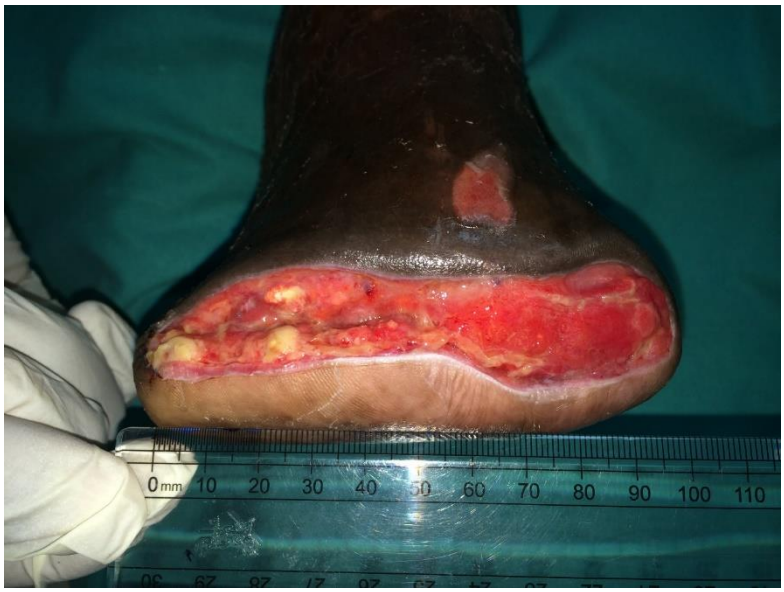


Figure 2c of case 2: Day 14 post commencement of taping of the amputation stump of the foot, the wound size measured 105mm X 15mm. Rapid shrinkage in the direction of the taping can be appreciated

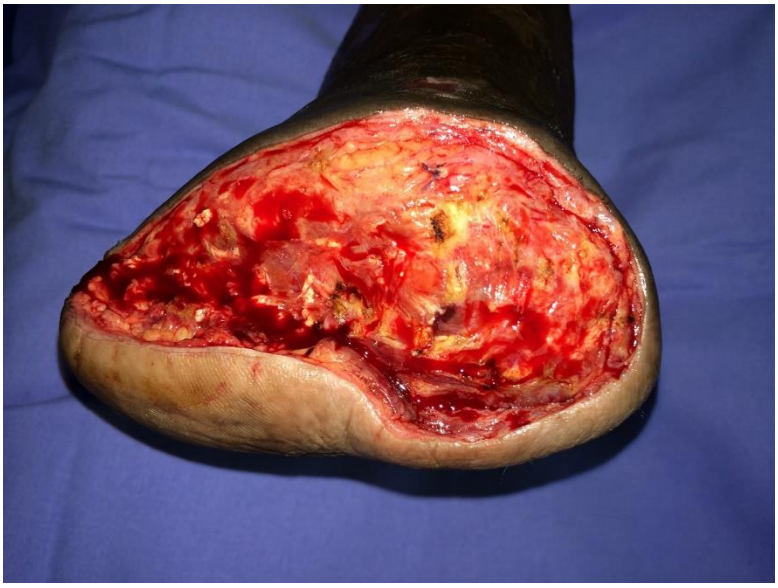
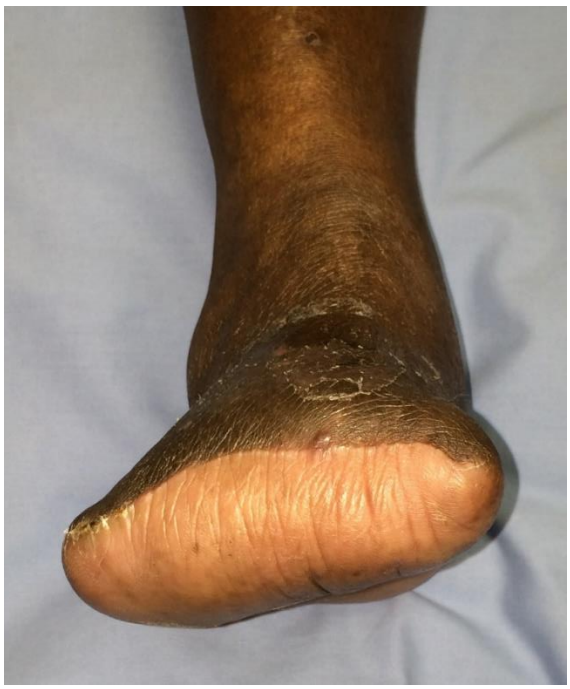


Figure 2d of case 2: A recreated defect is shown after excision of all the scar tissue in the wound edge and bed revealing good quality virgin tissue below. The surgical defect measured 140mm X 60mm



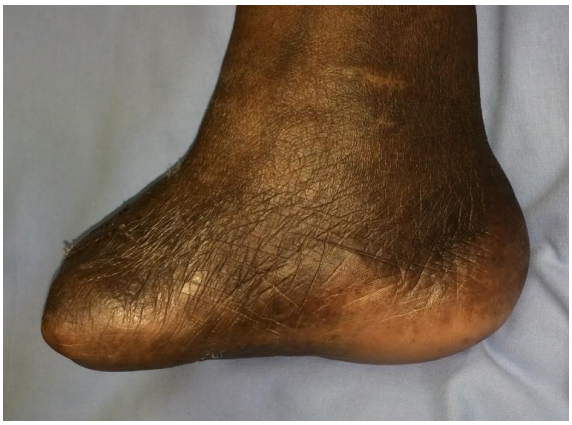


Figure 2e of case 2: A healed amputated foot stump with a good shape is shown in anterior view. The glabarous skin of the foot expanded to a larger extent than the dorsal skin during the time of expansion period and can be appreciated here (Left)
Figure 2f of case 2: A healed lateral view of the transmetatarsal amputation of the foot Right)

All patients presented with a considerable size defect and required between 2 to 33 applications of paper tape per case with interval of one to three days between each application. The size of defect ranged from 110mm X 70mm to 160mm X 150mm. In the 4th case specifically a single overnight application of paper tape was followed by repeat taping lasting just 10minutes prior to surgery. The length of time paper tape was applied per case ranged from 1 to 52 days. Of note in all subjects presenting with open wounds, tissue expansion process in case 1 and 2 lasted 10 and 14 days respectively. In the same two cases the size of the wound recreated at surgery approximated the original size of the defect irrespective of the demonstrable shrinkage of the wound with each serial taping. On the other hand case 3 lasted 52 days and demonstrated a smaller recreated defect after scar excision measuring 100mm X 55mm in comparison to the initial wound size was 170 mm X 100 mm.

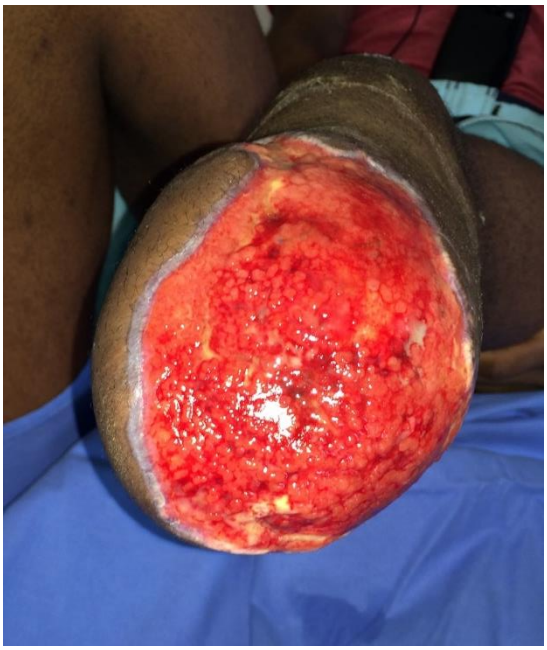


Figure 3a of case 3: High below knee amputation of the leg of case 3 is shown from below on day 21 post amputation with a wound measuring 170 X 100 mm before commencement of taping

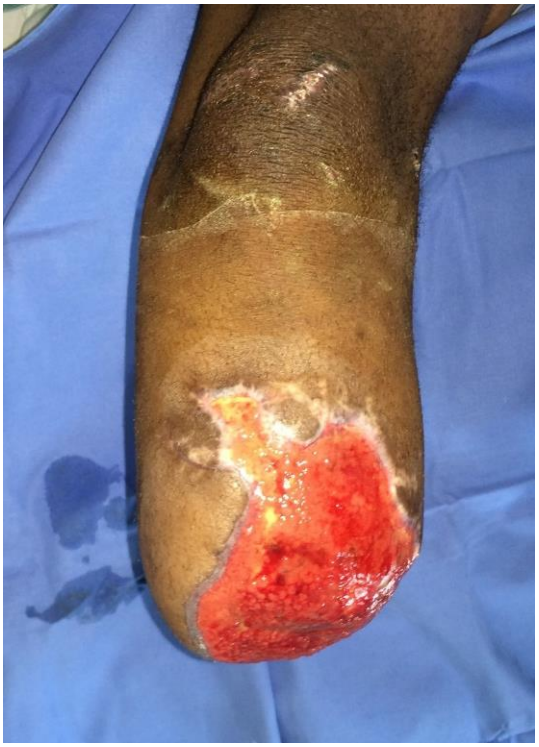


Figure 3b of case 3: An anterior view of the amputation stump of leg is shown

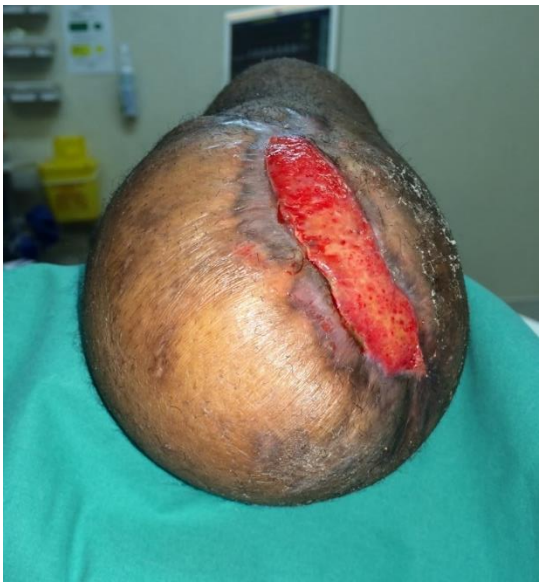


Figure 3c of case 3: Day 52 post commencement of taping of the amputation stump of the leg from below is shown. The wound size measured 70mm X 20mm. Shrinkage of the wound in the direction of the taping can be appreciated

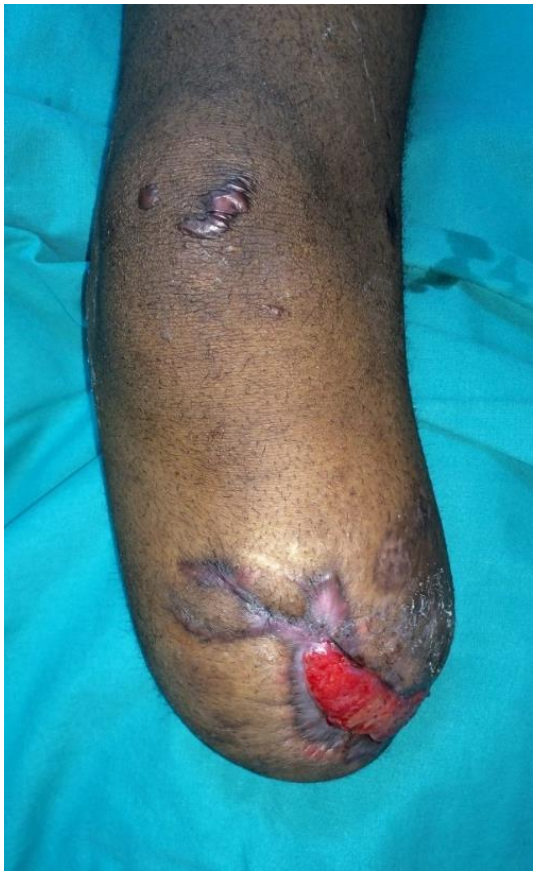


Figure 3d of case 3: Day of the surgery. Anterior view of the amputation of the stump of the leg is shown on day 52 post commencement of taping

In cases 1 to 3 skin closures were obtained in a single operation without significant undermining of the skin or without shortening of the bone. In case 4 skin closure was also obtained in a single operation but the skin was undermined extensively to gain access to the deeper lying muscles of the thigh which were then very easily migrated to cover the femur bone stump.

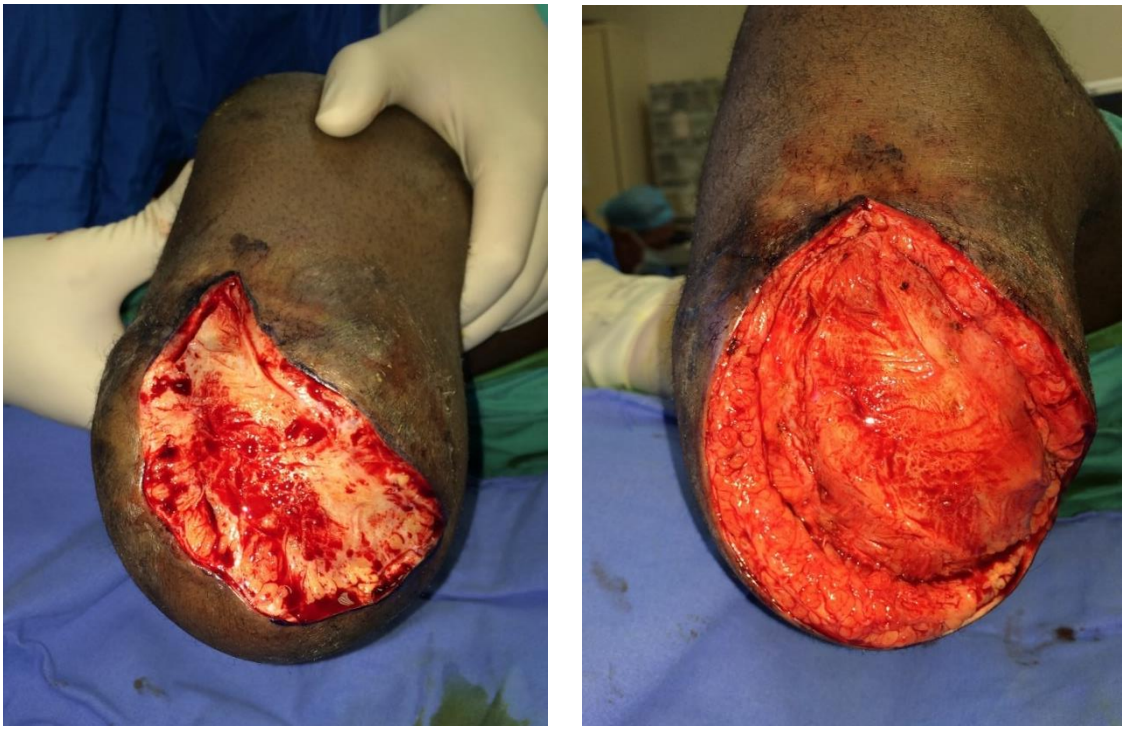
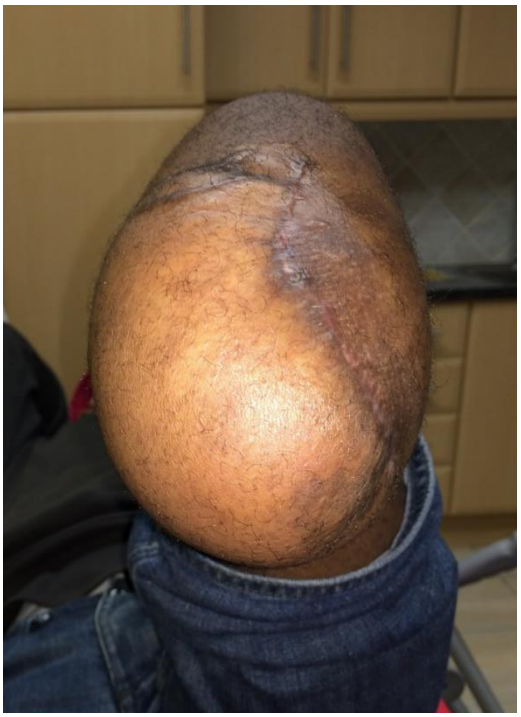


Figure 3e and f of case 3: A recreated defect is shown after excision of all the scar tissue in the wound edge and bed. The surgical defect measured 100mm X 55mm (Left). After undermining of a rim of 2 cm of the skin flap the wound expanded further to 130mm X 75mm (Right)



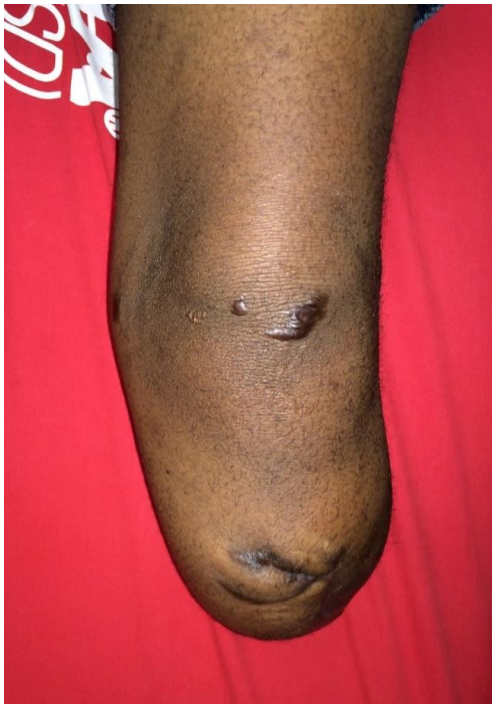


Figure 3g of case 3: A healed amputation stump is shown from below at 3 months of follow up (Left)
Figure 3h of case 3: An anterior view of a well-shaped amputation stump of the leg is shown (Right)

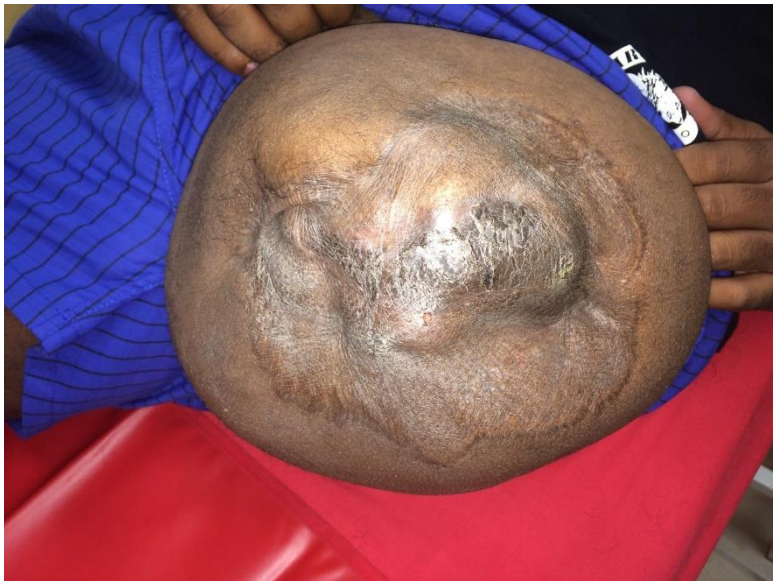


Figure 4a of case 4: Four years post amputation and skin grafting a high above knee amputation of case 4 is shown from below with poor quality scarring and in part tethered to the underlying bone measuring 170 X 100 mm before commencement of taping

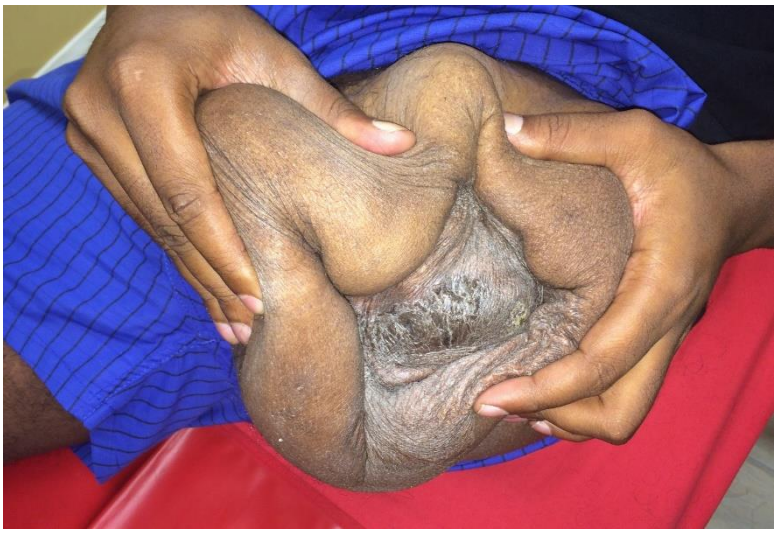


Figure 4b of case 4: The patient is demonstrating the intrinsic laxity of the skin prior to the application of the tape

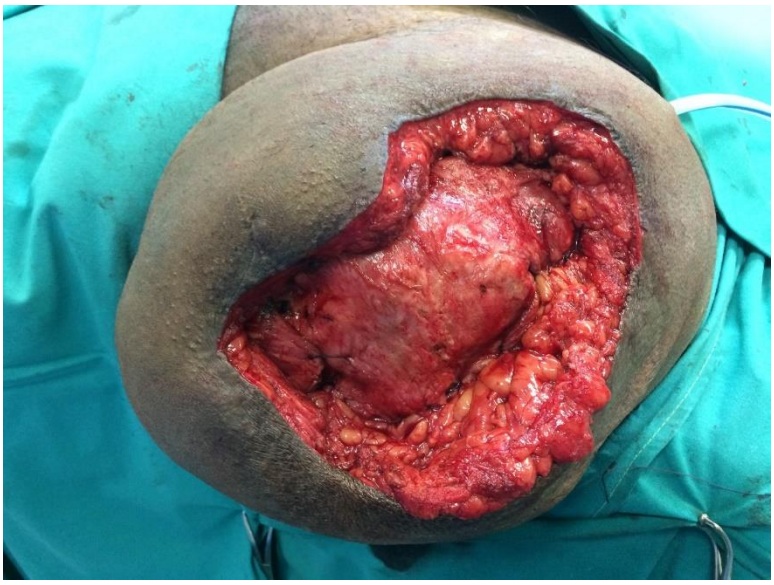


Figure 4c of case 4: A recreated defect is shown after excision of all the scar tissue. The skin flaps are extensively undermined to get access to deeper muscle tissue to cover the bony end of the femur. The surgical defect after muscle closure measured 150mm X 110mm

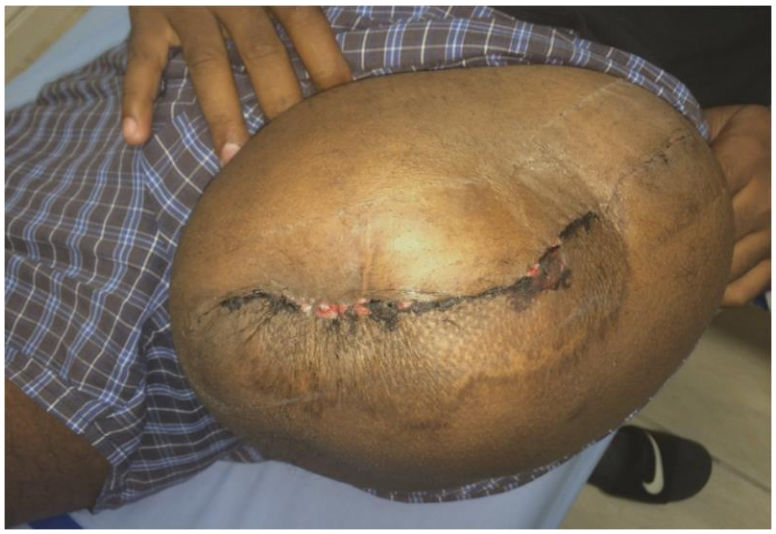


Figure 4d of case 4: A healed amputation stump is shown from below at 2 weeks of follow up

The only complication experienced was skin de-epithelialization which occurred in case 3. The abraded areas healed quickly by avoiding taping directly over them and traction application on the skin was stopped for a few days.

Discussion

Ordinarily amputations are not the surgical domain of the plastic surgeon. The specialities involved with them include general surgeons, orthopaedic surgeons and vascular surgeons. Either due to lack of exposure to the value of plastic surgery on the part of the treating surgeon or specifically in emerging countries due to the lack of expertise the patient is not offered a reconstructive salvage in preserving critical limb length. The surgeon at the outset may convert a guillotine amputation to a higher level to achieve skin cover for the stump. A higher level amputation requires higher energy expenditure for ambulation. Therefore in an old or an infirm patient walking with a prosthesis may not be achievable.

Tissue expansion both internal and external are not new in offering a reconstructive strategy in salvaging amputation stumps of critical length.(4, 5) A limb amputation stump may present to the reconstructive surgeon in the acute setting with open wounds associated with a deficiency of local tissue, or in the healed state with poor quality local tissue and/or unstable scarring. Rehabilitation of the patient with a prosthesis is dependent on good quality skin and soft tissue. Skin deficits can be overcome by the use of internal tissue expanders but a closed wound is a prerequisite for its use. If a wound is present then as part of a staged reconstruction by tissue expansion it has to be healed first by a skin graft. The shortcoming of this strategy is the time delay in achieving patient mobilisation which can run into months to a year or more. The alternative is an immediate closure of open wound by importing a distant flap.(6) The latter is complex and not always feasible because of unfavourable conditions associated with an amputation. There is an obvious advantage of tissue expansion in that is provides good quality like tissue which is sensate and durable.(5) But the use of tissue expanders themselves have a high

complication rate in limbs resulting in failure.(7) In the event of procedure failure once the complication is overcome and healing achieved one may need to reattempt tissue expansion at some time in the future. Alternatively one may choose to seek other solutions.(8)

External tissue expansion on the other hand can be used in the acute setting in patients presenting with amputation stumps with open wounds. Many techniques and devices have evolved over the last three decades.(1, 3, 9) They share negative attributes in that they are invasive, expensive and require labour intensive application. Other shortcomings are pain and need for skilled supervision. The technique that we are offering achieves the same but is non-invasive, economical and pain free.(10) The patient or a nonmedical assistant may easily learn to administer TATE.

All 3 patients with open wounds were candidates for any of the described techniques of external expansion. The degree of success of any of these techniques cannot be compared without a controlled trial. Nevertheless, an immediate observation on first episode of taping and removal was the significant reduction of tissue oedema and demonstration of good tissue migration. The obvious consequence of oedema reduction is improvement in tissue pliability producing the initial room for skin gain. In cases 1, 2 and 4 sufficient tissue expansion was achieved in less than 14 days.

Case 3 took 52 days of TATE to achieve closure. A possible reason for this is the fibrosis between multiple tissue planes occurring as result of the crush and extensive degloving injury. In our original series healed cases with a background of degloving injuries presenting for scar revision or deformity correction tissue expansions with the use of the paper tape failed to progress.(10) Our postulate was that fibrosis between tissue planes hindered skin migration. In case 3 because we persisted with the paper tape application, progress although slow was noted over time. The fact that the time lapse from injury to taping was 3 weeks may have been

of benefit for the observed progress. At three weeks of healing fibrosis may still be pliable enough for it to be overcome by the mechanical forces generated by the paper tape.

Ironically, although case 4 also had a background history of a crush and degloving injury, progress was rapid with skin expansion to achieve the reconstructive goals. It must be borne in mind that this case presented four years after amputation with a healed wound displaying a great degree of softening and skin laxity (Figure 4b). This may be indicative good scar maturation and softening with the passage of time or that the remaining tissues post trauma and surgery was not in the zone of injury. Degloving injuries therefore should not contraindicate the use of TATE. TATE can be abandoned at any stage if there is failure to progress and other strategies can be adopted to salvage the limb amputation stump.

As much as fibrosis can adversely affect the application of TATE. In other respects it may be of benefit. Collagen production and myofibroblast activity in a wound healing by secondary intention promotes the reduction of wound size until the wound is completely epithelialized. Scar contracture does not necessarily end at that point but may continue for some time thereafter. In TATE with the use of paper tape covering the wound and migrating skin towards it we noted a rapid reduction in the size of the wound with each episode of taping. Removing the paper tape between applications did not result in rebound expansion of the wound. The taping was actually assisting the wound contract complimenting the wound healing activity of the myofibroblast and the collagen production. This phenomenon can actually be thought of as traction assisted secondary intention wound healing. If desired complete wound healing as it would seem could be achieved with continuation of the taping until epithelialisation is achieved.

Our purpose in achieving closure of the stump after TATE was to remove the scarring to render good quality soft tissue for durability. At surgery and referring to

cases 1 to 3, although the wound edges could be approximated to each and significant wound reduction was achieved, the skin defect was recreated. An interesting observation about the size of the wound on excision, recreating the defect, was that it approximated the size of the original wound before taping in cases 1, 2 and 4.. In case 3 the surgical defect was 1/3rd the size of the original defect. The tissue expansion in this case occurred over a much longer period of time lasting 52 days. A possible explanation for this is that case 3 was able to produce a higher percentage of biological creep. Cases 1, 2 and 4 due to the much shorter period of acute expansion displayed mainly mechanical creep. The concept of mechanical creep versus biological creep is worthy of further exploration.

Irrespective of the mechano-biological reasons for the gain in skin length, the skin on either side of the wound demonstrated extraordinary extensibility and skin to skin closure was obtained without significant flap undermining. Removing the scar and wound mass also provided for additional space for the easy migration of the lateral skin flaps to each other.

Conclusion

TATE offers the treating surgeon and patient an easy strategy to achieve tissue expansion for stump cover with relative ease and comfort without the need elaborate resources and expertise. Tate with paper tape is user friendly and offers an effective and economical method of salvaging limb amputation with mild to moderate size skin defects. 3M Micropore tape application compliments secondary intention wound healing and its direct use on the wound did not in this small series have any significant detrimental effects. But, making a sterile kit available will provide a safeguard against bacterial wound colonization.

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Introduction to chapter 9

In Chapter 8, one the effects of taping open wounds of the amputation stumps using the TATE technique was the oedema control of the wound and the surrounding skin. The initial taping also involved the use of a contact dressing of the wound over which the micropore tape was applied. With the drop in the exudation level of the wound I was encouraged to use the tape as a direct semi-occlusive dressing over the wound whilst applying traction for tissue expansion. In the next chapter, Chapter 9, micropore tape was used to achieve the oedema reduction and at the same time produce skin stretch and wound reduction for a staged surgical closure of an acute forearm fasciotomy wound. Using a non-sterile product was a concern. Availability of a commercial preparation of a sterile packaged 3M™ Micropore™ Surgical Tape will be of benefit for use in clean acute wounds in future.

Chapter 9: The Successful Application of TATE to Achieve Fasciotomy Closure without Skin Grafting

Key words

Fasciotomy, fasciotomy closure, tissue expansion, traction assisted tissue expansion, 3M™ Micropore™ Surgical Tape

Summary

Fasciotomies are a necessity in relieving limb compartment pressure. It is limb preserving and potentially lifesaving surgical procedure. Despite this benefit, the major disadvantage is scarring because fasciotomies are usually closed by split skin grafting. The only way to minimize the scarring is to achieve a delayed primary closure of the fasciotomy wound. Both invasive and non-invasive techniques of achieving delayed direct closure of the limb fasciotomy have been described. We present a 38 year old male patient, providing a descriptive account of traction assisted tissue expansion (TATE) with paper tape to achieve a 2 stage closure of his fasciotomy wound of the forearm in a delayed primary setting. Although the use of adhesive tape is not new in preparing the surrounding skin for closure of the wound, our technique using paper tape offers additional advantages of wound oedema control whilst serving as a semi-occlusive wound contact dressing.

Background

Fasciotomy in limbs is required in many clinical situations to save a limb and its function. However, the wound and the long-term scarring associated with it pose treatment challenges. The nature of the clinical conditions that necessitate a fasciotomy and the treatment thereof result in swelling of the tissues of the released compartment. Consideration for skin closure is only possible once the swelling has dissipated, which may take a long time. Meanwhile the skin that has been incised

retracts and the wound bed granulates making for a direct delayed primary closure improbable.

There are reports of many strategies, both invasive and non-invasive that have been used to achieve direct closure and minimize scarring without compromising the tissues of the compartment.

A novel technique in the following case study is presented. It demonstrate the feasibility of achieving skin tissue expansion by the non-invasive, economical and pain free technique of TATE in preparation for a 2 stage surgical closure of a subacute fasciotomy wound of the forearm achieved in a period of two weeks.(1) The purpose of the study is to share our approach adding to the techniques already described in the literature on treatment of fasciotomy wounds of the limb.

Case Presentation

A 38 male subject sustained a sporting accident riding a mountain bike fracturing his previously plated right clavicle. This injury was complicated by right subclavian artery intimal tear resulting in distal thromboembolic phenomenon. Vascular intervention was required which included thrombolytic therapy during the procedure. During the same procedure the anaesthetist performed multiple failed arterial punctures of the left radial artery at the wrist to insert an arterial line. A few hours later the patient developed a tense compartment syndrome of the left forearm due to a hematoma. A fasciotomy was performed and hematoma evacuated.

The limb made a full recovery with no neurovascular deficit. The patient was referred to me for opinion 2 days later for exposed flexor carpi radialis (FCR) tendon. The patient shared then his misgivings about the large wound resulting from the complication.

On my examination the wound was clean and muscles were oedematous. The entire FCR tendon was exposed but was covered in parts by paratenon (Figure 1). The patient consented to the use of TATE to achieve delayed primary closure of the wound.

Traction assisted tissue expansion

The wound is first cleaned (figure 1). If the wound is noted to be exudating then gauze and adaptic roll is made to cover the central portion of the wound (Figure 2).

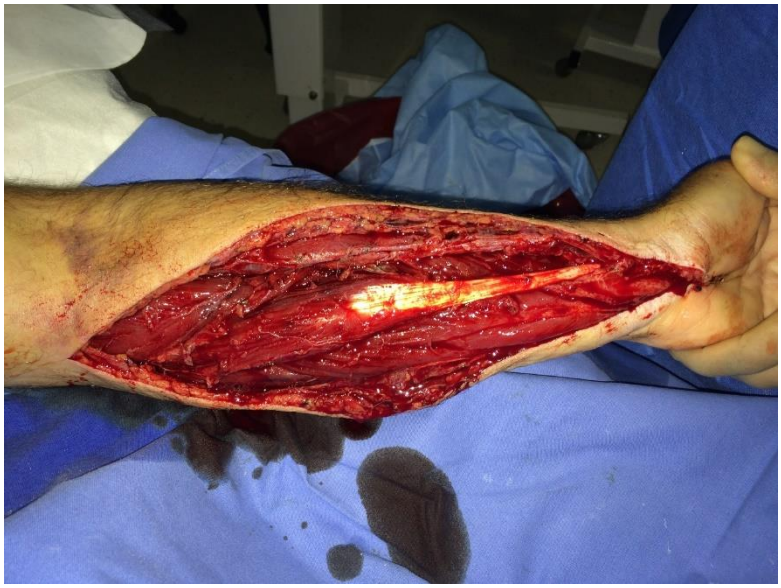

Figure 1: A gaping fasciotomy wound of the left forearm with the exposed FCR tendon is seen on Day 4.

A sparse amount skin barrier cream* is applied to the surrounding skin. The paper tape^ is applied migrating the skin flaps by traction from either side in the direction of the projected closure. The line of the closure can be manipulated as the taping progresses with each application. In a low exudating wound or when the exudation decreases the roll dressing can be omitted and the paper tape is directly applied and remains in direct contact with the wound and functions as a semi occlusive dressing (Figure 3). The application is repeated everyday but can be individualized depending on the gain in laxity to 2 to 3 days. The taped limb is covered with fluff

gauze and light crepe bandage after every application. Clinical judgement and pinch test is used to determine readiness for the excision and closure.

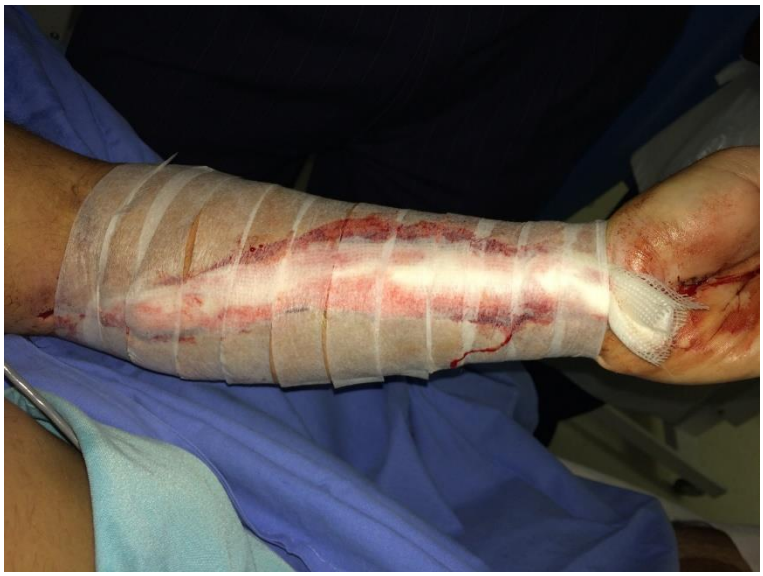

Figure 2: First application of Micropore tape over a dressing role in contact with the wound is seen on Day 4. The outline in the reduction in the defect is seen through the tape

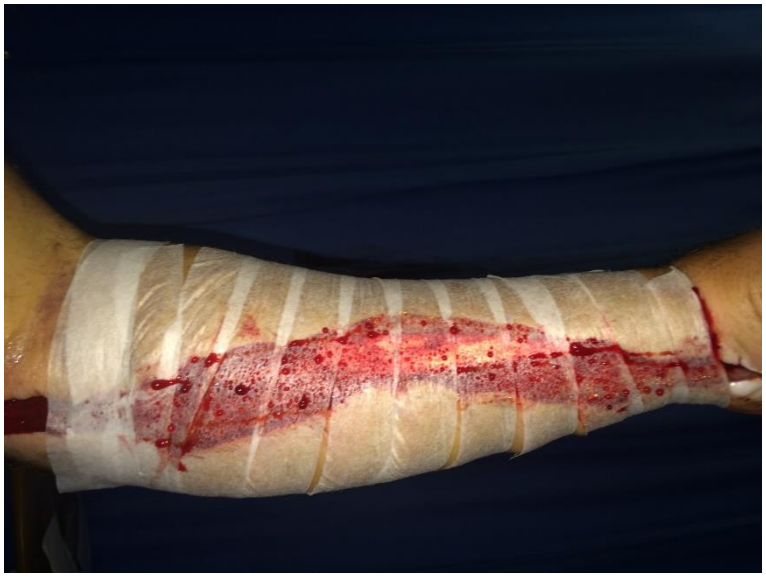

Figure 3: Second application of Micropore tape directly over the fasciotomy wound bed is seen on Day 6. Of note is that micropore allows for the egress of the edema fluid through the pores of the tape

In this case study taping was commenced on Day 4 (Figure 2) and repeated on Day 6 post fasciotomy (Figure 3). On repeat dressing there was considerable reduction in the oedema and generation of laxity in the skin.

* 3M^{TM}Cavilon^{TM} Durable Barrier Cream

^ 3M^{TM} Micropore^{TM} Surgical Tape

Surgery

On Day 7 the patient was taken to theatre. The paper tape was removed and another application lasting a duration of 10 minutes was performed before commencing surgical closure. The plan was to obtain complete closure but only the proximal 2/3rd could be closed. The residual muscle oedema prevented the distal closure. Distal taping was performed immediately at surgery (Figure 4).

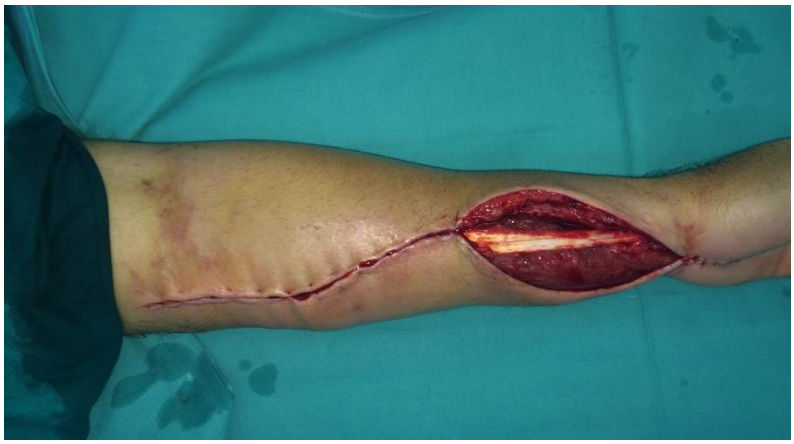

Figure 4: After the first stage of the closure of the forearm on Day 7 in theatre the remaining distal wound is shown in readiness for further tape application

The compartment of the forearm remained soft in the postoperative phase. Taping was recommenced on a daily basis on day 10 for 4 consecutive days. On Day 14 the patient was returned to theatre and for the final direct closure of the wound.

Outcome

The patient went on to heal uneventfully and on follow-up at 3 months post-surgery showed minimal residual scarring (Figure 5).

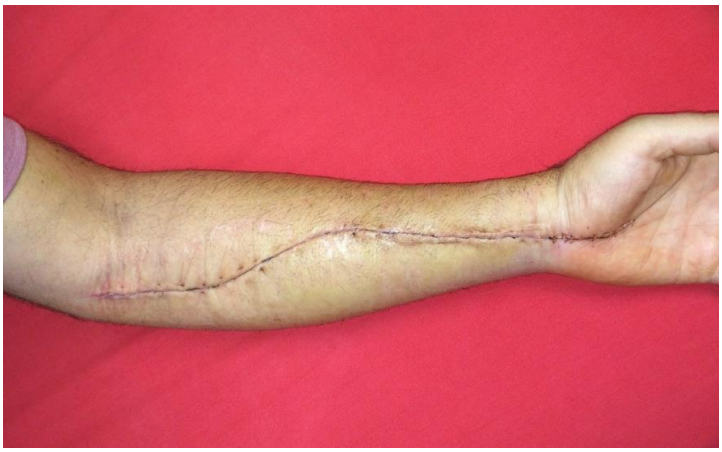

Figure 5: The final closure of the fasciotomy wound is shown 10 days after the 2nd stage closure

Discussion

Our literature review identified many techniques that have been used in the last 15 years to achieve a delayed primary closure of fasciotomy wounds. These strategies can be categorized from the historical perspective as follows:-

1. Dermatotraction techniques with Shoelace weave using either nylon suture or vessel loop and staples.(2, 3)
2. Pre-positioned intracutaneous monofilament or barbed suture placement.(4-6)
3. Tape traction with plaster tape or Steri-strip.(7-9)
4. Dermatotraction techniques assisted by designed external devices e.g.
    a. Suture Tension Adjustment Reel (STAR)(10)
    b. Sure-Closure device(11)
    c. Dynamic closure device (Canica Design, Inc.)(12)
    d. Wisebands wound closure device(13)
    e. Silver Bullet Wound Closure Device (SBWCD)(14)
    f. Ty-Raps(15)
    g. Silicone sheet tightening(16)
    h. Vacuum Assisted closure or Negative Pressure wound therapy in combination with dermatotraction techniques (17, 18)
    i. Limb elevation(19)
    j. Staged linear closure(20)

Dermatotraction techniques are recognized strategies in our attempt to obtain early skin closure thereby avoiding a skin graft. All of them seem to achieve a high success rate. The pros and cons of each of the techniques can be debated, but the pivotal issues will be cost, in-patient versus out-patient care, pain and discomfort, wound bed and oedema control, ease and simplicity of application, efficiency and rate of tissue expansion, availability and reliability of device.

Paper tape is a readily available product in our resource constrained setting which satisfies the above issues. It is a concern that paper tape does not come packaged as sterile, but this can be easily achieved by commercializing a sterile product package containing paper tape and a sachet of skin barrier cream. The use of paper tape to achieve tissue expansion is a tried and tested technique.(1)

Conclusion

TATE adequately addressed both the vascular surgeon's and patient's concerns of the exposed tendon and the forearm aesthetics. This case has shown that avoiding a split skin graft to heal a fasciotomy in clinical practice is feasible using TATE. Tape traction is not new as a modality for delayed primary fasciotomy closure, however the use of paper tape is novel. If not contraindicated, the serial application of paper tape with controlled tension recruits the viscoelastic properties of skin and achieves oedema control in preparation for surgical closure of a fasciotomy wound.

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Introduction to Chapter 10

In Chapters 8 and 9 the use of TATE to achieve surgical closure of open wounds was shown. Achieving closure by surgery affects healing by primary intention. Nature's way of closing a wound that is gaping or has associated loss of skin is by secondary intention. In humans this is a slow method of establishing a healed wound. The ability to accelerate wound closure is of definite benefit. Vacuum Assisted Closure is a known method that achieves accelerated closure with the use of negative pressure generating device and materials. A polyurethane sponge in contact with the wound under an occlusive dressing collapses and shrinks as the air is removed from it. This imparts forces of deformation and microdeformation which hastens the closure of the wound by accelerated secondary intention healing. Chapter 10 is about the use of 3M™ Micropore™ Surgical Tape in a case study where tension is applied on the surrounding skin and the wound to affect accelerated closure of the wound by the forces of deformation created by the tape. This was termed traction assisted closure (TAC).

Chapter 10: Traction Assisted Closure with 3M MicroporeTape of a Large Wound Resulting from Reconstructive Flap Loss

Key words

Secondary intention wound healing, traction assisted closure, VAC™, traction-assisted tissue expansion, 3M™ Micropore™ Surgical Tape.

Summary

Complex reconstructions with flaps following soft tissue tumor excision may occasionally completely or partially fail. The result is a large complex wound that needs to be healed. The usual option is to achieve this by another flap and/or split skin graft. Sometimes an opportunity to allow the wound to heal by secondary intention maybe at the disposal of the treating surgeon. The most significant drawback of this strategy is the long healing time and therefore inherent risk of further wound complication. We present a 50 year old lady who underwent reconstruction of the groin, perineum and the upper thigh with 2 large musculocutaneous flaps. There was partial loss of one of the flaps resulting in a large defect. The purpose of this case report is to share and introduce to you the use of traction assisted closure with 3M Micropore tape. The aim of this technique is to accelerate closure of the wound by forcibly migrating surrounding lax tissue over time to cover the wound by a process of serial taping. We describe the technique, producing a good outcome

Background

Complex flap reconstructions in plastic surgery is not without partial or total failures. The need for further flap reconstruction is determined by multiple underlying wound factors such as functional restoration, vital structure exposure and planned adjuvant radiotherapy. In the event of failure this needs to be balanced against salvaging the

situation by more complex surgery. Nature has provided us with a tremendous capacity to heal open wounds by the process of granulation, wound contraction and epithelialization. Generation of granulation tissue is its hallmark feature. It is potentially associated with delayed healing time, greater degree of scarring and soft tissue contracture that may compromise function. However some surgeons have chosen to make it their preferred method of healing following excisions for conditions like hidradenitis suppurativa, pilonidal disease and soft tissue sarcomas.(1-3) Theoretically secondary intention healing can continue unabated, provided local wound and systemic conditions in the patient remain conducive. Prolonged healing risks the wound lapsing into a decreased proliferative phase delaying or arresting the process. So it would make sense to decrease the secondary wound healing process. Hypothetically this could be achieved by accelerating the proliferative phase and epithelization of wound healing or by accelerating the naturally occurring reduction in the wound size or both.

In contrast healing by primary intention is obtained by direct wound approximation, almost always by surgical intervention. There is no granulation tissue generation and scarring and healing time is decreased.

In the last 2 decades we have seen an explosion of agents that assists the wound healing process. Vacuum assisted closure is one of them that has revolutionized clinical practice of achieving complex wound closure either with or without surgery.(4-6) If surgery is required then it can often be downgraded to a simple solution without compromise.

Mechanical forces have been recognized in repairing, regulating and remodeling tissue growth.(7) The advent of the VAC™ has revolutionized wound management and should not be thought of a dressing only. It should be thought of as an active device imparting mechanical forces. The initial device design concept primarily aimed to expedite the closure of the wound by secondary intention healing by

applying macrodeformation. In response to the sub atmospheric pressure, granulation tissue filled the wound at a greater rate than the control which was indicative an increased proliferation.(4) Two decades have passed since its initial description and its effects can be summarized. Primary effects include wound stabilization, fluid removal and microdeformation. Secondary effects include speeding wound healing, increasing blood supply, changes in bacterial burden, changes in wound biochemistry and improvement in wound bed preparation.(7)

A significant drawback of the device is cost therefore its use has to be supported by benefits to the wound at multiple levels. In the absence of experience, its use can be cumbersome and even high maintenance for both wound therapist and patient. In some anatomical areas it may even be difficult to apply. But, taking large wounds to a healed state with the use of the VAC™ device can prove to be expensive and labor intensive.

We present a novel technique in the following case study. It demonstrate the feasibility of achieving complete wound healing by the non-invasive, economical and pain free technique of traction assisted closure (TAC). The key feature of the TAC technique is the wound reduction. Wound reduction is a natural phenomenon that is orchestrated by the fibroblast/myofibroblast and their collagen production and rearrangement. Fibroblast activity is opposed by the surrounding tension forces which can cause wounds to gape depending on the location of the human body. So it stands to reason that the work load for the fibroblast is increased in high tension areas of the body leading to longer healing time. A randomized experiment in a porcine model showed that extent of wound contraction is dependent on site.(8) The use of micropore then in essence serves as an external splint for the wound as the scaffold of collagen is laid down and remodeled in the artificially contracted state. The collagen then serves to hold the wound in a reduced state despite some recoil as observed during each dressing change.

Case Presentation

A 50 year old female underwent a wide local excision for recurrent dermatofibrosarcoma protuberans with fibrosarcomatous malignant transformation involving the vulva, thigh and the groin. The defect measured 35 X 20 cm (Figure 1). She underwent reconstruction with a right pedicled vertical rectus abdominus flap and a pedicled gracillis musculocutaneous flap. By day 7 there was definitive evidence of soft tissue infection and the blood supply of the distal half of the GMCF was compromised (Figure 2). The flap was debrided and the underlying pus was drained and the wound bed was thoroughly washed out. The resulting wound defect was triangular in shape and measured 17 cm in height and 10cm at the base (Figure 3). Daily wound wash and dressing was commenced. On Day 14 once wound was deemed to be clean traction assisted closure (described below) was started and repeated every two to three days (Figure 4). This was performed initially as an inpatient (Figure 5). She was discharged from hospital on Day 45 post primary surgery to continue the taping and dressing at home.

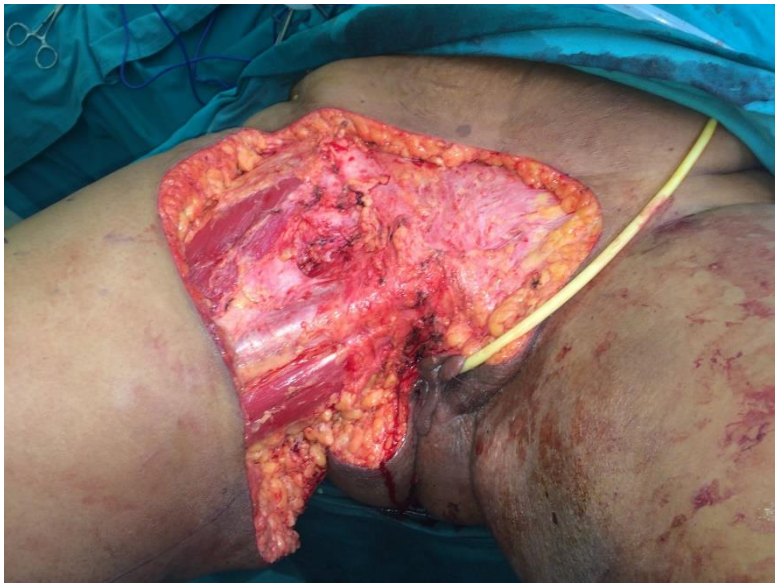

Figure 1: A defect measuring 35 x 20 cm following removal of dermatofibrosarcoma protuberans of the right perineum, groin and upper thigh is shown

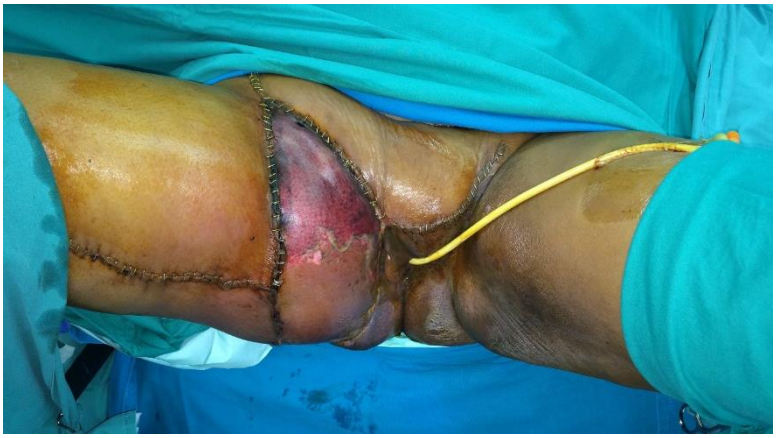

Figure 2: The defect was reconstructed with a left vertical rectus abdominus flap and right musculocutaneous gracillis flap. On day 7 post surgery there was obvious vascular compromise of the distal end musculocutaneous gracillis flap

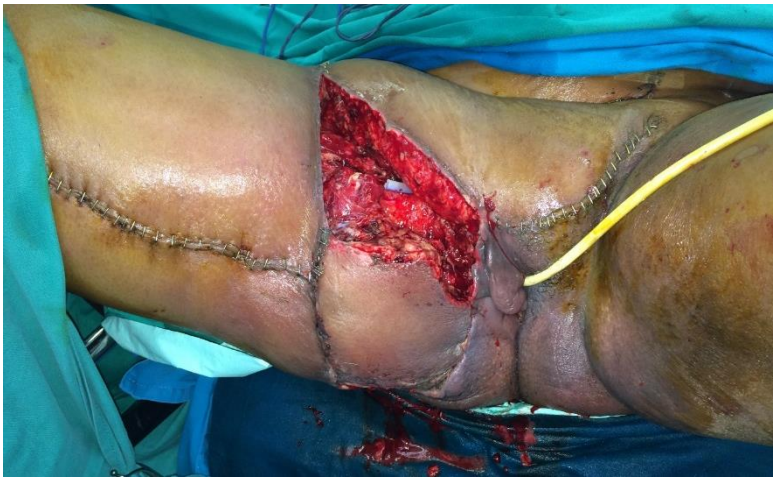

Figure 3: A defect of 17 x 10 cm followed a surgical debridement. The initial management was infection control and wound bed preparation

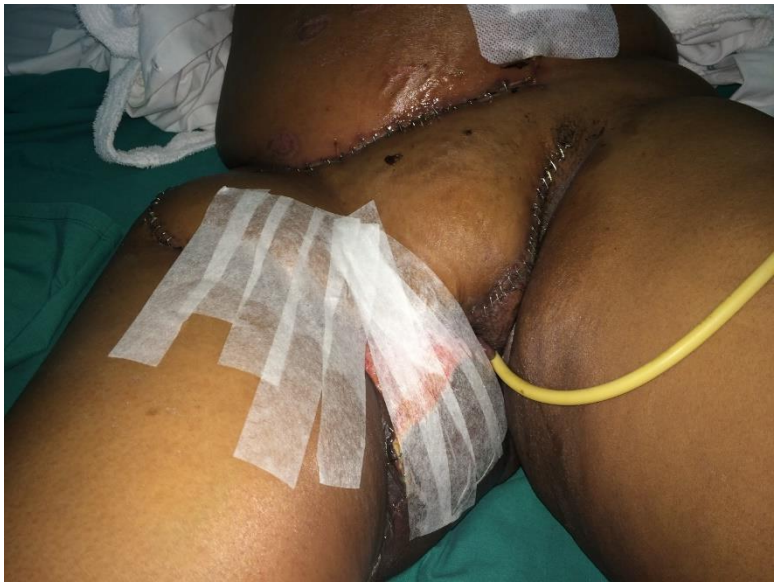

Figure 4: The taping was commenced on day 14. The direction of the taping was performed in line with proposed final closure

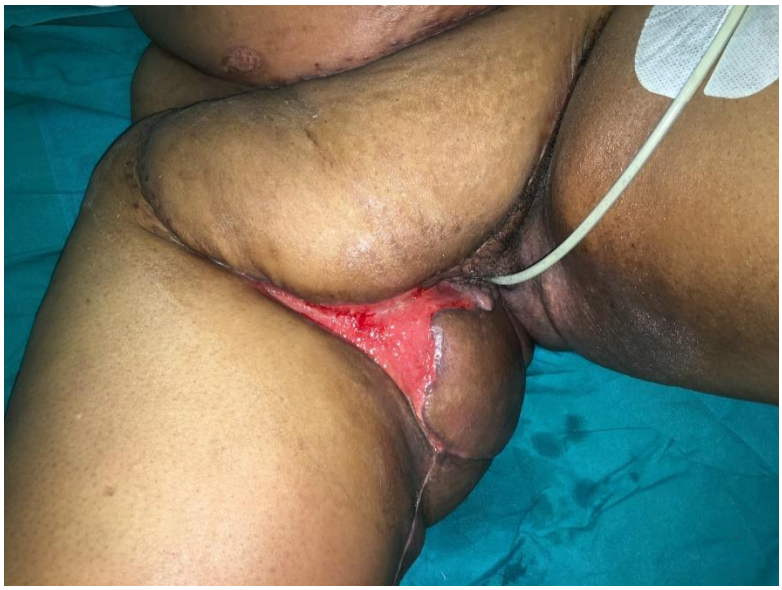

Figure 5: An intermediate result is shown 24 days after commencement of TAC

Traction assisted closure (TAC)

This technique is an extended application of traction assisted tissue expansion (TATE) with micropore tape. TAC is applicable to managing open wounds and it differs in that the closure of the wound is obtained by taping only. The process begins by cleaning the wound first. If the wound is noted to be exudating then gauze and adaptic roll is made to cover the central portion of the wound. A sparse amount skin barrier cream is applied to the surrounding skin. The micropore tape is then applied migrating the skin flaps by traction from either side in the direction of the projected closure. The line of the closure can be manipulated as the taping progresses with each application. In a low exudating wound or when the exudation decreases the roll dressing can be omitted and the micropore tape is directly applied and remains in direct contact with the wound. The application is repeated everyday but can be individualized depending on the gain in laxity to two to three days. The procedure is repeated until closure is achieve. The taping can be suspended or abandoned as required by prevailing wound conditions.

* 3M^{TM}Cavilon^{TM} Durable Barrier Cream

Outcome

Complete closure was reached by day 90 (76 days after commencing TAC). At eight month follow up the area of scarring from the healing associated with TAC was minimal (Figure 6). The scarring was a triangular area measuring 2,5cm in height and 1,5cm at the base.

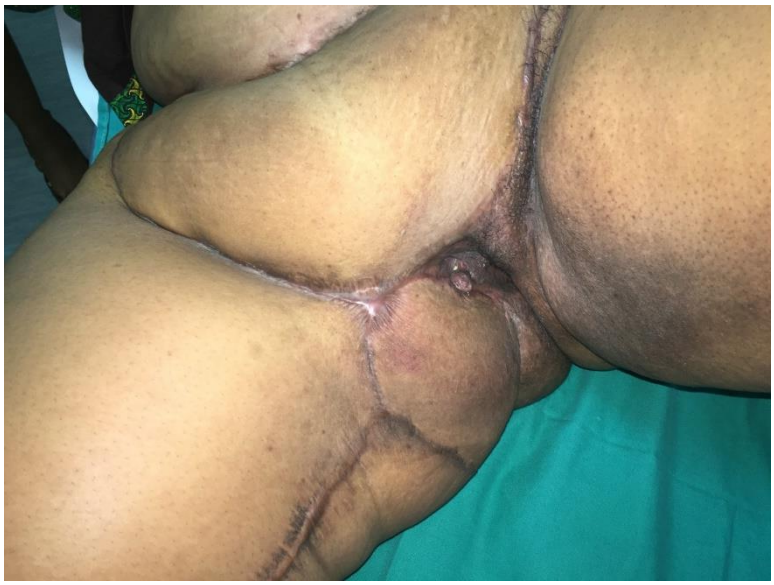

Figure 6: A final result is shown at 8 months follow up following the ablative sarcoma surgery. Note the minimal scarring

Discussion

TAC is not being claimed as a universal substitute for vacuum assisted closure. Compromised wounds may still be best managed by vacuum assisted closure. In wounds demonstrating the natural healing potential, if applicable anatomically, TAC can be considered to shorten the secondary intention healing. The use of TAC with micropore tape is inexpensive and easily applied by patient or caregiver. Mobility is also not likely to be compromised.

The primary aim of the technique is to provide a mechanical force of tension on the surrounding soft tissues, drawing them into the wound. An immediate secondary consequence on the surrounding tissues and the wound itself is that of compression generated by the inelastic tape applied under tension. Tension is produced by the natural recoil of the surrounding normal tissue. Our subjective clinical observations

in this case, as well as with use of TATE for other open clean wound applications primary effect of wound reduction was noted from the outset. In addition we noted secondary effects.

Two of them were reduction in wound exudate and reduction of edema in wound and surrounding tissues. This led to a discontinuation in the use of gauze and adaptic touch roll, as an absorbent contact dressing was no longer required. A clear advantage of this was space creation for the surrounding tissue to migrate over the wound with taping. In comparison the polyurethane foam used in VAC™ although it draws in tissue once under suction the bulk present limitation to surrounding tissue migration. But, the suspension of contact dressing did result in the micropore tape being applied directly onto the wound.

Micropore tape is not a wound dressing. But its porous nature, as we have observed seemed to allow serous fluid to pass through it. A good seal over the wound was frequently achieved allowing typical wound exudate synonymous with occlusive dressing to accumulate under the micropore in contact with the wound. Therefore it would seem that micropore appeared to serve as a semi-occlusive dressing promoting a moist wound healing environment. The obvious concern is that micropore does not come in sterile packaging and its use is not purposed as a wound dressing. However, a clean dressing technique was always observed. In our defense sterile technique has not shown to be superior to clean techniques in wound dressing.(9) Nevertheless micropore as a contact semi-occlusive dressing is worthy of further investigation.

The third secondary effect we noted was improved tissue compliance. The skin and the wound after the removal of the first application of tape showed a greater degree of deformation to tissue manipulation. There was a much softer feel to retaping for TAC. The improvement in compliance was most likely due to edema control and/or direct tissue response to the mechanical forces. Such forces influence gene

expression, synthesis of growth factors and inflammatory mediators and cellular processes like proliferation of many load-sensitive cells.(10) However the exact mechanism of these interactions will hopefully elucidated by ongoing research.

Repair of wounds is a complex biological process. But, wound management and wound dressings is central to optimizing long term management. A systemic review on topical dressing not including VAC™ demonstrated no ideal.(11) Traditional dry gauze application in addition was also likely to elicit the most pain in patients. The same center later demonstrated in a randomized controlled trial no difference in wound healing between moist and dry.(12) On the other hand Zhang in a split skin graft donor site model showed superior wound healing in an occlusive moist wound environment than a dry one.(13) There are many strategies available now days for a variety of wound conditions, but initial treatment by debridement and soft tissue infection control leading to wound bed preparation is vital. Most of these strategies aim to decrease the number of dressing changes and provide patient comfort, but a higher cost per dressing.

Conclusion

TAC can be thought of as an agent of providing accelerated wound closure by actively drawing in surrounding soft tissue, contraction of the wound (macrodeformation) and achieving complete epithelialization with reduced scarring than what one may expect from pure secondary intention wound healing. Additional research is required to understand this process from the mechano-biological, cellular and growth factor model point of view.

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Part 3: Generation of Mechanical Forces with the Use of Micropore Tape to Modulate Keloids and Hypertrophic Scars

In Part 2 various clinical applications of the taping to obtain wound closure in plastic and reconstructive surgery were studied. In the last chapter of Part 2 the use of taping was reported in a case study to achieve accelerated wound healing. A significant reduction in the wound was observed with TAC. Basic granulation structure is composed of the small blood vessels and capillaries interspersed within a mesh of collagen. Wound reduction i.e. granulation tissue reduction is synonymous with collagen reduction. This is likely to mean that there is either a reduction in collagen production and or increase in the resorption of collagen. In the next part, Part 3 Chapter 11, in a cohort study we test the ability of taping to reduce abnormal scars. The longstanding hypertrophic scars and keloids are treated by the application of tension reduction taping. Abnormal scars, like granulation tissue, are predominantly composed of collagen tissue but have a lower content of vascularity. Unlike granulation tissue, its surface is epithelialized which under normal circumstances is meant to switch off collagen accumulation and bring about scar maturation. In abnormal scars the fibroblasts continue to proliferate laying down collagen and/or the resorption of collagen is dampened resulting in the net growth of scar tissue. With the phenomenon of scar reduction that we see in 70% of patient studied in Chapter 11 and the granulation tissue reduction seen in the case studied in Chapter 10, collagen reduction is common to both. The mechanobiologically mediated response of the fibroblast and other cells in the environment to the taping, whether it is to achieve TAC for wounds or TRT for scars, are likely to have many common cellular and molecular response pathways for the decrease in granulation tissue and scarring..

Chapter 11 was published in Eur J Plast Surg in 2011

Chapter 11: Abnormal Scar Modulation with the Use of Micropore Tape. Daya M. Eur J Plast Surg (2011) 34:45–51, DOI 10.1007/s00238-010-0455-z

Keywords

Scar modulation; Keloids, Hypertrophic scars, Semiocclussive taping

Abstract

Background

Multiple modalities of treatment exist for the control of abnormal scars and their associated symptoms. In the literature the use of occlusive taping is prophylactic. Our aim was to measure the effects of the micropore taping on abnormal scars.

Method

Twenty-nine consecutive patients with a total of 42 abnormal scars were entered in a prospective trial. The patient's scars were taped in a specific manner. Both objective and subjective parameters were measured.

Results

Scar Thickness: 29 (69%) scars demonstrated a decrease with a range of 20 – 75% and an average of 39%. (n=42)

Scar Surface area: Eight scars (19%) demonstrated a decrease with a range of 3–50% and an average of 19%. Nine scars demonstrated an increase. Twenty five scars demonstrated no change. (n=42)

Pain score: The baseline pain score was 0 in three scars and remained unchanged at 10 for one scar. All other 28 scars demonstrated a score reduction. (n=32)

Itch score: The baseline pain score was 0 in 4 scars and an increase of 1point seen in 1. All other 27 scars demonstrated a score reduction. (n=32)

Scar quality: This remained the same in 12 scars. An improvement was seen in 28 scars. (n=40).

Photographic scoring demonstrated a high rate of decrease in scar redness, flattening and a decrease in the surface shine.

Conclusion

Abnormal scar taping is able to enhance the maturation of the scar and manage the related symptoms. Its use should be extended to managing established keloids and hypertrophic scars.

Introduction

Abnormal scar control is difficult and is associated with multiple modalities of treatment. These include often in combinations intralesional injection of steroids and chemotherapeutic agents, surgical excision, radiotherapy, pressure garments, topical application of oils and creams, laser therapy and occlusive taping with silicone sheeting. The use of semi-occlusive taping like micropore tape has documented use in prophylaxis of hypertrophic scars. It is postulated that the tape may serve to hydrate the scar. The efficacy of this treatment and the exact mechanism of the action have not really been determined.

Pain and itch associated with abnormal scars are also not well understood. The plastic surgeon not uncommonly fails to control the abnormal scar and the associated troublesome symptoms.

The aim of the study was to measure both objectively and subjectively the effects of the micropore taping in a physical manner that decreases the tension and applies external pressure on abnormal scars.

Method

A prospective study beginning in June 2005 and ending in April of 2007 was carried out in, all patients presenting to the clinic with symptomatic (pain and itch) abnormal scars. There were no exclusion criteria except patients with very large and extensive abnormal scars which made the application of micropore tape cumbersome.

Twenty nine patients, Six males and 23 females were recruited for the study. The subject racial constitution was 17 Negroids, 11 Asian Indians and one mixed race. The age range was 1 – 69 years (average = 36 years). The onset of the scar ranged from 1 – 20 years. The follow up of the subjects ranged from 1 – 19 months (average = 8.9 months). A total of 42 scars were assessed with an anatomical distribution of sternum=15, back=7, abdomen=5, deltoid=4, head and neck=4, lower limb=3 and others =4. The aetiology of the scar was spontaneous in 23, burn injury in eight, post-surgical in seven, post-traumatic in two, and a primary skin lesion in two e.g. acne.

Technique of Tape Application

The tape was not simply applied just to occlude the scar and the adjacent normal skin. The skin was washed and dried then followed by sparse application of Cavilon cream. The patient and the body part to be taped was positioned in a way that diminished or nullified the tension in the region of the scar. In addition, the surrounding skin was migrated towards the scar and held as former was noted to begin to crease. The tape was then applied thus retaining the position of the soft tissues (figure 1a). We surmised that this manuever interrupted the transmission of tension of the surrounding tissues on the scar. In addition, once applied the recoil in the skin also served to tension band the tape resulting in direct pressure application onto the scar. Using the same technique more tape was added parallel to the first tape until the entire scar was covered. Additional taping was added perpendicular to the first layer to reinforce the first layer (figure 1b). The tape was changed weekly by the patient with the aid of a helper as needed adhering to the

demonstrated technique. The patient showered normally on a daily basis. The taping was continued by the patients as directed. The following parameters were measured initially monthly and then every 3 months:

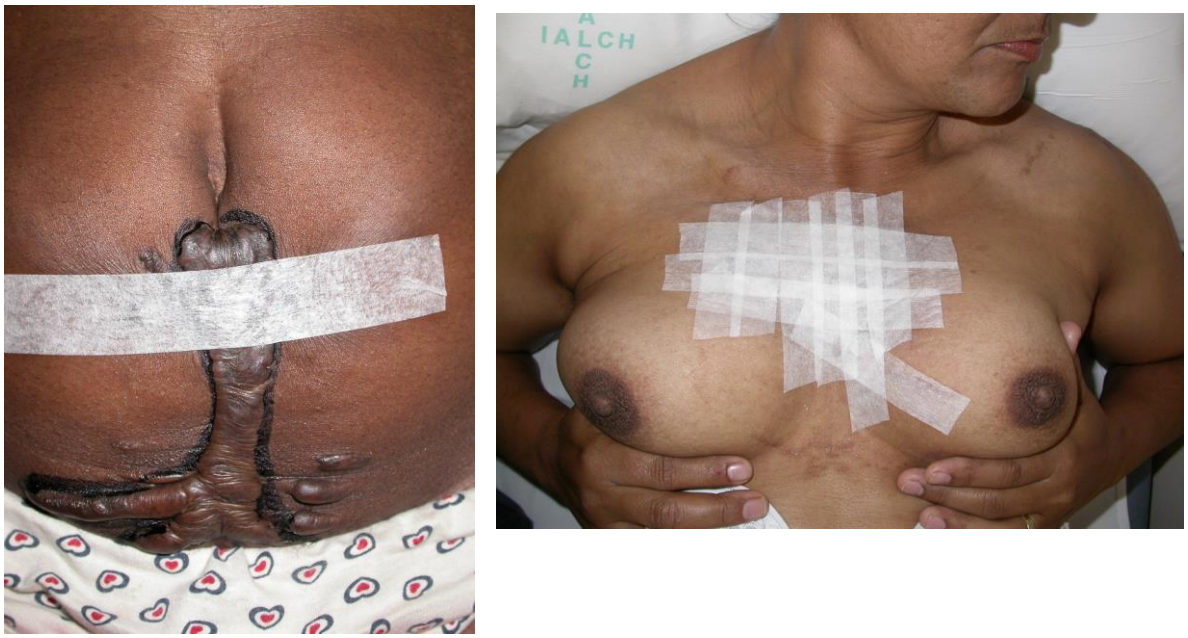

Figure 1a and b: The first tape is applied after the skin lateral to the scar is migrated towards it. Note the fine creasing of the skin along the scar under the tape (left). Reinforcement of the 1st layer with additional tape. Also note that the application of the entire taping is done after neutralizing the tension on the scar. As in this case of a sternal scar the patient is lying down and the breast a pulled medially (Right).

Objective Parameters

Surface area of the scar – The traced outline was mapped on a grid with 1 cm^2.

Thickness of the scar – This was measured at a spot which was deemed to be the thickest portion with a custom made depth gauge in 1mm increments from 1mm to 12mm. In large lesions with variable thickness multiple specified points were assessed and analysed. The average of the thickness was then assigned to that scar.

Pain and itch score on a scale of 0 to 10. The patient was asked to grade each symptom on a 0 to 10 scale at the outset and then on each review. The baseline score were grouped as follow: 0, 1 to 4, 5 to 7, 8 to 10.

Subjective Parameters

Scar pliability

H - Hard like cartilage

I - Intermediate

S - Soft like normal skin

Digital photographic records

Colour (redness)

Elevation

Flash reflectance (shine)

Each of the photographic parameters is then scored by assessing the first and the last photograph as:

-1 = improvement

0 = no change

+1 = deterioration

A composite photographic score is then given to each case. The theoretical score range is thus -3 to +3. The scoring was performed by 2 independent plastic surgeons

Statistical methodology

SPSS version 15.0 (SPSS Inc., Chicago, Illinois, USA) was used to analyse the data. A p value <0.05 was considered as statistically significant. One sample t tests were performed to compare the difference in percentage change from pre- to post-treatment in scar thickness, surface area and surgeon photographic scores to the null hypothesis value of 0. Paired t tests were used to compare levels of pain and itch pre- and post-treatment. McNemar-Bowker's test was used to compare ordinal levels of scar quality pre- and post-treatment, and Wilcoxon's signed ranks test was used to compare photographic score ratings of the two surgeons.

RESULTS

Thickness of the scar

The range was 1 – 12 mm before treatment. Twenty nine (69%) scars demonstrated a decrease with a range of 20 to 75%, a mean of 39%. One scar demonstrated an increase of 60%. Twelve (29%) scars demonstrated no change. The average percentage reduction for the entire series was 25.5% (n=42) with a standard deviation of 25.8% and a range of +60% to -75%. This represented a highly statistically significant decrease overall (p<0.001).

Scar surface area

The size of the scar ranged from 294 – 6370mm2 before treatment. Eight scars (19%) demonstrated a decrease with a range of 3 – 50%, and a mean of 19%. Nine scars demonstrated an increase with a range of 8 - 44%, a mean of 29%. Twenty five scars demonstrated no change in the surface area size. (n=42). The mean percentage change in surface area was an increase of 2.67% with a range from +44 to -50%. The increase was however not statistically significant (p=0.343).

Pain scale

The baseline pain score was 0 in three scars. Three scars from the 1 - 4 group demonstrated an average 1.3 point reduction, ten scars from the 5 – 7 group an average 4.4 point reduction and 16 scars from the 8 – 10 group an average 6.25 point reduction. A single scar from the latter group demonstrated a final unchanged score of 10 after a transient initial good response of 3 points. (n=32) In ten scars the baseline pain score was not recorded and therefore excluded from the analysis. There was a highly statistically significant reduction in pain score in these 32 participants from a mean of 6.69 to 2.06 (p<0.001).

Itch scale

The baseline itch score was 0 in four scars. Four scars from the 1 - 4 group demonstrated an average 1.25 point reduction. A single scar from this group demonstrated an increase of 1 point from the initial score of 4. Two scars from the

5 – 7 group demonstrated an average 2.5 point reduction and 22 scars from the 8 – 10 group an average 6.2 point reduction (n=32). In ten scars, the baseline itch score was not recorded and therefore excluded from the analysis. There was a highly statistically significant reduction in pain score in these 32 participants from a mean of 6.88 to 2.34 (p<0.001).

Scar quality

This remained the same in 12 scars with ten in the intermediate group, one in the soft group and one in the hard group. An improvement was seen in 28 scars. Twenty one of these showing a change from hard to intermediate, three from hard to soft and four from intermediate to soft. (n=40). The baseline grading for quality was not recorded in 2 scars. The improvement in scar quality was highly statistically significant (p<0.001). See table 1. Pre quality and Post quality cross tabulation and Table 2. Chi-Square test.

Table 1 Pre-quality + post quality cross-tabulation (as appeared in publication 2011,)

		post quality			Total
		soft	intermediate	hard	soft
pre quality	soft	1	0	0	1
	intermediate	4	10	0	14
	hard	3	21	1	25
Total		8	31	1	40

Table 2 Chi-square tests (as appeared in publication 2011)

	Value	df	Asymp. Sig. (2-sided)
McNemar-Bowker Test	28.000	3	.000
N of Valid Cases	40		

Highly significant improvement (p<0.001) in scar quality over time (McNemar-

Bowker test of paired proportions). In the table, the numbers highlighted in green are those where no change occurred, in blue changed for the worst (above the diagonal) and in yellow changed for the better (below the diagonal). There are much more in yellow and 0 in blue, therefore change was a significant improvement in quality.

Photographic score

The score given by two independent plastic surgeons are in table 3:

Table 3. Photographic total score provided by two independent plastic surgeons (as appeared in publication 2011)

Score	-3	-2	-1	0	1	2	3
Surgeon 1	21	8	4	7	2	0	0
surgeon 2	21	6	6	7	1	0	1

Table 4 (as appeared in publication 2011) contains samples of the cases with the some of the background information and the data collected for each one with the associated initial and the final photographs. This I feel will help the reader of the article verify some of the observations and data collected on the cases (Figs. 2, 3, 4, 5).

The mean score for surgeon 1 was -1.90 with a standard deviation of 1.3. This was highly significantly different to 0 ($p<0.001$). Surgeon 2 had a mean score of -1.81 with a standard deviation of 1.45, which was also highly significantly different from 0 ($p<0.001$). However, the two surgeons tended to rate the photographs the same, as there was no difference between the ranks of the rating of the two surgeons ($p=0.598$).

Table 4 Samples of the cases

Case	Age	Sex	Onset	Cause	Follow-up	Site	Taping	Thickness (mm)			Size (mm^2)	Pain	Itch	Quality	Surgeon 1				Surgeon 2				Figures
	Years				Months			Site 1	Site 2	Site 3					Col	Ele	Shi	S1	Col	Ele	Shi	S2	
1	59	F	>20 years	Spontaneous	3	Sternum	Pre	12			3,577	10	10	H	−1	−1	−1	−3	−1	−1	−1	−3	2a,b
							Post	8			2,597	1	2	I									
2	43	F	5 years	Surgery	18	Abdomen	Pre	4	5		3,087	10	10	H	−1	−1	−1	−3	−1	−1	−1	−3	3a,b
							Post	1	2		2,989	2	1	I									
3	67	F	4 years	Sternotomy	17	Sternum	Pre	4	5	4	686	8	9	H	−1	−1	−1	−3	−1	−1	−1	−3	4a,b
							Post	1	2	1	588	0	1	S									
4	5	F	2 years	Burn	11	Face	Pre	4			490	7	8	H	−1	−1	−1	−3	0	−1	−1	−2	5a,b
							Post	1			245	0	0	S									

Photographic scores in the table is the net change seen between pre-test and final post-test measurement: *S1* surgeon 1 total score, *S2* surgeon 2 total score, *Col* colour, *Ele* elevation, *Shi* shine. Quality of scar: *H* hard-like cartilage, *I* intermediate, *S* soft-like normal skin. Thickness, size, pain, itch, and quality associated with the scar: *Pre* pre-test values, *Post* final post-test values

Complications

Two patients developed a superficial rash around the scar. This required temporary suspension of the taping. The reaction was minor and transient and resolved without medical intervention. However in one patient temporary hyperpigmentation was noted.

DISCUSSION

Despite our modern advances, this fibroproliferative disorder remains ill-understood. However, many factors have been identified to predispose to abnormal scarring. The racial and genetic factors are important but not medically controllable. The physical property of tension across the scar even in the absence other factors is a major contributor. Certain areas of the body like the sternum and the deltoid region has multidirectional high tension forces acting on them. This may explain these areas having a higher predilection to abnormal scar formation.

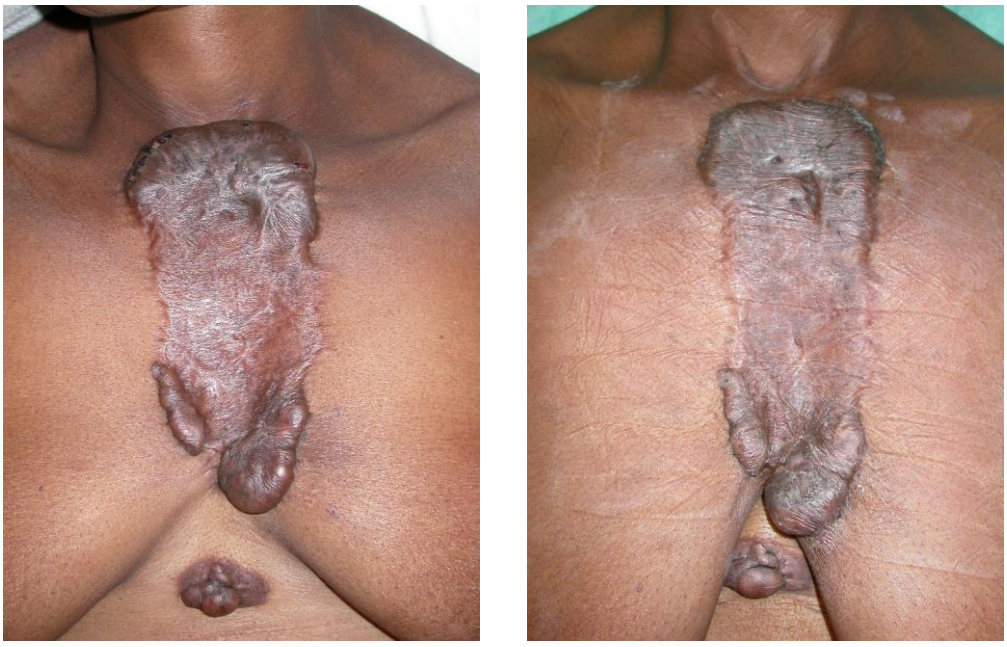

Figure 2a and b: A longstanding sternal keloid showing a regressed central portion (Left). The keloid demonstrates flattening and surface area reduction at 3 months at which time follow up was lost. Also note a decrease in the breadth of the lesion which is in the same direction of tension reduction achieved by the tape (Right)

The purpose of the study was to measure the effect of tension elimination with taping on the abnormal scar. This required the covering of the entire scar instead of dividing it into 2 for the purpose of having a control arm. The subjects also consisted of a heterogenous group with abnormal scars with various anatomical sites and varying scar age. A randomised control trial to test the mechanism of taping is also faced with many obstacles due to the multiple factors that contribute to abnormal scarring making matched groups a very difficult attainment.

Reiffel had good results using paper tape application for 2 months or more after excision of a hypertrophic scar.[1] Atkinson et al in a randomized controlled trial on 39 post-caesarean section patients, achieved similar results.[2].They both cited tension as the most significant factor in the promoting hypertrophic scars. Scars lying perpendicular to Langer's skin tension lines show a higher incidence of hypertrophic scarring. In contrast, incisions that are placed parallel to Langer's skin tension lines have a static, unidirectional force exerted along there axis, which also significantly reduces closing tension of the wound margins and is thus unlikely to form a hypertrophic scar. Stretching forces are controlled by the use of paper tape thereby preventing hypertrophic scarring.

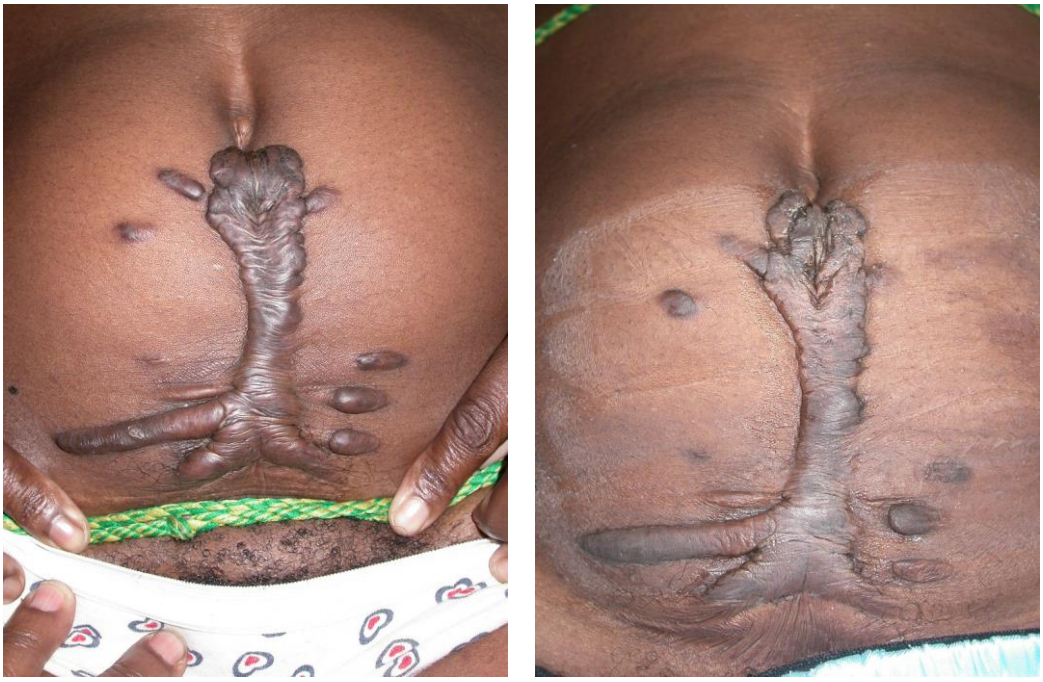

Figure 3a and b: A post midline laparotomy keloid (Left). The keloid demonstrates considerable flattening at 18 months with complete regression in some parts (Right)

Mustoe criticized the model because these scars are under minimal tension in these postpartum patients.[3] Instead he favours a mechanism by which the semi-occlusive properties of paper tape result in increased hydration levels of the basal cell layer by improving the water barrier function of the still immature stratum corneum of the wound. The hydration alters the cytokine and fibroblast activity with subsequent effects on the collagen milieu.

Chang in 122 randomized patients demonstrated that pressure garments showed no significant difference in time to scar maturation.[4] In our study our method of tape application added pressure to the scar in addition to reducing the tension and providing semi-occlusion on the scar.

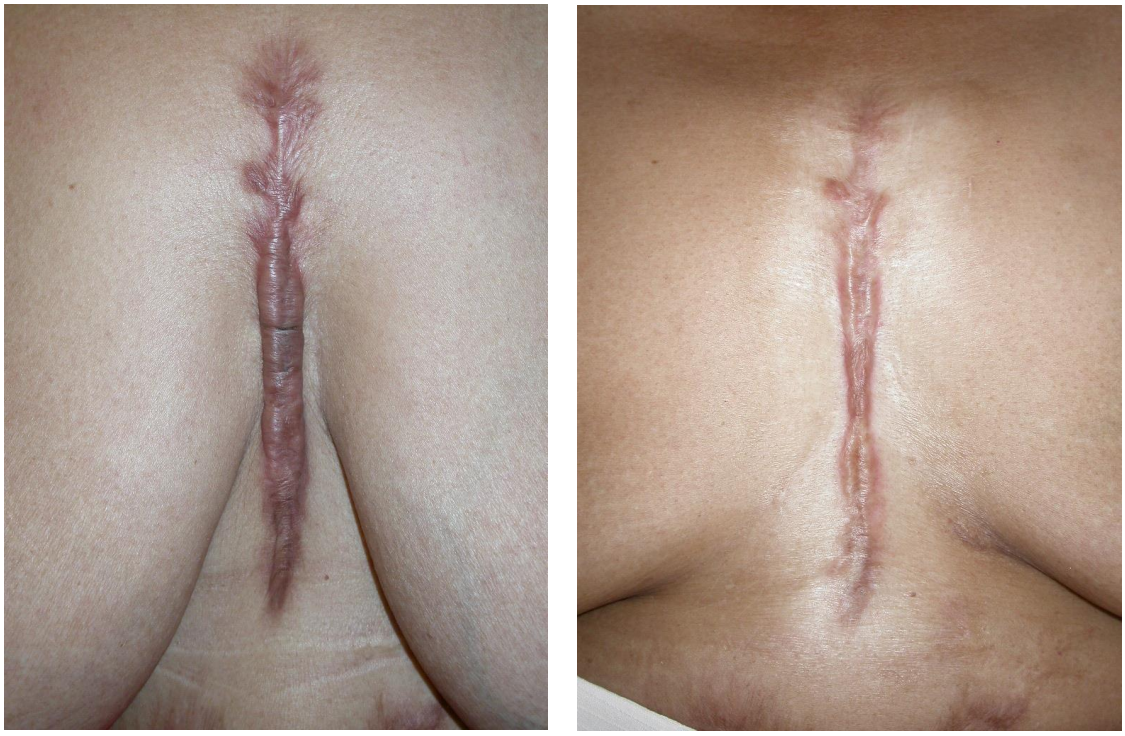

Figure 4a and b: A very hyperaemic post sternotomy keloid (Left). At 17 months the keloid is paler and flatter (Right)

Our report is the first to assess the use of paper tape in the management of established abnormal scars. To measure the outcome of scar management is a challenge. Van Zuijlen suggested several objective and subjective tools of scar assessment.[5] We used a cross section of parameters to produce a satisfactory standard of composite assessment. In clinical practice the maturation of the scar is reflected in the flattened, paler and less shiny scar. The scoring of the photographs to measure the maturity although useful remains subjective and non-standardised. Davey used computerized quantitative description of colours as a single parameter for the assessment of hypertrophic burn scars.[6]

All the patients in the study had established abnormal scars for period equal or greater than 2 years. Sixty-nine percent of the scars demonstrated a decrease in elevation and 29% no change. Our measuring technique was crude and therefore

subtle changes were not discernible. The use of ultrasound is useful to overcome this situation.[5] Nevertheless, only one scar showed increase in elevation. Sixty percent of the scars demonstrated no change in the surface area size. It is my feeling that our method of measurement was not a good indicator of the response because it was the outline of the scar that was traced. As in case 2 which showed only a $2cm^2$ decrease in surface area fails to do justice to the actual response that is seen (figure 3a and b). Planimetry by photography or 3 dimensional computer reconstruction may improve the yield of measuring a favourable response.

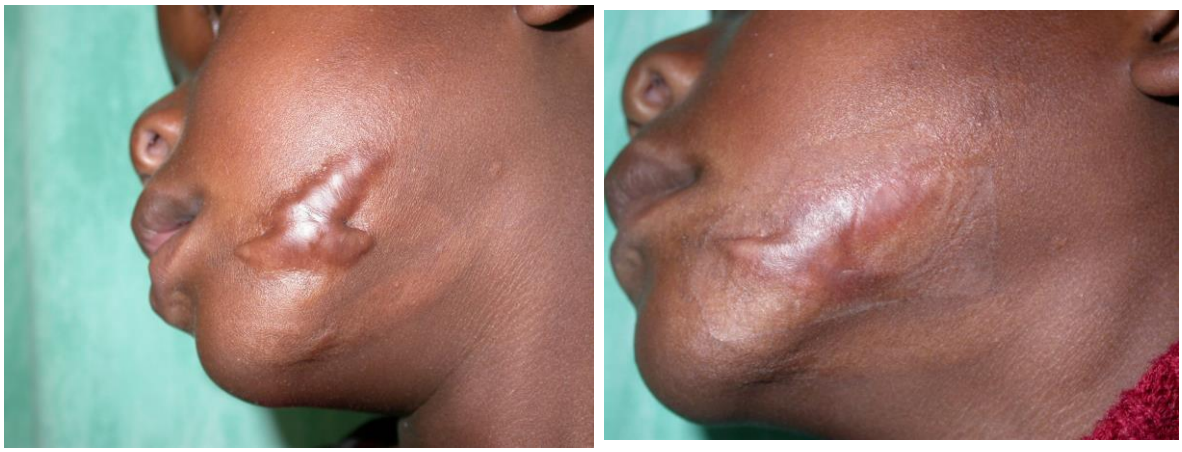

Figure 5a and b: A hypertrophic scar in a previous burn sustained 2 years ago (Left). At 11 months there is almost complete regression (Right).

The improvement in the pain and the itch related to the scar was impressive. The patient appreciated within days or weeks, and this improved the patient's compliance.

An improvement in the quality of the scar was noted in 79% of the scars. Our method was crude in comparison to several types of devices using different physics for a more objective and accurate measurement.[5]

The keloids showed an overall measured parameter response to the micropore taping technique. This we feel is indicative of the keloid regression and increasing maturity of the epithelium and the collagen.

Aarabi demonstrated for the first time that mechanical stress applied to a healing wound is sufficient to produce hypertrophic scars in mice.[7] The scars showed a 20 fold increase in volume and cellular density. Although keloids are histopathologically not the same entity tension reduction across the abnormal scars maybe an important factor in achieving collagen maturation.

Our study has certainly demonstrated that the scar undergoes some form of modulation in response to the taping. A number sternal keloids demonstrated a change in shape i.e. elongation in one direction and narrowing in the other over a period of time (figures 2a and 2b). This may be suggestive that the taping which was applied to counteract forces in a specific direction only failed to address other forces in the anatomic region of the keloid. Meyer demonstrated in his ten cadaver study that the tension forces on the sternal area is multidirectional as opposed to horizontal as one traverses in the midline form the xiphoid process towards the umbilicus.[8] A single patient in our study demonstrated continued growth in thickness and surface area. It is probable that we did not decrease the tension in the appropriate direction. Reiffel learnt in his clinical series that the direction of the tape application and tension reduction in relationship to Langer's line and the scar was important to prevent the formation of hypertrophic scars.

Conclusion

Clearly this is not a controlled trial comparing products. More importantly it does not need to be compared to an untreated group because these are established scars of greater than 2 years that have failed to improve spontaneously. In essence, the prior period represents an untreated control arm. Paper taping is a recognized modality in the prophylaxis of hypertrophic scars.[1,3] We believe that this study forms the basis

for its use in treatment of keloids and hypertrophic scars. The early response seen in the abnormal scars maybe indicative of the decrease in the water content of the tissue but later improvement seen has to be a reflection of changes in nature and content of the collagen and the extracellular matrix.[9] It will certainly be very interesting to see the further outcome of some of abnormal scars if amenable are excised followed by prophylactic taping as we have already demonstrated in a single patient presented in our series on traction assisted dermatogenesis.[10] It will also be valuable to measure the effect of this technique in a homogenous group of patients with established scars e.g. post-sternotomy keloid.

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Financial Disclosure and products page

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Part 4: Clinical Applications of the 3M Micropore Tape Goes Beyond Its Designed Use for Surgical Dressings

Chapters 2 to 11 of parts 1, 2 and 3 lay down the basis for Part 4. Chapter 12 is the crux of the PhD. The experiences and the knowledge gained in the run up to this chapter is shared hopefully to, benefit a wider readership from the various disciplines involved in medical care in a publication. In Chapter 12 the devised technique of paper taping is described for clinical applications in wound healing, tissue expansion and scar management, together with the basic fundamentals of physiological understanding for its use. It is hoped that the medical edification provided on the use of micropore™ taping in the last chapter will assist the clinician in the use of the technique beyond that of the described practical guidance.

Chapter 12: Taping Techniques using 3M Micropore Tape in Tissue Expansion, Wound Closure and Scar Management

Key words

Traction assisted dermatogenesis, traction assisted tissue expansion, tension reduction taping, traction assisted closure, vacuum assisted closure, secondary intention healing, hypertrophic scars, keloids.

Abstract

Introduction

Tissue expansion, non-surgical wound closure and scar management can be achieved using various modalities and/or techniques and devices. Tissue expansion can be achieved with tissue expanders and skin stretching devices. Non-surgical wound closure can be achieved by secondary intention wound healing and vacuum assisted closure. Abnormal scar management is generally multimodality. Paper tape was used in our local setting to achieve tissue expansion, wound closure and scar management. In this paper, we describe these techniques.

Material and Methods

The adhesive paper tape used exclusively in the application procedure is 3M™ Micropore™ Surgical Tape. The barrier cream used to protect the integrity of the skin from the tape adhesive and potential mechanical injury from the applied traction is 3M™Cavilon™ Durable Barrier Cream. Preparation for taping included hair clipping, cleansing, and barrier cream application. Techniques of taping in clinical use included:-

- *Traction assisted tissue expansion (TATE)*

Applied in preparation for creating skin for reconstruction. Cases included burn injuries, trauma, paediatric conditions, skin and soft tissue malignancies and patients with existing wounds.

- *Traction assisted closure (TAC)*

Applied to achieve wound closure by secondary intention healing and without surgical intervention.

- *Tension reduction taping (TRT)*

Applied to modulate and prevent abnormal scarring.

Results

The techniques have been applied successfully more than 250 unpublished and published cases managed by the first author.

Conclusion

The use of paper taping in various clinical settings is simple, economically viable, accessible and provided a high success rate in our cases selected for its use. It represents work in progress and its clinical use is likely to expand with time.

Introduction

Tissue expansion, non-surgical wound closure and scar management can be achieved using various modalities and/or techniques and devices. Tissue expansion can be achieved with the use of internal tissue expanders and externally applied skin stretching devices. Non-surgical wound closure can be achieved by secondary intention wound healing, vacuum assisted closure and skin stretching devices. Scar management especially when treating keloids is generally part of stepwise multimodality approach which may include topical application of creams and gels, physical therapies that applies pressure and/or reduces tension, occlusive therapy with silicone sheets and paper tape, intra-lesional injections of steroids and

chemotherapeutic agents, surgery and radiotherapy. Some of these strategies are also appropriate for managing hypertrophic scars and prevention thereof.

3M micropore surgical tape which has been designed to secure dressing and devices to skin, was used in our local setting to achieve tissue expansion, wound closure and scar management. The technical processes that are involved using the same devices in managing all 3 entities is the product of 11years of work in a variety of clinical settings.

In this study, we describe these novel techniques using micropore tape for tissue expansion, wound closure and abnormal scar modulation and prophylaxis against hypertrophic scarring. Results obtained in a series of over 250 patients indicate that the technique is feasible, simple and low cost, and requires no customised devices for the purpose. Doctors, patients and/or their assistants can easily be trained in these techniques. Complication rate is low but appropriately adapting the technique when risks are noted manages or prevents complications. The technique should be useful in both resourced and resource constrained settings. If the technique fails, one can easily default to alternative well described recognized strategies.

The study objectives for the clinician are:

1. To provide practical guidance in the technique of using 3M micropore tape for tissue expansion, wound closure and scar management.
2. To effectively manage patients that are deemed suitable for the application of 3M micropore paper tape for traction assisted tissue expansion (TATE), traction assisted closure (TAC) and scar modulation by tension reduction taping (TRT).

Material and Methods

1. Tools

The adhesive paper tape used exclusively in the application procedure is 3M™ Micropore™ Surgical Tape. The barrier cream used to protect the integrity of the skin from the tape adhesive and potential mechanical injury from the applied traction is 3M™Cavilon™ Durable Barrier Cream. When required the topical contact dressing used is ADAPTIC TOUCH™. Ordinary dry gauze is used for padding and as a means of absorbing exudate. Hypafix® is used as required to secure in place any applied dressing.

2. Preparation for taping

The area to be taped including the scar/wound and surrounding skin is washed with ordinary bath soap and water and thoroughly dried. If a wound is present, cleaning with an antiseptic solution or saline maybe appropriate. The surrounding skin if hair-bearing is clipped with a hair clipper before washing. Shaving with a razor should be avoided due to the inherent risk of breaching the normal skin. The skin and scar is moisturised with sparse quantity cavilon cream in preparation for taping. The cream is not applied to any wounds that maybe present. If too much is applied then the tape does not adhere adequately on application of traction. If the tape does slip on application, the residual cream is simply wiped off with a gauze or tissue paper.

3. Techniques of taping in clinical use

3.1 Traction assisted tissue expansion (TATE)

This form of taping is applied in preparation for creating skin. Some of the sample cases from our cohort of patients are demonstrated below with picture strip depiction of the technique

1. Resurfacing of scars
    a. Burn alopecia scalp (Figure 1a to e)
2. Reconstructing surgically created defects following lesion excision
    a. Congenital giant melanocytic nevus (Figure 2a to d)

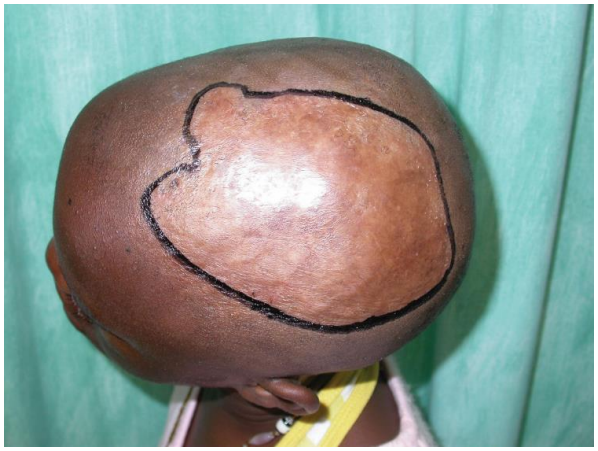
b. Recurrent myelomeningocele (Figure 3a to c)
c. Malignant skin lesions (Figure 4a to e)
d. Soft tissue sarcomas (Figure 5a to c)

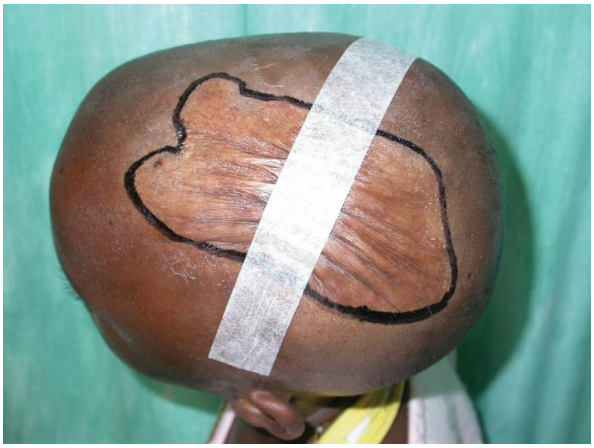
3. Surgically closing wounds.
    a. Limb amputation salvage (Figure 6a to f)
    b. Fasciotomy closure (Figure 7a to d)

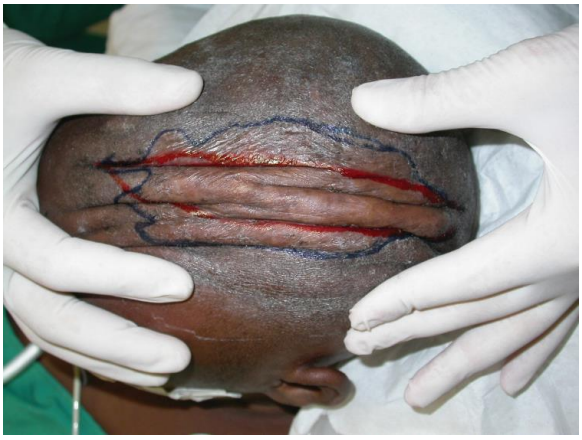
Once the skin has been prepared the surrounding normal skin is then stretched to its maximum, in the direction appropriate for obtaining final closure by the flap advancement. A single strip of 1 inch micropore 3M tape is then applied to hold this position of stretch of the normal skin (figure 1b). The first strip is usually applied at the central section of the advanced skin. Bilaterally more tape is applied to the first one along the line of advancing skin. Each tape application partially overlaps the already applied tape along its length. This seems to improve the integrity of the tape construct. It is sometimes also necessary to apply a single tape perpendicular to load bearing tape to cover its free edge on either side (Figure 2b). The first tape is retained for a period up to 1 hour for the technique of pretaping (Figure series of 4), or up to 1 day (Figure series of 2,6,7), or up to 1 week (Figure series of 1,3,5) for TATE depending on the indication for taping. If more than 1 application is required, the preferred tape change for wounds is 1 to 3 day intervals for scar resurfacing or skin lesions is from 1 to 7 days. Sometimes the taping interval within reason is performed for the convenience of planning a revisit to the treating doctor. Pretaping, a form of TATE for small skin lesions, usually a single application is sufficient (Figures 1a to e). If a repeat taping is required, then it is reapplied in theatre for a period not exceeding 15mins as the patient is induced and prepared for surgery.

Tape application lasting for days, the patient is allowed to bath normally when applied for scars or skin lesions. Direct application of soap over the tape is avoided, but running water over the tape is well tolerated. In the event that the tape does become undone then it is simply reapplied by the patient. The approach for managing wounds is different. The taped area is not allowed to be washed. For all

situations when removal of the tape is due, it is removed, the skin, scar or wound is washed and prepared again with cavilon cream application to the skin and scar. A new application of tape is performed upon stretching the skin further recruiting the developed laxity from the previous application. At each application the direction of tissue advancement can be controlled by the direction of the tension generating taping (Figure 6c).







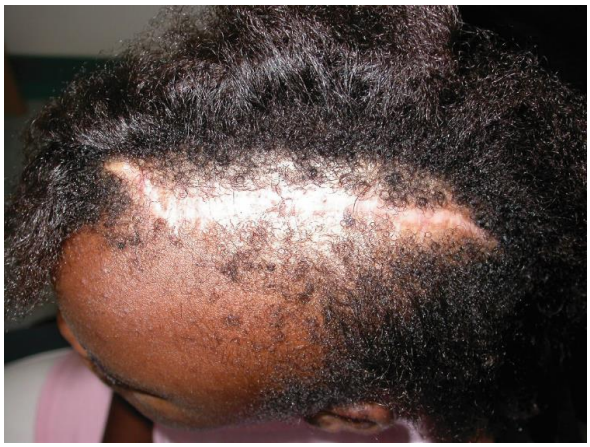
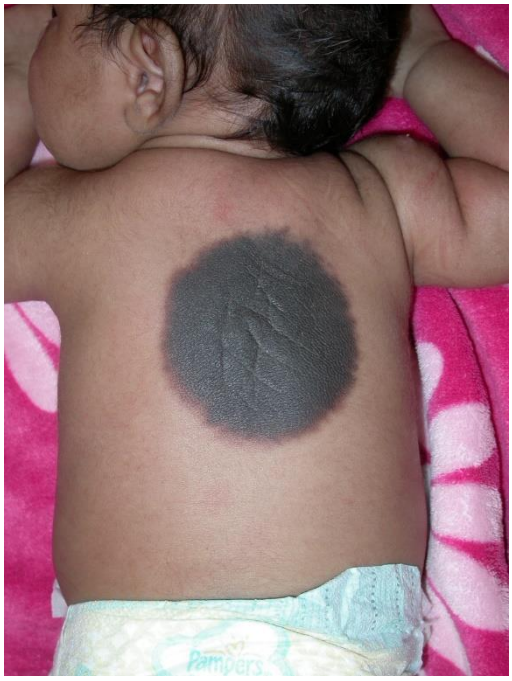
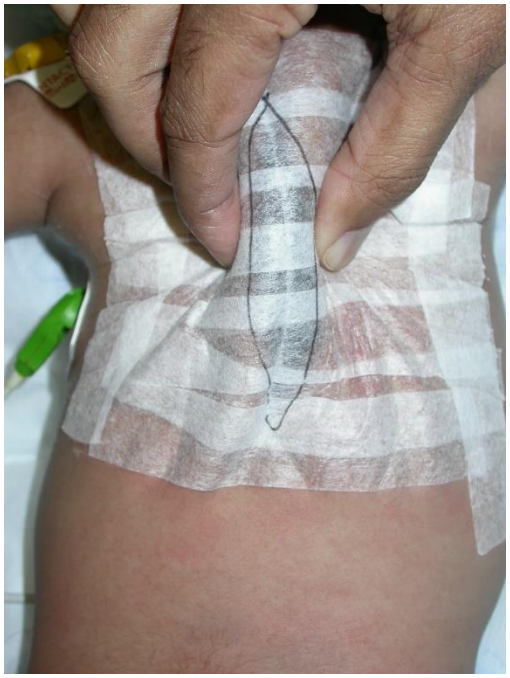


Figure 1a to e: Burn alopecia of the scalp was tissue expanded by traction taping resulting in a 2 stage surgical reconstruction by direct scalp advancement. The tape was changed once a week (Sequence of photographs Above left, Above right, Centre left, Centre right, Below)





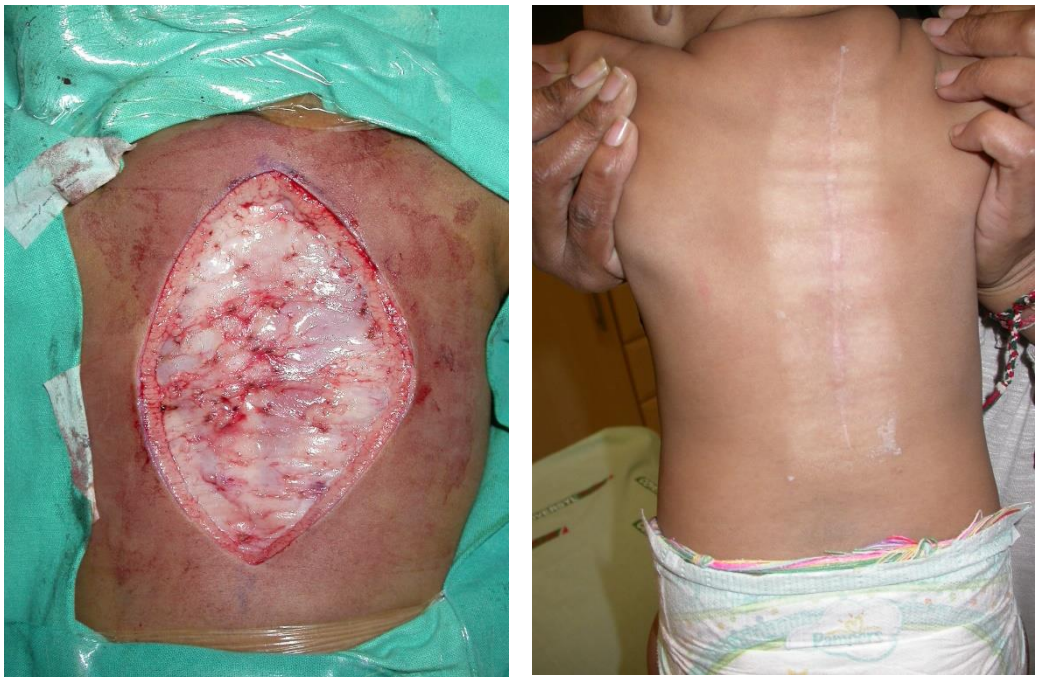


Figure 2a to d: Congenital giant melanocytic nevus of the back expanded by traction taping with 2 application over 2 days. Single stage excision performed and direct skin closure. The tape was change daily (Sequence of photographs Above left, Above right, Below left, Below right)

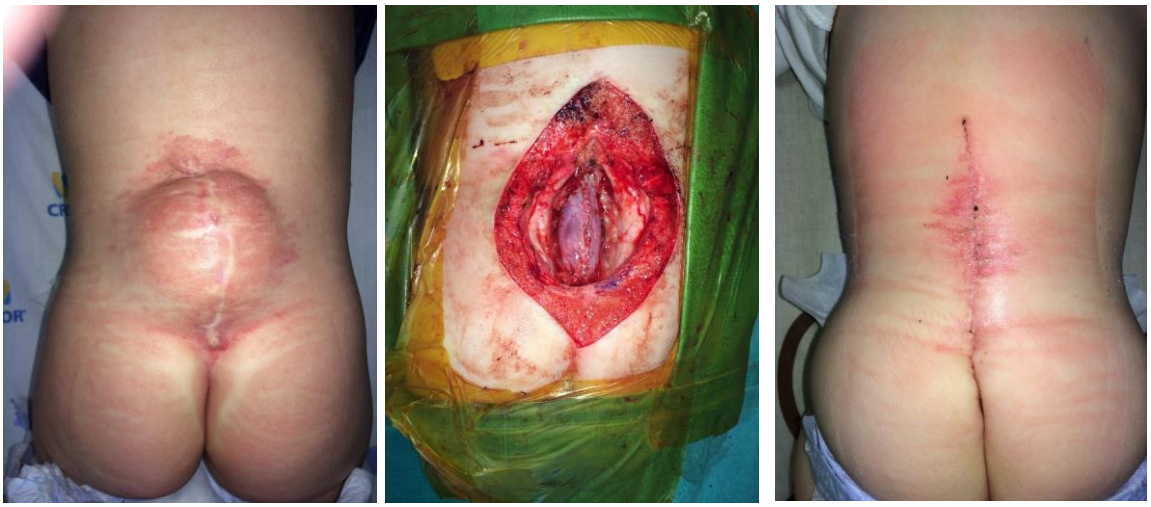


Figure 3a to c: A 1 year old child with a recurrent myelomeningocele having undergone 3 weeks of TATE to achieve surgical closure of defect in multiple layers after excision of the sac and overlying skin. The tape was changed every 3rd day (Sequence of photographs Left, Middle, Right)

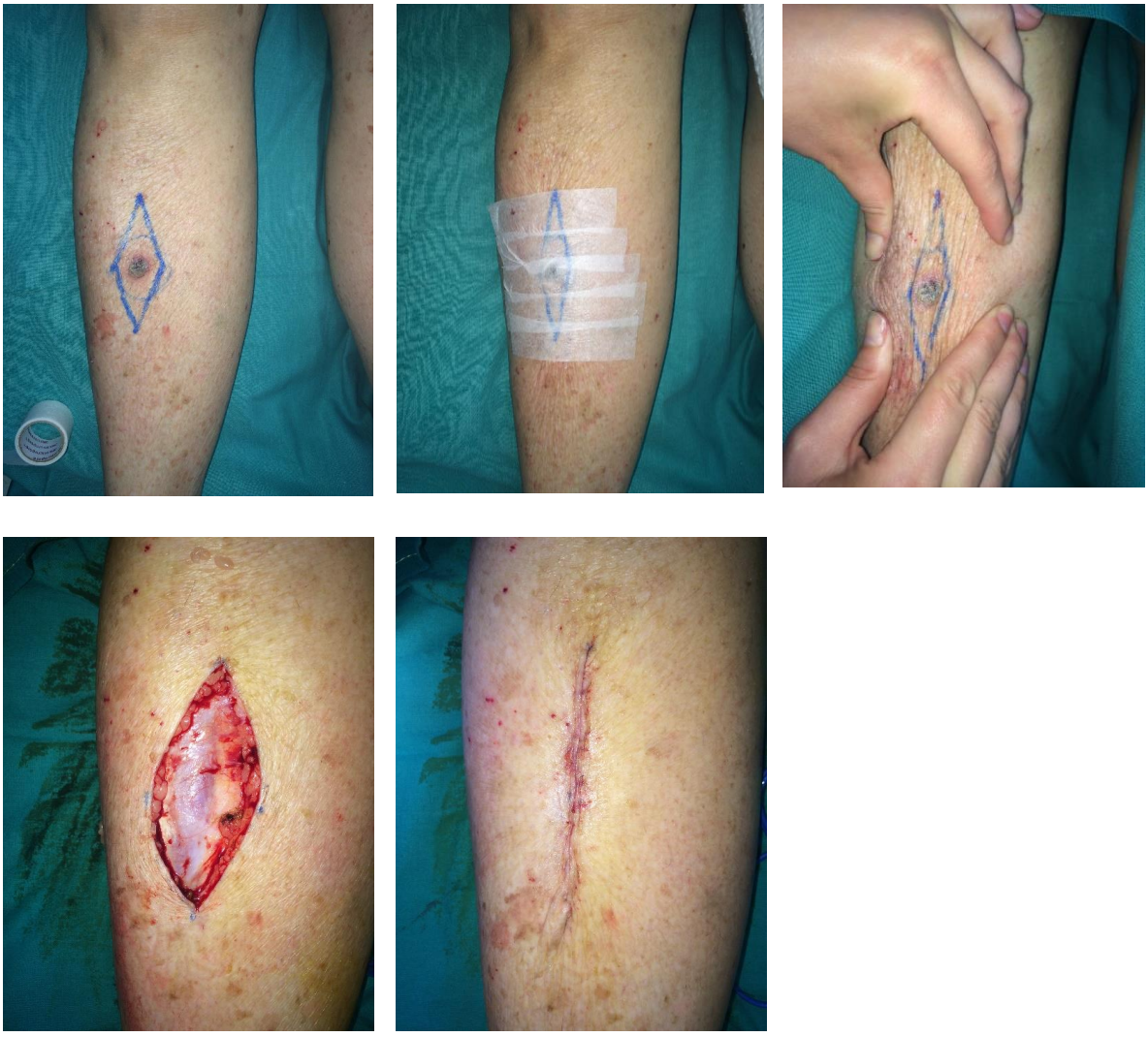


Figure 4a to e: A pretibial Squamous cell carcinoma for wide local excision with single application of pretaping lasting 1 hour prior to surgical excision and direct closure (Sequence of photographs Above left, Above middle, Above left, Below left, Below right)

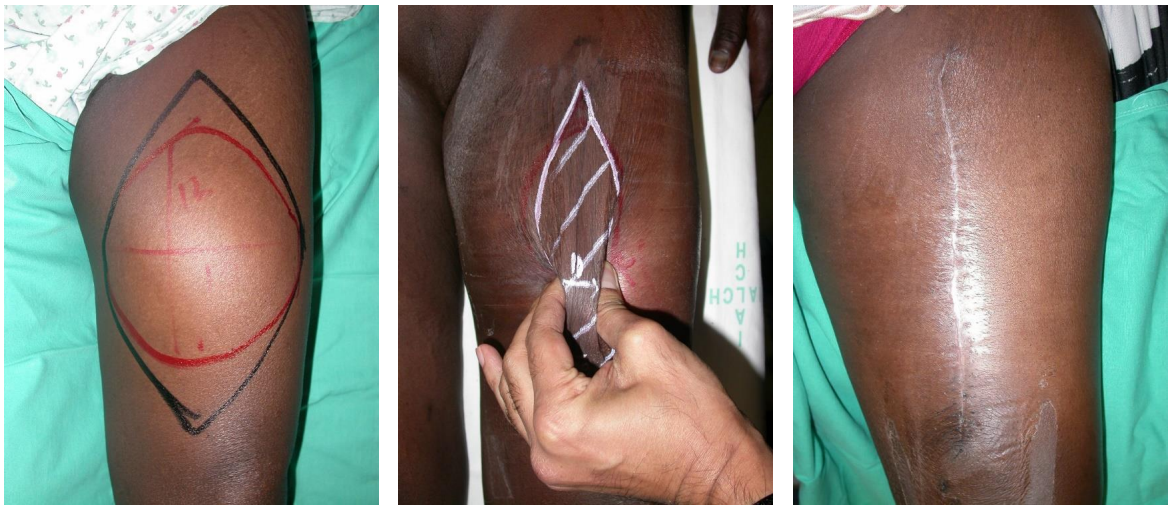


Figure 5a to c: A soft tissue sarcoma of the anterior compartment of the thigh requiring skin sacrifice with wide local excision of tumor. The skin expanded with traction taping over a period of 3 week. The tape was initially changed weekly and then changed one day before the surgery (Sequence of photographs Left, Middle, Right)

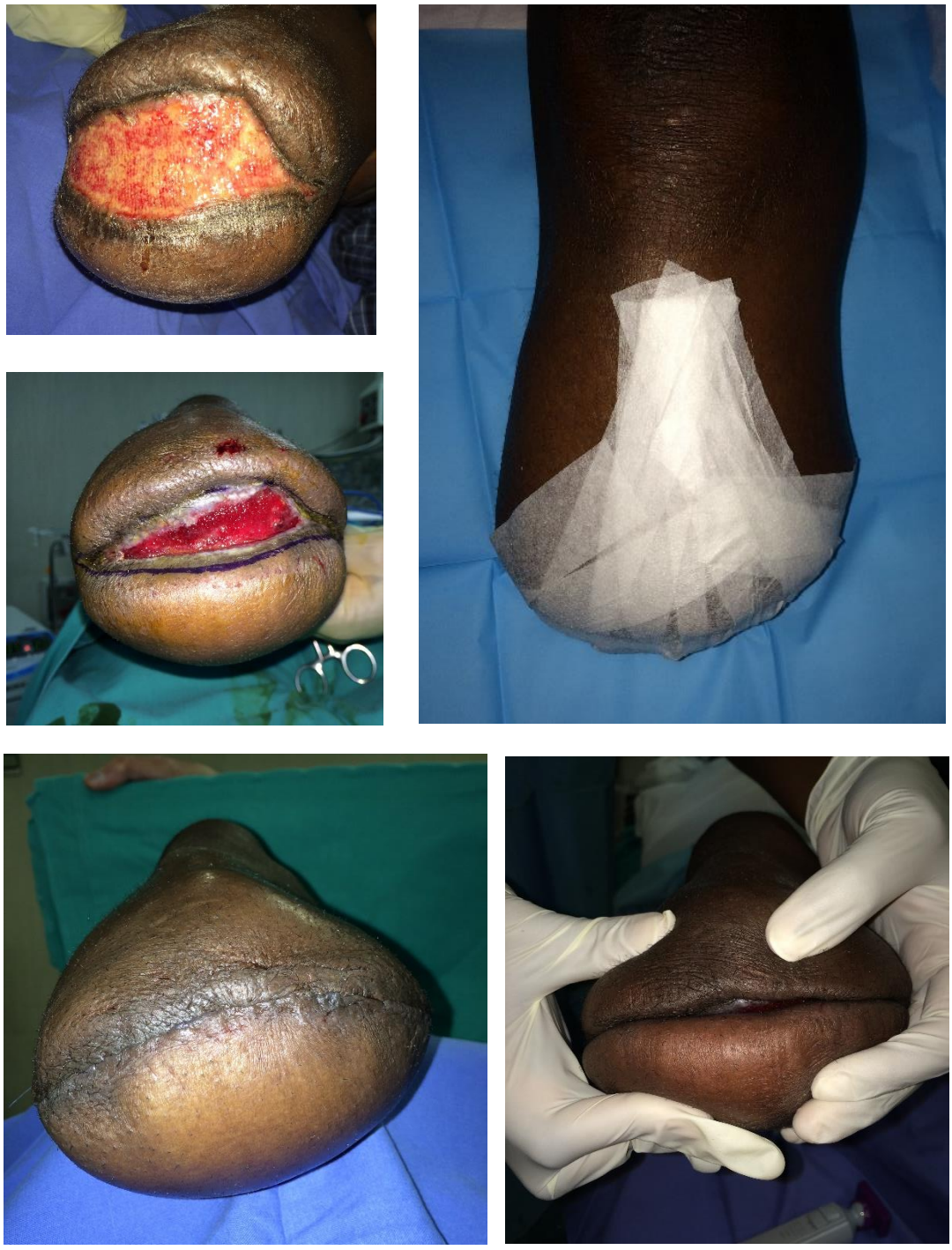


Figure 6a to f: Guillotine below knee amputation salvage with traction taping over a period of week to achieve stump closure. The tape was changed on a daily basis (Sequence of photographs Above left, Above middle, Centre left, Below left, Below right)

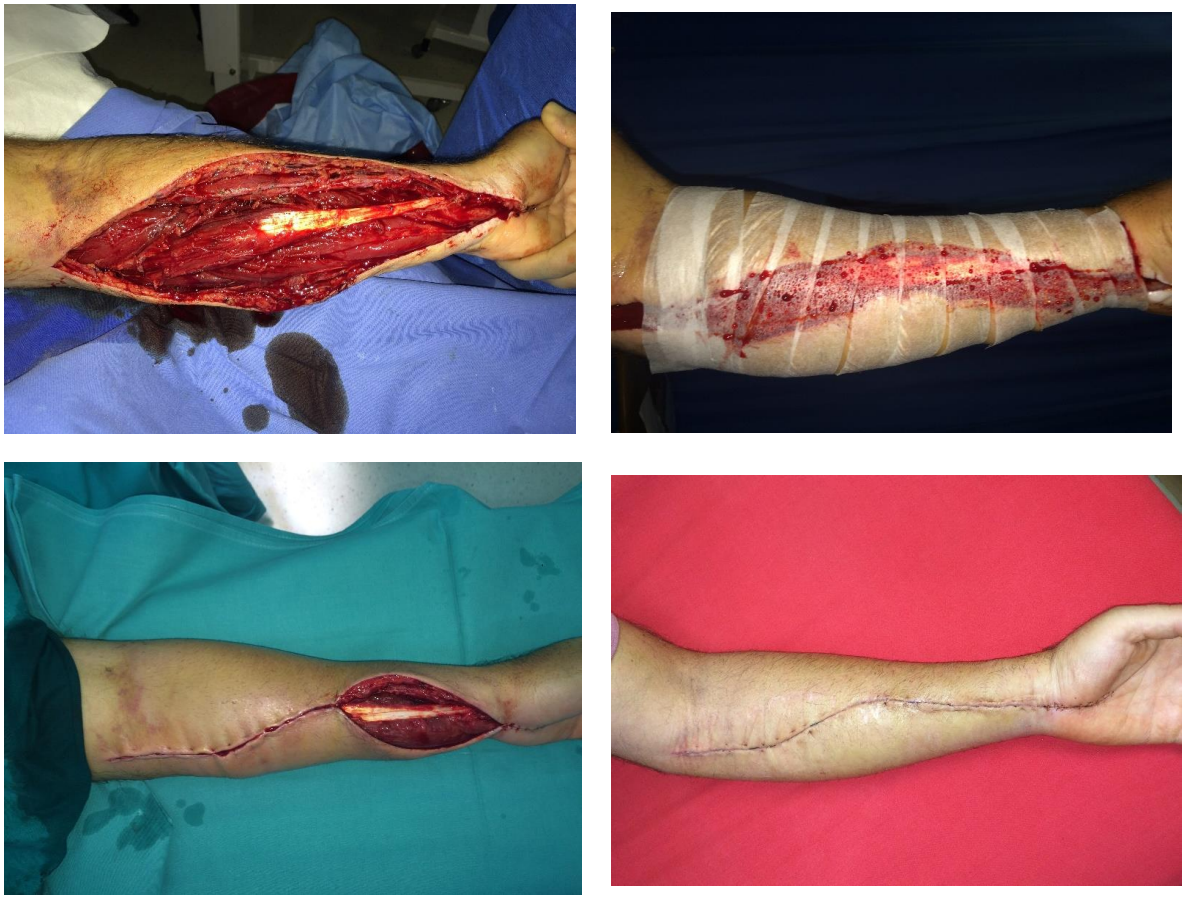


Figure 7a to d: Fasciotomy of the forearm, a 2 stage surgical closure achieved after 2 weeks of traction taping. The tape was changed on a daily basis (Sequence of photographs Above left, Above right, Below left, Below right)

When the expansion is deemed to be adequate the patient is taken in for surgical closure. If not deemed to be adequate and the latter 3 taping episodes do not generate additional laxity a staged surgical closure should be considered (Figure series 1 and 7). At surgery whether deemed to be adequate or not the area to be resurfaced or covered with skin is managed as follows:-

The border between the scar/wound and the normal skin on either side is incised. The normal skin is then advanced over the scar/wound. If direct closure can be obtained with or without undermining then the entire scar/wound is excised and lateral skin is advanced to close. If the overall skin advancement falls short then the

advanced skin is sutured to each other only where it can be mated. The other section with incomplete skin advancement only the underlying scar or wound to the advance skin is excised. Closure is then achieved with the advanced skin edge to the residual scar or lesion or wound. Incomplete closure across or along the scar/lesion/wound is often predictable preoperatively. If this is envisaged either preoperatively or operatively then one must not be tempted to undermine the skin at operation to close. Undermining will increase the zone of fibrosis with new healing making the yield for additional TATE less rewarding.

Not for all conditions is achieving incomplete normal skin closure acceptable. For such cases a backup plan for complete closure is mandatory before engaging in surgical reconstruction (Figure series 3). If a staged closure is an acceptable form of management then tissue expansion by taping is resumed at surgery or a few days later. Generation of further skin laxity can initiated by repeating the cycle of taping to achieve final closure in one or more additional operations (Figure series 1, 7).

At surgery a multi-layered closure is to be performed. First buried interrupted absorbable suture are placed followed by a final subcuticular absorbable suture. My aim is to achieve maximum wound tension reduction, but without skin strangulation. My final dressing of choice is application of hypafix directly to the sutured wound, providing splintage and support for the initial wound healing and reducing further the tension at the suture line. Application of the micropore tape is continued for a period of 3 months for the dual purpose of supporting the healing wound and managing the scar.

3.2 Traction assisted closure (TAC)

This form of taping is applied to achieve wound closure by secondary intention healing and without surgical intervention.

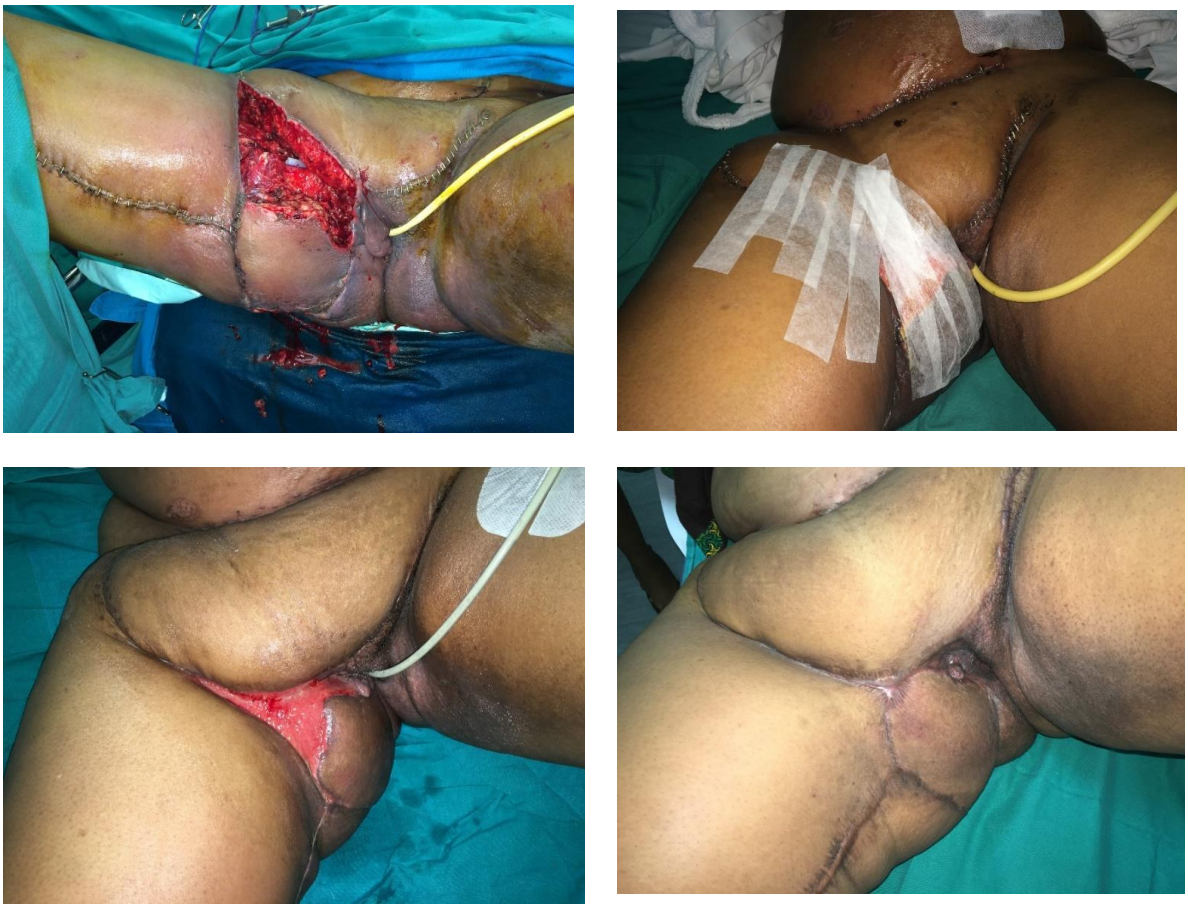


Figure 8a to d: Large wound of the thigh resulting from debridement of a necrotic flap following sarcoma reconstruction. The wound healed by secondary intention assisted by traction taping over a periods of 3 months. The tape was changed every 2 to 3 day (Sequence of photographs Above left, Above right, Below left, Below right)

This technique is an extended application of traction assisted tissue expansion (TATE). After preparation of the skin and wound, if the wound is noted to be exudating then gauze and adaptic roll is made to cover the central portion of the wound before the applying tape. In a low exudating wound or when the exudation decreases the roll dressing can be omitted and the micropore is directly applied and remains in direct contact with the wound. The procedure is maintained until closure is achieved. The taping can be suspended or abandoned as required by prevailing wound conditions.

3.3 Tension reduction taping (TRT)

3.3.1 Abnormal scar

This form of taping is applied to modulate scarring in keloids and hypertrophic scars. The tape is not simply applied just to occlude the scar and the adjacent normal skin. Once the scar and the skin has been prepared the tape application commences in similar manner to TATE. Because the purpose is not tissue expansion, the normal skin stretch is not at the maximum. The patient and the body part to be taped is positioned in a way that reduces or nullifies the tension in the region of the scar. The surrounding skin is migrated towards the scar and held as the skin is noted to begin to crease. The tapes are then applied thus retaining the position of the soft tissues (figure 9b). I surmise that this manoeuvre interrupts the transmission of tension of the surrounding tissues on the scar. In addition once applied the recoil in the skin also serves to tension band the tape resulting in direct pressure application onto the scar. Because the tape is applied on the body part in a reduced tension state, normal posture and ambulation by the patient brings higher pressure to be applied on the abnormal scar during the course of daily activity e.g. the deltoid region taping is done with the arm abducted at 90 degrees. It is also our hypothesis the tension created is absorbed by the tape and transmitted as pressure on the scar. If required additional taping is added perpendicular to the first layer to reinforce the first layer (figure 10a). This is especially important if the tension generation on the keloid is multidirectional e.g. presternal keloid. The tape is changed weekly by the patient with the aid of a helper as needed, adhering to the demonstrated technique. The taping was continued by the patients as directed.

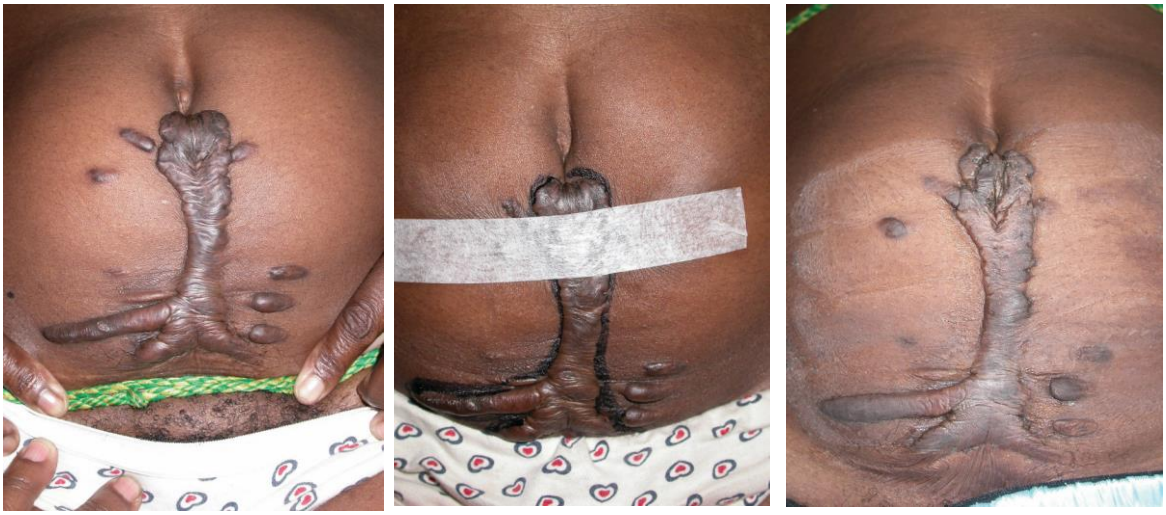


Figure 9a to c: Longstanding post laparotomy keloid managed by tension reduction taping, showing response after one year. The tape was changed on a weekly basis (Sequence of photographs Left, Middle, Right)

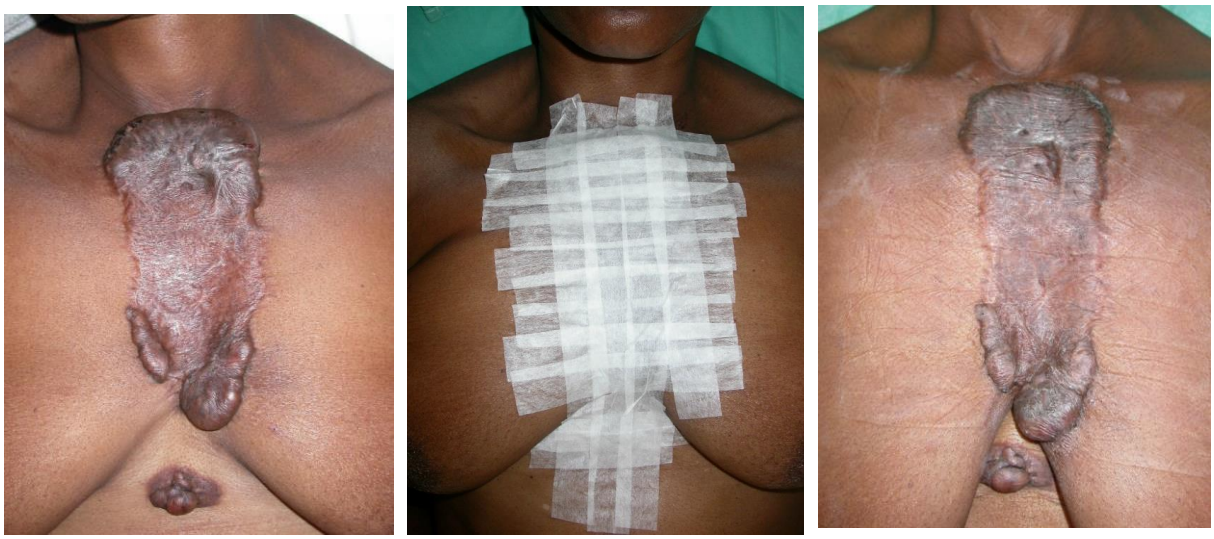


Figure 10a to c: Longstanding keloid of the sternum managed by tension reduction taping, showing response in scar reduction after 1 month. Also important to note the change in the footprint of the keloid which from biomechanical point of view is interesting. The tape was changed on a weekly basis (Sequence of photographs Left, Middle, Right)

3.3.2 Normal scar

This form of taping is applied to support, splint and reduce tension across the suture line while healing is occurring. It is my hypothesis that this will reduce the scarring potentially producing aesthetically pleasing scars. I use it in cosmetic surgery of the abdomen and breast, limbs and scar revisions on concealed section of the body. The tape application strategy is similar to abnormal scars. Sample scenarios are the abdominoplasty and breast reduction.

1. Abdominoplasty: the tape is applied in the supine position with the hips flexed at about 45 degrees for tension reduction tape application. (Figure 11)
2. Breast: the tape is applied in the supine position with the breast held in position over the chest as opposed to laterally drifted breast. With the breast held with the hand and supported, breast the tension across the suture line is reduced. The scar is then taped while the breast held in position. (Figure 12)

The tape is changed every 5 days. And discontinued by 3 months.

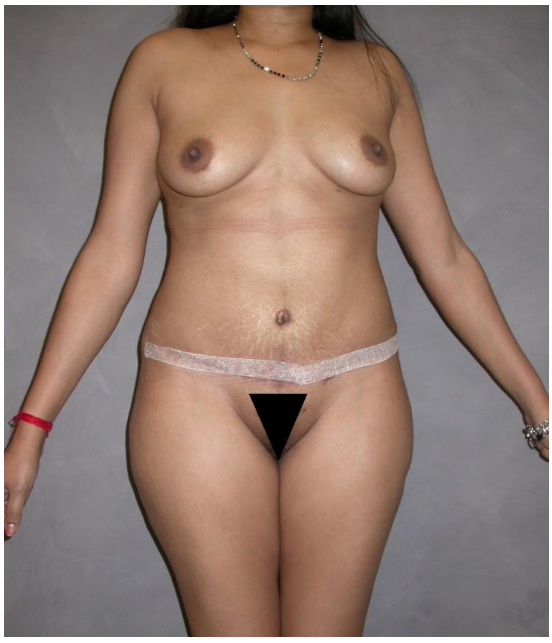


Figure 11: Tape as applied shown at 6 weeks following lipoabdominoplasty. The tape was changed on a weekly basis

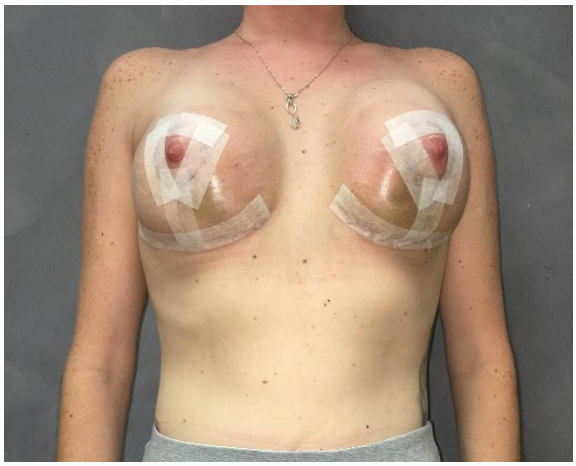


Figure 12: Tape as applied shown at 2 weeks post one stage breast lift and augmentation. The tape was to be changed a weekly basis

Results

The techniques described for the clinical use of 3M Micropore tape in tissue expansion, wound closure and scar management inclusive of normal, hypertrophic and keloid scars are based on various clinical settings. This clinical settings and the number of instances/conditions treated for the period beginning 2003 to date includes the following:

Table 1: Use of 3M Micropore tape in various clinical settings

Clinical setting	Year of onset	No. of instances
TATE for scar resurfacing	2003	51
TATE for giant melanocytic nevus	2013	1
TATE for recurrent myelomeningocoele	2014	1
TATE for fasciotomy	2015	1
TATE for salvaging guillotine limb amputations	2014	4
Pretaping for skin and soft tissue tumour	2009	14
TAC for wound closure	2015	3
Scar management in cosmetic surgery	2011	126
Scar modulation for abnormal scars	2005	62
Total	To date	263

The technique of skin tissue expansion with the use of 3M micropore tape was borne out of necessity in the year 2003. Against the background of tissue expansion using the traditional technique of tissue expanders in the leg being high risk for failure and then commercially available skin stretching devices being invasive despite its success, a pilot study with 2 patients presenting with pretibial scars measuring an excess of 6 cm in width was managed by TATE to prepare for excision of the scar and skin closure. The success associated with these 2 cases lead to the design of a prospective study from the year 2005 to 2007 to test the technique in a cohort of 26 consecutive patients for resurfacing scars in various anatomical regions of the body.(1) This was then referred to as traction assisted dermatogenesis. We have since changed the terminology to TATE.

During this study certain observations prompted us to test the technique of taping in managing abnormal scars. In another prospective study of a cohort of 29 consecutive patients presenting with long standing keloids were managed with taping technique which have termed as TRT.(2) The good response seen in this study encouraged use of a similar technique, since 2011 for prophylaxis against abnormal scarring in cosmetic surgery in surgical practice. The recommendation for the use of this technique for this purpose is based on clinical observations made from 126 consecutive patients undergoing breast and abdominal cosmetic surgery and that none of these patients developed hypertrophic scarring with its use after 6 months of follow up.

The concept of pretaping for skin and soft tissue lesion was born in 2009 as the use of TATE was extended to incorporate other clinical entities. The purpose of pretaping was to acutely stretch skin in preparation for an elliptical skin excision to treat malignant skin lesions avoiding complexities related to flap surgery or the application of skin grafts. The technique was uniformly successful in 14 lesions in adults managed in this manner. Other cases managed successfully with this

concept were a giant congenital melanocytic nevus of the back in a neonate and a recurrent lumbar myelomenigocoele in a 1 year old child.

In 2014 the technique TATE was extended for use in open wounds. In 4 patient with lower limb guillotine amputations performed at various levels, at lengths that needed preservation of this length for successful rehabilitation, all reached adequate tissue expansion for stump closure. In the year 2015 in a single patient an open wound of the forearm after fasciotomy closure was achieved in 2 surgical stages. In all of these patients final closure was established surgically following an appropriate time interval of TATE.

But not all patients with open wounds proceeded to surgical closure after a period of TATE. Three patients taping was continued until final closure was reached by secondary intention. Taping performed for this purpose we then termed as TAC.

Complications associated with taping and management thereof

1. Skin blistering may occur with TATE and is likely to be a sign of excessive tension beyond the tolerance of the skin. This was experienced in 4 cases. Its treatment is to avoid taping in the area of blister. If blistering is generalised then the taping can be temporarily suspended until the skin recovers.
2. Dermatitis may occur with the use of the tape. This was experienced in 1 cosmetic surgery case after 4 weeks of use. To treat it, the taping is halted and the few days of topical steroid cream clears the skin reaction. Future use of the 3M micropore tape is best avoided.

Table 2: Structural components of skin contribute to its mechanical integrity

1. The epidermis which is constituted predominantly of keratinocytes that are spatially anchored to each other by specialised structures called desmosomes. Keratinocytes are also active in the production of growth factors and cytokines. These cells respond to mechanical signalling and play an important role in wound healing. The basement membrane, constituted mainly of collagen IV attaches the epidermis to the dermis.
2. The dermis is a complex structure of specialised cells in an intricate matrix. It is largely responsible for the mechanical properties of skin. Some of the cellular components include fibroblasts, endothelial cells, monocytes and macrophages, schwann cells and nerve endings, and mesenchymal stem cells. The acellular matrix is composed of collagen and elastic fibers embedded within ground substance glycosaminoglycans (GAGS), the most common being hyaluronic acid. The other components of the dermis include a network of blood vessels and skin appendages. Additional keratinocyte regenerative capacity is harboured in the bulge of the hair follicle by the presence of stem cells.
3. The component deep to the skin is the subcutaneous tissue organised within a fibrous network containing adipose deposits. The subcutaneous layer is attached to the deep fascia which forms the envelope for the musculoskeletal component of the human body.

Discussion

The techniques described generate traction and compression to render the changes that are noted in the skin and tissues to which it is applied, and the surrounding area. The skin is an organ that has many functions but of importance to this technique are elasticity and mechanical integrity.(3) Several structural components contribute to the skins response and its tolerance to the taping techniques (Table 2). The desmosomes, cytoskeletal components of cells and structural proteins provides the stability to the epidermis of the skin allowing it to behave as a single unit to which external mechanical forces can be applied or tolerated. The acellular dermal matrix beneath the epidermis which is largely responsible for the mechanical properties respond by deformation to the applied forces. The fibrous network attachments of the subcutaneous tissues also transmits surface forces applied to the skin to the deeper structures. The ultimate effect of the applied forces on the composite of tissues and its response will be

dependent on its tolerance to the magnitude of the tensile, shear and compressive forces.

Structural composition is largely responsible for skin's mechanical properties.(4, 5) One important property is its ability to tolerate and respond to application of tension. The tensile strength, a measure of the skin's tolerance is provided by the collagen. In the natural state collagen arrangement in skin is haphazard. On application of tension skin begins to stretch, and the collagen responds by extending and rearranging parallel to each other. As the skin lengthens stiffness of the skin increases. The recoil of the stretched skin on removal of the mechanical stress is the function of the relatively sparsely interspersed elastin. The interfibrillar matrix is composed of proteoglycans which provides the lubricant for the movement and assist in directing the formation of collagen. The biomechanics of skin is best understood by familiarizing oneself with the stress-strain curve, some of the common descriptive terms and definitions (Figure A and Table 1). With reference to skin as a biomaterial some of the terminologies used in the literature serves to describe the biomechanics of skin. These are especially important for understanding TATE and TAC.

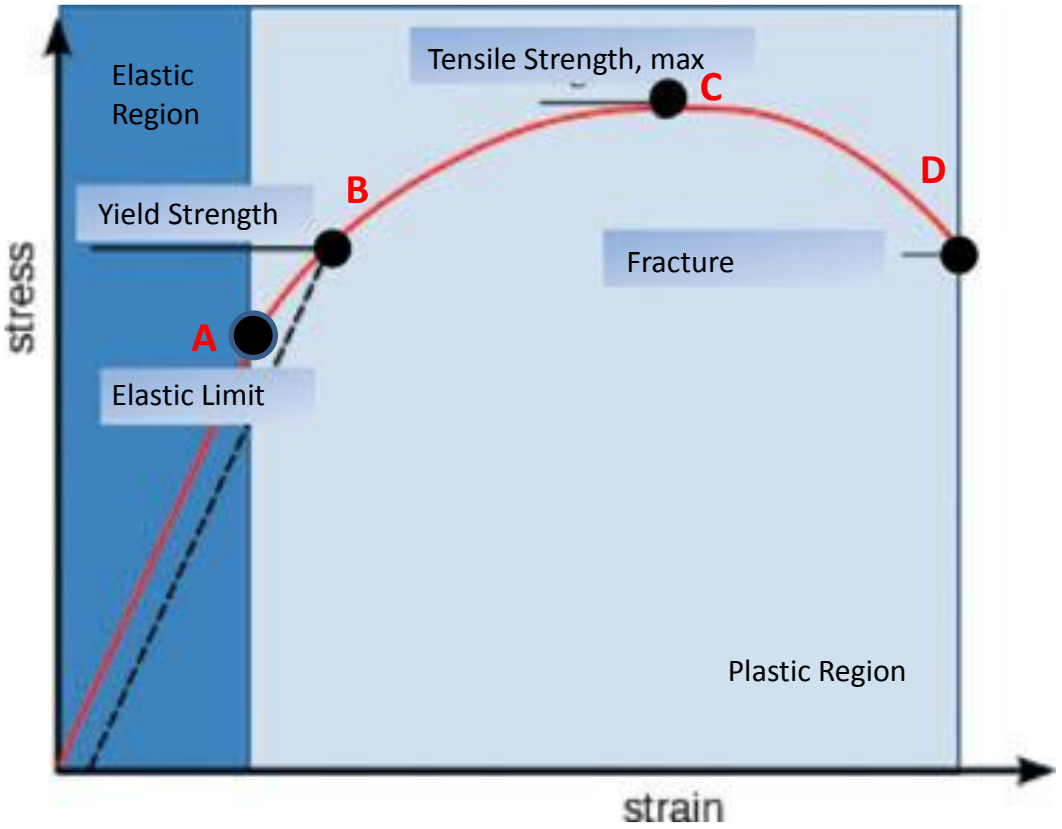


Figure A: Stress–strain curve. (A) Elastic limit. (B) Yield strength. (C) Maximal tensile strength. (D) Fracture. The surgeon seeks to work between B and C, where application of stress produces the greatest strain but does not exceed the tensile strength of the skin. (Hussain et al 2013)

Table 2. Definitions of Biomechanical terms

1. Stress = pressure = force applied on or felt within the skin per unit area.
2. Strain = deformation experienced by the skin expressed as a percentage change in length.
3. Creep = is the slow deformation of the skin under influence of stress.
4. Mechanical creep = growth in the skin over a period of time in response to a continual stress.
5. Stress relaxation = change (decrease) in stress within skin subjected to constant strain.
6. Stress relaxation time = is the time span of constant strain required to result in the reduction of the stress (tension) in the skin.
7. Skin stress strain curve. The behaviour of skin in terms of the stress experienced due to the increasing strain in the skin as a result of forces or displacement applied. The stress response is from elastic to plastic. In the plastic region of the curve to increasing strain, the yield point precedes the tensile strength, which precedes the fracture point. (Figure A)
8. Elasticity = the ability of the deformed skin to return to original shape and size on removal of the force. This is represented by a linear relationship on the elastic portion of the stress-strain curve.
9. Hysteresis = this is the non-linear relationship of the plastic region of the stress-strain curve resulting in less reversal of deformation as the force is removed.
10. Viscoelasticity = is a combination of elastic and viscous behaviour. Once stress is applied, the response of the skin is related to the time it is applied for. Quick removal of stress the deformation is temporary (elastic), and if maintained then deformation is permanent (viscous). This transition in behaviour is more or less synonymous with the yield point.
11. Tensile strength = is the maximum stress the skin can bear before failure of integrity.
12. Extensibility = the maximum value of strain reachable before fracture of the skin.
13. Anisotropy = different values of extensibility demonstrated in different axes of the skin. This variation can be affected by multiple factors e.g. anatomic region, sex, age, body mass index, oedema, inflammation, etc.
14. Poisson's effect = when the skin is stretched, it usually tends to contract in the directions transverse to the direction of stretching. Or when the skin is compressed in one direction, it usually tends to expand in the other two directions perpendicular to the direction of compression. Poisson's ratio is then negative strain in one direction/ strain orthogonal direction and is a measure of compressibility
15. Modulus of elasticity = is the ratio of tensile stress/tensile strain and is a measure of elasticity.

Another aspect in basic science that is influenced by TATE and TAC is wound healing. TATE is followed by surgical closure. TATE when used in an open wound setting e.g. guillotine amputations and fasciotomy closure, the wound healing is being influenced directly by the taping as the surrounding skin is being expanded.

In the absence of an open wound, the use of TATE is very likely to indirectly influence the wound healing of the closed wound as the mechanobiological effects of traction continue to bear influence. When TATE's use was extended to achieve closure without surgery it got referred to as TAC. Our observations of wounds that are being taped seem to suggest there is accelerated secondary intention wound healing as evidence by the rapid wound shrinkage. Therefore, mechanical influence on the wound that is being taped is unavoidable. The influence on wound healing by taping is worthy of exploration but at this juncture a grasp of the pathophysiological basis for wound healing is important.

A wound with unopposed skin edges, repair by wound healing occurs by scar formation. Opposing the skin edges primarily, healing with minimal scarring can be achieved. In primary wound healing the phases of wound healing are limited and granulation process does not occur. In comparison secondary intention wound healing essentially occurs by granulation, epithelialisation and wound contraction. It is a time honoured process largely dependent on the size of the wound, provided all wound and systemic factors are favourable. Wound healing is best thought of, described and understood in phases, but these phases are not necessarily mutually exclusive. Balanced wound healing is not always achieved. Wounds can fail to heal or heal in excess with exuberant scar formation which can handicap aesthetics and function. Wounds can occur as a result of multiple aetiologies, a fresh full thickness gaping wound of the skin not closed surgically will left heal by secondary intention. Wound healing is summarised below in table 3.

Table 3: Phases of wound healing

There are 2 phases viz. early and cellular. Early phase is haemostasis and cytokine release. The cellular phase is inflammatory, granulation tissue synthesis, epithelialisation, and scar formation and wound volume reduction.

3.1.1 Haemostasis

Vasoconstriction is the immediate response. Platelet activity is also triggered releasing a host of molecules which together with coagulation cascade results in clot formation with fibrin. The fibrin can serve as scaffold for epithelial migration and cellular infiltration. The clot also contains extracellular matrix (ECM) ligands. The released platelet derived growth factor (PDGF) and transforming growth factor Beta (TGF) enhance fibroblasts and endothelial cells.

3.1.2 Inflammatory Phase

This phase lasts about 3 to 4 days. Neutrophil and macrophage arrival has the combined function of scavenging debris and bacteria. Macrophages in concert with other cell types release more cytokines promoting the migration, proliferation, and differentiation of fibroblasts and endothelial cells. Macrophages coordinate the inflammatory and reparative process by producing signalling molecules for epithelial cells, endothelial cells and fibroblasts differentiating into myofibroblasts.

3.1.3. Re-epithelialisation

It begins on day 1 – 2 and the process is driven by epithelial mesenchymal interaction resulting from the secretion of epidermal growth factor (EGF) and TGF beta by platelets, macrophages and keratinocytes. Epidermal cells by abandonment of desmosome expression in favour of peripheral cytoplasmic actin filament expression permits cell detachment and subsequent migration. Migration is from the edge to centre until cover is restored. Epidermal cells interact with ligands to undermine the eschar during migration. Plasmin and collagenase assist in removal of fibrin clots and damaged stroma for the migration. Hair follicles are a source of stem cells as well. Ultimately the new epidermal tissue is different in that rete ridges are not formed on the repaired construct of collagen and extracellular matrix.

3.1.4 Fibroblast and myofibroblasts activity

It begins on day 4 to 14. The activity is dominated by progressive alignment, collagen production and matrix contraction. Fibroblasts are laid stratified parallel to epidermal surface. Collagen in a fabricated ECM contracts to reduce volume of the wound. Contraction occurs by collagen cross linking and extracellular ligands and collagen enabling myofibroblast, adhering, moving through and contracting the ECM.

3.1.5 Endothelial cell proliferation and angiogenesis

It begins on day 4. With granulation new blood vessels are formed. Angiogenesis is stimulated by vascular endothelial growth factor (VEGF), fibroblast growth factor and TGFb.

3.1.6 Neodermis formation

It is a combination of fabrication which begins on day 4, lasting 2 weeks, and alteration which begins at week 2, lasting months. The reconstruction of acellular dermis requires fibroblastic synthesis of collagen, elastic fibres and ground substance and ECM modelling enzymes. Initially type I and type III collagen make up the matrix, but is remodelled to mostly type I. The maximum tensile strength of 80% is reached by 3 months.

At 2 weeks there is an abundance of collagen. Excess is removed by collagenase and matrix metalloproteinases (MMPs). Excess MMP activity may result in excess breakdown and development of chronic wounds.

Elastic fibre role is not clear in wound repair. Ground substance another major component consists mainly of Glycosaminoglycans and scar tissues contain typically hyaluronic acid.

4. Excessive wound healing

There is an amplified inflammatory response with overproduction of growth factor. The fibroblast and myofibroblast expression of TGF b receptors are up regulated in keloids thus the collagen levels are found to be 2 to 3 times higher. Hypertrophic scars carry a higher subpopulation of myofibroblasts than keloids.

Skin structure, biomechanics of skin and its wound healing profile provided the fundamental basis for the use of taping in tissue expansion, wound healing and scar modulation. However, skin's response is not only determined by these physical laws related to a biomaterials. Skin is far from a mechanical scaffold. Skin is a living organ and cells respond to these mechanical forces via cell signalling transduction pathways by secreting cytokines and growth factors. The mechanobiology of skin as it is referred to, in response to stress or reduction thereof is another important facet in creating an understanding in the use of taping for purposes of tissue expansion and scar modulation and wound healing. (Will cite the mechanobiology review article here)

Tissue expansion is characterised by fibroblast activity and keratinocyte activity creating more skin not to dissimilar to skin creation, for example skin expansion of the abdomen during a pregnancy. Appendages are not known to increase, but the keratinocyte numbers and the collagen content and ground substance definitely increases. Dermatogenesis (skin growth) is occurring in response to the traction being applied to the skin by the 3M micropore tape, is a reasonable postulate.

In response to the traction created by the taping, cells and extracellular tissues transmit forces. In the finite element model it was proposed that wound healing was accelerated through transmission of forces from the external environment. It has been previously shown that cells that are allowed to stretch tend to proliferate whereas those cells that obtain a spherical conformation and not allowed to stretch become cell cycle arrested and apoptotic.(6, 7) The effect of macrodeformation on wound healing as a source of accelerating wound healing is well supported. 3M micropore paper traction taping produces these forces and macrodeformation, stimulating the cell signalling transduction pathways which theoretically accelerates wound healing. TAC we feel in some form is achieving this.

In response to the generated traction variation in tissue response is to be expected. The response of normal skin versus wounded skin versus a wound is likely to vary. Aside from the cellular response, taping also harnesses the mechanical properties of skin to produce tissue expansion of the skin surrounding the wound. Strain produced on the surrounding skin achieves progressive wound closure by the migration of the skin over the wound. In addition the wound as observed is also simultaneously undergoing artificial wound reduction by the application paper tape. This is achieved by augmenting the natural tendency of the wound to contract. In normal wound healing the natural contraction of the wound is significantly influenced by the conversion of fibroblast to myofibroblast. How taping affects this cell response in producing wound contraction is not known.

In many instances wound contraction is welcomed because it reduces scar formation. At the other end of the spectrum excessive wound healing can also occur. Keloids and hypertrophic scar formation have many predisposing factors. Tension on the skin is one such enabler. Aikashi et al demonstrated that stretching tension is an important factor in keloid formation.(8) Fibroblast activity resulting in collagen formation as well as remodelling is stimulated by tension. The tension at the growing edge of the keloid has been demonstrated to be greater than that at its centre. This may explain the regression of the central part of the keloid as the keloid ages and matures. The “neurogenic inflammation hypothesis” states that mechanical stress including skin stretching stimulates the mechanosensitive nociceptors on sensory fibres in the skin.(9) The neuropeptide and cytokine release activate fibroblasts, endothelial cell and influence the vascular smooth muscle cells. The numbers of macrophages, lymphocytes and mast cells are significantly higher than in normal skin.(10, 11) Neuropeptide activity in skin inflammation can be observed in the form of erythema, oedema, hyperthermia and pruritus. Aarabi et al reported in the hypertrophic scar model that scars subjected to tension demonstrate decrease apoptosis.(12).

Our primary aim of the taping for abnormal scars was to decrease or nullify the tension and splint scars with the tape. TRT theoretically shares the tension load the scar is subjected to. A secondary effect of the taping was production of pressure on the scar. Chang in a randomized controlled trial demonstrated the value of pressure garments for scar maturation in burn patients, but showed no statistical significant difference.(13) Van den Kerckhove et al in a similar randomised controlled trial found that applying pressure of at least 15mmHg tend to accelerate scar maturation.(14) The biological effect of pressure on a scar still needs to be elucidated.

The response observed in our series with TRT for abnormal scars, it was reasonable to postulate that taping has a role to play in the prophylaxis of abnormal scars. I routinely use the TRT in all my cosmetic cases, scar revisions and in any postsurgical scar management when requested by a patient. Although, my experience is anecdotal and that evidence base can only be provided by a prospective randomised controlled trial, I still will like to recommend this protocol, which at minimum is supported by the evidence provided by Reiffel and Mustoe.(15-17)

Conclusion

Although our understanding of the mechanobiological response to traction and tension reduction created by our technique 3M micropore tape application in tissue expansion, wound healing and scar modulation has not been elucidated, its clinical use is evolving. Clinical settings in which this tape has been used needs to be viewed in context against the background of other solutions that could have been offered. The greatest advantage that we have realised in our treated cases for the various clinical settings has been simplicity, economic viability, accessibility and a high success rate in our cases selected for its use. We foresee persistence in its use and the use of this technique as part of the armourmentarium of managing similar cases is encouraged.

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Part 5:

This will be the conclusion to the thesis

Chapter 13: Synthesis and Discussion

In plastic surgery, tissue expansion with use of tissue expanders is an important tool used in reconstruction. The obvious benefit is the creation of additional skin that is made available for the cover of existing or created defects without significant donor site morbidity. The process is multistaged and is associated with failure determined by various factors.(1, 2) Tissue expanders are not usable in open wound conditions.(3) This role is relegated mainly to devices that produce two dimensional external tissue expansion.(4) Both techniques are invasive, associated with economic costs, rely on surgery for the initial installation of device and render a time lag to producing a final reconstruction or repair.

Open wounds that are associated with soft tissue loss, or skin edge retraction without sufficient local tissue availability for simple closure, require skin grafting or flap surgery. The size and type of the wound determines the choice of cover, but if it could be left alone and is of a reasonable size it should heal by secondary intention with a greater potential for scarring.(5)

3M™ Micropore™ Surgical Tape is surgical tape designed to hold wound dressings on skin. To test this product to achieve tissue expansion and modulate scarring has not been reported. The tolerance of the skin to withstand direct traction to the surface was a concern at the concept stage but it is likely that many surgeons if not all will see this as a significant limitation. The development of the technique and modification thereof using a single product for tissue expansion, scar modulation and wound healing is novel and exciting. This thesis provides evidence based on more than a decade of research work that is likely to make a significant contribution to knowledge on the topic.

Reflecting on the research question and objectives designed to test the hypothesis, it is clear that paper taping with 3M™ Micropore™ Surgical Tape has a significant

place in tissue expansion, wound healing and scar modulation. With regards to tissue expansion, biomechanics of skin can be harnessed with taping to create tension to produce dermatogenesis. A review of mechanobiology clearly demonstrates that the mechanical force of tension by mechanotransduction influences cellular and molecular biology, producing cellular proliferation and migration and in turn growth in the tissue.(6, 7) In abnormal scar formation tension is the same force that continues to fuel the cellular apparatus to produce an exaggerated inflammatory process resulting in hypertrophic scars and keloids.(8-13) The purpose of mechanotherapy is to shield newly formed scars and existing abnormal scars against this intrinsic tension that exists in the skin, to limit or regress scarring.(14-18) To explore wound healing and taping was not an objective in the research. But as the depth and width of the research increased and a realization that wound healing is the backbone of tissue expansion and abnormal scarring the influence taping had on wound healing did not come as surprise. It is at that point not more than two years ago that the concept of traction assisted closure was born.

In exploration of tissue expansion by taping, the first clinical series reported using traction assisted dermatogenesis (now referred to as traction assisted tissue expansion) for resurfacing of scars, demonstrated a success rate of 82% (18 of the 22 patients after excluding cased that defaulted during the trial). Other series e.g. pretaping for skin lesions (n=14) and guillotine amputation salvage by taping (n=4) showed a 100% success rate. Other cases successfully treated included a giant congenital melanocytic nevus of the back in a one month old infant, a recurrent myelomeningocoele in a one year old child and a closure of a fasciotomy wound of the forearm in the subacute stage of wound healing, in two stages in an adult male. The only other notable case report in part two of the thesis produced a perception that the large wound closures can be accelerated by taping and that surgery can be avoided. It consolidated our observations from other open wounds treated by taping, that taping not only causes tissue expansion of the surrounding skin, but

also wound shrinkage by forced deformation with the added consequence of less scarring.

In the exploration of using 3M™ Micropore™ Surgical Tape to modulate abnormal scars (n=42) there was a decrease in the thickness of the scar, an improvement in the pain and itch scale and an improvement in the quality of the scar and photographs showing pre-test and post-test to two independent plastic surgeons indicated improvement in all measured parameters. All results were statistically significant. All abnormal scars treated by this form of mechanotherapy were present for more than two years. The nature of the disease is such that keloids continue to proliferate, therefore demonstrating an improvement with tension reduction taping in the absence of control arm in the study is a significant finding.

The strength of the study is that it demonstrates that the technique of taping to produce TATE, TRT and TAC is viable. The unpublished work in the thesis on tissue expansion further cements the technique and products used therein, that it can be used for other areas of soft tissue reconstruction successfully, without the handicaps and risks associated with the other techniques available in plastic surgical practice. The value of the practical guidelines in the manuscript in the thesis is to provide the medical fraternity with an educational tool to learn the technique, empowering them to use the technique in their clinical practice. The message is certainly to begin with simple things as the confidence and experience grows more complex conditions can be given consideration. The greatest advantage is that the patient or a caregiver can easily learn the technique under supervision by the physician and then follow through with self-administration. Most other techniques, if not all, require direct involvement of the treating doctor during the process of tissue expansion. TRT for the mechanotherapy for preventing and treating abnormal scars, is especially easy for the patients to learn and manage on their own.

The practical guidance manuscript promotes the use of the TRT for prevention of poor quality scarring in patient undergoing cosmetic surgery. This recommendation is based on anecdotal experience with the technique and that patients tolerated it well and none of them demonstrated abnormal scarring. This position can be strengthened by performing a prospective randomized controlled trial where in the same patient the one half of the body bearing the sutured wound is taped and the other is not. The ethics of the research has to be carefully considered. This will be invaluable future research however we are not anticipating different results showed in a similar study that used a tension shielding device.(19)

There were some limitations in the studies undertaken. The level of scientific evidence that this thesis has provided across all the studies was not at the highest levels according to Chung *et al*.(20) The clinical studies were a combination of case series (prospective cohort studies and retrospective medical record reviews), case reports, a review article on mechanobiology and a scholarly article that provides guidelines for the use of the paper taping technique. Case reports chart reviews often become the building blocks for research for those conditions when exploring new concepts. This is where research begins for all novel techniques. This technique of using 3M™ Micropore™ Surgical Tape is innovative and the results have made an original contribution of knowledge in the research arena of tissue expansion and abnormal scar modulation. One must bear in mind that paper taping has not been tested in this application previously in the literature.

Limitations of the technique to produce TATE for the various conditions that can be potentially managed in reconstructive surgery has not been tested. Producing sufficient skin for resurfacing has not been worked out in terms of the ratios between the area of the zone to be resurfaced, the area of the skin available for taping and the area of the zone of expansion that is outside the tape. Data accumulated and analysed by taking prospective measurements may reveal scientific guidelines for

considering TATE in various clinical situations. This is certainly a consideration for the future.

The use TATE and pretaping for reconstructive purposes in the presence of soft tissue and skin tumours need to be debated. There is no research or literature on this technique for this use. However we surmise that short period of tape application is not likely to produce an adverse event. The application of taping is designed to place the surrounding skin and soft tissues under traction for the effect of stretching the skin. The tumour by application of the tape is placed under compression and risk associated with this theoretically can be dissemination and/or bleeding.

The review of the mechanobiology with regards to tissue expansion, wound healing and scarring was vital to the study. It provided generic information on the current understanding on the topic. Some of the future studies with the use of taping and its influence as a mechano-therapy agent in the mechanobiology of wound healing and scarring, will be important to validate some of our clinical observations.

Taping in the techniques already described is an integral part of my clinical practice. My current thinking is being directed towards taping to produce TAC in managing both simple and complicated wounds. The understanding of mechanobiology and its effects on cells and tissue has improved our interpretation of some of the observations that have been made so far. As experience in this field grows it likely to produce very interesting results for future publications.

3M™ Micropore™ Surgical Tape as a wound care product is not ideal in its current presentation. It does not come in a sterile package and the application with gloved hands is generally difficult. This is a handicap that must be addressed with the manufacturers. The impression is that the 3M™ Micropore™ Surgical Tape behaves like a semi-occlusive dressing and unlike other occlusive dressing its application is being put under tension.(21) This renders the topical dressing to become fairly rigid.

A rigid surface in vitro has been shown to favour keratinocyte proliferation and migration.(22) So from the product point of view, if the need arises, relationships with the manufactures will have to be fostered to develop the tape for wound care purposes. This will undoubtedly require further joint research and development.

In our initial experimentation with the taping to produce traction, blistering of the skin was a problem. The use of 3M™Cavilon™ Durable Barrier Cream has almost eradicated this problem. The barrier cream seems to have improved the skin's tolerance to the traction being applied. Blistering could mean that the epidermis was separating from the dermis. Studies to calculate the amount of traction that can be tolerated by the skin will be valuable. How the forces of traction dissipate to more peripheral and deeper tissue is also worthy of joint research with an engineering department in the university. The taping also delivers pressure to the tissue. How much pressure can be safely delivered without causing critical ischemia to tissue is another worthwhile laboratory study.

Conclusion

The salient feature of the thesis is that taping to produce tissue expansion, wound healing and scar modulation is new. The degree to which this strategy of taping will become a recognised modality, is dependent on the willingness of the treating physician or surgeon to try these techniques of paper tape use. Advantages include cost effectiveness and safety. If it fails in anyone's hands then one can easily and without compromise default to any of the other recognized strategies. As it finds a place in the art and science of plastic and reconstructive surgery further expansion in research will naturally occur.

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Appendices

Appendix 1: The Study Protocol

Title of study

The use of paper tape application in skin tissue expansion and abnormal scar modulation

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1 Introduction

The main purpose of the study will be to explore the use of paper tape application in skin tissue expansion and abnormal scar modulation, provide a theoretical framework based on a literature review and provide practical guidelines for its use. Tape application by a researcher developed technique, appears not to be reported in the literature. This delivers mechanical stimuli including a combination of tension, compression shear forces, occlusion and pressure. It is hypothesised that these mechanical forces generated by a paper tape can result in skin tissue expansion and scar modulation.

The study population will be enrolled by the researcher from the clinic in Albert Luthuli Central hospital and private practice in Umhlanga Hospital.

In the 1st phase the study will be prospective preliminary case studies to develop the technique.

In the 2nd phase, 2 prospective cohort studies will test the clinical efficacy of the technique in tissue expansion and abnormal scar modulation. Following this by retrospective chart review technique modifications and reconstructive applications in clinical settings will be described.

In the 3rd phase the clinical findings in the cohort study on abnormal scar modulation will be validated by determining pre- and post-test changes in scar size, quality, symptom profile, photographic scar characteristics produced by the scar modulation.

This novel technique is non-invasive, low cost and may even supersede other conventional techniques for certain anatomic body regions and reconstructive indications. The production of practical guidelines for the use of paper tape will benefit doctors and patients in the global community.

The structured sketch of the protocol is as follows (Numbered points 6 to 10 are structured by the objecives of the study):-

2. Background
3. Aims of study
4. Objectives
5. Research questions
6. Studies
    - 6.1 Study design
    - 6.2 Study setting
    - 6.3 Study population
    - 6.4 Study eligibility criteria
7. Study outcomes
8. Study Procedures
    - 8.1 Technique of paper tape application and surgery
    - 8.2 Data collection tool
    - 8.3 Data collection process
    - 8.4 Data analysis and statistical considerations
9. Ethical considerations
10. Outcomes and significance

2 Background

2.1 Problem statement

The use of paper tape application in skin tissue expansion and abnormal scar modulation has not been explored.

2.2 Paper Tape

The paper tape is used as a device to hold dressings on to skin in wound care management. Literature search on Medline and Cochrane library demonstrated only a single where paper tape was used in clinical practice. This was for prophylaxis against hypertrophic scarring following skin incisions and closure.[1] No studies were reported in the use of paper tape application to the scar and the skin to produce skin tissue expansion or abnormal scar modulation. Each of these of these phenomena are addressed separately in 2.3 and 2.4.

2.3 Skin tissue Expansion

Acute skin tissue expansion exploits the viscoelastic properties of skin. Skin within limits of the force applied and the duration of the time it is applied for, has the intrinsic capacity to respond by elongation and has the capacity to return to the original state. The 3 major components viz. Collagen, elastin and ground substance in the dermis is responsible for this. If the force applied does not exceed the tensile strength of the skin and the force can be cyclically applied then the skin responds in 2 phases. The initial acute phase is called mechanical creep which occurs by the reconfiguration of the collagen and the second phase is biological creep which occurs by the proliferation of the collagen and keratinocytes which occurs over a period of time.[2] The conventional method of achieving this phenomenon in surgery is with the use internal tissue expanders and external tissue expansion devices.[3, 4]

The main purpose of the tissue expansion is to create normal skin adjacent to disfigured skin from various causes or wound defects. In wound defect closure only external devices are applicable. The major drawback of internal devices is the risk of complications, failure

in reaching reconstructive goals, pain and temporary disfigurement, the need for multiple surgeries, cost of the devices and the procedure, and surgical expertise and supervision is essential. This is hardly an exhaustive list.

In the local community that our institution serves scarring secondary to disease, trauma and burns are not uncommon. This can be a problem across all anatomic regions and age groups. Patients seek to have these scars resurfaced with good quality normal skin. Our default management is by a multistaged reconstruction of the deformity using internal tissue expanders. In developing countries like South Africa the economic burden of scar management is not seen as priority and in fact medical insurance will not fund this type of surgery. Failures and complications further results in wastage of resources.

The fundamental requirement for skin tissue expansion is an application of a mechanical force of tension. Paper tape is relatively inelastic, with adequate tensile strength and has sufficient non allergenic adhesive properties. It adheres to the skin but its ability to render tension on the skin by traction needs to be tested. In the context of serving the local community and against the background deficient literature on the topic, it will be of benefit to answer the first portion of the research question “Is the use of paper tape in skin tissue expansion effective?”

2.3 Abnormal scar modulation

Abnormal scars are hypertrophic scars and keloids. The fundamental difference between them is that keloids is a fibroproliferative disorder characteristic of being able to invade normal tissue[5]. There are many theories in the formation of the abnormal scars. Important strategies include compression therapy, tension reduction, and scar occlusion. These strategies alter the biological response of the scar that is under the influence of mechanical forces. [6][7] The success in management of these abnormal scars by any one modality on its own is in general poor. In clinical practice multimodality treatment has a higher success rate.

Our hospital in Durban, South Africa serves a population group mainly of black origin. Against the background of a high disease burden of trauma and burn injury, keloids and

hypertrophic scars are common. The most troublesome symptom in abnormal scarring is pain and itch. The conventional treatment that is offered in our centre for very large abnormal scars are pressure garment therapy and aqueous creams, and for smaller lesions in cosmetically sensitive regions are intralesional therapy, surgical excision and radiotherapy. The large patient load cannot be effectively served by the resource strained health care service.

In concept the paper tape can be used as a single modality treatment for the modulation of the abnormal scarring by the physical means of reducing the tension forces, delivering direct compression or pressure and occlusion. In the context of serving the local community against the background deficient literature on the topic, it will be of benefit to answer the second portion of the research question “Is the use of paper tape in abnormal scars effective?”

2.4 Research question

Is the use of paper tape application in skin tissue expansion and abnormal scar modulation effective?

Before attempting to answer this question a pilot study will be performed to test the proposed technique of paper tape application. A small group of patients will be recruited to test the feasibility of technique.

To answer the first part of the question, consecutive patients presenting to our centre for scar revision surgery, in whom tissue expansion is the preferred treatment will be offered serial intermittent paper taping. In this cohort of patients the goal will be the excision of the deformed area on the skin and replace it with expanded normal surrounding skin. The efficacy of the taping will be measured by clinical outcome, change in scar size and serial photographic records.

To answer the second part of the question consecutive patients presenting with hypertrophic scarring or keloids will be offered serial taping. In this cohort of patients the efficacy of the taping will be determined by clinical outcome, and change in scar size,

quality, symptoms of pain and itch and independent scoring of before and after photographs of abnormal scars.

In the event that the study proves to be of clinical benefit and the technique clearly establishes itself as a good method of reconstruction, then it will reasonable to test the feasibility of paper taping in various other conceptually suitable clinical applications in plastic and reconstructive surgery.

2.5 Current research

There is a deficiency of research on the use of paper tape in tissue expansion and abnormal scar modulation. However in the last decade, literature bears a richer understanding of mechanical forces influencing cellular and biochemical biology in tissue expansion and in abnormal scar modulation.[8-10] This study will explore the therapeutic effects paper tape application. A positive finding will result in the introduction of novel technique of skin tissue expansion and abnormal scar modulation. This will supplement existing techniques in the literature with a major advantage of low cost and universal applicability.

3. Aim of study

The aim will be to explore the use of paper tape application in skin tissue expansion and abnormal scar modulation, provide a theoretical framework based on a literature review and provide practical guidelines for its use.

The study hopes to establish whether there is role for paper taping in the phenomena of skin tissue expansion and abnormal scar modulation. Since the proposed technique is novel, yet totally non-invasive and simple in physical application, providing theoretical support for its use will improve its scientific appropriateness. The clinical materials supported by an understanding of the mechanobiology of forces on tissues, the ultimate objective will be to develop practical guidelines for its use.

4. Objectives

1. To identify a suitable tape and application method for skin tissue expansion and abnormal scar modulation.
2. To explore in scar management the therapeutic effect of the paper tape application in skin tissue expansion.
3. To explore in scar management the therapeutic effect of the paper tape application in abnormal scar modulation.
4. To describe the use of paper tape application in other reconstructive clinical settings.
5. To determine the effect on the symptoms of pain and itch associated with abnormal scars.
6. To determine the effect on size of the abnormal scar.
7. To determine the effect on scar quality of the abnormal scar.
8. To determine by independent expert review the change in abnormal scar.
9. To postulate a theoretical framework in the use of paper tape in skin tissue expansion and scar modulation.
10. To develop practical guidelines for the use of paper tape.

5. Research Question

Is the use of paper tape application in skin tissue expansion and abnormal scar modulation effective?

6. Studies

Different research methods will be used to study each objective.

6.1 Study Design

6.1.1 Objective 1

This will serve to test the feasibility of the use of the paper tape application to achieve skin tissue expansion and abnormal scar modulation. Since the main role of paper tape

is for holding wound dressings, a suitable paper tape needs to be identified and an appropriate technique and method of the application needs to be developed at the same time offering safety and benefit. Pending a successful outcome the ensuing objectives will be explored.

6.1.2 Objective 2

Consecutive patients presenting to the general plastic clinic with skin deformities for reconstruction by resurfacing that are deemed to be suitable for skin tissue expansion, will be offered paper tape application.

Although conducting a study with control arm will be of greater value, it is not possible to randomise and match the groups for the diverse and variable clinical findings that patients present with for treatment.

6.1.3 Objective 3, 5, 6, 7 and 8

Consecutive patients presenting to the general plastic clinic with hypertrophic scars or keloids that are deemed to be suitable for scar modulation by taping will be offered paper tape application. The purpose of the study will be to measure the effect of tension elimination or reduction by taping on the abnormal scar. The devised technique requires that the entire scar be covered. Therefore dividing the scar into two portions for the purpose of having a control arm cannot be considered. The subjects are also likely to be a heterogeneous group with abnormal scars in various anatomical sites and of varying scar age. A randomised control trial to test the mechanism of taping is also faced with many obstacles due to the multiple factors that contribute to abnormal scarring making matched groups very difficult to attain.

6.1.4 Objective 4

In the event that both studies 6.12 and 6.13 test to demonstrate a successful outcome in terms of the research question, we anticipate adopting this modality of treatment in both skin tissue expansion and abnormal scar modulation in the department of Plastic and Reconstructive surgery. This adoption will result in additional cases being performed as

part of normal clinical practice. These cases will at some point in time be examined by chart review identifying those for whom indications for the taping technique was novel. These reports will be descriptive and clinical outcome based.

6.1.5 Objective 9

Mechanical forces are delivered by the use of taping. A review of the literature will be performed, investigating the potential forces delivered to the tissues by taping with the view to developing a theoretical framework that best explains the study outcomes.

6.1.6 Objective 10

The purpose of this objective is purely to disseminate information. Use of the paper tape in clinical practice has a learning curve. Its educational content will assist new users of the technique.

6.2 Study setting

6.2.1 Objective 1

Single centre study Inkhosi Albert Luthuli Hospital in the department of Plastic and Reconstructive surgery.

6.2.2 Objective 2

Single centre study Inkhosi Albert Luthuli Hospital in the department of Plastic and Reconstructive surgery.

6.2.3 Objective 3 and 5 to 8

Single centre study Inkhosi Albert Luthuli Hospital in the department of Plastic and Reconstructive surgery.

6.2.4 Objective 4

A single centre study at Umhlanga Hospital from the researchers limited private practice.

6.2.5 Objective 9

A Cochrane library and Pubmed database searches on the topic of mechanobiology will be conducted.

6.2.6 Objective 10

This is not a study but production of guidelines for first time users.

6.3 Study population

6.3.1 Objective 1

Subjects with longitudinal normal or abnormal scars on lower limbs who present for scar revisional surgery will be offered a trial of the paper tape application. In our department this group of patients are generally excluded from surgical revision by traditional internal device skin tissue expansion because of the high complication and failure rate. Because the researcher deems 3M micropore paper tape to have a high safety profile based on the prophylactic use of this tape in scar prophylaxis by other researchers; testing in this anatomic region is best commenced with the use of this tape which is easily available in the clinic. Patients will benefit with minimal if any risk. 2 patients will be chosen.

6.3.2 Objective 2

Any subject with normal or abnormal scars on any portion of the body presenting for scar revisional surgery in whom the paper taping is deemed to be feasible will be offered a trial of the paper tape application. An excluded patient and those fail to progress with taping will be offered alternative reconstructive options.

6.3.3 Objective 3 and 5 to 8

Any subject with abnormal scars on any portion body presenting for treatment in whom the paper taping is deemed to be feasible will be offered a trial of the paper tape application. Patients with scars of greater duration than 1year will be chosen to exclude scars that are likely to spontaneously regress. It is assumed that scars with duration greater than 1 year will continue to grow if no intervention is given. This in general is the behaviour pattern of abnormal scarring. The antecedent history of 1 year of abnormal

scarring becomes a substitute for a control arm of the study because both objective and subjective attributes will mark the end period of 1 year of no treatment and in the same patient this base line is useful comparative. An excluded patient will be offered alternate treatment.

6.3.4 Objective 4

All subjects anticipated to be surgically treated by the researcher outside the scope of the cohort studies of objective 2 and 3, in his clinical practice using the described technique of taping for skin tissue expansion and abnormal scar modulation will be retrieved from the hospital and private patient data bases.

6.3.5 Objective 9

Studies in the literature on the Pubmed database.

6.3.6 Objective 10

Not applicable

6.4 Eligibility criteria per objectives

6.4.1 Objective 1

a) Inclusion criteria

- Any patient with lower limb longitudinal scar deformity

b) Exclusion criteria

- Less than 10 years of age or not likely to be compliant
- Scars not exceeding 5cm in width
- Medical or psychiatric illness
- Unfit for surgery
- Skin disorders

c) Patient exit from study

- The patient has right to resign from the study at any stage

6.4.2 Objective 2

a) Inclusion criteria

- Any patient presenting with skin deformity assessed by the researcher to be of a reasonable size and in an anatomic region that permits the use of the taping technique

b) Exclusion criteria

- Less than 7 years of age or not likely to be compliant
- Medical or psychiatric illness
- Unfit for surgery
- Skin disorders

c) Patient exit from study

- The patient has right exit from the study at any stage.
- The patient develops difficulties with the technique
- The patient is observed to show no progress in tissue expansion after 3 applications or develops an adverse reaction.

6.4.3 Objective 3 and 5 to 8

a) Inclusion criteria

- Any patient presenting with hypertrophic scars and/or keloids that have associated pain and itch symptoms, are judged by the researcher to be an anatomic region that permits the use of the technique

b) Exclusion criteria

- Very large and extensive abnormal scars.
- Psychiatric illness
- Skin disorders

c) Patient exit from study

- The patient has the right resign from the study at any stage.

- The patient develops difficulties with the technique, or develops an adverse reaction.

6.4.4 Objective 4

a) Inclusion criteria

- All cases that are to be treated for a presenting problem in whom the taping technique is to be used for novel disease indications that do not feature in the studies 6.2 and 6.3

b) Exclusion criteria

- none

6.4.5 Objective 9

a) Inclusion criteria

- review articles
- animal based studies
- human based studies

b) Exclusion Criteria

- none

6.4.6 Objective 10

Not applicable

Objectives 9 and 10 will no longer feature in the rest of the protocol because the method of the study to arrive at a theoretical framework for the taping outcome and the format of the planned practical guideline medical education will be decided on the completion of objectives 1 to 8.

7. Study outcomes

The study outcome assessment of Objectives numbered 7.1 to 7.4 will be based on observations and will subjective and descriptive in nature

7.1 Objective 1

The parameters that we will be seeking to assess clinically and by photographic records will be:-

- Elongation of the surrounding skin with each taping.
- Change in the quality and the size of the deformity.
- Clinical outcome as assessed by adequate skin creation to progress to surgery by deformity excision and direct closure with the generated surrounding skin.
- Nature of wound healing achieved by 6 weeks.
- Complication profile of the technique.

7.2 Objective 2

The parameters that we will be seeking to assess clinically and by serial longitudinal photographic records will be:-

- Elongation of the surrounding skin with each taping.
- Change in the quality and the size of the deformity.
- Clinical outcome as assessed by adequate skin creation to progress to surgery by deformity excision and direct closure with the generated surrounding skin.
- Nature of wound healing achieved by 6 weeks.
- Complication profile of the technique

In addition, in the event of failure to progress with taping following factors related to the skin and scar factors will be assessed in terms of:-

- Thickness of skin
- Scar thickness
- Adherence of scar

7.3 Objective 3

The modulatory effect of the taping on abnormal scars will be observed for change clinically and by serial longitudinal photographs records.

7.4 Objective 4

Tissue expansion and scar modulation effect of the taping will be observed for change both clinically and by serial longitudinal photographic records and the observed changes will be documented by the photographs of each subject. Background information on each case will be reported and the rationale for using this technique of taping will be shared.

The study outcome assessment of objectives numbered 7.5 to 7.8 of cohort study 2 in objective 3 will be performed using objective parameters.

7.5 Objective 5

Pain and itch, a common feature in patients presenting for treatment will be measured.

7.6 Objective 6

Thickness and surface area of the scar will give a good indication of the extent of change in the size of the scar will be measured.

7.7 Objective 7

Pliability of the scar, a good indicator of the quality of scar will be measured by it consistency. Hard is a reflection of immature collagen and soft reflects the maturation process of the collagen. Immature collagen is the fundamental basis for keloids and hypertrophic scarring.

7.8 Objective 8

Change in maturation in the abnormal scar will be by assessed by specific markers in photographs. Elevated, red and shiny scars are signs of immaturity of the collagen. Immature collagen is the fundamental basis for keloids and hypertrophic scarring.

8. Study procedures with regards to taping

8.1 Technique of paper tape application and surgery as per objectives

Once the patient is enrolled in each study the subject will be undergo serial intermittent taping of the relevant anatomic area with the devised technique. A description of the technique is given below.

8.1.1 Objective 1

The area of the scar to be resurfaced with surrounding normal skin will be delineated. The surrounding skin if hair-bearing will be shaved. The surrounding normal skin is then stretched to its maximum in the direction that is appropriate for obtaining the final closure by flap advancement. A 1-inch 3M micropore paper tape will then be applied to hold this position of stretch of the normal skin. Further tape will be applied for the rest of the scar and the surrounding skin in the same manner. The patient will be allowed to bath normally. The tape will be retained for a period of 1 week. It will then be removed and the skin washed and dried. The patient will be washed and prepared by a nurse at the clinic and then taped by the researcher and/or his assistant. A new application of tape will be performed once the skin is stretched, further recruiting the developed laxity following the last application. The process will be repeated weekly. During the process the patient will be questioned about any complaints with the aim to assist the subject. The skin will be monitored for any adverse reaction. When the expansion is deemed to be adequate the patient will be taken to the operating room. At surgery incisions will be made in the border between the scar and the normal skin on either side. The normal skin will then be advanced over the scar. The lateral normal skin on either side will advanced medially with or without undermining. If the migration of the skin is deemed to be adequate then the entire scar will be excised. The 2 lateral skin flaps will then be sutured to each other. Inadequate skin expansion could possibly result in incomplete scar excision. Finally a simple dressing will be applied to the suture line. The patient will be discharged the next day barring any postoperative complications. The patient will then be reviewed at 1 week and then 6 weeks postoperatively.

8.1.2 Objective 2

This will be performed as described in objective 1 but it may include technique refinements emanating from the preliminary study in objective 1.

Addendum to protocol

During the study of objective 2 - Cavilon a barrier cream was applied to the skin and scar in preparation to each taping episode in response to observed blistering of the skin.

8.1.3 Objective 3 and 5 to 8

The tape will not be applied just to occlude the scar and the adjacent normal skin. The skin will be washed and dried. The patient and the body part to be taped will be positioned in such a way that diminishes or nullifies the tension in the region of the scar. In addition, the surrounding skin will be migrated towards the scar and held as the former is noted to begin to crease. The tape will then be applied thus retaining the position of the soft tissues. Using the same technique, more tape will be added parallel to the first tape until the entire scar is covered. Additional taping will be added perpendicular to the first layer at the edges to reinforce the first layer. The tape will be changed weekly by the patient with the aid of a helper as needed adhering to the demonstrated technique. The patient showered normally on a daily basis. The taping will be continued by the patients as directed.

Addendum to protocol

During the study of objective 2 - Cavilon a barrier cream was applied to the skin and scar in preparation to each taping episode in response to observed blistering of the skin. This step was then added to the taping procedure for study in objective 3 from its commencement.

8.1.4 Objective 4

This will be performed as described in objective 1 but it may include technique refinements emanating from the studies in objective 1,2 and 3.

8.2 Data collection tools

8.2.1 Objective 1

- Clinical notes in patient files will include records as detailed below:-
    - ♦ Age
    - ♦ Sex
    - ♦ Race
    - ♦ Allergies
    - ♦ Cause of the skin deformity
    - ♦ Anatomical region of reconstruction
    - ♦ Skin or scar quality
    - ♦ Problems associated with the taping

- A plot graph of the area to be reconstructed will be taken pre- and post-testing with each serial taping to measure its dimensions.
- Photographs of the body part undergoing reconstruction by taping and surgery will be taken at each serial application of the tape.

8.2.2 Objective 2

As per objective 1 in 8.21

8.2.3 Objective 3

- Clinical notes recorded in the patient files are detailed below:-
    - ♦ Age
    - ♦ Sex
    - ♦ Race
    - ♦ Cause of the abnormal scarring
    - ♦ Anatomical region of abnormal scarring
    - ♦ Onset of scar
    - ♦ Follow up period
    - ♦ Complications

- Problems associated with the taping

- A plot graph of the area to be reconstructed will be taken pre- and post-testing with each serial taping to measure its dimensions.
- Photographs of the body part undergoing reconstruction by taping and surgery will be taken at each serial application of the tape.

8.2.4 Objective 4

- Clinical records to be extracted from patient files are detailed below:-
    - Age
    - Sex
    - Race
    - Cause of skin deformity or wound
    - Anatomical region of deformity or wound
    - Onset of deformity or wound
    - Follow up period
    - Dimensions of the deformity and with each application of tape.
    - Number of sessions of the taping
    - Time interval between taping
    - Quality of wound healing and scar quality
    - Modifications in technique if any
    - Complications, if any

- Photographs of the body part undergoing reconstruction by taping and surgery will be taken at each serial application of the tape.

8.2.5 Objective 5

The visual analog scale, scoring from 0 to 10, will be used to score both the pain and the itch associated with the abnormal scars.

8.2.6 Objective 6

The scar surface area, pre- and post-testing will be measured from plot graphs, outlining perimeter of the abnormal scar at each patient visit at least once a month

The thickness of the scar will be measured in increments of 1 mm using a custom made thickness gauge from 1 to 12mm on each patient visit at least once a month.

8.2.7 Objective 7

The scar quality will be recorded and graded by its quality by comparing to the following

H – Hard like cartilage

I - Intermediate

S - Soft like normal skin

8.2.8 Objective 8

Digital photographic records collected during the study will be reviewed to by 2 independent plastic surgeons of more than 5 years of clinical practice. Colour (redness), elevation and flash reflectance (shine) of pre- and post-treatment photographs will be scored.

8.3 Data collection process

8.3.1 Objective 1

a) Clinical notes

The patient clinical notes will be printed after each visit and the filed by subject number in a study file.

b) Plot graphs

The interface of the area of skin deformity and the normal skin will be outlined with a permanent marker. This outline will then be traced onto a clear plastic film sheet using a permanent marker. Any change in shape and size will recorded by the outline tracing performed before and after the application of the tape. The tracings labelled as pre and post testing. The tracing will also be dated and be given a subject number. This will be

attached to the clinical note for that day. The file will be stored in my locked office. The file will accompany me to the clinic each week for data collection and filing.

c) Photographs

The photographs will be in digital format. From the memory card the images will be transferred and stored in date chronological order as per subject numbered folders. The computer will be a departmental computer in my office. The files will be updated as new records are made.

8.3.2 Objective 2

As per objective 1 in 8.31

8.3.3 Objective 3

The data collection will take place monthly for 2 visits and then 3 monthly

a) Clinical notes

The patient clinical notes will be printed after each visit and then filed by subject numbers.

b) Plot graphs

The surface outline of the abnormal scar will be traced onto a clear plastic film sheet using a permanent marker as described in 8.31 of objective 1. The position of the measure for scar thickness will also be demarcated on the graph for referencing for all measurement of thickness in the future. The tracing will be dated and be given a subject number. This will be attached to the clinical note for that day. The file will be stored in my locked office. The file will accompany me to the clinic each week for data collection and filing.

c) Photographs

The photographs will be in digital format. From the memory card the images will be transferred and stored in date chronological order as per subject number folders. The computer will be a departmental computer in my office. The files will be updated as new records are made.

8.3.4 Objective 4

Patient charts will be reviewed, producing individual case studies utilizing the tools identified in objective 4 in 8.24. Each case study will be given a subject number identification.

The photographs will be retrieved from the departmental patient database in which all patients with photographic records are kept. The photographs records will be assessed over the time period of treatment.

8.3.5 Objective 5

The patient will be asked to score both itch and pain on a scale of 0 to 10. Zero being no symptoms and 10 being unbearable symptoms. The base line score will be recorded at the inception of the study. Re-assessment will occur at each visit to the researcher and scores recorded in the patient notes.

8.3.6 Objective 6

Plot graphs will be made by transposing the outline of the scar onto a clear plastic film sheet. Any change in shape and size will recorded by the outline tracing performed before and after the application of the tape. The tracings labelled as pre and post testing. The subject number will be assigned to the plot graph and the data filed in a folder which will be kept in the researcher's office. This will serve as raw data for surface area calculations. Records will be taken and dated at each visit.

During the plot graph mapping process to record the outline of the abnormal scar the points of measurement will be specified on the map because variable thickness scars are anticipated. Measurements will be taken at the same points at each visit and recorded in the patient notes and plot map graph. Up to 3 points will be measured

8.3.7 Objective 7

The scar will be examined by the same clinician (researcher) and classified using the described pliability scale as it is assessed by examination with finger tips of the

researcher/assistant. The nature of the scar will be recorded without referring to the previous recordings on the patient's notes.

8.3.8 Objective 8

The collected photographs will be archived on the departmental computer in my office. At the end of the study the before and after photographs will be retrieved per subject placed side by side on a power point slide. 2 independent plastic surgeons will then examine each slide and will be asked to score the before and after photographs based on the parameters noted in 8.28.

8.4 Data analysis and statistical considerations

8.4.1 Objective 1

Statistical analysis is not applicable

8.4.2 Objective 2

The data analysis will include the following:-

- Age range and average
- Sex distribution
- Race distribution
- Causal distribution of the deformity
- Anatomical and regional distribution of the skin deformity
- Size range of the skin deformity
- Clinical changes in the tissues being tested
- Success rate of taping and surgical reconstruction
- Range and average follow up of subject post surgery
- Range and average of taping sessions
- No of patients defaulting treatment
- No of patients failing to progress with tissue expansion after taping

Statistical analysis is not applicable.

8.4.3 Objective 3

The data analysis will include the following

- Age range and average
- Sex distribution
- Race distribution
- Range and average history in terms of time of scar presence
- Causal distribution of the abnormal scar
- Anatomical and regional distribution of the abnormal scar
- Success rate of taping
- Range and average follow up
- Complication rate of taping
- Subjective assessment of serial photographs to note change

Statistical analysis is not applicable.

8.4.4 Objective 4

These will be individual observational case studies and therefore statistical considerations will not applicable.

Statistical methodology for objectives 5 to 8

SPSS version 15.0 (SPSS Inc., Chicago, Illinois, USA) will be used to analyse the data. A p value <0.05 will be considered as statistically significant. One sample t tests will be performed to compare the difference in percentage change from pre- to post-treatment in scar thickness, surface area and surgeon photographic scores to the null hypothesis value of 0. Paired t tests will be used to compare levels of pain and itch pre- and post-treatment. McNemar–Bowker's test will be used to compare ordinal levels of scar quality pre- and post-treatment, and Wilcoxon's signed-rank test will be used to compare photographic score ratings of the two surgeons.

8.4.5 Objective 5

The subject pain and itch scores will be grouped in 0, 1 to 4, 5 to 7 and 8 to 10 groups at the inception of the study which will be the base line score. Demonstration of change will

be more valuable than the actual value. Patient scores will be recorded at each session of visit to the researcher. The number of patients per group will be determined. An average score will be calculated for each group at the beginning and at the end of the study to determine the extent of change in average score.

Statistical analysis will be performed with paired *t* tests to compare levels of pain and itch pre- and post-treatment

8.4.6 Objective 6

The outline on the plot graph will be traced onto a grid scale paper with $1cm^2$ blocks. By the counting the number of squares occupied by the outline, the surface of the scar will be calculated for pre and post treatment recording.

A surface area measurement taken per scar will be calculated for each of these records. Subjects will be grouped and tallied according to those showing an increase, decrease or no change in surface area. A range in percentage change and the mean of change for each group will be determined from pre- to post-treatment.

An average of the scar thickness measurements taken per scar will be calculated. This average will be used for quantifying the pre- and post-treatment values. Subjects will be grouped and tallied according to those showing an increase, decrease or no change in thickness. A range in percentage change and the mean of change for each group will be determined from pre- to post-treatment.

Statistical analysis will be performed by one sample *t* tests to compare the difference in percentage change from pre- to post-treatment.

8.4.7 Objective 7

The subject numbers will be grouped according to groups of H, I and S before and after treatment. Scar pliability score will be recorded for each subject before and after treatment.

Statistical significance analysis will be performed by taking the pliability score for before and after treatment and then cross tabulating to determine the number of subjects demonstrating, improvement, no change or worsening using the Mcnemar-Bowker test.

8.4.8 Objective 8

Each plastic surgeon will then score the photographic parameters of colour, elevation and flash reflectance according to the following scale. -1 = improvement; 0 = no change and +1 = deterioration. A composite photographic score will then given to each subject case. The theoretical score range will be -3 to +3.

Statistical significance analysis will be performed by determining the mean score and standard deviation of each surgeon by using one sample *t* test. The ratings of the surgeons to each other will also be compared by using the Wilcoxon's signed-ranked test.

9. Ethical considerations

9.1 Objective 1

In line with good clinical practice, the interest of the patient will be placed over that of science. The patient will be informed about the proposed technique of achieving the reconstructive goals. It will be iterated that this is a novel technique. However in its favour is that it is non invasive and avoids preliminary surgery by use of tissue expanders placed surgically. In the lower limb anatomic site that the patient wants treated has a high complication rate or failure rate. The patient will benefit by avoiding the first stage surgery and avoid a significant failure rate in reconstruction by the conventional methods. The researcher strongly feels that in theory the technique works and that it needs to be tried to determine the feasibility of the technique as a potential solution to skin tissue expansion and scar modulation before continuing to the next phase of larger study to add validity to the study. We trust that taping procedure is risk free and we do not foresee any adverse reactions and in the event that one does occur it can be reported to us. This reaction will be managed on its merit. The subject may choose to abandon the process at any stage without offering any reasons and he is free to proceed to any alternate form of treatment voluntarily. If paper taping fails to show any benefit then the process will be stopped.

Informed consent will be obtained for the taping and the surgery and this will be filed in the hospital records. The information given to the patient will be done at the outset of entering the patient for the trial. Children less than 18 years of age will be consented for by their parents or legal guardian.

9.2 Objective 2

As per objective 1 in 9.1

In essence this is the same as the objective 1. In the event of success of the technique in the preliminary cases we will want to be recruiting subjects with scar deformities in a variety of anatomical regions to the determine its efficacy in skin tissue expansion in a larger cohort of patients.

9.3 Objective 3

In line with good clinical practice, the interest of the patient will be placed over that of science. The patient will be informed about the proposed technique of taping for anticipated improvement in the abnormal scar. It will be iterated that this is a novel technique. However in its favour is that it is non- invasive. Against the background of the multiple modalities in management of abnormal scars it will make sense to do this study because the response to conventional modalities is in general not uniform. Many of the more topical treatments for these scars are expensive and not provided in the state hospital. The researcher strongly feels that in theory the technique works and that it needs to be tested to determine its efficacy in abnormal scar management. The biggest advantage being that of a low cost. We trust that taping procedure is risk free and we do not foresee any adverse reactions, and in the event that one does occur it can be reported to us. This adverse reaction will be managed on its merit. The subject may choose to abandon the process at any stage without offering any reasons and he is free to voluntarily proceed to any alternate form of treatment.

Informed consent will be obtained for the taping. The information given to the patient will be done at the outset of entering the patient for the trial. Children less than 18 years of age will be consented for by their parents or legal guardian.

9.4 Objective 4

This will be a retrospective chart review of all the cases performed for skin tissue expansion and scar modulation in the department of Plastic and Reconstructive surgery. The records will be in a public domain and the patients are not likely to derive any direct benefit or harm from the study therefore the informed consent will not be required for the study and publication purposes. All patients that have undergone surgery would have given informed consent to the researcher and would be available in the patient's hospital records.

9.5 Objective 5 to 8

As per objective 3 in 9.3

10. Outcomes and significance

10.1 Objective 1

The researcher is anticipating a successful outcome in the study. The benefit to the society will be that the proposed technique is non-invasive and not likely to result in any pain or discomfort. The device used will be simple and the cost of administration of the therapy is likely to be low cost in comparison to traditional techniques. This will be of benefit to healthcare funders and the public health sector which can be constrained in developing nations. The technique if proves to be of overall benefit, will certainly augment the strategies at the disposal of the plastic surgeon to enable him to assist future patients once the study is the public domain. It may potentially encourage other researchers in this scientific arena to perform further research on aspects related to this technique which will grow our understanding on this phenomenon. More importantly human society as a whole will benefit from this research and future associated research. Our ultimate aim will be to provide a practical guide in the use of the paper tape in skin tissue expansion and scar modulation.

10.2 Objective 2

As per objective 1 in 10.1

10.3 Objective 3

As per objective 1 in 10.1

In addition South Africa has a large black population which has a large disease burden of hypertrophic scars and keloids. Genetic, racial and trauma factors are important contributors to this disease burden. Conventional treatment strategies are multiple and not universally successful. Many strategies of variable efficacy are high cost and therefore in the face of limited resources in the state not deliverable. Seeking simple solutions even for partial alleviation at low cost will benefit the community greatly.

10.4 Objective 4

The purpose will be mainly to establish potential scope for this technique of taping in medical and surgical care entities of scar management and other reconstructive challengers in Plastic and Reconstructive surgery.

10.5 Objective 5 to 8

As per objective 3 in 10.3

11. Bibliography

1. Mustoe, T.A. and O. Kloeters, *A randomized, controlled trial to determine the efficacy of paper tape in preventing hypertrophic scar formation in surgical incisions that traverse Langer's skin tension lines - Discussion.* Plastic and Reconstructive Surgery, 2005. **116**(6): p. 1657-1658.
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7. Ogawa, R., *Mechanobiology of scarring.* Wound Repair and Regeneration, 2011. **19**: p. S2-S9.
8. Agha, R., et al., *A Review of the Role of Mechanical Forces in Cutaneous Wound Healing.* Journal of Surgical Research, 2011. **171**(2): p. 700-708.
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Appendix 2: Ethical approvals

UNIVERSITY OF KWAZULU-NATAL
INYUVESI YAKWAZULU-NATALI

17 March 2016

Dr M Daya
Clinical Medicine
NRMSM
dayam@iafrica.com

Dear Dr Daya

Protocol: The use of paper tape application in skin tissue expansion and abnormal scar modulation.
Degree: Non-degree
BREC reference number: BE298/15

EXPEDITED APPLICATION

The Biomedical Research Ethics Committee has considered and noted your application received on 01 July 2015.

The study was provisionally approved pending appropriate responses to queries raised. Your responses dated 04 February 2016 to queries raised on 06 October 2015 have been noted and approved by a sub-committee of the Biomedical Research Ethics Committee. The conditions have now been met and the study is given **full ethics approval.**

This approval is valid for one year from **17 March 2016.** To ensure uninterrupted approval of this study beyond the approval expiry date, an application for recertification must be submitted to BREC on the appropriate BREC form 2-3 months before the expiry date.

Any amendments to this study, unless urgently required to ensure safety of participants, must be approved by BREC prior to implementation.

Your acceptance of this approval denotes your compliance with South African National Research Ethics Guidelines (2015), South African National Good Clinical Practice Guidelines (2006) (if applicable) and with UKZN BREC ethics requirements as contained in the UKZN BREC Terms of Reference and Standard Operating Procedures, all available at http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx.

BREC is registered with the South African National Health Research Ethics Council (REC-290408-009). BREC has US Office for Human Research Protections (OHRP) Federal-wide Assurance (FWA 678).

The sub-committee's decision will be **RATIFIED** by a full Committee at its meeting taking place on **12 April 2016.**

We wish you well with this study. We would appreciate receiving copies of all publications arising out of this study.

Yours sincerely

Professor J Tsoka-Gwegweni
Chair: Biomedical Research Ethics Committee

Biomedical Research Ethics Committee
Professor J Tsoka-Gwegweni (Chair)
Westville Campus, Govan Mbeki Building
Postal Address: Private Bag X54001, Durban 4000
Telephone: +27 (0) 31 260 2486 **Facsimile:** +27 (0) 31 260 4609 **Email:** brec@ukzn.ac.za
Website: http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx

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KWAZULU-NATAL
INYUVESI
YAKWAZULU-NATALI

RESEARCH OFFICE
BIOMEDICAL RESEARCH ETHICS ADMINISTRATION
Westville Campus
Govan Mbeki Building
Private Bag X 54001
Durban
4000
KwaZulu-Natal, SOUTH AFRICA
Tel: 27 31 2604769 - Fax: 27 31 260-4609
Email: BREC@ukzn.ac.za
Website: http://research.ukzn.ac.za/ResearchEthics/BiomedicalResearchEthics.aspx

20 October 2015

Dr M Daya
Clinical Medicine
NRMSM
dayam@iafrica.com

Dear Dr Daya

Protocol: The use of paper tape application in skin tissue expansion and abnormal scar modulation.
Degree: PHD
BREC reference number: BE298/15

A sub-committee of the Biomedical Research Ethics Committee has considered your correspondence dated 29 September 2016 requesting the change for the above BREC approved study for degree purposes.

The Committee has **noted and approved** the above study for **degree purposes (PhD).** The Postgraduate approval letter dated 05 October 2016 has been noted by BREC.

This approval will be **ratified** at the next BREC meeting to be held on 08 November 2016.

Yours sincerely

Mrs A Marimuthu
Senior Administrator: Biomedical Research Ethics

health
Department:
Health
PROVINCE OF KWAZULU-NATAL

DIRECTORATE:
Health Research & Knowledge Management

Physical Address: 330 Langalibalele Street, Pietermaritburg
Postal Address: Private Bag X9051
Tel: 033 395 2805/ 3189/ 3123 Fax: 033 394 3782
Email: hrkm@kznhealth.gov.za
www.kznhealth.gov.za

Reference: 325/15
KZ_2015RP57_746

Date: 17 November 2015

Dear Dr M. Daya
(University of KwaZulu Natal)
Email: dayam@iafrica.com

Approval of research

1. The research proposal titled **'The use of paper tape application in skin tissue expansion and abnormal scar modulation'** was reviewed by the KwaZulu-Natal Department of Health.

   The proposal is hereby **approved** for research to be undertaken at Inkosi Albert Luthuli Central Hospital.

2. You are requested to take note of the following:
   a. Make the necessary arrangement with the identified facility before commencing with your research project.
   b. Provide an interim progress report and final report (electronic and hard copies) when your research is complete.

3. Your final report must be posted to **HEALTH RESEARCH AND KNOWLEDGE MANAGEMENT, 10-102, PRIVATE BAG X9051, PIETERMARITZBURG, 3200** and e-mail an electronic copy to hrkm@kznhealth.gov.za

For any additional information please contact Mr X. Xaba on 033-395 2805.

Yours Sincerely

Dr E Lutge
Chairperson, Health Research Committee
Date: 17/11/15

health

Department:
Health
PROVINCE OF KWAZULU-NATAL

Inkosi Albert Luthuli Central Hospital
Ethekwini Health District
Office of the Medical Manager
Private Bag X 03, Mayville, 4058
800 Bellair Road, Mayville, 4058
Tel.: 031 240 1059,
Fax.: 031 240 1050
Email.:ursulanun@ialch.co.za
www.kznhealth.gov.za

26 October 2015

Dr M Daya
Department of Plastic Surgery
IALCH

Dear Dr Daya

Re: Approved Research: Ref No: BE 298/15: The use of paper tape application in skin tissue expansion and abnormal scar modulation.

As per the policy of the Provincial Health Research Committee (PHRC), you are hereby granted permission to conduct the above mentioned research once all relevant documentation has been submitted to PHRC inclusive of Full Ethical Approval.

Kindly note the following.

1. The research should adhere to all policies, procedures, protocols and guidelines of the KwaZulu-Natal Department of Health.
2. Research will only commence once the PHRC has granted approval to the researcher.
3. The researcher must ensure that the Medical Manager is informed before the commencement of the research by means of the approval letter by the chairperson of the PHRC.
4. The Medical Manager expects to be provided feedback on the findings of the research.
5. Kindly submit your research to:

   The Secretariat
   Health Research & Knowledge Management
   330 Langalibalele Street, Pietermaritzburg, 3200
   Private Bag X9501, Pietermaritzburg, 3201
   Tel: 033395-3123, Fax 033394-3782
   Email: hrkm@kznhealth.gov.za

Yours faithfully

.....

Dr L Mtshali
Medical Manager

health

Department:
Health
PROVINCE OF KWAZULU-NATAL

Inkosi Albert Luthuli Central Hospital
Ethekwini Health District
Office of the Medical Manager
Private Bag X 03, Mayville, 4058
800 Bellair Road, Mayville, 4058
Tel.: 031 240 1059,
Fax.: 031 240 1050
Email.:ursulanun@ialch.co.za
www.kznhealth.gov.za

Reference: BE 298/15
Enquiries: Medical Management

26 October 2015

Dr M Daya
Department of Plastic Surgery
IALCH

Dear Dr Daya

RE: PERMISSION TO CONDUCT RESEARCH AT IALCH

I have pleasure in informing you that permission has been granted to you by the Medical Manager to conduct research on: **The use of paper tape application in skin tissue expansion and abnormal scar modulation**

Kindly take note of the following information before you continue:

1. Please ensure that you adhere to all the policies, procedures, protocols and guidelines of the Department of Health with regards to this research.
2. This research will only commence once this office has received confirmation from the Provincial Health Research Committee in the KZN Department of Health.
3. Kindly ensure that this office is informed before you commence your research.
4. The hospital will not provide any resources for this research.
5. You will be expected to provide feedback once your research is complete to the Medical Manager.

Yours faithfully

.....
Dr L Mtshali
Medical Manager

PERMISSION TO CONDUCT A RESEARCH STUDY/TRIAL

This must be completed and submitted to the Medical Superintendent/s / Hospital Manager/s for signature.

For **King Edward VIII Hospital (KEH)** and **Inkosi Albert Luthuli Central Hospital (IALCH)** studies please submit the document together with the following:

1. Research proposal and protocol.
2. Letter giving provisional ethical approval.
3. Details of other research presently being performed by yourself if in the employ of KEH, (individually or as a collaborator).
4. Declaration of all funding applications / grants, please supply substantiating documentation.
5. Complete the attached KEH Form - *"Research Details"*

Once the document has been signed it should be returned to: Biomedical Research Ethics Administrator, Room N40, Govan Mbeki Building, Westville Campus, University of KwaZulu-Natal.

To: Chief Medical Superintendent / Hospital Manager

Permission is requested to conduct the above research study at the hospital/s indicated below:

Site 1 address:
IALCH

Investigator/s:
Principal: M PAYA.
Co-investigator:
Co-investigator:

Signature of Chief Medical Superintendent/Hospital Manager:

Date: 26-10-2015

Site 2 address:

Investigator/s
Principal:
Co-investigator:
Co-investigator:

Signature of Chief Medical Superintendent / Hospital Manager:

Date:

NB: Medical Superintendent/s / Hospital Manager/s to send a copy of this document to Natalia

Netcare Hospitals (Pty) Ltd

Tel: + 27 (0)11 301 0000
Fax: Corporate +27 (0)11 301 0499
76 Maude Street, Corner West Street, Sandton, South Africa
Private Bag X34, Benmore, 2010, South Africa
www.netcare.co.za

RESEARCH OPERATIONS COMMITTEE FINAL APPROVAL OF RESEARCH

Approval number: UNIV-2015-0078

Dr M Daya

E mail: dayaplasticsurgery@telkomsa.net; dayam@iafrica.com

Dear Dr Daya

RE: THE USE OF PAPER TAPE APPLICATION IN SKIN TISSUE EXPANSION AND ABNORMAL SCAR MODULATION

The above-mentioned research was reviewed by the Research Operations Committee's delegated members and it is with pleasure that we inform you that your application to conduct this research at Netcare Umhlanga Hospital, has been approved, subject to the following:

i) Research may now commence with this FINAL APPROVAL from the Netcare Research Operations Committee.

ii) All information regarding Netcare will be treated as legally privileged and confidential.

iii) Netcare's name will not be mentioned without written consent from the Netcare Research Operations Committee.

iv) All legal requirements regarding patient / participant's rights and confidentiality will be complied with.

v) The research will be conducted in compliance with the GUIDELINES FOR GOOD PRACTICE IN THE CONDUCT OF CLINICAL TRIALS IN HUMAN PARTICIPANTS IN SOUTH AFRICA (2006)

vi) Netcare must be furnished with a STATUS REPORT on the progress of the study at least annually on 30th September irrespective of the date of approval from the Netcare Research Operations Committee as well as a FINAL REPORT with reference to intention to publish and probable journals for publication, on completion of the study.

vii) A copy of the research report will be provided to the Netcare Research Operations Committee once it is finally approved by the relevant primary party or tertiary institution, or once complete or if discontinued for any reason whatsoever prior to the expected completion date.

viii) Netcare has the right to implement any recommendations from the research.

ix) Netcare reserves the right to withdraw the approval for research at any time during the process, should the research prove to be detrimental to the subjects/Netcare or should the researcher not comply with the conditions of approval.

x) APPROVAL IS VALID FOR A PERIOD OF 36 MONTHS FROM DATE OF THIS LETTER OR COMPLETION OR DISCONTINUATION OF THE TRIAL, WHICHEVER IS THE FIRST.

We wish you success in your research.

Yours faithfully

20/11/2015

Prof Dion du Plessis
Full member: Netcare Research Operations Committee & Medical Practitioner evaluating research applications as per Management and Governance Policy

Shannon Nell
Chairperson: Netcare Research Operations Committee
Netcare Hospitals (Pty) Ltd
Date: 20/12/2015

Instructions: Please copy content onto hospital/site/division letter head

LETTER CONFIRMING KNOWLEDGE OF NON-TRIAL RESEARCH TO BE CONDUCTED IN THIS NETCARE FACILITY

Dear __Mahendra Daya_____(Name of applicant)

Re ___The use of paper tape application in skin tissue expansion and abnormal scar modulation _____ (Title of research)

We hereby confirm knowledge of the above named research application to be made to the Netcare Research Operations Committee and in principle agree to the research application for Netcare _Umhlanga_____ Hospital/site/division, subject to the following:

1. That the data collection may not commence prior to receipt of FINAL APPROVAL from the Netcare Research Operations Committee.
2. A copy of the research report will be provided to the Netcare Research Operations Committee once it is finally approved by the tertiary institution, or once complete.
3. Netcare has the right to implement any recommendations from the research.
4. That the Hospital/Site/Division Management reserves the right to withdraw the approval for research at any time during the process, should the research prove to be detrimental to the subjects / Netcare or should the researcher not comply with the conditions of approval.

We wish you success in your research.

Yours faithfully

21/10/2015

Signed by Hospital/Site/Division Management **Date**

Hospital General Manager

(Specify designation)

Netcare Management (Pty) Limited

APPLICATION TO CONDUCT NON-TRIAL RESEARCH IN A NETCARE FACILITY

Name of Applicant Mahendra Daya

Contact details

Landline (031) 566 2996 CellularPhone 083 6771130

e-mail address dayam@iafrica.com

ID Number 6508285185084

Gender M Race South Africa

State the reason for the research (e.g. Masters, PhD, etc) – non degree

Name of company where employed University of Kwazulu-Natal

Title of the research applied for in this instance
The use of paper tape application in skin tissue expansion and abnormal scar modulation

Netcare hospital(s)/site(s)/division(s) in which research may be undertaken
Umhlanga hospital, treatment rendered in hospital

Date of application 20th October 2015

Signature of Applicant

Netcare Management (Pty) Limited

DECLARATION BY RESEARCHER IN RESPECT OF NON-TRIAL RESEARCH TO BE CONDUCTED IN A NETCARE FACILITY

I, Mahendra Daya_____,

hereby confirm that I have applied to conduct research titled __The use of paper tape application in skin tissue expansion and abnormal scar modulation _____ _____ at

Netcare __Umhlanga_____ Hospital(s)/site(s)/division(s)

Should permission be granted, I confirm that:

1. I will not commence with the research prior to receipt of FINAL APPROVAL LETTER from the Netcare Research Operations Committee.
2. All information will be treated as confidential.
3. Netcare's name will not be mentioned in the research without written consent from the Netcare Research Operations Committee.
4. Where Netcare's name is mentioned, the results will not be published without written permission from the Netcare Operations Committee.
5. I will comply with all legal requirements regarding patient / participant rights and confidentiality (if patients / participants are to be included in the research).
6. Netcare Research Operations Committee must be furnished with a STATUS REPORT on the progress of the study at least annually on 30th September irrespective of the date of approval from Netcare Research Operations Committee.
7. A copy of the research report will be provided to Netcare Research Operations Committee once it is finally approved by the tertiary institution, or once complete.
8. I confirm that Netcare has the right to implement any recommendations from the research.
9. I agree that Netcare reserves the right to withdraw the approval for research at any time during the process, should the research prove to be detrimental to the