DISSERTATION SUBMITTED FOR STUDY OF COMPARISON BETWEEN SKIN SUTURES AND SKIN STAPLERS

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CERTIFICATE

This is to certify that this dissertation entitled **"A STUDY OF COMPARISON BETWEEN SKIN SUTURES AND SKIN STAPLERS"** is bonafide work done by **Dr.C.ANAND** under our guidance and supervision in the Department of surgery, Madurai medical college, Madurai submitted for the M.S.,(General surgery) BRANCH 1 EXAMINATION, to be held in March 2008, by the Tamilnadu DR.M.G.R. Medical university, Chennai.

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DECLARATION

I **Dr. C. ANAND** solemnly declare that the dissertation titled "A STUDY OF COMPARISON BETWEEN SKIN SUTURES & SKIN STAPLERS" has been prepared by me. I also declare that this bonafide work or a part of the work was not submitted by me or any other for my award, degree, diploma to any other university & board wither in India or abroad.

This is submitted to The Tamilnadu Dr. M.G.R. Medical University, Chennai in partial fulfillment of the rules & regulations for the award of M.S. (General Surgery) Branch – I to be held in March – 2008.

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CONTENTS

INTRODUCTION

Accurate tissue approximation is essential for operative repair of defects and execution of defects and execution of safe healing process. Aside from gentle handling of tissues and careful dissection, the approximation must be achieved without tension and without compromising the integrity of the blood supply which is essential for healing process .The perfect ness of tissue approximation and type of approximation influences the tissue healing rate, post operative early and late complication of surgical wound and economical burden of the hospital.

Though the age's man sought for methods of binding wounds to promote healing. In olden days spider webs, warrior ants etc were used till suture materials were discovered. In this modern era broadly speaking the materials or gadgets for approximation of tissues are the sutures, staples or clips, glues, steritapes etc, the secret to achieve a good wound healing lies in meticulous tissue dissection selection of suture material, methods of wound closure and post operative complications. The key principles involved to achieve perfect healing are preservation of blood supply, minimal tissue damage, approximation of edges without tension, correct suture spacing and suture bites with proper selection of suture materials.

In conclusion the surgical technique is far more important than the sutures used but a good scientific knowledge of different sutures and needles and how they perform, will aid the surgeon to achieve optimum wound healing. Since suture technology has kept in pace with advances in surgical techniques, it is imperative on the part of the surgeon not only to be fully aware of them but also to keep them in their surgical armamentarium. Skin staplers are far better for skin closure in terms of effectiveness, cost and in terms of compliance and complications.

This study is conducted for comparison of skin closure by using skin sutures and skin staplers with respect to effectiveness and complications.

HISTORICAL REVIEW

Surgery and suture and surgeon and sutures are inseparable. Suture technology and suture sterilization and wound closure has started even before Christian era but kept in pace with the rapid improvements in the craft of surgical field.

Eyed needles invented in 5000-3000B.C. Bore needles were of standard unsurpassed till renaissance 2000B.C.

North American Indians used cautery and closed the protruding edges of wounds in a figure of eight manner. South Americans used large black ants, which bite the wound edges together, their powerful acting in similar manner to Michel clips for wound closure and homeostasis. The ant's body is then twist off leaving the head in place.

One of the earliest Indian surgical texts written by Susruta described in detail about the triangular, round bodies, curved and straight needles. Sutures were made from flax, hemp, bark fiber or hair.

Corenlius celsus in De-Re medicine mentioned about characters of suture materials and small metal clip similar to Michel clips.

John Hunter (1728-93) was of the opinion that sutures were basically undesirable but if needed they should be interrupted sutures.

Lord Lister (1867) suggested the use of antiseptic ligature soaked in an antiseptic solution of carbolic acid. Era of synthetic absorbable sutures came from 1930s.

AIM OF STUDY

To study the outcome of wound closure by skin sutures and skin staplers in terms of effectiveness and complications –a comparison study.

METHODS AND MATERIALS

This is a prospective type of comparison study conducted from May 2005 to October 2007 at GRH; Madurai includes 200 patients who underwent various surgical procedures.

The patients included in this study were randomly selected from those who under went various surgical procedures including.

-Elective

-Emergency procedures with various incisions.

The relevant data of patients included in the study were collected and recorded as follows. Age of the patient, sex, occupation, type of incision, length of incision, gadget used for skin closure, time taken for skin closure, post operative complications namely wound infection, seroma formation, stitch abscess, stitch granuloma, wound gaping and adverse scars were observed for and recorded in the Proforma.

The post operative day of suture removal was also observed. The final out come of the scar whether good, fair or ugly was observed in the follow up period and recorded in the Proforma.

Skin closure was done by using suture materials namely silk, Prolene, nylon etc., and compared with staplers and the outcome were observed and recorded. The methods used for skin closure with suture materials were simple, mattress and subcuticular sutures using various suture materials which are chosen based on the availability of suture materials in the operation theatre.

REVIEW OF LITERATURE.

Interaction between local tissue mediators and cells that migrate into the wound. Migration of epithelial cells has been shown to occur within the first 12 to 24 hours but further new tissue formation occurs over the next 10 to 14 days.

WOUND HEALING:

Normal wound healing is a series of complex events which occur in an orderly and predicable fashion. During the course of normal healing a variety of cells, proteins, proteases, growth factors and matrix components interact in a coordinated fashion leading to anatomical and functional integrity. The non healing wound is a major health problem costing billions of dollars each year in addition to pain and suffering. Failure to heal may be the result of diseases or metabolic factors. Healing depends more on the human body than if does on what cream, salve or ointment, suture applied to that wound. Although treatment of the disease or correction of a metabolic deficiency may enable healing in most of the cases, this wound will not close unless the healing process is stimulated in some manner.

Healing is the highly regulated process of cellular, humoral and molecular events activated at the time of acute injury and resulting in a time dependent but predictable and orderly pattern of tissue repair.

Four phases of wound healing have been identified and studied on the cellular and molecular level. These four distinct phases that is hemostasis, inflammation, tissue formation and tissue remodeling.

Initial injury leads to the recruitment of inflammatory cells into the wound once a clot forms in response to disrupted blood vessels. This scenario entails a complex

Epithelization and neovascularization result from the increase in cellular activity. Thus new tissue, called granulation tissue depends on specific growth factors for further organization to occur in the completion of the healing process. This physiologic process occurs over several weeks to months in a healthy individual.

Finally tissue remodeling, in which wound contraction and tensile strength is achieved, occurs in next 6 to 12 months.

In the primary intention method, surgical wound closure facilities the biological event of healing by joining the wound edges. Surgical wound closure directly opposes the tissue layers, which serves minimize new tissue formation within the wound. However, remodeling of the wound does occur and tensile strength is achieved between the newly opposed edges. Closure can serve both functional and aesthetic purposes. Those purposes include elimination of dead space by approximating the subcutaneous tissues, minimization of scar formation by careful epidermal alignment and avoidance of a depressed scar by precise eversion of skin edges. If dead space is limited with opposed wound edges then new tissue has limited room for growth. Correspondingly atraumatic handling of tissues combined with avoidance of tight closures and undue tension contribute to a better result.

The secondary intention method is ancient and well established. It can be used in view of complicated reconstruction for certain surgical defects. This method also depends on the stages of wound healing to achieve the ultimate result.

CATEGORY-1:

Wound healing by primary intention occurs within hours of repairing a full thickness skin incision. This surgical insult results in death of minimal number of cellular constituents.

CATEGORY-2:

If the wound edges are not reapproximated immediately, delayed primary wound healing transpires. This type of healing may be desired in case of contaminated wounds. By fourth day, phagocytosis of contaminated tissues is well under way and the process of epithelization, collagen deposition and maturation are occurring. Foreign materials are walled off by macrophages that may metamorphose into epitheliod cells, which are encircled by mononuclear leucocytes, forming granuloma. Usually the wound is closed surgically at this juncture and if the cleansing of the wound is incomplete chronic inflammation can ensue, resulting in prominent scarring.

CATEGORY-3:

Third type of healing is also known as healing by second intention. In this type of healing, a full thickness wound is allowed to close and heal by itself resulting in an inflammatory response that is more intense than with primary wound healing. In addition, a larger quantity of granulomatous tissue is fabricated because of the need for wound closure. Secondary healing results in pronounced contraction of wounds. Fibroblastic differentiation into myofibroblasts which resemble contractile smooth muscle is believed to contribute to wound contraction. These myofibroblasts are maximally present in the wound from 10^{th} to 21^{st} days.

CATEGORY-4:

Epithelization is the process by which epithelial cells migrate and replicate via mitosis and traverse the wound. In wounds with partial thickness involving only the epidermis and superficial dermis, epithelization is the predominant method by which healing occurs. Wound contracture is not a common component of this process if only the epidermis or epidermis and the superficial dermis are involved.

STAGES OF WOUND HEALING

INITIAL PHASE- HEMOSTASIS:

Following tissue injury via an incision, the initial response is usually bleeding. The cascade of vasoconstriction and coagulation commences with clotted blood immediately impregnating the wound leading to hemostasis and with dehydration a scab forms.

Following vasoconstriction, platelets adhere to damaged endothelium and discharge adenosine diphosphate, promoting thrombocytes clumping and formation of platelet plug. The inflammatory phase is initiated by the release of numerous cytokines by platelets. Fibrinogen is cleaved into fibril and the framework for completion of the coagulation process is formed. Fibrin provides the structural support for cellular constituents of inflammation. This process starts immediately after the insult and may continue for few days.

SECOND PHASE OF INFLAMMATION:

Inflammation is crucial to the highly orchestrated response to tissue injury. The latest understanding indicates however that inflammation persists throughout all wound healing phases, stimulating and coordinating the essential functions of wound repair. Within the first 6 to 8 hours the next phase is under way. Polymorphonuclear neutrophils cleanse the wound clearing of the debris. PMN attain their maximal numbers in 24 to 48 hrs and commences their departure by hour 72.

As the process continues, monocytes also exude from the vessels. These become macrophages which continue the cleansing process and manufacture various growth factors in 3 to 4 days.

The earliest acute wound inflammatory signals are released after platelet after platelet degranulation and from the traumatized cells at the disrupted edges of the skin wound. Hemostasis and inflammation are stimulated simultaneously by the release of multiple soluble factors.

THIRD PHASE- GRANULATION:

This phase consists of different sub phases. These are fibroplasias, matrix deposition, angiogenesis and reepithelialization. Preparation for the cellular influx occurs in early phases as the cellular influx occurs in early phases as the proximal matrix is restructured. Within hours of wounding, basal keratinocytes from the wound edges begin to migrate laterally to cover the defect. The infiltration of fibroblasts into the wound begins the first day after wounding and fibroblasts become the predominate cell type by day 4.

In 5 to 7 days, fibroblasts have migrated into the wound laying down new collagen of sub types 1 and 3. Early in normal healing, type 3 collagen predominates but is later replaced by type 1 collagen. The wound is also suffused with glycoseaminoglycans like heparin sulfate, hyaluronic acid, chondraitin sulfate and keratin sulfate.

Angiogenesis is the product of parent vessel offshoots. The formation of new vasculature requires extracellular matrix and basement membrane degradation followed by migration, mitosis and maturation of endothelial cells.

Reepithelialization occurs with the migration of cells from the periphery of the wound and adnexal structures. This process commences with the spreading of cells within 24hrs. Division of peripheral cells occurs in 48 to 72 hrs results in thin epithelial cell layer which brides the wound.

FOURTH PHASE- REMODELLING AND CONTRACTION:

Wound remodeling is highly orchestrated operation as the earlier phases of wound healing. After third week, the wound undergoes constant alterations known as remodeling, which can last for years after the initial injury occurred. Collagen is degraded and deposited in an equilibrium producing fashion, resulting in no change in the amount of collagen present in the wound. Contraction of the wound is an ongoing process resulting in part from the proliferation of the specialized fibroblasts termed myofibroblasts, which resemble contractile smooth muscle cells. Maximal tensile strength of the wound is achieved by the 12^{th} week and the ultimate resultant scar has only four fifths or 80% of the tensile strength of the original skin that it has replaced.

Wound contraction is an essential aspect of wound healing that decreases the area of the wound defect, promoting easier wound closure.

FACTORS AFFECTING WOUND HEALING:

LOCAL	SYSTEMIC
Infection	Malnutrition
Poor blood supply	Anemia
Excess movement	Diabetes mellitus
Foreign body	Steroids
Radiation injury	Uremia
Loss of sensation	Jaundice

SUTURE MATERIALS:

History:

In surgery, the choice of suture materials has been largely empirical. In this thesis I would like to present few of important historical events and characters of each suture materials.

One of the earliest Indian surgical texts written by Susrutha describe s in detail about triangular, round bodied, curved, straight needles. Sutures were made from flax, hemp, bark fiber and hairs.

Aurelius Cornelius census, a Roman medical journalist, wrote a monumental book in medicine (A.D. 30) and it is known as De Re medicina. He also described small metal clips similar to Michel clips of today.

Galen of Pergamam (A.D. 150) in his work De methods-medendi, comments for the first time on the use of catgut which makes it clear that the ancients knew it. Origin of word catgut is obscure and all we can say is that it never had anything to do with cats!

In 1867- Lister had formulated and published his monumental work and now the long carbolic crusade began. However Lister's scientific acumen was not limited to antisepsis. Two years later, he published an article," observation of ligature of arteries on the antiseptic system".

He noticed that fragments of glass or needles inadvertently left in a wound did not give rise to suppuration. He felt that harmful bacteria must lie with in the interstices of silk and if they could be killed, a ligature could be safely left in the body. Lister had one more contribution to make to the manufacture of surgical catgut. In attempt to delay the absorption of catgut so that wound and blood vessels wound have more time to heal with safe, Lister turned to the leather trade and found they used chromic acid to tan leather. He incorporated this into his formulation.

Silk was the next choice in non absorbable suture large. It becomes popular because of its excellent handling properties. It was extensively used in all surgical procedures including cardiovascular surgery. Halstead was its main proponent.

In the second half of the sixties, it was discovered that polyglycolic acid could be processed into an absorbable suture with very favorable properties. In 1970 and 1971 the first suture from polyglycolic acid was introduced in the clinical practice.

SUTURE CHARACTERS.

The choice of suture material should be based on the patient, wound, tissue characteristics, anatomical location etc. A surgeon selection may not be specifically based on scientific data, but rather on the preference that he or she learned from mentors and or in training.

Understanding the various characteristics of available suture materials is important to make an educated selection. No one suture possesses all desirable characters. The optimal suture should be easy to handle and have high tensile strength and knot security. Any tissue reaction should be minimal and the material should resist infection and have good elasticity and plasticity to accommodate wound swelling. A low cost is preferred. Although some of the newer materials available have many of those properties, no one material is ideal and compromise must be made.

Physical characters of a suture material determine its utility; these characteristics include configuration, diameter, fluid absorption, tensile strength, knot strength, elasticity, plasticity, memory etc.

CONFIGURATION:

The configuration of a suture is based on the number of strands of material used to fabricate it. A suture can be monofilament (ie, single-stranded) or multifilament (ie, multistranded). Multifilamentous sutures are twisted or braided.

SIZES

United States Pharmacopoeia (USP) sizes are standardized and related to a specific diameter range (in millimeters) that is necessary to produce a certain tensile strength. These diameter ranges vary with the different categories of suture material. These categories include natural collagen and synthetic absorbable and nonabsorbable materials. Sizes are expressed with zeroes, that is, more zeroes indicate a smaller size.

TENSILE STRENGTH

The tensile strength of a material is determined by the weight required to break a suture divided by its cross-sectional area. The rate of tensile strength loss is not the same as absorption and varies among suture materials. The implantation and tying of a suture decreases its strength. Dry, unused absorbable suture loses 4-13% of its initial strength after being soaked in sodium chloride solution for 24 hours. Knotted sutures have two-thirds the strength of unknotted sutures. In selecting suture material, remember that the tensile strength of a suture does not need to exceed that of the tissue it is securing.

KNOTS

The knot is the weakest portion of the suture. Its strength is defined by the force necessary to cause slippage. The 2 types of knots used in dermatologic surgery are flat knots and sliding knots, with flat knots being more secure than sliding knots. Flat knots include square knots and surgeon's knots. A surgeon's knot differs from a square knot in the initial throw. Two wraps around the needle driver define the surgeon's knot. Although this initial throw adds no strength to the knot, it decreases the tendency of the wound to separate as the suture is tied. Three-throw flat knots are appropriate for use in dermatologic surgery; however, the suture material may affect the number of throws needed for security. Extra throws do not increase the strength of a properly tied knot, but they do add to its bulk and, therefore, to any potential tissue reaction.

PLASTICITY AND ELASTICITY

Plasticity is the ability of the suture to retain its new form and length after stretching. Plasticity allows a suture to accommodate wound swelling, thereby decreasing the risk of strangulated tissue and crosshatch marks. However, as swelling subsides, the suture retains its new size and may not continue to adequately approximate the wound edges.

Elasticity is the ability of a suture to regain its original form and length after stretching. After the swelling of a wound recedes, the suture returns to its original length and keeps the wound well approximated. Most sutures are elastic; few are plastic.

Memory is the ability of a suture to return to its original shape after deformation by tying. Memory is related to plasticity and elasticity. Sutures with a high degree of memory, particularly monofilament sutures, are stiff and difficult to handle; the knots are less secure and may require an extra throw to prevent loosening.

HANDLING CHARACTERISTICS

Handling characteristics of suture materials are defined by their pliability and coefficient of friction. Pliability refers to the ease with which a suture can be bent. The coefficient of friction is a measure of the slipperiness of the suture. Sutures with a high coefficient of friction, generally multifilament sutures, are more difficult to pass through tissue, thereby causing a greater degree of tissue injury (and potential discomfort) during placement and removal. However, these sutures are easier to handle and manipulate for tying knots.

TISSUE REACTION

Different suture materials produce varying degrees of tissue reaction, specifically inflammation. Significant inflammation reduces the resistance to infection and delays the onset of wound healing. The type of material and size of the suture are thought to be the major factors contributing to this reaction. Natural materials are absorbed by proteolysis, which causes a prominent inflammatory response, while synthetic materials are absorbed by hydrolysis, which produces a minimal reaction.

Multifilamentous sutures have a high degree of capillarity, which is correlated with a tendency to absorb and retain both fluid and bacteria. These materials are associated with greater reactivity and may promote infection if bacterial contamination occurs during or shortly after surgery.

SUTURE MATERIALS.

Sutures are classified as absorbable or Nonabsorbable, natural or synthetic, and multifilament or monofilament.

Absorbable suture materials

Absorbable sutures are defined by the loss of most of their tensile strength within 60 days after placement. They are used primarily as buried sutures to close the dermis and subcutaneous tissue and reduce wound tension. The only natural absorbable suture available is surgical gut or catgut. Synthetic multifilamentous materials include polyglycolic acid. Monofilaments forms include polydioxanone, Polytrimethylene carbonate, Polyglecaprone…

PROPERTIES OF ABSORBABLE SUTURE MATERIALS.

Property	Gut	Poly glycolic Acid	Poly glactin	Poly dioxanone	Poly trimethylene Carbonate	Poly glecaprone
Handling	Fair	Fair-good	Good	Poor	Good	Excellent
Knot security	Poor	Fair-good	Fair	Poor	Good	Good
Tensile strength	Low proteolysis at 60-90 d, unpredictable	High hydrolysis at 90-120 d	High hydrolysis at 60-90 d	Moderate hydrolysis at 180-210 d	High hydrolysis at 180-210 d	High hydrolysis at 90-120 d
Coefficient of friction	High	High	Medium	Low	Low	Low
Memory	Low	Low	Low	High	Low	Low
Tissue reactivity	High	Low-moderate	Low-moderate	Low	Low	Low
Uses	Sutures in mucosal tissues, vessel ligation	Buried sutures	Buried sutures	Buried sutures in wounds requiring longer dermal support	Buried sutures in wounds requiring longer dermal support	Buried sutures
Other		Low elasticity, clear or green	Low elasticity, clear or violet	Clear or violet	Clear or green	High elasticity, clear

NONABSORBABLE SUTURE MATERIALS:

Nonabsorbable sutures are defined by their resistance to degradation by living tissues. They are most useful in percutaneous closures. Surgical steel, silk, cotton, and linen are natural materials. Synthetic monofilament sutures are most commonly used in cutaneous procedures and include nylon, polypropylene, and polybutester. Synthetic multifilament sutures, including nylon and polyester, are used infrequently in dermatologic surgery.

Nonabsorbable Suture Characteristics

Properties	Silk	Nylon, Monofilament	Nylon, Multifilament	Polyester	Polypropylene
Handling	Excellent	Poor	Fair-good	Good	Poor
Knot security	Excellent	Poor	Fair-good	Good	Poor
Tensile strength	Low	High	High	High	Moderate
Coefficient of friction	High	Low	High	High	Very Low
Memory	Low	High	Medium	Medium	High
Tissue reactivity	High	Low	Moderate	Low-moderate	Low
Uses	Sutures in mucosal tissues or conjunctive or intertriginous zones to elevate or retract tissues	Percutaneous sutures, buried sutures if prolonged dermal support is needed	Minimal use in dermatologic surgery	Minimal use in dermatologic surgery	Percutaneous sutures, buried sutures if prolonged dermal support is needed, running subcuticular closures

OPERATIVE TECHNIQUE FOR SUTURING SKIN WOUNDS USING SUTURE MATERIAL

Skin suturing is of several types:

1. The simple interrupted suture
2. The vertical mattress suture
3. The horizontal mattress suture
4. The half buried horizontal mattress sutures
5. The subcuticular continuous sutures
6. The continuous over and over sutures

SKIN STAPLERS

Introduction:

During the last four decades, there have been revolutionary advances in the development of skin staples as well as tissue adhesives. It is one of the established alternative methods of wound closure.

SKIN STAPLES

The use of mechanical means for wound closure first appeared in ancient Hindu medicine. Insect mandibles were employed for wound closure in the jungles of southern Bhutan at the foot of the Himalayas.[1] Victor Fischer, an ingenious designer of surgical instruments, was the inventor of the first surgical stapler that used metal staples.[2] He designed and developed different gastrointestinal staplers for Hümér Hütl, one of the leading surgeons at the St. Rokus Hospital in Budapest. In 1920, Aladár von Petz, a young surgical assistant at the University of Budapest, designed a stapler weighing only 1 kg that became the prototype for future GI staplers.

Subsequently, a great impetus to mechanical stapling devices was given by the Institute for Experimental Surgical Apparatus and Instruments in the mid-1950s.[3]The early experience of Steichen and Ravitch[4] with the original Soviet staplers convinced them of their potential uses in surgery, which provided the stimulus for American designers and manufacturers to create a family of staplers. Although many of the original staplers were developed from the basic principles utilized in the Soviet instruments, the skin stapler was a totally new kind of instrument in conception. This stapler, manufactured in the United States utilized a disposable, preloaded, presterilized magazine that contained 25 staples. A small sterile disposable cylinder containing carbon dioxide provided the driving force for the formation of rectangular skin staples. Steichen and Ravitch[4] reported that this instrument saved considerable time during the operative procedure.

The first major change in the design of this skin stapler was to replace the carbon dioxide cartridge with a mechanical power source, a movable handle. By compressing the movable handle against a fixed handle, the surgeon generated sufficient force to form the rectangular staple. This metal stapler, which had to be cleaned and autoclaved before each surgical procedure, employed a sterile, disposable cartridge containing

25 to 35 staples that were easily positioned in the delivery end of the stapler. The time required to clean and autoclave these staplers was circumvented by then developing sterile disposable skin staplers.[6]

Several studies have been conducted to compare the use of staples and nylon sutures on the trunk, head, and neck; these revealed comparable cosmetic results. Advantages of staples include a decreased risk of tissue strangulation and infection, improved wound eversion, and minimal tissue reactivity. Disadvantages include the need for a second operator to evert and reapproximate skin edges during staple placement, greater risk of crosshatch marking, and less precise wound approximation. The cost is usually more than that of suture material.

It is one of the purposes of this report to describe the scientific basis for the selection of skin stapling techniques. By understanding the influence of these staple closure devices on the biology of wound repair and infection, the surgeon can accomplish staple closure with the most aesthetically pleasing scar and with the lowest incidence of infection.

METAL SKIN STAPLES.

Staples are formed from high-quality stainless steel and are available in regular and wide sizes. Staples are composed of

(1) A cross-member that lays on the surface of the skin perpendicular to the wound,

(2) Legs that are vertically placed in the skin, and

(3) Tips that secure the staple parallel to the cross-member.

Staples are relatively easy to place and may shorten the closure time by 70-80%. The primary utility of staples is in the closure of wounds under high tension on the trunk, extremities, and scalp. They are also used to secure split-thickness skin grafts. They are not used in delicate tissues or wounds in finely contoured areas, over bony prominences, or in highly mobile areas.

The surgeon's selection of a disposable stapler is determined by several important parameters of mechanical performance, including 1) handling characteristics, 2) maximal angle of visual access to the staple, 3) angle at which the staple enters the tissue, 4) ease of positioning, 5) prepositioning mechanism for staple, 6) staple release mechanism, 7) texture, and 8) weight.

Stapler design must strive to diminish energy expenditure. The weight of the stapler is an important consideration to avoid hand fatigue. Using light tools for light tasks is a worthwhile rule. The investigations of Comaish and Bottoms[8] and Naylor[9] provide a basis for including texture among the important design elements of staplers. A slippery finish demands energy expenditure for retention in the surgeon's hands. Texture that is too coarse can lead to discomfort, skin irritation, and diminished efficiency. Actuating the stapler should be accomplished with ease. Strength differences between men and women provide a basis for using women's strength as a standard when determining forces needed to form staples. Once the staple is formed, all stapler handles are spring-loaded, which returns them to their resting position, reducing work expenditure.

All staplers are designed with fixed and movable handles. For skin staplers operated by grip activities, the surgeon usually compresses the movable handle with the index, long, ring, and little fingers against the fixed handle, which is stabilized against the plane of the hand. The distance between the movable and stationary handles is an important consideration in stapler design. Surgeons prefer to compress a movable handle whose contact surface is 5.5-8.0 cm from the contact surface of the stationary handle, because they can exert maximal grip strength at these distances without becoming fatigued.[11] When this distance is short (≤3.0 cm), the surgeon's grip strength on the movable and fixed handles is limited, predisposing to fatigue after repeated staple formations.

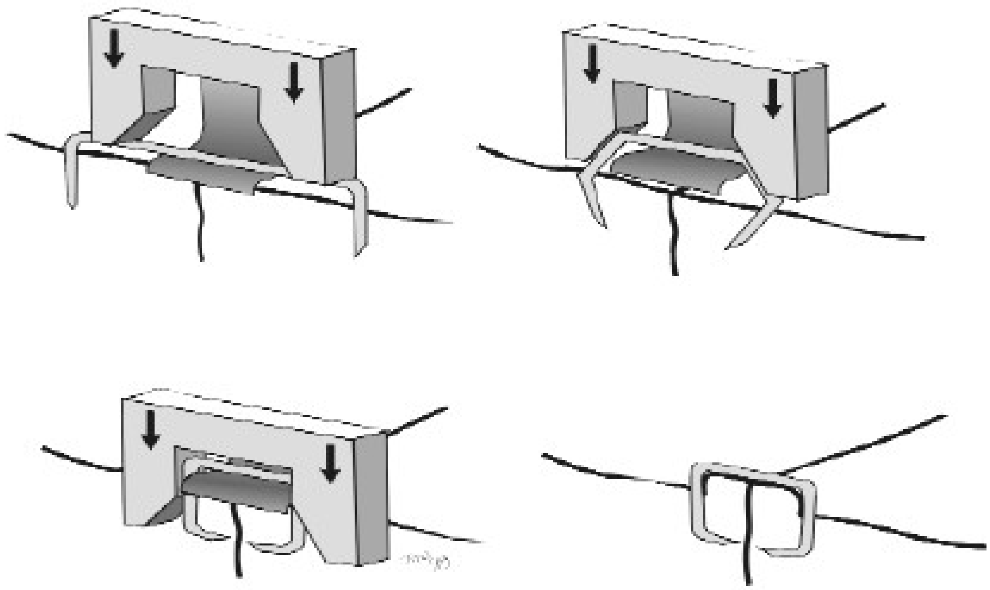
In dermatologic surgery, the staplers used are disposable and loaded with 5-35 staples, depending on the manufacturer. They are lightweight and have handles that are easy to grip and control. The width and height of the staples vary with the manufacturer. Most regular staples are 4- to 6-mm wide and 3.5- to 4-mm high. Wide staples for use in thicker skin are 6.5- to 7.5-mm wide and 4- to 5-mm high.

An important additional feature of the skin stapler is its prepositioning mechanism, which allows the surgeon to hold the staple in various positions during its formation. A clutch-like mechanism has been incorporated into the stapler, which allows the surgeon to release pressure on the moveable stapler handles without losing control of the partially formed staple. The delivery end of the skin stapler cartridge should assume a 60° angle with the underlying skin, which provides intimate contact with the skin with only a 1 mm deep recess in which the staple is formed. When the staple is delivered to the wound at this 60° angle, it tends to assume an upright position that is perpendicular to the wound. This additional space allows the entrapped tissue to expand during healing without contacting the staple topspan, thereby decreasing the likelihood of the development of transverse skin scars (cross-hatching) beneath the topspan.

Once the staple is formed, the stapler should have an automatic release system that separates the staple from the stapler. After firing all of the staples in a cartridge, the cartridge should be removed from the instrument and replaced with a new cartridge if additional staples are needed to staple the incision or graft. Finally, the handling characteristics of the stapler should be such that the surgeon can easily implant a large number of staples without becoming fatigued.

Like surgical needles, the configuration and position of the pointed legs of the staple may influence the performance of the stapler. The geometry of the staple should assume a rectangular shape in the tissue. The uniform geometry of the stainless steel staples has been attributed to both the position of dimples, or indentations, in the staple wire and to the geometry of the staple wire. Dimples or indentations in the wire have been inset at the junction of the topspan and its legs. These dimples facilitate the positioning of the wire on the anvil and the creation of a uniform staple. In addition, the flattened topspan of the staple gains intimate contact with the anvil, this contributes to uniform staple geometry.

SKIN STAPLING:



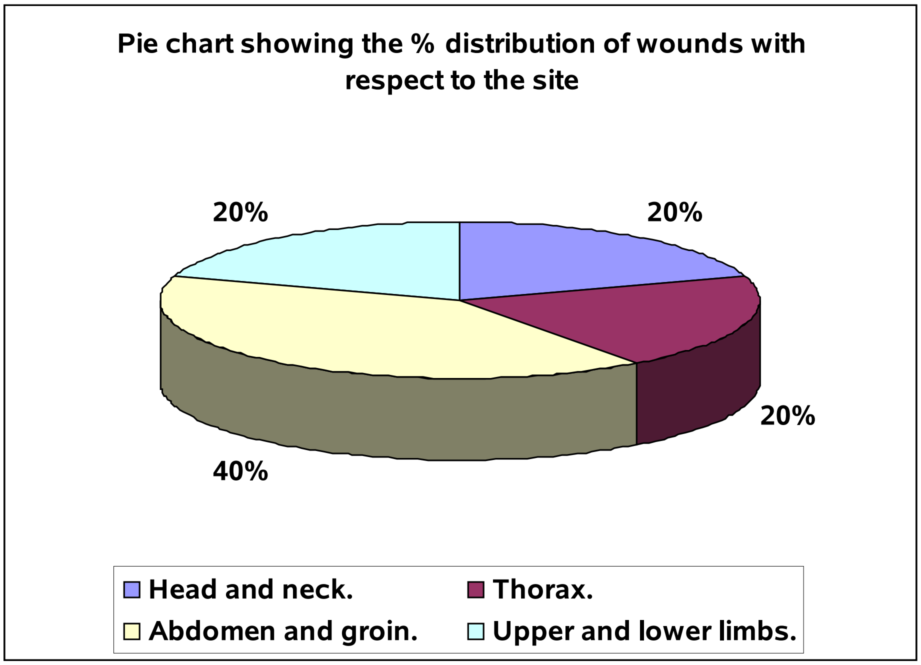
Skin Staplers:

OBSERVATION

This study included total of 200 cases that underwent various surgical procedures at various site, various type of incision from the period of May 2005 to March 2007. Out of these 200 cases 100 cases underwent skin closure by sutures and 100 patients underwent skin closure by skin staplers.

Table showing % distribution of site of wounds:

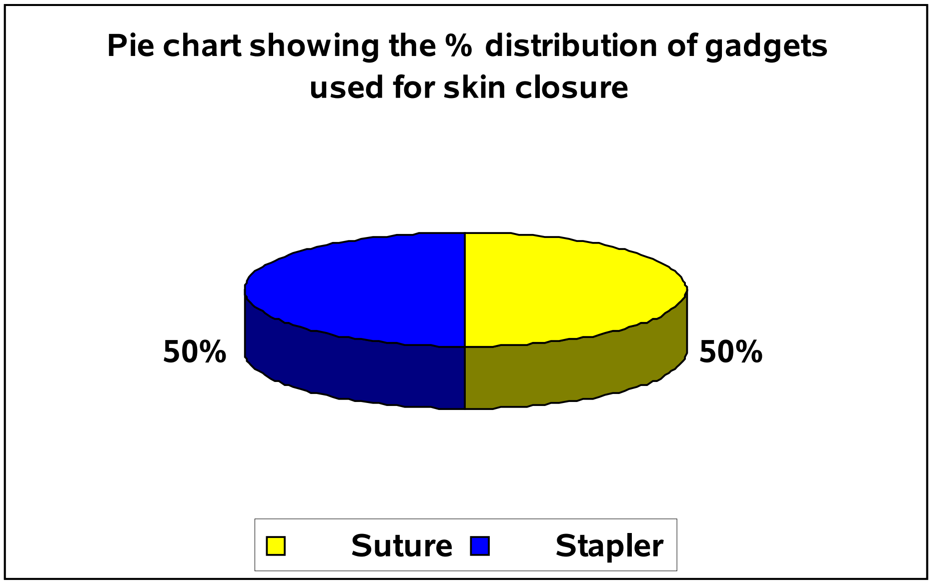
Sl No	Site of wound	No. of patients	Percentage
1.	Head and neck.	40	20%
2.	Thorax.	40	20%
3.	Abdomen and groin.	80	40%
4.	Upper and lower limbs.	40	20%



The methods adopted for skin closure was chosen randomly in this study revealed that suture materials were used in 100 patients and staplers in 100 patients.

GADGETS FOR `SKIN CLOSURE:

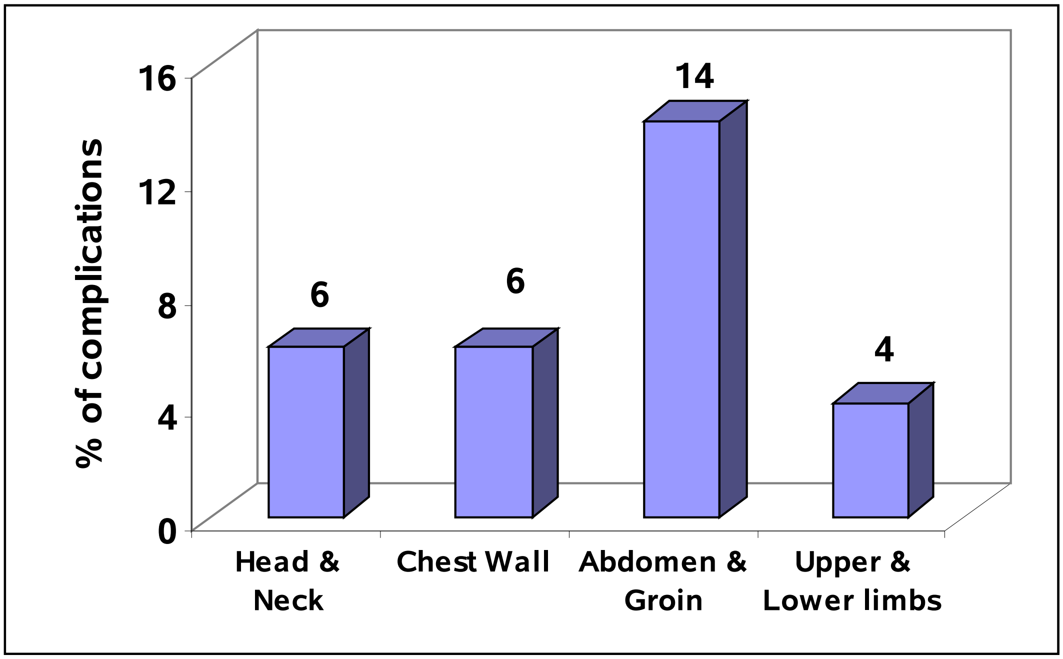
Si no:	Gadget used	No. of patients	Percentage
1.	Suture	100	50%
2.	Stapler	100	50%



OUTCOME FOR SKIN SUTURES:

Site of the wound.	Average length of wound.	Type of suturing.	Average speed of closure – minutes / 10cm wound.	Materials used.	% of complications
Head and neck.	7.3cm.	Simple (for face) & vertical mattress (for scalp) & subcuticular	8.04.	Prolene for face and neck and silk for	6.

		(for neck) .		scalp.	
Chest wall.	9.05cm.	Vertical mattress.	3.5.	Silk	6.
Abdomen and groin.	12.9cm.	Vertical mattress.	8.52.	Silk.	14.
Upper and lower limb.	10.3cm.	Vertical mattress.	6.23.	Silk.	4.



Bar chart showing the % distribution of complication rates among wounds closed with skin sutures

Complications studied are wound gaping, wound infection, seroma formation, tissue reaction around the suture material, suture line necrosis, stitch abscess, granuloma and ugly scars.

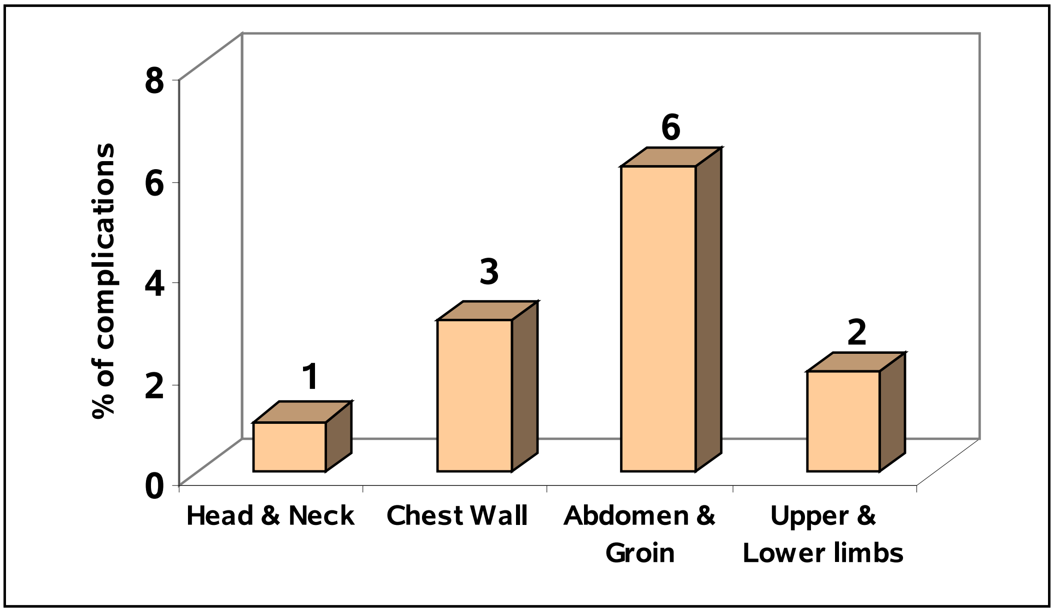
Average length of wound and time of closure is nothing but the arithmetic mean obtained from the master chart.

CALCULATION:

- Length of each wound and its time taken for closure using skin sutures is calibrated for length of 10cm.
- Thus the average time taken for closing 10cm wound with skin sutures is $=\sum x/n=$ 6.61 minutes (please refer to master chart for data).

OUTCOME FOR STAPLERS:

Site of wound.	Average length of wound.	Materials used.	Average speed of closure in -minutes/10cm wound.	% of complications.
Head and neck.	7.52cm.	Staplers.	1.74.	1.
Chest wall.	8.5cm.	Staplers.	2.43.	3.
Abdomen and groin.	9.95cm.	Staplers.	1.65.	6.
Upper and lower limbs.	10.9cm.	Staplers.	1.54.	2.



Bar diagram showing % distribution of complication rates with skin staplers with respect to various site:

Complications studied are wound gaping, wound infection, seroma formation, tissue reaction around the suture material, suture line necrosis, stitch abscess, granuloma and ugly scars.

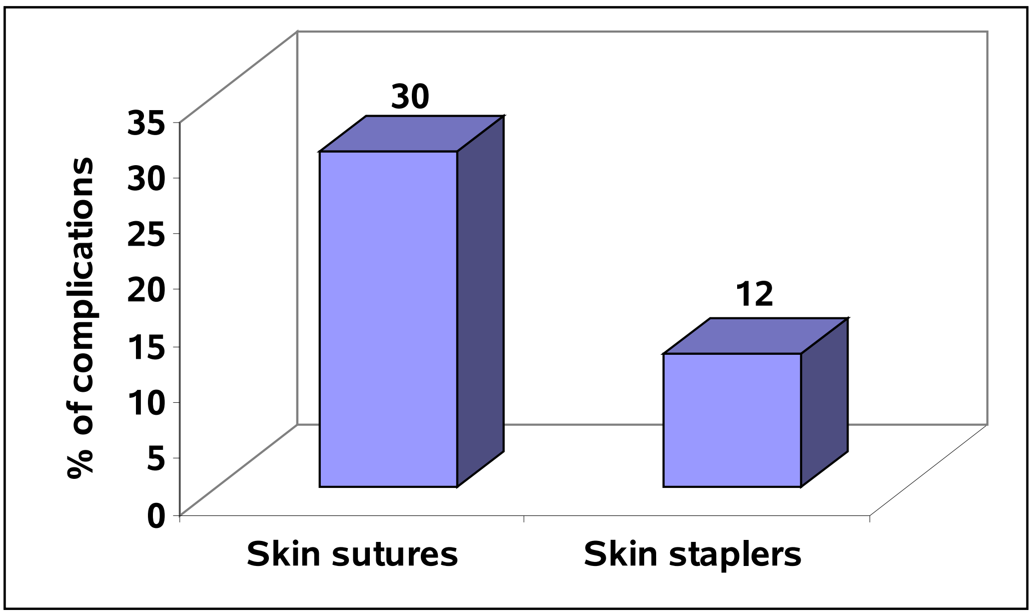
Average length of wound and time of closure is nothing but the arithmetic mean obtained from the master chart.

CALCULATION:

- Length of each wound and its time taken for closure by using is calibrated for length of 10cm.
- Thus the average time taken for closing 10cm wound with skin staplers $=\sum x/n = 1.84$ minutes (please refer master chart for data).

COMPARISION BETWEEN SUTURES AND STAPLERS:

Gadgets used.	Average speed of closure in minutes per 10 cm wound.	Compliance of patients and surgeon.	Incidence of complications.
Suture.	6.61.	Fair.	30%.
Stapler.	1.84.	Good.	12%.



Percentage distribution of complications for sutures versus staplers

TESTING THE SIGNIFICANCE (USING NULL HYPOTHESIS):

Si no:	No. of patients with complications.	No. of patients without complications.	Total.	Complication rate.
Sutures.	30.	70.	100.	30%.
Staplers.	12.	88.	100.	12%.
Total.	42.	158.	200.	

By using the formula $\sum(O-E)^2/E$ the Chi-square value (X^2)is calculated as 9.76.

The degree of freedom for the above table is calculated by using the formula (Column-1) × (Row-1) and the value is 1.

From probability distribution table the P value for the obtained values is as follows:

The value of Chi square for a probability of 0.05 is 3.84 which is less than the calculated value.

Also the value of Chi square for a probability of 0.005 is 7.88 which is less than calculated value.

But, for the probability of 0.001 the Chi square value is 10.83 which is more than the actual value.

DISCUSSION

- A study conducted by Kanegaye et al – 1997, USA-studied 88 patients from 13 months to 16 yrs, attending the emergency department with scalp lacerations. Staples cost 39% less than per wound closure & the complications reported were none. Stapling was fast than suturing per wound.
- A study conducted by Ritchie AJ & Roke LG -1989, Northern Ireland -studied 200 cases with lacerated wound in scalp. Average speed of repair for staplers is 49 seconds and for skin sutures is 6 min & 20 sec. woun repair by staples is less painful than with skin sutures. There were no significant difference in cost & complications.
- A study Brickman KR & Lambert RW in 1989 –USA –studied 76 patients with lacerations in scalp, trunk & extremities. Average time taken for staplers is 30 sec. one scalp wound & one leg wound dehisced. Staplers were cost effective than sutures & compliance of was good.
- A study by MacGregor FB et al in 1989, Scotand -100 patients with lacerated wounds. Mean time for stapler repair is 18.6 sec & for suture

is 124 sec. the cost of repair and the complication rate were almost same. Patient compliance with stapler is good than sutures & no local anesthesia applied for stapling.

- A study by Orlinsky M et al in 1995, USA –studied patients presenting in emergency department with lacerations of scalp, trunk and extremities. The average speed of stapling is 8.3 seconds per cm wound for staplers & 63.2 seconds per cm wound for sutures. The cost of wound repair per wound was significantly higher in skin sutures than staplers.
- In this study the average time taken for skin closure by staplers is 1.84 min per 10 cm of wound & for skin sutures, it is 6.61 min per 10 cm of wound. Complication rates for suturing is 30% & for staplers, it is about 12%.

CONCLUSION

- From the P value it is concluded that staplers are effective in terms of lower incidence of complication rate at the probability of 0.005.
- Staplers consume less time when compared to skin sutures particularly in major cases and in emergency which can reduce the duration of anesthesia.
- Since staplers by reducing the complication rate it is cost effective.
- Compliance for surgeon and patient is also good for staplers.
- Apart from gadgets that are used in wound closure there are other significant factors that contribute to over all complication rates that is 21% in this study (that is 6% for skin staplers and 15% for skin sutures).
- Outcome of staplers is cosmetically superior to skin sutures.

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PROFORMA

CASE-NO

NAME: AGE/SEX: IP NO:

WARD/UNIT: OCCUPATION:

CITY:

WEIGHT:

SITE OF WOUND:

TYPE OF WOUND:

WOUND LENGTH:

GADGET USED:

TYPE OF SUTURING:

TIME TAKEN FOR CLOSURE:

SUTURES /STAPLERS REMOVED ON: __________ POD

COMPLICATIONS:

OUTCOME OF SCAR:

REMARKS: