STAPLES VERSUS CONVENTIONAL SUTURES FOR ABDOMINAL SKIN WOUND CLOSURE - A RANDOMISED CONTROL TRIAL

By

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DISSERTATION

Submitted to the

K.L.E University, Belgaum, Karnataka

In partial fulfilment

of the requirements for the degree of

M.S

in

GENERAL SURGERY

DEPARTMENT OF GENERAL SURGERY,

JAWAHARLAL NEHRU MEDICAL COLLEGE,

BELGAUM, KARNATAKA.

MAY 2013

ENDORSEMENT BY THE H.O.D, PRINCIPAL/HEAD OF THE INSTITUTION

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ABBREVATIONS

EGF : Epidermal growth factor

FGF : Fibroblast growth factors

IL-1 : Interleukin 1

LTB4: LEUCOTRIENE B 4

PDGF : Platelet derived growth factor

PDS : Polydiaxonone

TGF-ß : Transforming Growth factor ß

ABSTRACT

TITLE : STAPLES VERSUS CONVENTIONAL SUTURES FOR ABDOMINAL SKIN WOUND CLOSURE-A RANDOMISED CONTROL TRIAL AT K.L.E.S PRABHAKAR KORE HOSPITAL AND RESEARCH CENTRE, BELGAUM, DURING DECEMBER 2010-NOVEMBER 2011

BACKGROUND AND INTRODUCTION

Wound closure is as important as any other action performed by the surgeon. And apart from the need for producing a healthy and strong scar, it is the surgeon's responsibility to ensure its aesthetically pleasing physical appearance. Skin staples are an alternative to regular sutures in offering this advantage. The present study has helped to highlight the benefits of skin stapler.

METHODOLOGY

The study was carried out at K.L.E.S DR PRABHAKAR KORE Hospital and research centre, Belgaum, where 100 participants who underwent abdominal skin closure with either staples or conventional vertical mattress suturing with Ethylon over a period of 1 year.

Out of the 100 participants, 50 underwent skin closure with Stainless steel skin staples and the remaining 50 with non-absorbable Ethylon mattress sutures. All these participants were allotted to either group according to random number table. All cases were elective surgeries and the mode of anaesthesia was either General Anasthesia, Spinal

anaesthesia or short GA. They all received one mandatory dose of pre operative parenteral antibiotic 1 hour prior to the incision.

On the 3rd postoperative day, the wound was evaluated for inflammation, infection and wound gape.

Participants were re-evaluated for infection / gape / inflammation during follow-up on 15 days / 1 month.

The wounds were evaluated at 1 months follow up which were rated for cosmesis on a previously validated cosmesis Visual Analogue Score.

Statistical evaluation was done after consulting statistician. Using the student's unpaired 'T' test and Mann-Whitney test the p value was calculated.

RESULTS

Infection was seen in 4% patients of the stapled group and 10%patients of the suture group. Wound gaping was seen in 2% patients of the stapled group and 6% of the ethylon sutured group.

VAS in stapled group was 71.88 (± 5.50) whereas in the Ethylon-sutured group it was 64.44(±6.17), which is statistically highly significant.

CONCLUSION

a. Preventing wound infection, especially inabdominal wounds, is of utmost importance as it may lead to wound gaping, occurence and recurrence of hernia.
b. Incidence of post-operative wound infection was less with skin staples.

c. Cosmesis is essential and important aspect in this day and age. A cosmetic scar not only gives satisfaction to the patient but also mental ease to the surgeon. Skin staplers also provided better cosmetic result when compared with vertical mattress suturing with Ethylon.

KEY WORDS - Skin Staples, Wound Healing, Wound Infection, Stainless Steel staples.

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INTRODUCTION

SURGERY is derived from the earlier name chirurgery, which means handwork. It is a science and art that shows the manner in which to work on man's body exercising all manual operations necessary to heal or as much as possible by using most expedient medicines or techniques.

The goal of surgery is to achieve healing by such means with minimal oedema, no serous discharge or infection, without separation of the wound edges and with minimal scar formation.

After any surgical procedure (assuming there are no tension and a good blood supply) careful approximation of the tissues will allow healing by primary intention.

Precise approximation of skin incisions and lacerations with wound closure devices is critical for a favourable cosmetic and functional surgical result. Principles of wound closure focus on relieving tension on the wound and bringing the skin edges together in an everted orientation If sutures are tied too tight or left in too long, they may leave permanent suture tracts If sutures are removed before adequate healing, the lack of wound tensile strength may result in wound dehiscence or a widened scar.

Wound closure includes ensuring a clean wound with satisfactory vascularity and haemostasis and apposition without wound tension. Principles of wound closure focus on relieving tension on the wound and bringing the skin edges together in an everted orientation

"***Surgery is the first and the highest division of the healing art, pure in itself, perpetual in its applicability, a working product of heaven and sure of fame on earth"*** ***SUSHRUTA (400 B.C)***

Surgical Site Infection (SSI) is the most common nosocomial infections reported in the hospital patients. Up to 2.5% of the patients undergoing clean extra abdominal operations and up to 20% of intra abdominal operations will develop SSI.

Surgical site infection remains a complication of surgical procedures resulting in increased morbidity, mortality and cost.

Infection remains the most significant factor affecting wound healing. A closure that penetrates the epidermis and dermis only serves to auto innoculate the wound of the patient, driving surface flora deep into the subcutaneous tissue.

Percutaneous suture closure provides an extra source of contamination via the suture canal and results in a thin perisutural cuff of dead epidermis, dermis and subcutaneous fat. Suture closure also is a potential source of foreign body reaction within the susceptible subcutaneous tissue.

The type of suture material for skin closure is also reported to influence postoperative wound complications. However, several other studies have failed to demonstrate significant differences between different types of suture material.

The surgical scar remains the only visible evidence of the surgeon's skill and not infrequently, all of his efforts are judged on its final appearance.

Skin staples give a neat scar with good wound eversion and minimal cross hatching effect. They can be placed faster than sutures and have a lower predisposition to infection because they do not penetrate entirely through the wound and do not produce a complete track from one wound to the other.

Hence this study was undertaken at **JAWAHARLAL NEHRU MEDICAL COLLEGE, BELGAUM, KARNATAKA.**

OBJECTIVES OF THE STUDY

1. To compare the incidence of post operative wound infection between skin staples and Conventional sutures in abdominal skin closures.
2. To compare the cosmetic outcome of stapled closure with conventional sutures.

REVIEW OF LITERATURE

History [1,2,3]

The act of sewing is as old as Homo sapiens. In Susruta samhitha 600 BC there is mention of suture material made from animal sinews, braided horsehair, leather strips, and vegetable fibers.

The earliest wound closure can be found in the Edwin Smith papyrus, the oldest surgical attempt at medical record know to man, written in Egypt around 3000 to 2500 BC. As early as 5000-3000 BC eyed needles were used, to pass suture material through surgical wounds.

North American Indians used cautery. East African tribes ligated blood vessels with tendons and closed wounds with strips of vegetation wound round the protruding ends in a figure of eight.

The mandibles from a certain 'soldier ant' were used to close these types of wounds. This technique is also found, in Asia, Africa and South America. The mandibles from the *Eciton burchell* are particularly large. Its Mandibles would close on the wound and the body would then be pinched off. Contemporary clips work according to the same principles but the 'ant-method' is still practiced by some South American tribes.

Egyptian literature of about 1600 BC mentions the use linen strip coated with an adhesive mixture of honey and flour thereby creating the original skin closures strips.

Aurelius Cornelius Celsus, a Roman and a medical journalist wrote a monumental book in medicine about 30 AD and it is known as De Re Medicina. Celsus mentions that sutures were of ancient origin should be soft and not over twisted, so that they may be easier on the part. Whether he was referring to wool or linen is uncertain. He also described small metal clips similar to Michael clips of today.

Galen of Pergamon A.D 150 in his work, De Medendo, comments for the first time on the use of catgut but makes it plain that it was, known to the ancients. Catgut made from the twisted intestines of herbivorous animals is still used today and indeed, accounts for nearly half the usage of all sutures and ligatures.

Avicenna, known as the prince of physicians, contributed to suture development by his realization that traditional materials like linen thread, when used in presence of gross infection tended to break down rapidly. In search of more suitable material, he turned to pig's bristles and so invented the first monofilament suture.

The prince of surgeons is undoubtedly Albucasis, born in 936 AD. He used sutures and was the first to describe a double suture, a technique still used today.

Ambrose Pare described a method of dry suturing for wounds of the face. This consisted of sticking strips of plaster down each side of the wound and then sewing the strips together. The object of this indirect stitch was obviously cosmetic.

John Hunter (1728-93) was of the opinion that sutures were basically undesirable but if needed they should be interrupted sutures. He preferred to use bandage or sticking plaster across the wound.

Following Hunters preference for adhesive strips to close or assist in the closing of a wound, Physick's experimented with adhesive strips made of leather. He noticed that these strips were dissolved after contact with fluids discharged from wounds and it occurred to him that ligatures which would dissolve in the body would be of considerable benefit.

He then experimented on a horse with a ligature of buckskin, which proved successful. He followed this by trying kid parchment, varnished leather, tendon and catgut, but found that catgut did not dissolve easily enough. His experiments were historic, for no one had previously considered the possibility of an absorbable suture, which would perform its function and then disappear.

By 1867, Lister had formulated and published his answer and now the long 'carbolic crusade' began. But Lister's scientific acumen was not limited to antisepsis. Two years later he published an article 'observations of ligature of arteries on the antiseptic system. He was aware of Physics work and had himself noticed that fragments of glass or needles inadvertently left in the wound did not give rise to suppuration. He conceived that harmful bacteria must lie within the interstices of silk and if they could be killed a ligature could be left in the body. Thus came the concept of antiseptic ligatures.

Lister had also contributed in the manufacture of surgical catgut. He observed that chromic acid was used to tan leather, which he incorporated into his formulation. By 1900 the catgut industry was firmly established in Germany due to the use of sheep intestine in their sausage industry. Many methods of sterilization were used but

the introduction of iodine sterilization by Claudius in 1902 established what was to become the standard method of preparation for nearly half a century.

With the advent of World War I, Britain was left in an embarrassing situation of having little or no catgut industry. Some farsighted Edinburgh surgeons realizing the problems requested the local pharmacist, George Merson to undertake the commercial manufactures of this material. Merson also began to sell eyeless needled sutures where one strand of suture material is attached to the butt of the needle. These patented products were called 'mersutures' and greatly reduced the tissue damage caused by pulling through a double strand of material. Of the many technical advances in suture manufactures was the introduction of sterilization by irradiation in 1960 using cobalt^{60} isotope. This allowed sutures to be packed and sealed and then sterilized, there by eliminating the dangers and difficulties of aseptic transfers. This revolutionary development was a breakthrough, which brought in its wake many improvements in packaging.

As mentioned earlier, Linen and Cotton were already in use. Silk was the next suture of choice in non-absorbable suture range. It became very popular because of excellent handling properties. It is extensively used in all surgical procedures. Halstead was its main proponent.

These natural non-absorbable sutures had certain disadvantages and with the technological advance, polyester and polyamide were introduced and replaced the previous non-absorbable sutures in many surgical procedures. Polyester was made available as braided, coated and non-coated. Recently polyester is made available as Monofilament in fine size. Later on monofilament polypropylene was made after

extensive research. It is a very strong suture material fulfilling many characteristics of ideal suture material. It is very extensively used today almost replacing the silk, cotton and linen.

Then came the era of Synthetic absorbable sutures. The development of these began in 1931 with the production of synthetic absorbable fibre of polyvinyl alcohol. In the second half of sixties it was discovered that polyglycolic acid can be processed into an absorbable suture material with very favourable properties. Subsequently, Glycolide and Lactide were combined in suitable proportions to develop a suture known as polygalactin 910. Later, this was coated to make smooth. Further research resulted in development of PDS, VICRYL and MONOCRYL.

Suture technology and suture sterilization has thus kept its pace of advancement along with the latest techniques in surgery and provided the surgical fraternity in a wide range of sutures in different sizes swaged to needles as fine as 30 microns.

A surgeon of today would not have been able to perform the various surgical procedures and achieve the excellent results without these sutures and needles.

Surgical stapling was developed in 1908 by Hulti Humer in Australia. The original instrument was massive by today's standards weighing 7.5 pounds. Modifications performed by Von Petz provided a lighter and simpler device, and in 1934 Fredrick of Ulm designed an instrument that resembled the modern linear stapler. The next major advances came from Russia after World War II. In 1958,

Ravich, who, through research and development, refined the instruments to their current state and wide spread use today.

John T Kanagaye, Cheryl W Vance, Linda Chan, and Nancy Schonfeld at the Children's hospital, Los Angles, USA, following a study, revealed that staple closure was safe, rapid and cost effective. Staples were six times faster than the standard sutures with no observed complication rate. Removal was less painful and the scar was cosmetically acceptable.[4]

Eldrup et al analyzed 137 patients undergoing abdominal or thoracic surgery, and concluded that the main advantage of using staples was the time saved, as closure with mechanical sutures took one third of the time required for the conventional method. On the other hand closure with staples resulted in the major disadvantages of additional expense, as the cost was forty seven times higher than that of the suture with Dermalon[5].

Meiring et al reported slightly better cosmetic results in a group of 40 patients undergoing laparotomy with an 80% in time saving. They also concluded that the final cost of the stapler was crucial for selecting the method.

Harvey and Logan studied a group of 20 patients undergoing surgery for varicose veins in both lower limbs, using a different method of skin closure in each leg. They reported a saving of 66.6% in closure time and a similar cosmetic result. They considered the use of staples a valid method for selecting patients with a large number of wounds; however the additional cost would not be justified for small sutures.

Zwart and Ruiter achieved better cosmetic results with the sub cuticular suture than with metal suture 1 month after surgery; however, after 6 months, the results of both the methods were similar. They argued that it is advantageous to use sutures with staples in contaminated surgery.

Ranabaldo and Rowe-Jones compared sutures with staples and sub cuticular suture in 48 patients undergoing laparotomy and concluded that the difference in time was significant. Nevertheless, the cost was five times greater with staples; hence, the use of subcuticular sutures was preferred[6].

Luiz R Medina dos Santos et al in their study of 20 consecutive patients concluded that the use of skin staplers speeds up closure by 80%, with a better cosmetic results, ands does not increase the incidence of complications, although the slightly higher cost was involved[7].

TECHNIQUES OF WOUND CLOSURE

Surgeons must be very careful

When they take the knife!

Underneath their fine incisions stirs the culprit – LIFE

Emily Dickinson.

The poignant poetry of Emily Dickinson eloquently emphasizes the primacy of the surgical operative event. The surgeon must exhibit a capability for compassionate interest and concern in all that illness implies to the patients and the patient's family, he or she must also devise an objective pattern for decision making in the most impersonal aspect of the operative procedure. The discipline is properly named: surgery is derived from its earlier name chirurgery which means "hand work" Halstedian teaching emphazied gentle handling of the tissues careful haemostasis to enhance healing to prevent infection. These principles remain valid today[8,9,10].

BASIC PRINCIPLES :

Wound healing is a complex and dynamic process and is influenced by surgical technique. Optimal wound healing, with a minimal scar that compromises neither appearance nor function, is the desired result. This process is affected by both local and systemic factors. Many local conditions are readily controlled at the time of wound closure, and several fundamental principles of surgical wound closure exist that should be adhered to in the management.

An incision is properly planned as to shape, direction, and size. In general incisions are made along the normal skin lines. Skin margins should be handled gently to minimize necrosis that may promote infection or delay wound healing.

In closing wounds, sutures are either used in an interrupted or continuous fashion. The purpose of a suture is to hold tissues in apposition until the wound has healed sufficient enough as to be self-supportive.

The following important points must be remembered.

1) Adequate incision should be taken.
2) Tissues should be handled gently.
3) Heavy retraction of tissues should be avoided.
4) No mass ligature should be applied as it will cause necrosis of large amount of tissue.
5) Excessive use of cautery should be avoided.
6) Appropriate needle and suture should be used for a given procedure.
7) Use of eyeless needle sutures will avoid tissue trauma.
8) Dead space should be obliterated and meticulous haemostasis should be obtained.
9) Wound should be drained only if indicated.
10) Sutures should be removed when union is sound.

In wound closure, the surgical technique is quite important 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 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.

Various types of skin stitches in common uses are : -

- Continuous over hand sutures
- Continuous blanket
- Ordinary interrupted sutures
- Eversion suture
- Subcuticular suture
- Automatic skin staplers
- Superficial sutures either they may be continuous or interrupted.

Simple suture is the most widely accepted technique. The point of needle is driven into one skin edge a little distance from the margin and perpendicular to the surface using the curve of the needle. The point is taken across the wound at depth and then directed through the subcutaneous tissue of the other edge aiming a little beyond the intended spot of penetration. The point is then drawn back to its intended position and then taken out through the other skin surface, again perpendicularly,reef or squire knot is then tied adjusting the tension on the first throw. In this way skin edges are little everted so counteracting any tendency to invert[23].

In certain situations the tendency to invert is so marked that positive steps must be taken to evert the skin edges. Interrupted mattress sutures do this.

In vertical mattress suture the first step is same as the simple suture but then the needle is passed back taking tiny bites of both the skin edges in the same vertical plane and tied.

In the horizontal mattress suture after placing what is essentially simple suture another one is placed in the opposite direction. A few mm along and the ends are tied again. These sutures should not be used on the face.

Continuous subcuticular suture is an excellent technique, when it has been mastered. Either monofilament or absorbable suture material may be used. Starting at one end of the wound, thread is first fixed by placing a simple suture or by tying over a beady working inside the wound, small equal bites of tissue are taken alternating at each skin edge just below the surface. When the end of the wound is reached, a suture is taken back to the surface through a single puncture. The tension is carefully adjusted along the length of the wound and then tied, again with a single suture or a bead. They lower the skin tension on the skin margins and allow earlier removal to avoid hatch markings. These should not be placed in the superficial dermis. Carefully placed subcuticular sutures give an excellent scar[20].

In many situation absorbable subcuticular sutures may be used to approximate the dermal layer so that skin stitches do not require inserting or removing. Their insertion requires a careful technique to avoid an irregular scar and it is essential that the knot is placed well away from wound edge[22].

Continuous over and over suture is quick to insert but some times does not give a very satisfactory cosmetic result and should certainly to be avoided on the face. Continuous suture saves much time in the closure of a long wound. However should infection or hematoma formation occurs it is necessary to remove a part of the suture for drainage. Sharp needles and fine suture materials should be used for all wound repairs, the suture being evenly placed and tied without strangulating the tissues.

Interrupted sutures should be removed early, 4 to 5 days on the face and 7 days elsewhere, but longer in the lower limb and vertical abdominal wounds.

Non absorbable material with a smooth surface should be employed for skin use.

Silk allows accurate tension to be applied to each knot where as nylon requires additional hitches for security.

All knots are placed to lie at one side of the wound so that they do not become buried in the scar.

SUTURE MATERIALS

Sutures may be described by several characteristics:

- The diameter of a suture is stated numerically with the number of zeros in the suture size increasing as the diameter of the material decreases.

  E.g.8-0 silk suture is thinner than 5-0 silk suture

- The number of strands present
- Ability of the tissues to absorb suture

CLASSIFICATION[14]

Sutures are conveniently classified into two broad groups

1) Absorbable
2) Non absorbable

Absorbable can further be classified into

1) Natural and synthetic
2) Non-absorbable can also be classified into natural, metallic and synthetic.

Table 1: Classification Of Suture Materials

SUTURE MATERIALS	**ABSORBABLE**	**NON-ABSORBABLE**
MONOFILAMENT	1.Surgical gut Plain and Chromic 2.Collagen Plain and Chromic 3.Monocryl 4.PDS II 5.Polyglactin 910	1.Polyamide 2. Polypropylene 3. Stainless steel 4.Polyester
MULTIFILAMENT	Polygycolic Acid Polygalactin 910	Surgical silk Surgical linen Cotton Polyamide braided Polyester braided Stainless steel
Others		Surgical Stapling

ADVANTAGES AND DISADVANTAGES

Multifilament sutures consist of multiple strands braided together, to increase the flexibility, tensile strength, and knot holding capability. Multifilament sutures are generally easier to handle and to tie than monofilament sutures. However, they can harbour bacteria and are not suitable in the presence of infection and contamination[12].

Monofilament sutures are more smooth and strong. They do not allow any bacteria to survive. The drawback of monofilament is they do not handle as good as multifilament sutures.

For skin closure, the non-absorbable suture materials used fall into two broad categories;

- Braided materials – such as silk and nylon
- Monofilament – such as nylon, polypropamide

Monofilament consists of single strand on synthetic material. This reduces the resistance of passing the suture tissues and decreases the bacterial adherence because of smooth surface contour. But any crushing or kinking of the suture may result in a weak spot in the strand and can lead to surface breakage. Knot slippage is greater with monofilament suture.

Braided materials are easier to handle. And the knot and the tension of the stitch can be adjusted very accurately. They suffer from producing the degree of drag through the tissues. And by their capillary action may cause tissue reaction at the stitch, which may lead to stitch abscess[13].

A 3-0 gauge suture material on a straight cutting needle will be found suitable for most minor surgical procedure.

The quantity of suture used must be adequate to secure the tissue, but excess material increases tissue reaction (foreign body) and inflammation of healthy tissues. Therefore the surgeon must base the suture material on the tissue being repaired, the size and the design of the suture and its ability to retain tensile strength.

Absorbable suture is prepared from either from animal tissue or synthetic polymers. Those from natural sources elicit a foreign body response from tissues with resultant digestion from tissue enzymes, where as synthetic absorbable polymers are hydrolyzed to smaller monomers which are metabolized by tissues.

Non-absorbable sutures are permanent and resist digestion by body enzymes or hydrolysis by tissue.

Strength of Suture

Strength of suture material is expressed using the terms Stress and Strain.

Strength represents instantaneous force applied to the sutures (N/Msq).

Strain is a measure of instantaneous length / starting length (Units).

Strength is peak stress at the point of suture rupture whereas the toughness is the energy required to rupture the suture (J/mtq).

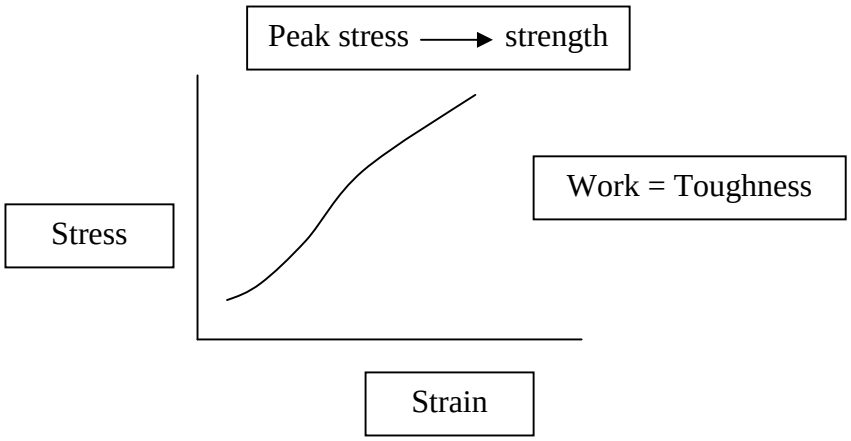


Figure 1: Showing Suture Strength Vs Stress

STRENGTHS AND TOUGHNESS OF COMMONLY USED SUTURE[12]

MATERIALS	Strength (10 10 n/m2)	Toughness (10 7 J/m2)
Polyester	2.32	6.20
Silk	0.85	2.35
Polyglyconate	0.83	2.36
PDS	0.97	2.38
Nylon	2.54	5.55
Prolene	2.99	4.87

(Measurement made with 60 suture materials after six week of incubation in a rat model).

Absorbable sutures

Absorbable sutures are made of materials which are broken down in tissue after a given period of time, which depending on the material can be from ten days to eight weeks. They are used therefore in many of the internal tissues of the body. In most cases, three weeks is sufficient for the wound to close firmly. The suture is not needed any more, and the fact that it disappears is an advantage, as there is no foreign material left inside the body and no need for the patient to have the sutures removed.

Absorbable sutures were originally made of the intestines of sheep, the so called catgut. The manufacturing process was similar to that of natural musical strings for violins and guitar, and also of natural strings for tennis racquets. Today, gut sutures are made of specially prepared beef and sheep intestine, and may be untreated (plain gut), tanned with chromium salts to increase their persistence in the body (chromic gut), or heat-treated to give more rapid absorption (fast gut). However, the majority of absorbable sutures are now made of synthetic polymer fibres, which may be braided or monofilament; these offer numerous advantages over gut sutures, notably ease of handling, low cost, low tissue reaction, consistent performance and guaranteed non-toxicity. In Europe and Japan, gut sutures have been banned due to concerns over bovine spongiform encephalopathy (mad-cow disease), although the herds from which gut is harvested are certified BSE-free. Each major suture manufacturer has its own proprietary formulations for its brands of synthetic absorbable sutures; various blends of polyglycolic acid, polylactic acid or caprolactone are common.

Following are the list of Absorbable Sutures:

Natural Absorbable Sutures

1. Catgut Sutures- Plain catgut and Chromic catgut sutures

Synthetic Absorbable Sutures

2. Polyglycolic Acid Sutures (PGA sutures)- coated and braided suture
3. Polyglactin 910 Sutures (PGLA sutures)- coated and braided suture
4. Poliglecaprone Sutures (PGCL sutures)- monofilament suture
5. Polydioxanone Sutures (PDS Sutures)- monofilament suture

NON ABSORBABLE SUTURES

SILK [26]:

Silk is derived from the cocoon of the silkworm larvae. It is basically a protein like keratin of hair and skin and is covered initially by an albuminous layer. This albuminous layer is removed by a process of degumming prior to making of sutures. The suture is braided around a core and coated with a wax to reduce capillary action.

The material has high tensile strengths, which is probably totally lost after two years. Tissue reaction is greater to silk than to synthetic non-absorbable sutures, due to the fact that silk is a foreign protein. The cellular reaction is usually polymorphonuclear and is of less intensity than surgical gut. Encapsulation of the silk with a fibrous capsule usually occurs in 14-21 days. Handling properties are probably best of all suture materials and it knots easily and securely. It is sterilized by gamma irradiation.

Surgical silk is available as Eyeless needled sutures in sizes 7-0 to 1. it is also available as suture pack pre cut sutures in sizes 6-0 to 3 and 0 reels as non sterile sutures in sizes 6-0 to 4.

Virgin silk is available for ophthalmic surgery in sizes 9-0 and 8-0 and on special micro point needles

NYLON :

Nylon is available in both monofilament and Multifilament form. Although nylon is not absorbed, progressive hydrolysis of the nylon in vivo may result in gradual loss of tensile strength over time. So nylon suture should not be used in suturisation when permanent retention of tensile is required[30].

PROLENE (POLYPROPYLENE) [29,30]

Is a monofilament synthetic suture material and is chemically extruded from a purified and dyed polymer, which is neither absorbed nor weakened by the action of tissue enzymes. It has an extremely high tensile strength, which it retains indefinitely on implantation. This lack of adherence to tissues facilitates its use as a permanent suture. It can extend up to 30% before breaking and hence is useful in situations to accommodate the post operative swelling, and there by helps to prevent tissue strangulation. Handling is good and knotting is very secure since the material deforms on knotting and allows knot to bend down on itself. It has no coefficient of friction and slides through tissue readily. By tapering the end of the suture it may be swaged in to a needle of similar diameter which provides a haemostatic advantage in vascular anastomosis

It is extremely smooth and it is less thrombogenic as compared to silk. It is inert and non-biodegradable. Being monofilament, it should be carefully handled during surgery, as rough handling and inadvertent crushing will damage it. Rough handling may cause a fracture on the strand, which may break later in the postoperative period. It is sterilized by ethylene oxide.

COTTON :

Cotton is derived from the hair of the seed of the cotton plant. It is twisted to form a suture. Tissue reaction is like silk and linen tends to be a polymorphonuclear cellular type. Handling is good but not so good as silk. It is weaker as compared to linen.

LINEN :

Linen is made from flax and cellulose material. It is twisted to form a fiber to make a suture. Tissue reaction is similar to silk and the material handles and knots well. It gains 10% in tensile strength when wet and is fairly unique in this respect. It is very extensively used for tying pedicles and as ligatures. It has excellent knotting properties.

STAINLESS STEEL :

Stainless steel has an enviable reputation among non-absorbable sutures for strength and low tissue reaction (Inertness). The steel techniques are very exacting and the penalties for poor techniques costly. Steel can pull or tear out of tissues and necrosis can result from too tight a suture. Barbs at the end of steel can tear gloves,

breaking sterile techniques or traumatizing surrounding tissues. Kinks in the wire can render it practically useless[31].

STAPLERS[11]

Humer Hulti in Australia developed surgical stapling in 1908. the original instrument was massive by today's standards, weighing 7.5 pounds. Modifications performed by Von Petz provided a simpler and lighter stapling device and in 1934 Fredrick of Uln designed an instrument that resembled the present modern linear stapler.

The most major advances came from Russia after world war II in 1939. The instrument was brought to the US by Ravitch, whose research and development refined the instrument to the current state and the wide spread use today. The most significant modification has been the introduction of absorbable staples. When these are used in gynecological operations morbidity related to infectious granulomas and dyspareunia has been diminished[26].

Automatic skin staples were first introduced in 1972 and were based on earlier Russian tissue stapling devices. They are reported to be easy to use and to save considerable operating time. Studies have shown that staples are associated with lower wound infection rates, and are more resistant than conventional sutures to infection from a Staphylococcus aureus inoculum. Furthermore, the use of stapling devices abolishes the risk of needle stick injury.

Staples are formed from high-quality stainless steel and are available in regular and wide sizes. Staples are composed of the following: a cross-member that lays on the surface of the skin perpendicular to the wound, legs that are vertically placed in the skin, and 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.

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, the greater risk of crosshatch marking, and less precise wound approximation. The cost usually is more than that of suture material.

Clinical studies have found that for the scalp, neck, trunk, and extremities, staples produce a cosmetic result that is identical to that from sutures. Staple removal requires a special instrument that deforms the top and spreads open the points.

A variety of stapling devices is available for wound closure. With all devices, the staple creates an incomplete rectangle: the legs of the staple extend into the skin, and the cross-limb lies on the skin surface across the wound. Each device may differ

in its handling characteristics, visual access, and the angle at which the staples enter tissues, the ease of position and the pre-cocking mechanism. Optimal visibility as the staple is placed in the skin is important, as is the angle at which the staple enters the skin because insertion of the staple perpendicular to the surface of the skin results in deep penetration that increases the likelihood of tissue strangulation and permanent cross-hatching of the wound. The ability of the staple end to swivel allows the head to be adjusted for use in deep recesses. Finally, the presence of a pre-cocking mechanism allows the practitioner to maintain constant control while stapling the skin.

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.

For staple placement, the stapler is gently held on the surface of the skin, perpendicular to the wound, and the handle is squeezed, plunging the staple into the skin to form an incomplete rectangle. The depth of penetration is based on the pressure exerted on the stapler against the skin.

To disengage the staple, the handle is released. If the stapler has an ejector-spring release, it is lifted vertically off the skin. If not, the stapler must be moved anteriorly or posteriorly.

The placement of staples is critical to avoid complications such as tissue strangulation and crosshatch marking. Staples should be inserted at 45° or 60° angles. As a wound swells, a staple placed at an acute angle rotates into a vertical position, leaving a space between the cross-member and the skin surface to accommodate swelling. If placed at a 90° angle, the staple cannot move and is likely to strangulate the tissue during swelling.

INDICATIONS

The Skin Stapler has application for routine skin closure in a wide variety of surgical procedures.

CONTRAINDICATIONS

• When it is not possible to maintain at least a 5 mm distance from the stapled skin to underlying bones, vessels, or internal organs, the use of staples for skin closure is contraindicated.

• Wounds that are to be closed with tension

• Known allergy to nickel or chromium

INSTRUCTIONS FOR USE

Verify compatibility of all instruments and accessories prior to using the instrument

Evert and approximate skin edges as desired. Several techniques are suggested:

a) With one tissue forcep, pull skin edges together until edges evert OR

b) With two tissue forceps, pick up each wound edge individually and approximate the edges. OR

c) Apply tension to either end of the incision, such that the tissue edges begin to approximate themselves. One forcep can be used to ensure that the edges are everted. Position the instrument over the everted skin edges, aligning the instrument arrow with the incision. Squeeze the trigger until the trigger motion is halted. Release the trigger and remove the instrument from the fired staple.

FORMED STAPLE DIMENSIONS

Regular staples have an approximate diameter of 0.53 mm, span of 5.7 mm, and leg length of 3.9 mm. Wide staples have an approximate diameter of 0.58 mm, span of 6.9 mm, and leg length of 3.9 mm.

ADVANTAGES

1. Time
2. Cosmesis
3. Prevention of need stick injury

DISADVANTAGES

1. Cost
2. Pain
3. Requires an second operator for wound eversion[70].

AFTERCARE AND REMOVAL

Skin staples should be removed at the same time that sutures would be removed, based on wound location and tension. For scalp wounds, staples should be removed on day 7 after insertion. For trunk and extremity wounds, staples should be removed between days 7 and 14. Wounds closed with staples may be covered with a

topical antibiotic cream or ointment. Patients may bathe or shower the next day, but should avoid prolonged exposure to moisture. When used on the scalp, patients should be very careful about combing or brushing their hair.

BIOLOGICAL RESPONSE OF TISSUES TO SUTURE MATERIALS

A cellular response occurs whenever a foreign material is implanted in living tissues[18]. This response is generally is very mild with most surgical sutures, or more marked if complicated by infection or trauma. If uncomplicated, the acute response usually changes in about 3 days and the original population if replaced by predominantly monocytes, plasma cells and lymphocytes. Small sprouts of fragile blood vessels infiltrate the area and eventually fibroblasts and connective tissue proliferates. This cellular response can be graded or evaluated according to its degree or area size on morphological grounds by observing the type and population of the responding cells in microscopic preparations. In addition to such morphological observations, studies of the enzymes activity at suture sites have been undertaken. Enzyme Histochemistry has demonstrated that all the cellular changes are accompanied by the presence of a variety of enzyme patterns. These studies have been valuable in indicating in-vivo mechanisms involved in the absorption of both surgical catgut and newer synthetic absorbable and also indicate the degree of tissue reaction and also loss of tensile strength of non-absorbable sutures.

The study of biological response to sutures helps in suture selection for a given surgical procedure and assist in the future development of improved suture materials.

The methods of study are :

1. **Implantation in laboratory animals[6] :**

   Rats' gluteal muscle or lumbar muscle.

   Rabbits' sub cutaneous tissue.

   These tissues are chosen because of consistent cellular response.

   Although a precise comparison can not be made, the reaction in humans is generally similar to but less intense than that seen in the experimental animals transfer of findings in animal studies would therefore appear to be acceptable with only moderate limitations. Results in animals in all probability represent a faster rate of healing than occurs in human since the animal experiments are controlled and carried out in most ideal circumstances and do not have the varying adverse influence of long standing pathology, debility, infection, pyrexia and pulmonary complication as occurs in human post operative cases.

2. **Histological evaluation of suture implant sites :**

   This is carried out with absorbable and non-absorbable sutures.

   Tissue reaction to plain gut is more to chromic than to natural absorbable sutures.

   It has been observed that the tissue reaction to polypropylene is minimal followed by polyamide and polyester while tissue response to silk, linen, and cotton is more pronounced.

3. Suture tensile strength retention in tissues[14,22] :

Adequate suture tensile strength is required in surgery; however a suture usually needs to be no stronger than the tissues, which are sutured. Animal model systems have been developed for evaluating tensile strength retention in-vivo for both non-absorbable and absorbable suture materials.

Suture strands were implanted sub continuously in rats and rabbits. Animals were sacrificed at various time periods: 0, 56, 90, 180, 390 days for non absorbable sutures; 0, 7, 14, 18 and 21 days for absorbable sutures. The breaking strength of the recovered suture strands was measured with a strong testing machine.

4. Suture strength and suture absorption :

It is important to realize that the rate of tensile strength loss and the rate of suture absorption are separate event. For e.g. a suture sample can lose tensile strength rapidly in tissues and yet absorb slowly, or it may vary adequate tensile strength during the vital period of wound healing and then absorb rapidly. This later relationship would make the most effective absorbable sutures[5].

5. Enzyme histochemical studies[19] :

These help to study the mechanisms of suture absorption in tissues. It has been found that cellular protease usually supplied by macrophages are required for surgical gut absorption. With the synthetic absorbable sutures, cellular enzyme activity was not played a key role in the metabolism of suture breakdown products.

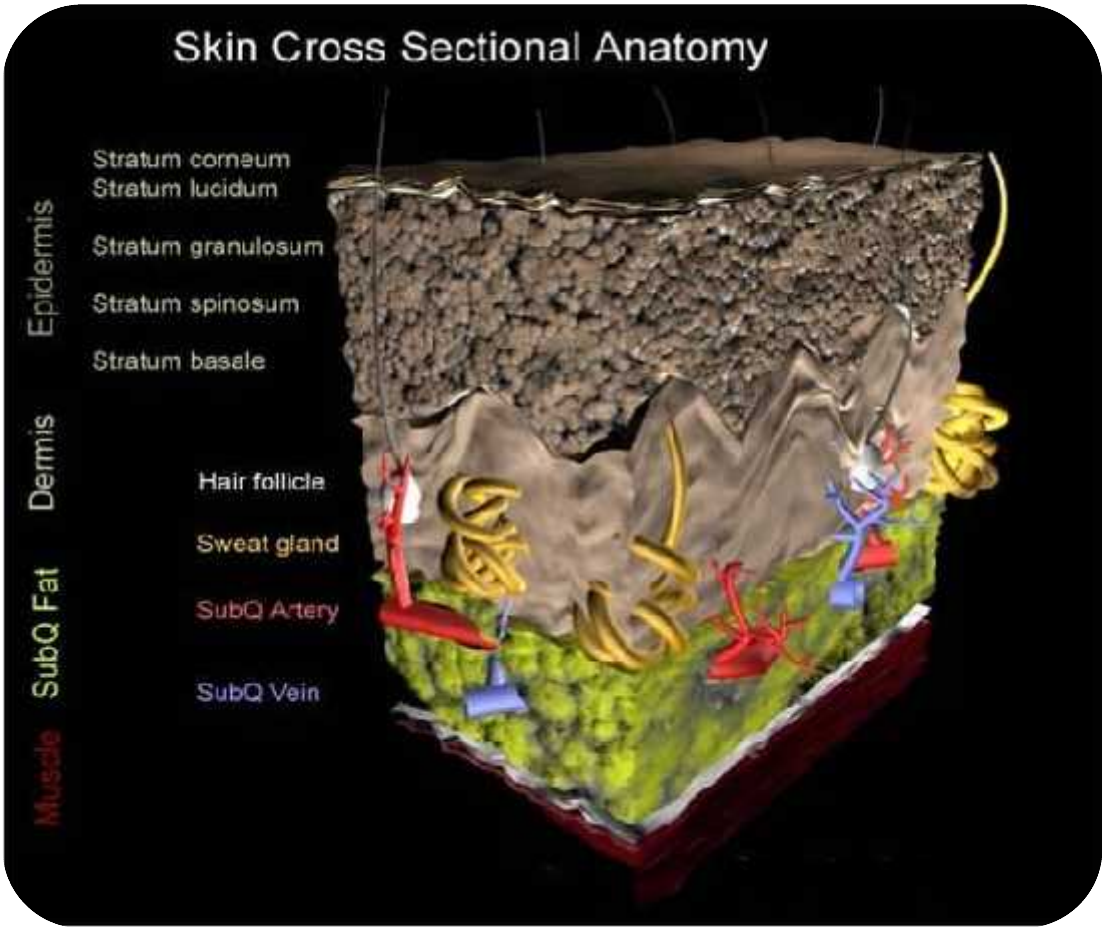
6. Rabbit ear chamber studies :

Implantation of absorbable sutures in the rabbit ear chamber can supply valuable data of the in-vivo absorption characteristics. Direct and continuous microscopic observations of suture behavior in the tissues are not readily obtained by other methods. This technique is particularly useful for the examination of the new absorbable materials implanted in tissues.

TISSUE REACTION FOR STAPLERS

Staplers are made up of stainless steel. They are virtually inert. They have uniform shape and constant staple depth providing even wound tension. Rectangular staple design minimizes tissue trauma and minimizes tissue compression, there by causing minimal tissue reaction and trauma.

ANATOMY OF SKIN[28]



Skin consists of two components; epidermis and dermis. The surface epithelium of the skin is the epidermis and is of the keratinized stratified squamous variety. Various skin appendages – sweat glands, sebaceous glands, hair, and nails are specialized derivatives of this epidermis, which is ectoderm in origin.

The deeper dermis is mesoderm in origin and consists mainly of bundles of collagen fibres together with some elastic tissue, blood vessels, lymphatic and nerve fibres. While partly due to its thickness and blood flow, the main factor determining the colour of the skin is the degree of pigmentation produced by melanocytes, which are mainly found in the basal layer of the epidermis. The differences in the skin colour between the light and the dark skinned races are not due to differences in melanocyte numbers, for these are similar in number in all; in the darker skin the melanocytes are more active and thus produce more pigments, but there are also racial differences between melanin which vary in colour from yellow to brown and black.

Sweat glands are distributed all over the skin except on the tympanic membranes, lip margins, nipples, surface of prepuce, glans penis and labia minora. The greatest concentration is in the thick skin of the palms and soles and on the face. Sweat glands are coiled tubular structures that extend in to the dermis and sub cutaneous tissue. Cholinergic fibres of sympathetic nerves supply them. Apocrine glands are large modified sweat glands confined to the axilla, areola, periumbilical, genital and perianal regions. Ducts of these glands open into hair follicles or directly on to the skin surface. Their odorless secretion acquires a smell through a bacterial action. They enlarge at puberty and under go cyclic changes in relation to the menstrual cycle in females. They are supplied by adrenergic fibres of sympathetic nerves.

Sebacious glands are small saccular structures in the dermis, where they open in to the side of the hair follicles. They also open directly on to the surface of the hairless skin of the lips, nipples, areola, inner surface of prepuce, glans and labia minora. Not present on the palms and the soles. They are particularly large on the face. Androgens act locally on these glands which have no motor innervation.

The arteries of the skin are derived from a tangential plexus at the boundary between the dermis and sub cutaneous tissue. Branches from this plexus form a sub papillary network in the dermis. Arterio-venous anastomoses are abundant in the skin. The veins have a similar arrangement to the arteries. From a meshwork of lymphatic capillaries in the papillary layer of the dermis, lymphatic pass to a network between the dermis and hypodermis.

Cutaneous nerves carry afferent somatic fibres mediating general sensation, and efferent autonomous fibres, supplying smooth muscle fibres of blood vessels errector pili muscles and sweat glands.

Tension lines of the skin are formed, due to the pattern of arrangement of collagen fibres in the dermis. Skin creases, such as the flexure lines over joints and wrinkles of aging, run parallel with tension lines. Incisions made along skin tension lines heal with minimum of scarring.

WOUND HEALING

"*A wise physician skilled our wounds to heal is more than armies for the common weal*".

HOMER.

"*No where I the gap between basic research and clinical application more glaring than in biology of wound healing*".

EARL A PEACOCK.

Wound and their management is fundamental to the practice of surgery. The word healing means replacement of destroyed tissue by living tissue. The tissue injury or frank necrosis causes human to repair by forming the scar tissue. Knowledge of wound healing allows the physician to manipulate the wound to achieve an optimal result in a rapid period of time. All repairs occur through an over lapping series of orchestrated event to limit the damage and restore the function and integrity of the structures[19].

The amount of damage, time to healing and residuum of scar are all affected by intrinsic and extrinsic factors. The amount of tissue lost or damaged, the amount of foreign material or bacterial inoculation and the length of time of exposure to the toxic factors will affect the period of time to recovery. The greater the insult, longer the reparative process and the greater amount of residual scar.

Intrinsic factors such as atherosclerosis, cardiac or renal failure, chemotherapeutic agents and location on the body, will affect the wound healing.

Blood supply in the lower extremity is worst in the body; blood supply in the face and hands is the best. Older the patient the slower the healing[20].

Wound can be classified into acute and chronic

Acute wounds proceed in an orderly manner and timely repair proceeds to achieve sustained restoration of structure and function.

Chronic wounds, for some reason does not proceed to a restoration of functional integrity. It is stalled in the inflammatory phase and does not proceed to closure. [19]

TYPE OF WOUND CLOSURE

a) Primary
b) Secondary
c) And tertiary repair

Primary Intention

Most heal by primary intention, where the wound edges are brought together (apposed) and then held in place by mechanical means shortly after injury(adhesive strips, staples or sutures), allowing the wound time to heal and develop enough strength to withstand stress without support. It is also the way most surgical wounds heal. Typically such wounds are created in aseptic conditions with minimal bacterial contamination and a minor amount of tissue damage. They have accurately apposed and sutured wound edges. Epithelialization and contraction have little role in this type of healing.

Secondary intention

Healing by secondary intention happens when the wound is left open because of the presence of infection, excessive trauma or skin loss, and the wound edges come together naturally by means of granulation and contraction. There are 3 main reasons why wound will undergo this form of healing wound infection, substantial tissue damage or lack of skin edge apposition. This form of repair is also encountered following ulceration, abscess formation, major superficial wounds or tissue infarction. Healing by secondary intention allows the natural processes to occur without surgical closure. Wound contraction is the most important factor that aids secondary healing.

Tertiary Intention or Delayed primary closure

Often performed in contaminated wounds, does not retard wound strength. Thus delayed closure may decrease wound morbidity without impairing wound strength.

MECHANISM INVOLVED IN WOUND HEALING

Distinct biological mechanisms are involved in all wounds healing process, however there are significant differences in the contribution of each mechanism, depending on the type of wound.

1. **EPITHELIALISATION** : - Is the process where by keratinocytes migrate and then divide to re surface partial thickness loss of skin or mucosa. Eg; abrasions, blisters, partial thickness skin grafts donor sites and first and second degree burns.

2. **CONTRACTION :** - Is the mechanism where by there is spontaneous closure of full thickness skin wounds or constriction of tubular organs such as common bile duct or esophagus after injury.
3. **CONNECTIVE TISSUE MATRIX DEPOSITION :** - It is the process where by fibroblasts is recruited to the site of injury and produce a new connective tissue matrix. This process is of major importance in primary wound closure, be it skin, tendon or intestinal anastomosis. The cross linked collagen and its organization in the connective tissue formed in the process provide the strength and integrity of all tissues.

PHASES OF WOUND HEALING[16]

Inflammatory phase also called as reactive phase. The body's defenses are aimed at limiting the amount of damage and preventing further injury.

Proliferative phase also called as regenerative phase is the reparative process with reepithelialisation, matrix synthesis, and neo vascularisation to relieve the ischaemia of trauma itself.

Maturational phase or modeling phase. It is the period of scar contracture with collagen cross linking, shrinking and disappearance of edema.

In a long wound such as pressure sore, the eschar or fibrinosis reflects the inflammatory process, the granulation tissue is a part of prolifirative phase, the contracting or advancing edge is part of the maturation phase. All these may occur simultaneously, and the phases with their individual process may overlap.

Inflammatory phase : During immediate reaction of tissues to the injury, hemostasis and inflammation occur. These are attempt to limit the damage by stopping the bleeding sealing the surface of the wound and removing any necrotic tissue, foreign debris or bacteria present.

HEALING RESPONSES

Hemostasis	1. Stop bleeding	Inflammatory phase
Inflamation	2. Chemotaxis	(Reactive)
Connective tissue	3. Epitherial migration	
Ingeneration	4. Proliferation	Proliferation phase (Regenerative)
	5. Maturation	
Contracture	6. Contraction	Maturational phase
	7. Scarring	(Remodeling)
	8. Remodeling of scar	

Hemostasis;

Disruption of endothelium and exposure of type IV & V collagen leads to platelet aggregation. These platelets release biologically active proteins like (i) From alpha granule platelet derived growth factor (PDGF), transforming growth factor (TGF) –β, insulin like growth factor (IGF)– 1, fibronectin, fibrinogen, thombospondin and von willebrand factor (ii) From dense bodies – serotonin (iii) From Lysosomes – hydrolase & protease. The clotting cascade is initiated through both the intrinsic and the extrinsic pathways. The fibrin strands trap red cells, from a clot, and seal the wound[17].

Leukocytes :

Leukocytes are chemoattracted and activated, adhering to the endothelium in the area of injury. C5a and leukotriene B4 promote neutrophil adherence and chemoattraction. Monocytes & endothelial cells produce interleukin (IL)-1 tumor necrosis factor (TNF) – a these chemotactic factors bring about 'diapedesis', facilitated by capillary permeability caused by serotonin, histamine and bradykinin. Neutophils with the help of lgG and complement system phagocytose the bacteria. The activated Neutophils can scanvenge necrotic debris, foreign material & bacteria. Although this activity (forming hydroxyl radicals, O-H) is helpful for debriding the wound and allowing the scaffolding of the reparative process to be laid down, it is also further destructive to surrounding viable tissue. Thus, early intervention to debride a wound and remove bacteria will limit the amount of inflammation (especially "oxidative burst") and subsequent scarring.

Lymphocytes :

The macrophage processes the foreign debris including bacteria or enzymatically degraded host proteins and presents these to lymphocytes. This will stimulate lymphocyte proliferation and cytokines release. T-cells produce IFN-γ, which targets the monocytes, or macrophage, stimulates them to release TNF alpha & IL-1, INF- γ also inhibits monocyte migration, which probably keeps these cells at the site of injury. IFN - γ can cause glycosaminoglycan (CAG) synthesis and suppress collagen synthesis. Thus, this may be an important mediator of the chronically open, nonprogressing wound[26].

Macrophages :

The macrophage is the one cell that is truly central to wound healing, serving to orchestrate the release of cytokines and stimulate many of the subsequent processes of wound healing. Monocytes are chemoattracted later than leukocytes and at the same time as lymphocytes. Monocytes convert to macrophages in the wound. Some wound macrophages, however are tissue macrophages that proliferate locally. Bacterial debris, C5a and TGF-β are chemotactic for monocytes and activate it to release cytokines like IL-1. The activated macrophages release free radicals as well. Macrophages also includes Phospholophase thus degrading cell membrane phospholipids releasing thromboxane A2, prostaglandin F2α, LT B4 & LTC4. LTB4 is a potent chemotactic for Neutrophil. Macrophages secrete collagenase when activated by bacterial degradation by products through cyclic AMP pathway. TNF alpha and IL-1 induces fever, increases collagenase production, cartilage and bone resorption. Macrophages release several different colony- stimulating factors to induce proliferation and differentiation of stem cells from the bone marrow. Activated manocytes release TGF α and β. TGF- α stimulates epidermal growth and angiogenesis. TGF β is the most potent stimulant of fibroplasia and chemotactic for monocytes. As the concentration of TGF β rises in the inflammatory site, the fibroblasts are directly stimulated to produce collagen and fibronectin, thus leading into the proliferative phase.

PROLIFERATIVE PHASE

As the acute responses of hemostasis and inflammation begin to resolve, scaffolding is made for repair of the wound. Central to this phase are the repair processes of angiogenesis, fibroplasia, and epithelialization. This stage characterized by the formation of granulation tissue, consisting of a capillary bed, fibroblasts, macrophages, a loose arrangement of collagen, fibronectin, hyaluronic acid and bacteria[23].

Angiogenesis : Epithelial cells migrate through degraded basement membrane of postcapillary venules. Activated endothelial cells also degrade the basement membrane. Migrating endothelial cells divide and form tubule or lumen. Eventually basement membrane is deposited forming new capillary. Both acidic and basic fibroblast growth factors (FGF) stimulate angiogenesis. Heparin not only stimulates the migration of capillary endothelial cells but also adheres many growth factors like basic FGF, endothelial cell growth factor, cartilage derived growth factor etc, to basement membrane. TNF α is chemotactic for endothelial cells and stimulates endothelial cell proliferation to form capillary tube. TGF β is a chemoattaractant for fibroblasts and assists angiogenesis by signaling the fibroblasts to produce the FGFs. Several of the matrix materials from the wound site are angiogenic like fibronectin and hyaluronic acid. The complex interaction of extracellular matrix material and cytokines causes angiogenesis. Angiogenesis is necessary to support a wound environment that can repair the injury.

Fibroplasia : Fibroblasts are chemoattracted to the inflammatory site by noxious stimuli, where they divide and produce the components of the extracellular matrix. PDGF and basic FGF make fibroblasts competent to replicate. IGF and epidermal growth factor stimulates the competent fibroblasts to replicate. As the early activities of wound healing progress, the interaction of several different cell lines and cytokines result in the fibroblast proliferation that characterizes a wound cleft.

Epithelialization : When a gap occurs in the epidermis, the wound is first sealed by a blood clot. Epidermal cells migrate from the periphery or the depth of epithelium lined skin appendages to resurface the wound. Some cellular proliferation occurs as well. If the basement membrane zone is intact, epitheliazation proceeds more rapidly. The basal cells are stimulated to migrate, their attachment to adjoining cells and to the dermis loosen, and those epithelial cells that are in the leading edge of migration becomes phagocytic. Cells slightly behind the leading edge begin to divide. The epithelial cells move as an intact sheet until the edges establish contact. if the basement membrane zone is not intact, it will be repaired first. Initially wound cleft is coated with fibrin, fibronectin, laminin, type IV Collagen and hyaluronic acid. Epithelial cells by expressing fibronectin receptors and releasing proteases migrate through the wound cleft. Matrix material like vitreonectin, collagen types I, III, IV, Tenascin and laminin bring about epithelil adhesion and spreading.

Collagen structure: Collagen is a triple helix molecule. The fibers forming collagen are type I, III, V and XI. Procollagen synthesized at rough endoplasmic reticulum is secreted to extracellular space. Several Proteases cleave the procollagen, forming the collagen monomers. The monomers assemble into fibrin. Lysyl hydroxylysyl

oxidation and cross linking occur, forming the collagen fiber. Ascorbic acid Stimulates collagen synthesis. TGF- β, IGF-1 and IGF-2 increase collagen synthesis. Gluconcortiocoids and IFN-γ inhibits procollagen gene transcription. Several genetic disorders are caused by abnormalities in collagen. Osteogenesis imperfecta is caused by a deletion of one procollagen alpha - allele. Variations of Ehlers –Danlos syndrome are caused by abnormal type III collagen, deletion of part of the type I collagen gene, abnormal copper utilization, or deficiency in Lysol hydroxylase, all of which combine to form abnormal collagen. Collagen type VII absence leads to Epidermolysis Bullosa as the anchoring fibrils connecting the lamina densa in the basement membrane zone fail to anchor the epidermis to the underlying dermis.

Elastin : Both IGF-1 & TGF-β stimulate production of elastin. Glucocortiocoids reduce adult skin cell production of elastin, as does basic FGF. Matrix metalloproteases (MMP's) produced by fibroblast and monocyte degrade the elastin in the wound cleft.

Glycosaminoglycans : Are found in the tissues, i.e. on the surface of the cells. These molecules support cells, provides tissue turgor and facilitates cell-cell interaction. Wound cleft has sulfated GAG along with fibrin, fibronectin, and hyauronic acid. Fibroblasts deposit the collages into a fibronectin and GAG scaffold. The proteoglycans (e.g.: Heparan sulfate) in general are important as a cushioning effect for tissue such as cartilage because they resist compression owing to the hydration shell that accompanies them. Dermatan sulfate is increased in granulation tissue and collagen deposition. As they are able to bind water and cation, they selectively attract these in the extracellular.

MATURATIONAL PHASE ***:*** All wounds contract. As they do so, they pull normal surrounding tissue into the area of wound, reducing the amount of disorganized scar that eventually must remain. However, although scar Contraction is normal, scar contracture is not. Contracture results when an important area has too much Scar to prevent the normal wound contraction from causing a functional disability. Wound contraction appears to occur by complex interaction of the extracellular materials and Fibroblast. In a contracting wound, fibroblasts undergo change to stimulated cells called as Myofibroblasts. They have contractive ability. MMP's also play an important role in wound contraction. They allow cleavage of the attachment between the fibroblasts and the collagen so that the lattice can be made to contract. Once the wound is healed, the wound will remodel and mature.

The fibroblast population decreases, and the dense capability network regresses. Wound strength increases rapidly Within 1 to 6 weeks and then levels off as sigmoid curve up to 1 year after the injury. Cross linking of Collagen causes further wound contraction and increase in strength, it also results in a scar that is more brittle and less elastic than normal skin.

Table 2: Showing Cell Type And Mediator In Wound Healing

Process	**Cell Type**	**Mediator**
Wounding	**Injured cell membrane**	**Phospholipase A** **Prostagladins**
Coagulation	Platelets	IL-1 PDGF TGFB
Inflammation	Lymphocytes Macrophages Granulocytes	FGF TGFB
Angiogenesis		
Proteoglycan Synthesis Collagen Deposition	Fibroblasts	
Epithelialization	Epithelial cells	EGF
Remodeling	Fibroblasts	

Classification of wounds

Table 1: Classification of operative wounds based on degree of microbial contamination

Classification	**Criteria**
Clean	Elective, not emergency, non-traumatic, primarily closed; no acute inflammation; no break in technique; respiratory, gastrointestinal, biliary and genitourinary tracts not entered.
Clean-contaminated	Urgent or emergency case that is otherwise clean; elective opening of respiratory, gastrointestinal, biliary or genitourinary tract with minimal spillage (e.g. appendectomy) not encountering infected urine or bile; minor technique break.
Contaminated	Non-purulent inflammation; gross spillage from gastrointestinal tract; entry into biliary or genitourinary tract in the presence of infected bile or urine; major break in technique; penetrating trauma <4 hours old; chronic open wounds to be grafted or covered.
Drty	Purulent inflammation (e.g. abscess); preoperative perforation of respiratory, gastrointestinal, biliary or genitourinary tract; penetrating trauma >4 hours old.

Classification of wound infections

In 1992, the US Centres for Disease Control (CDC) revised its definition of 'wound infection', creating the definition 'surgical site infection' (SSI) to prevent confusion between the infection of a surgical incision and the infection of a traumatic wound.. Most SSIs are superficial, but even so they contribute greatly to the morbidity and mortality associated with surgery. Estimating the cost of SSIs has proved to be difficult but many studies agree that additional bed occupancy is the most significant factor.

DEFINITION OF SSI-

Superficial Incisional Surgical Site Infection

Infection occurs within 30 days after the operation and infection involves only skin and subcutaneous tissue of the incision and at least one of the following:

1. Purulent drainage with or without laboratory confirmation, from the superficial incision

2. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision

3. At least one of the following signs or symptoms of infection: pain or tenderness, localised swelling, redness, or heat and superficial incision is deliberately opened by surgeon, unless incision is culture-negative

4. Diagnosis of superficial incisional SSI made by a surgeon or attending physician

Deep Incisional Surgical Site Infection

Infection occurs within 30 days after the operation if no implant is left in place or within one year if implant is in place and the infection appears to be related to the operation and infection involves deep soft tissue (e.g. fascia, muscle) of the incision and at least one of the following:

1. Purulent drainage from the deep incision but not from the organ/space component of the surgical site

2. A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever (>38°C), localised pain or tenderness, unless incision is culture-negative

3. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination

4. Diagnosis of deep incisional SSI made by a surgeon or attending physician

Organ/Space Surgical Site Infection

Infection occurs within 30 days after the operation if no implant is left in place or within one year if implant is in place and the infection appears to be related to the operation and infection involves any part of the anatomy (e.g., organs and spaces) other than the incision which was opened or manipulated during an operation and at least one of the following:

1. Purulent drainage from a drain that is placed through a stab wound into the organ/space

2. Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space

3. An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination

4. Diagnosis of organ/space SSI made by a surgeon or attending physician.

Table 4: Classification Of SSIs

Superficial incisional surgical site infections	**Deep incisional surgical site infections**
Superficial incisional surgical site infections must meet the following two criteria: • occur within 30 days of procedure • involve only the skin or subcutaneous tissue around the incision. *Plus* At least one of the following criteria: • purulent drainage from the incision • organisms isolated from an aseptically obtained culture of fluid or tissue from the incision • at least one of the following signs or symptoms of infection - pain or tenderness, localised swelling, redness or heat - and the incision is deliberately opened by a surgeon, unless the culture is negative • diagnosis of superficial incisional SSI by a surgeon or attending physician The following are not considered superficial SSIs: • stitch abscesses (minimal inflammation and discharge confined to the points of suture penetration) • infection of an episiotomy or neonatal circumcision site • infected burn wounds • incisional SSIs that extend into the fascial and muscle layers *(see* deep SSIs).	Deep incisional surgical site infections must meet the following three criteria: • occur within 30 days of procedure (or one year in the case of implants) • are related to the procedure • involve deep soft tissues, such as the fascia and muscles. *Plus* At least one of the following criteria: • purulent drainage from the incision but not from the organ/space of the surgical site • a deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms - fever (>38°C), localised pain or tenderness - unless the culture is negative • an abscess or other evidence of infection involving the incision is found on direct examination or by histopathologic or radiological examination • diagnosis of a deep incisional SSI by a surgeon or attending physician.

FACTORS AFFECTING WOUND HEALING

Various factors which influence wound healing can be divided into two groups:

Systemic (General) factors & local factors.

Systemic factors (General factors) :

Age: The aging process effects all the stages of wound healing, but macrophages are particularly impaired. As these play such a central role in the wound healing process, there is significant delay from this aging effect alone.

Nutrition :

(i) ***Protein deficiency :*** Protein depletion causes impairment of granulation tissue and collagen formation. It is not always due to inadequate intake but may be due to excessive loss e.g.: nephritic syndrome, cirrhosis etc. in a malnourished patient wound healing is badly affected both delayed and qualitatively poor wound healing. Especially methionine and cystine have beneficial effects if they are provided in nutrition.

(ii) **Vitamin C** : It is required for normal collagen synthesis. Enhances conversion of proline to hydroxyl proline and lysine to hydroxylysine. Maturation of collagen does not occur in the absence vit C.

(iii) **Vitamin A**: It is required for proper epithelialization. Deficiency of vit A will impair lymphocyte activation, fibronectic deposition that further affects cellular adhesion, and compairment of the TGF-β receptors.

Zinc, Calcium, Copper, Manganese deficiency : Zinc is a necessary cofactor for RNA polymerase and DNA polymerase (enzymes of protein synthesis). There is some failure of granulation tissue formulation in case of Zinc deficiency. Others are essential minerals, which are also required for proper wound healing. These may be depleted in intestinal fistula and burns.

Oxygen : Oxygen is required for normal wound healing. Hypoxia causes defective wound healing. Oxygen is required for all metabolic activities of wound healing and for synthesis of oxygen radicals for wound debridement.

Hematological derangement: Neutrophil deficiency, bleeding disorders and anemia all cause defective wound healing and certain genetically inherited phagocytic and chemotactic deficiencies affect wound healing.

Metabolic diseases :

(i) **Diabetes mellitus :** Impairs wound healing at all stages of the process. The basement membranes of the capillaries are thickened causing decreased perfusion in the microenvironment. Lymphocyte and leukocyte function is impaired, and there is increased collagen degradation and decreased collagen deposition. The collagen that is formed is more brittle than the normal collagen, probably owing to glycosylation from the increased levels of glucose present in the extracellular matrix.

(ii) **Jaundice :** Impaired fibroblast function and delay in angiogenesis is seen in jaundiced patients.

(iii) **Uremia:** Retards connective tissue formation and slows epithelial repair.

Drugs and Corticosteroids : - Some exogenous drugs directly inhibit wound healing. Doxorubicin (Adriamycin) is a potent inhibitor of wound healing. Nitrogen mustard, cyclophosphamide, methotrexate, and bis-chloroethyl-nitrosourea (BCNU) are the other most potent wound inhibitors. Tamoxifen is known to decrease cellular proliferation, due to decreased TGF- β production.

Glucocorticosteroids impair fibroblast proliferation and collagen synthesis. The amount of granulation tissue formed is also decreased. Steroids stabilize the lysosomal membranes. This particular effect can be reserved by the administration of vitamin A[18].

Lonizing radiation : Causes endothelial cell injury with endarteritis resulting in atrophy, fibrosis and delayed tissue repair. As its greatest effect is on cells the G2 through phase, rapidly dividing cell populations are most sensitive to radiation. This would include the keratinocytes during the wound healing process, impairing epithelialization.

Local factors :

i. **I**nfection**:** Wound infection is the most common cause of delayed healing. If the bacterial count in the wound exceeds 10^5 organisms per gram of tissue, or if any beta-hemolytic streptococcus is present, the wound will not heal by any means including flap closure, skin graft placement, or primary sutures. The bacteria prolong the inflammatory phase and interfere with epitheliazation, contraction and collagen deposition. The endotoxins themselves destroy surrounding previously normal tissue. Treatment to decrease the bacterial

count, either mechanically or with the use of systemic antibiotics, will therefore limit the amount of inflammation and allow closure of the wound.

ii. Blood supply **:** Local adequacy of blood supply for wound healing is necessary. Wounds with poor blood supply heal slowly e.g.: wound over pretibial region, on the legs with varicose veins, on ischaemic limbs, etc.

iii. Foreign bodies**:** Impairs and prolongs the wound healing.

iv. Tissue tension, hematoma formation.

v. Recurrent trauma.

vi. Complication of radiotheraphy

vii. Excessive use of topical corticosteroids.

WOUND CARE[9,14,18] :

1. Local environment condition must be optimal for cellular metabolism.
2. Drying of exposed tissues not only kills surface cells but also destroys normal blood flow in small vessels some distance from the surface.
3. A suture under tension cause choking off all local blood flow as tissue swell
4. External pressure from carelessly applied dressing can decrease local tissue perfusion.
5. Preparation solution for skin like Iodine, Ether, Alcohol if poured into an open wound would kill cells on contact. Open wound must be protected from all substances harmful to living cells.
6. Removal of all dead materials and prevention of fluid collection.

7. Copious stream of saline will flush foreign bodies, undesirable organisms and other surface contaminants.
8. Frequent wet-to-dry dressing can produce debridement.
9. Infection, fibrosis, Hypertrophic, scars and foreign body granulumas follow careless handling.
10. When doing primary closure, wounds should not be closed under tension. Failure to recognize this results in wide scars, wound dehiscence, or necrosis of wound margins.
11. Absorbable sutures are used when infection is known to be present or when debridement has been difficult. Non absorbable suture materials produce less tissue reaction but in areas where infection develops it can harbor organisms and infection will not subside until sutures are removed.

WOUND DRESSING[28] ***:***

Dressing for primarily closed wounds generally have been over emphasized. During the 48 hours dressing is required to protect the wound from environment and to absorb wound drainage. After the first 48 hours an epithelial seal is present, and the dressing is merely for appearance or possible comfort.

Dressing used in plugging and concealing wound such as lint, cotton wool or passive dressing. New dressing such as polymeric films and foams, hydrogels and hydrocolloids known as interactive dressing, the provide a micro environment which is conductive to healing. One of the hydrocolloid dressing (Duoderm / Granuflex), provides a healing environment that improves healing and also stimulates angiogenesis.

Cultured autografts and allografts: biological wound covering with epidermal autografts and allografts showed to be replaced rapidly by host keratinocytes thus acting as temporary coverage with stimulating healing process[6].

Dressing that deliver specific growth factors, pharmacological agents to stimulate healing or serve as transducers to provide physical forces to wound like electrical stimulation, ultrasound are under trait for managing chronic wounds[10].

FETAL WOUND HEALING[17,19]

Fetal tissues repair themselves without scar formation is a recent discovery. The fundamental differences in the fetal tissue repair process compared with the adult are

1. Lack of inflammatory response to injury may be due to either sterile environment or due to fetal immune system is immature with decreased chemotaxis, opsonisation and complement activity.
2. Distinct different composition of extracellular matrix containing abundant hyaluronic acid, a glycosaminoglycan rather than collagen (because of persistence of hyaluronic acid stimulation activity (SASA).
3. Low concentration or absenece of peptide growth factors.
4. Fetal cells may be programmed for repair by regeneration, a trait that disappear postnatally.

COMPLICATIONS OF WOUND HEALING[28]

1) Wound dehiscence (bursting) occur in the first few weeks after surgery before substantial completion of collagen cross-linking. Excessive wound tension, sudden increase in mechanical stress, poor metabolic status (hypoproteinemia, Vit C deficiency) result in weak scars and increase likelihood of dehiscence.
2) **Hypertrophic scars and keliod :** Result from post-traumatic tissue over production of connective tissue leading to firm raised flesh.

Hypertrophic scar	**Keliods**
Develop soon after surgery	May not begin for many months
Usually subside with time (maturation)	Rarely subsides with time.
Limited boundary	Overgrow their boundaries
Size commensurate with injury	Minor injury may produce larger lesion
Occur with motion (Compression)	Independent of motion
Usually occurs across flexor surfaces	Areas of high predilection (earlobes, sternum) rarely across joints
Improve with appropriate surgery	Often worsened by surgery

Etiology :

1) Trauma 2) Tension 3) Hormonal changes

4) Familial predisposition – autosomal recessive or dominant.

5) Associated with other dermatologic disorders – Dissecting cellulitis of scalp, Acne Vulgaris, Acne Conglobata, Hydradenitis suppurtiva, Pilonodal sinus, Foreign boy reactions.

6) Certain infections – Herpes zoster, small pox, Vaccinia.

7) Certain connective tissue diseases : Ehler – Danlos Syndrome, Rubinstein – Taybi syndrome, pachyderma periostosis, scleroderma.

Clinical features : Predilection sites – Earlobes, shoulders, anterior chest, upper arms, mandibular angles.

Pathophysiology : Increased cellularity and metabolic activity. Most prevalent glycoprotien is choSndroitin – 4 sulphate.

Pathology : Avascular collagen nodules.

Treatment :

A) Intralesional corticosterioid : (Triamcilone acetonide) treatment – various needle and syringes described.

Lever – LOK needle and syringe.

2) Mechanical injectors - spring or CO2 powered e.g.: ligmajet mechincal injector. This therapy may be combined with cryotherapy or surgery.

Local complications: Hypopigmentation, telangiectasia, atrophy, ulceration and necrosis. Systemic complications: Cushingoid habitus.

B) Surgery : Indication – Keloids that do not respond to corticosteroids, pressure therapy, or other topical therapies. Laser surgery can be used.

C) Adjuvant therapy:

1. Oral antihistamines
2. Pentoxifylline
3. Pencillamine (lyayl oxidase inhibitors) or colchicines following surgical excision.
4. Pressure therapy.
5. Radiation therapy (Total dose 1,500 to 2000 rads).
6. Electrical stimulation following excision.
7. Topical retinoids such as 0.025% retinoic acid or 0.05% Tretenoic cream.
8. Human recombinant interfection Gamma (IFN-γ).
9. Silicon gel.

3) Cicatrization or Contractures : Exaggeration of wound contraction process (action of myofibroblasts) results in severe deformity at and around the wound site.

Neoplasia: An enhancement in the rate of cell turnover inereases the likelihood of tumour indication.

Others : Like painful scars, weak scars, pigmentary changes, implantation cysts, wound failure including anastamotic leakage, hernia recurrence or fracture non union.

NEW HORIZONS IN WOUND HEALING[3,30,8]

Research in the field of wound healing is targeted towards the concept of wound manipulation. Clinical trials have shown the beneficial effect of treatment of chronic wounds with growth factors. Although this treatment is still quite costly, as technology improves, this non-operative treatment may eventually be less costly than repeated operative intervention. Prospective randomized studies have shown more rapid closure of venous stasis ulcer, pressure sores, and diabetic foot wounds using a variety of cytokine such as TGF-β and PGDF. But this therapy is very costly. Unless the precise cytokine deficit is known for each wound type, application of growth factor remains an educated guess. Chronic wounds have a significant increase in MMPs (Matrix Metalloproteases). This increase in wound gelatinase and collagenase compared with acute wounds may cause enzymatic degradation of the drug treatment as it is placed in wound before it has the opportunity to effect an improvement. Some investigators are examining be effect of blockage of the MMPs either directly or by increasing the amount of tissue inhibitors of the MMPs. The growth factors are too expensive to simply place in the wound and allow them to be degraded before they interact with the cellular components of the wound. Also chronic wounds in diseases like diabetes the cause is the cellular dysfunction in the fibroblast. Such cases would prevent use of endogenous growth factor. Addition of exogenous growth factor is therefore unlikely to be helpful.

Further manipulation of the wound is possible with genetic intervention. If the application of expensive growth factors donot allow a chronic wound to proceed to closure, thengene intervention can be tried. Safety factor with viral vectors, such as the adenovirus or the herpes simple virus, continue to limit this research to animal and invitro models. Mechanical means such as micro injunction or particle bombardment are less efficient but do not hold the risk of oncogenesis perceived with virul vectors.

Electrical stimulation[3] : Various experiments have been performed to examine the effect of electrical stimulation on the wound healing process. An increase in the number of fibroblasts has been seen in incisional and second degree burn wounds often stimulated with electrical currents. The motility of fibroblasts has also been found to be influenced by electrical fields. Fibroblasts exposed to a continuous electrostatic field have shown a significant increase in collagen synthesis and DNA. Increase in DNA protein stimulation of fibroblasts depending on the intensity. Electrical stimulation has been shown to increase the expression of receptors for TGF-β. Reich et at reported the effect of electrical stimulation in reducing the number of mast cells that have been associated with a variety of wound healing complications including fibrosis and hyertrophic scars.

Ultrasound[30] ***:*** Ultrasound refers to high frequency mechanical vibrations created by conversion of electrical energy into sound waves that are inaudible to human beings. When ultrasonic waves are applied to soft tissue, they serve as a source of absorbable energy. The absorption of this energy by various tissue components initiates variety of physiological response. The physical effects of ultrasound fall into two categories:

***Thermal and non thermal*[8].**

Thermal effects: Beneficial effects of this therapy include decrease in paid, decrease in muscle stiffness and spasm, increase in collagen elasticity and acceleration of wound healing. The effect of wound healing has been attributed to thermal enhancement of metabolism and enzyme activity.

Non-thermal effects : Non thermal effects of ultrasonic induction derive primarily from changes in cellular membrane permeabilities as a result of three types of physical forces generated namely: Cavitation, streaming and standing wave formation. Cavitation refers to the formation of microscopic bubbles on any fluid medium upon which the sound waves impinge. Streaming is a measurable mechanical force induced by ultrasound that is unidirectional and steady. The permeability changes generated by cavitational and streaming may affect the diffusion of cellular metabolites, which can elicit a therapeutic benefit. Specific stimulatory effects have also been documented in fibroblasts and macrophages and on angiogenesis.

MATERIALS AND METHODS

The present study was carried out at K.L.E.S Prabhakar Kore Hospital and Research centre, Belgaum where 100 patients underwent abdominal skin closure with either staples or conventional vertical mattress suturing with Ethylon .

Out of the 100 patients, 50 underwent skin closure with Stainless steel skin staples and the remaining 50 with vertical mattress suturing with Ethylon All these patients were allotted to either group according to random number table .

Sample size: 100

The following formula was used to calculate the sample size required for this study.

$$N= [2(Z\alpha+Z\beta)^2 pq]/ d^2$$

$$P=(p1 +p2)/2=(12+0)/2=6$$

$$q= 100-p$$

$$d=12-0=12$$

$$Z\alpha=1.65$$

$$Z\beta=0.84$$

$$N=48$$

So calculated sample size on each wing is 48, taking into account cases losing to follow up, sample size on each wing would be 50(50+50=100).

Inclusion criteria

- All patients undergoing elective abdominal surgeries
- Patients giving consent for the trial.

Exclusion criteria

- Patients having lacerated wounds with skin loss.
- Patients having diabetes mellitus.
- Patients with immune compromised status like AIDS/HIV infection.

- Patients having severe co-morbidities i.e. shock, septicaemia , failure of other organ systems, recent MI, malignancy.

Ethical clearance has been obtained from our institution for conducting this study.

Method of collection of data

A detailed history of each patient was obtained starting with history of presenting symptoms and any co-existing, co-morbid conditions like, DM, HTN and Jaundice were ruled out.

A thorough general physical examination was done to rule out presence of pallor, icterus and cachexia.

Preoperatively all patients underwent following investigations

CBC, urine examination

Blood sugar, Blood urea. Serum creatinine

LFT (wherever needed)

Chest x-ray, ECG (wherever needed)

All cases were elective surgeries and the mode of anaesthesia was either General Anasthesia, Spinal anaesthesia or short GA. Shaving was done the night before surgery. They all received one mandatory dose of pre operative parenteral antibiotic 1-hour prior to the incision.

Painting was done with 10% povidone iodine solution for all cases.

Closure technique

After the subcutaneous fat was sutured with 2-0 vicryl,

Suture group

Skin was approximated with vertical mattress sutures using non-absorbable 2-0 Ethylon at a distance of 1 cm from each other.

Stapled Group

Before inserting staples, it is important to line up the wound edges with the centerline indicator on the head of the stapler to make sure that the legs of the staple will enter the skin at equal distances on either side of the wound edge. Each edge is typically picked up with a forceps, everted and precisely lined up. The staples are then used to close the wound while the first assistant advances the forceps, everting the edges of the wound. They are placed at a distance of 5mm from one another. This technique is continued until the entire wound is everted and closed with staples.

The time required for skin closure was recorded. For the sutures group, betadine ointment was applied and a packed dressing given. For the stapled group simple dry gauze dressing was given. Post operatively all patients received a total of 3 days of parenteral and oral antibiotics. The patients who underwent Mesh repair received a total of 5 days of parenteral and oral antibiotics.

On the 3rd postoperative day, the wound was evaluated for inflammation, infection and wound gape.

Inflammation was defined as excessive redness and tenderness of incision site with induration.

Infection was defined as any persistence of superficial cellulitis or induration with serosanguinous or pus discharge from wound site lasting beyond 7^{th} postoperative day.

Patients were usually discharged after suture removal on 7-8^{th} day for the sutures group and the stapled group patients after the 1^{st} wound evaluation if there was no wound inflammation/ infection. In case of wound infection or discharge in any group, the discharge was sent for culture and sensitivity. The total hospital stay was

noted. Patients were re-evaluated for infection / gape / inflammation during follow-up on 15 days / 1 month

Statistical analysis was done using the Mann Whitney test and the p value was calculated.

At 1 month follow up :

The wounds were evaluated at 1 months follow up which were rated for cosmesis on a previously validated cosmesis Visual Analogue Score which has been demonstrated to be reliable and valid outcome measure of cosmesis.

The cosmetic VAS is a 100-mm line with worst scar at 0 and best scar at 100. A senior surgeon rated photographs unaware of the method used to close the wound.

Using the line as a continuous entity the surgeon marked the patient's scar on the line. The score was then measured in millimetres from 0 to 100. The mean VAS for each group was calculated.

Statistical evaluation was done after consulting the college statistician. Using the student's unpaired 'T' test ,the p value was calculated.

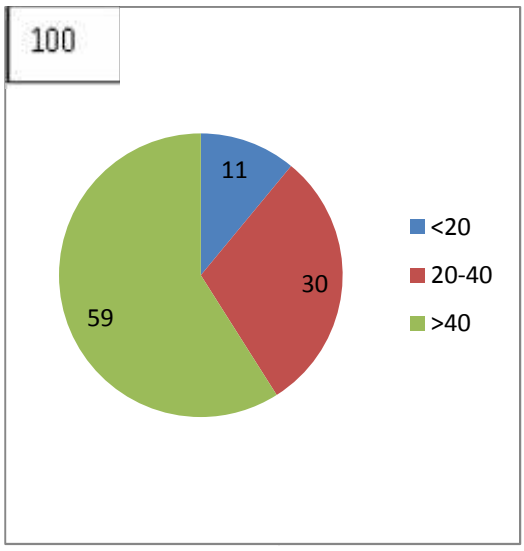
OBSERVATIONS & RESULTS

The present one year randomised controlled trial was conducted in the Department of Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum during the year December 2010 to November 2011. Data obtained was tabulated and analysed as below.

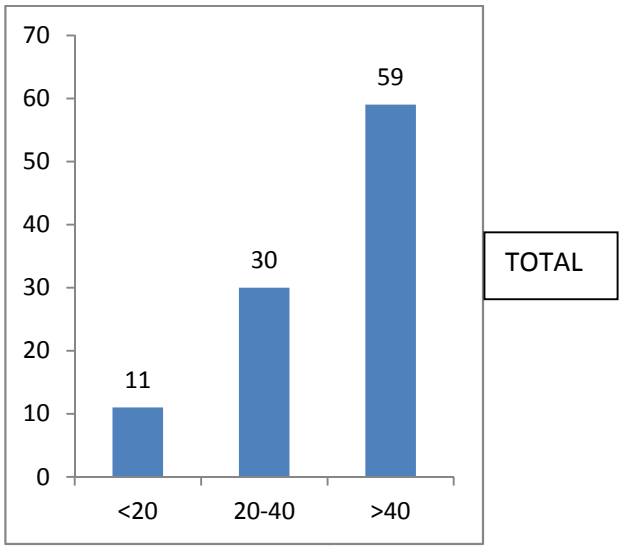
TABLE 05. AGE DISTRIBUTION

AGE DISTRIBUTION	STAPLES	CONVENTIONAL METHOD	TOTAL
<20YRS	4	7	11
20-40YRS	15	15	30
>40YRS	31	28	59
GRAND TOTAL	50	50	100

Graph 2A

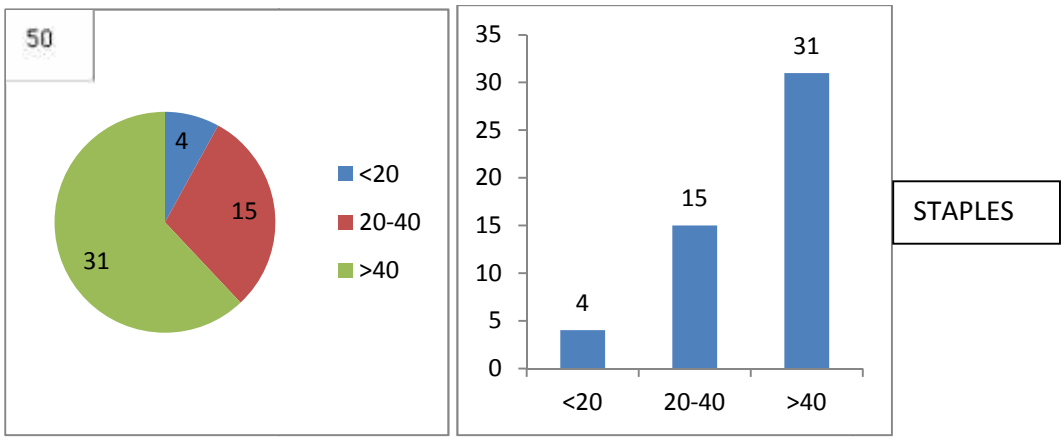


Graph 2a



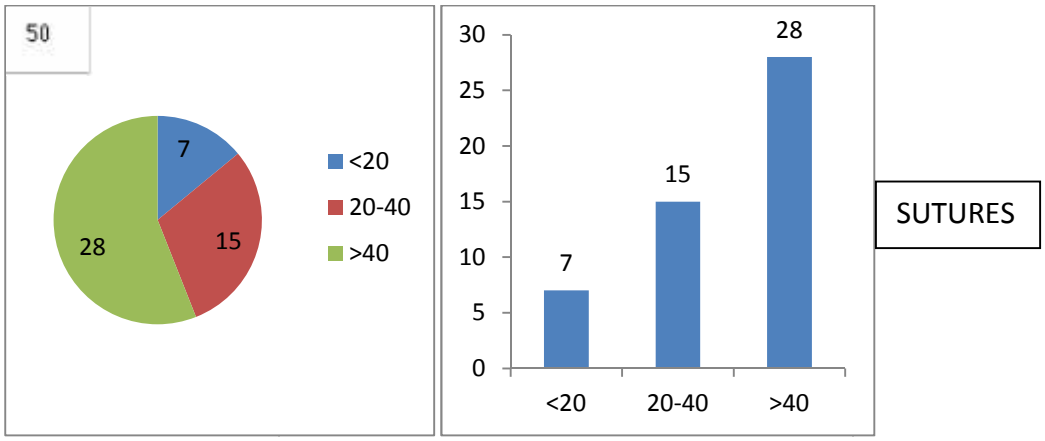
Graph 2A and 2a shows the age distribution of the study population. The graphs show that the majority(59%) were in the 40+years age group.11 % were in the below 20 years age group.

Graph 2B **Graph 2b**



Graph 2B and 2b shows the age distribution in staples group. The graphs show that the majority were in the 40+years age group.

Graph 2C **Graph 2c**

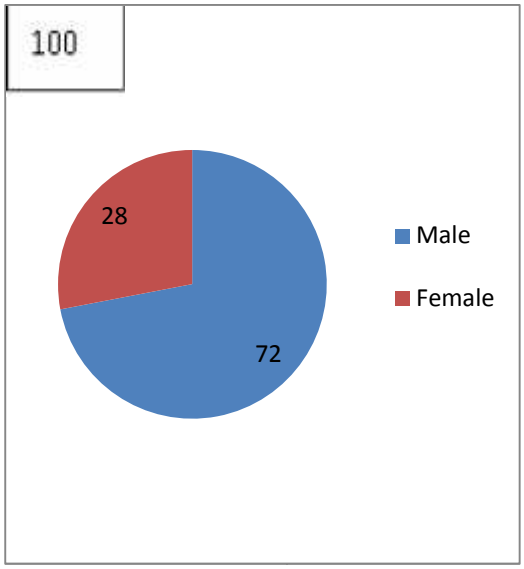


Graph 2C and 2c shows the age distribution in conventional suture group. The graphs show that the majority were in the 40+years age group.

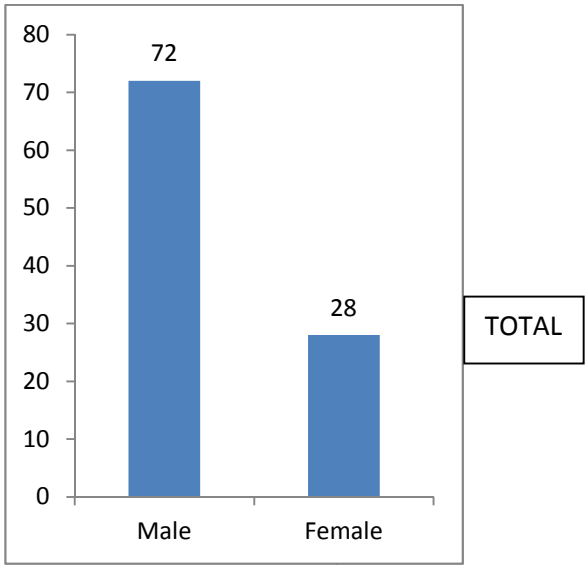
TABLE 6:SEX DISTRIBUTION

SEX	STAPLES	CONVENTIONAL METHOD	TOTAL
MALE	34	38	72
FEMALE	16	12	28
GRAND TOTAL	50	50	100

Graph 3A

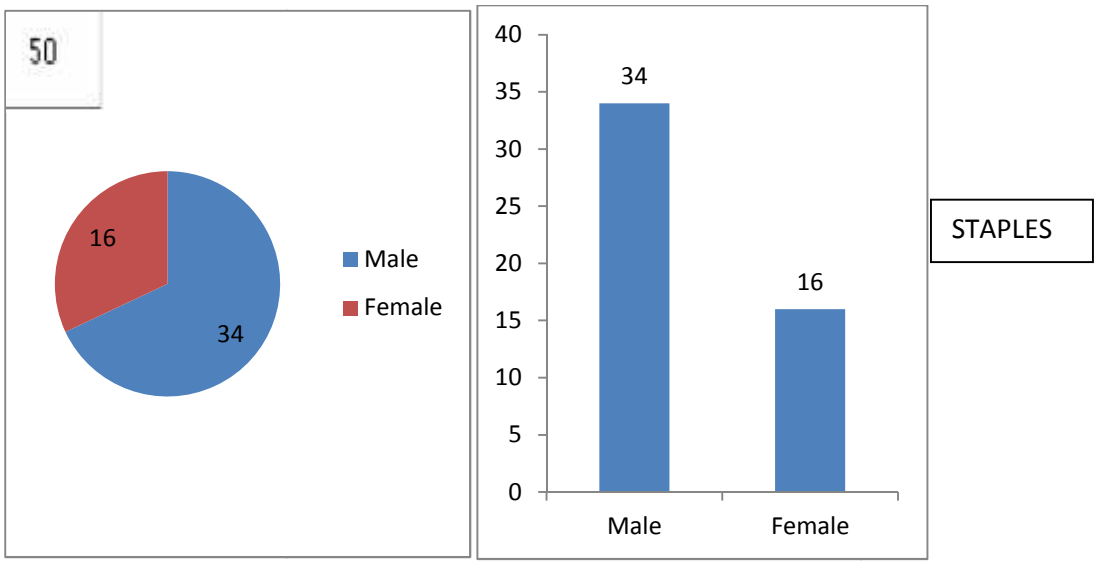


Graph 3a



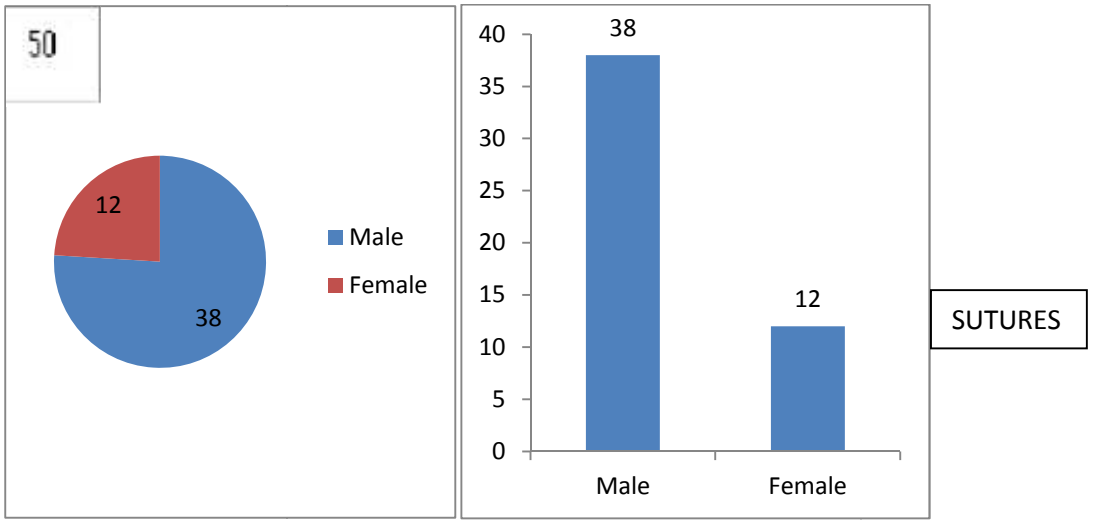
Graph 3A and 3a shows the sex distribution of the study population. The pie chart shows that 72% of the study population were males and the remaining 28% were females.

Graph 3B **Graph 3b**



Graph 3B and 3b shows the sex distribution of the staples group. The pie chart shows that 34 of the study population were males and the remaining 16 were females.

Graph 3C **Graph 3c**

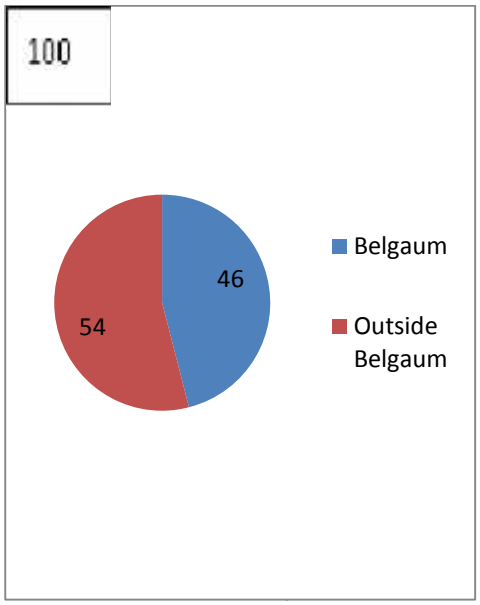


Graph 3C and 3c shows the sex distribution of the conventional sutures group. The pie chart shows that 38 of the study population were males and the remaining 12 were females.

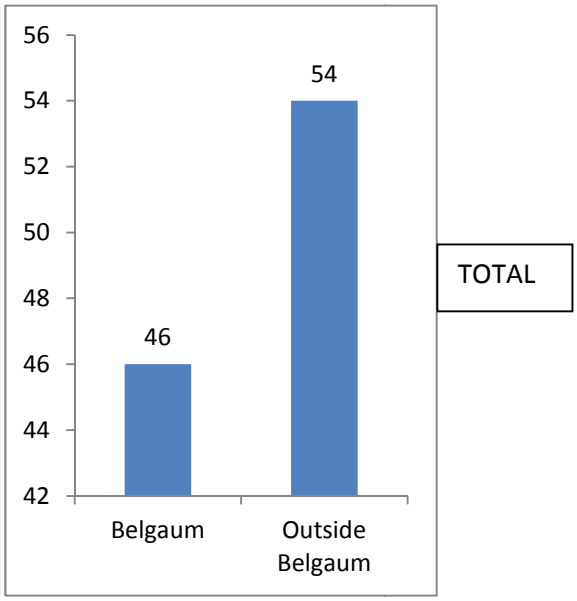
TABLE 7:RESIDENCE

PLACE	STAPLES	CONVENTIONAL METHOD	TOTAL
BELGAUM	21	25	46
OUTSIDE BELGAUM	29	25	54
GRAND TOTAL	50	50	100

Graph 4A

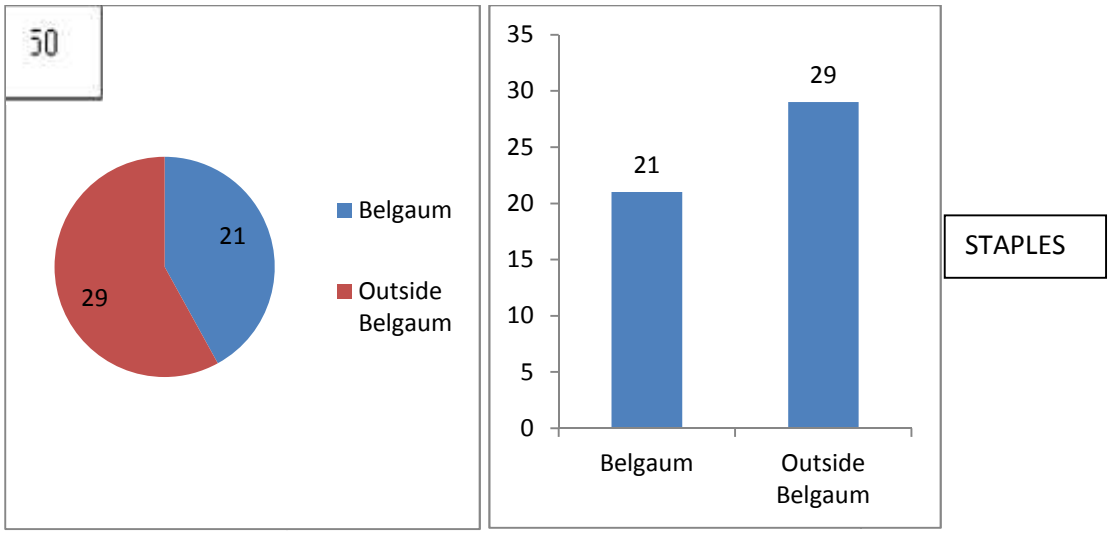


Graph 4a

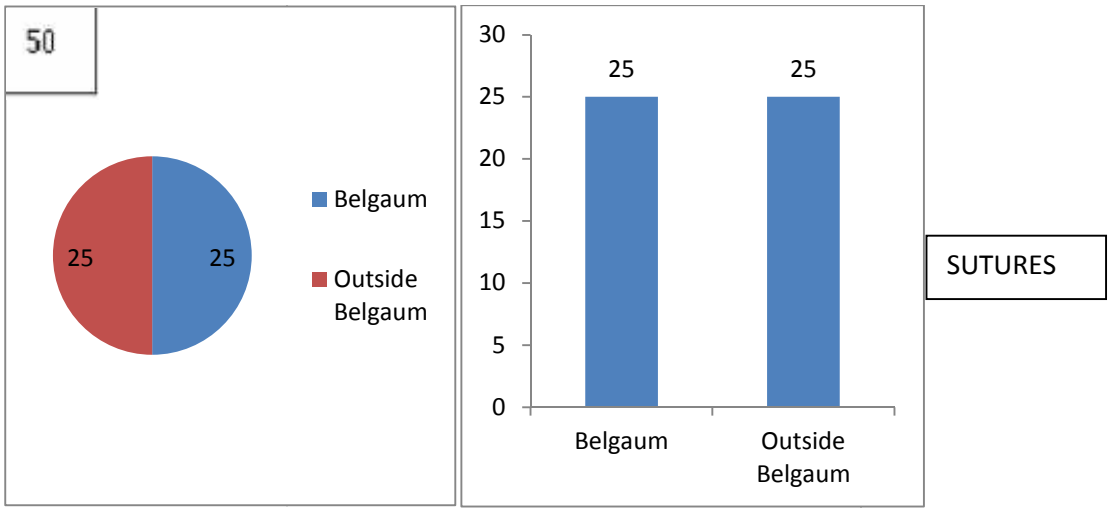


Graph 4A and 4a shows the residence of the study population. The graph shows that 46% were from belgaum and nearby areas whereas the remaining 54% were from other towns/cities in karnataka.

Graph 4B **Graph 4b**



Graph 4B and 4b shows the residence of the study population. The graph shows that 21 out of 50 were from belgaum and nearby places whereas the other 29 are from other cities/towns. **Graph 4C** **Graph 4c**

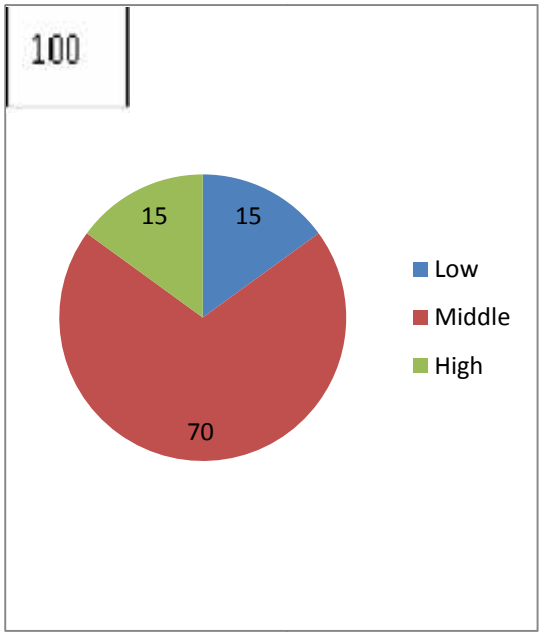


Graph 4C and 4c shows the residence of the study population. The graph shows that 25 out of 50 were from belgaum and nearby areas whereas the other 25 are from other towns/cities.

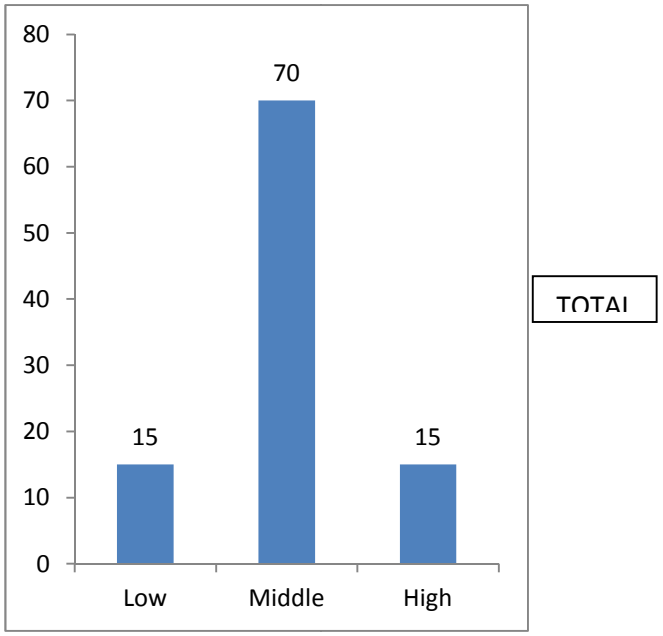
TABLE 8:SOCIO ECONOMIC STATUS

SOCIO ECONOMIC STATUS	STAPLES	CONVENTIONAL METHOD	TOTAL
LOW	-	15	15
MIDDLE	39	31	70
HIGH	11	4	15
GRAND TOTAL	50	50	100

Graph 5A

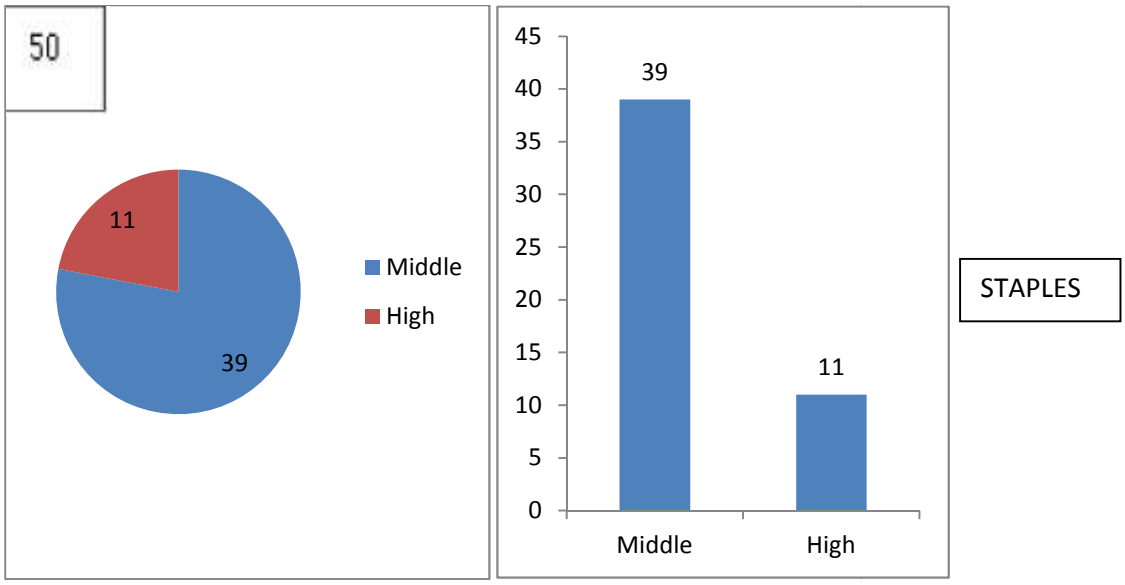


Graph 5a



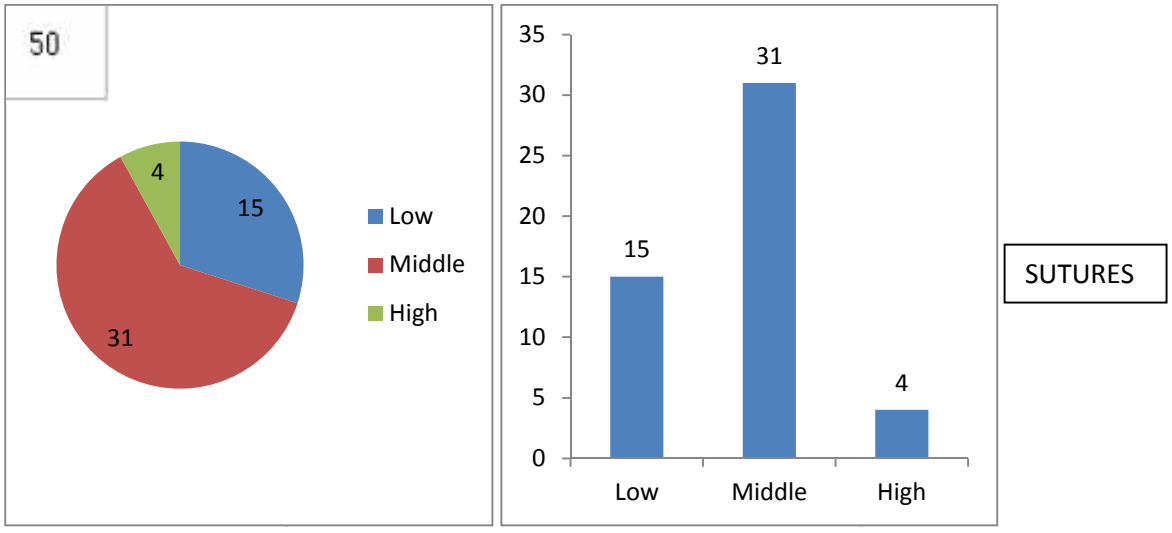
Graph 5A and 5a shows the social class of the study population. The graph shows that the majority (70%) were in the middle income group and the remaining (15% each) were in the low and high income group.

Graph 5B **Graph 5c**



Graph 5B and 5b shows the social class of the staples group. The graph shows that the majority (39 out of 50) were in the middle income group and the remaining (11) were in high income group.

Graph 5C **Graph 5c**

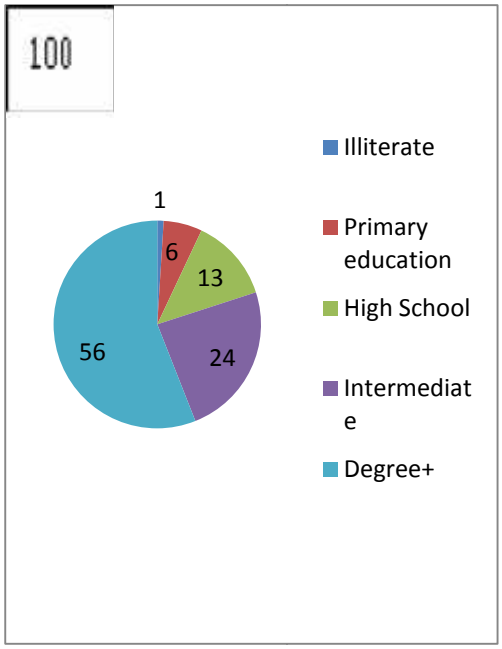


Graph 5C and 5c shows the social class of the conventional sutures group. The graph shows that the majority (31 out of 50) were in the middle income group and the remaining (15 and 4) were in the low and high income group respectively.

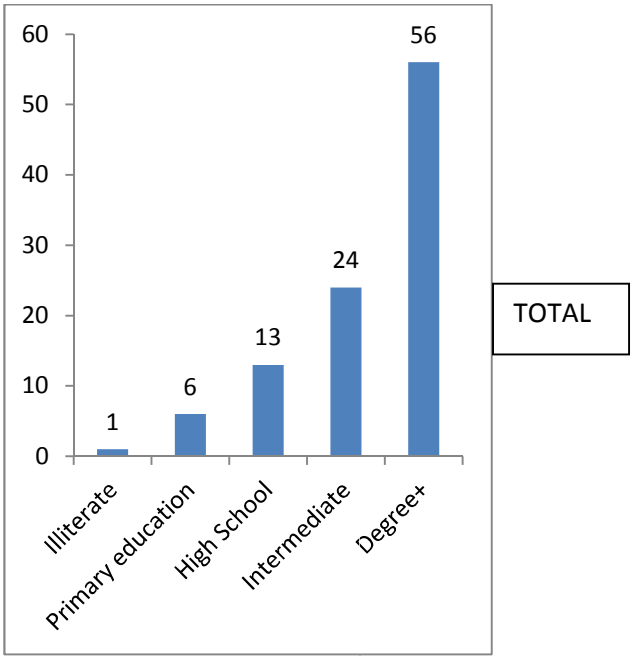
TABLE 9:LITERACY OF THE STUDY POPULATION

EDUCATION	STAPLES	CONVENTIONAL METHOD	TOTAL
ILLITERATE	1	1	2
PRIMARY EDUCATION	7	5	12
SECONDARY	-	6	6
INTERMEDIATE	8	16	20
DEGREE+	34	22	36
GRAND TOTAL	50	50	100

Graph 6A

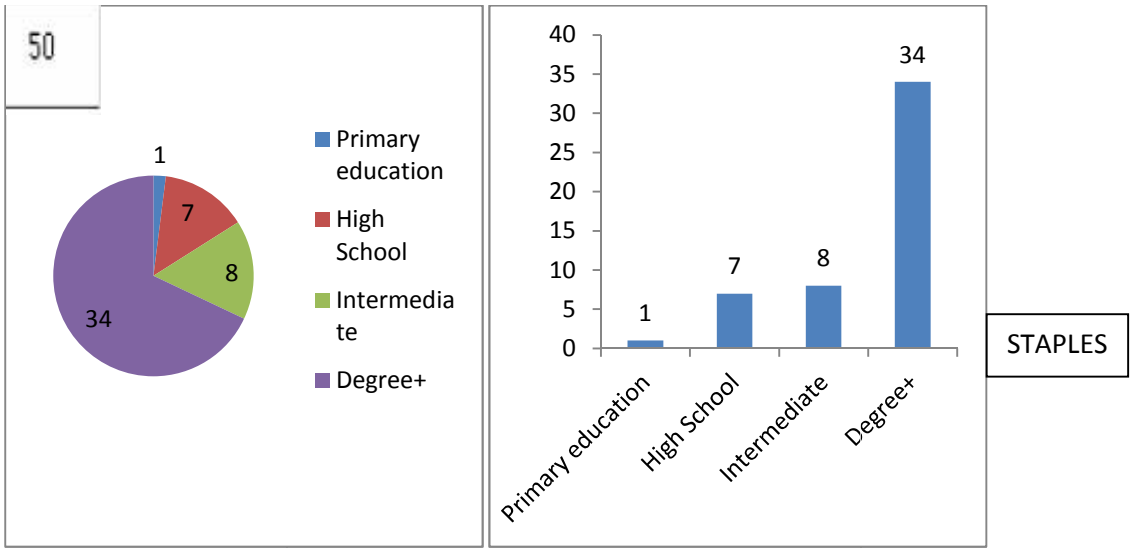


Graph 6a



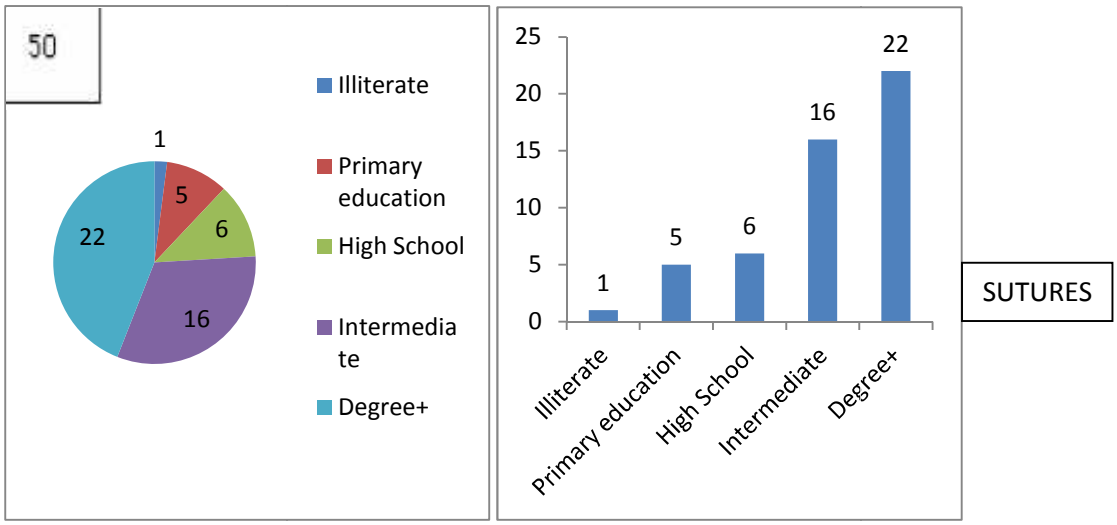
Graph 6A and 6a shows the education status of the study population. The graph shows that 1 % of study population were illiterate. 6% were educated upto primary school level. 13% were educated upto high school level. 24% were educated upto intermediate level. 56% were educated upto degree level or above.

Graph 6B **Graph 6b**



Graph 6B and 6b shows the education status of the staples group. The graph shows that 1 out of 50 of study population was educated upto primary school level. 7 were educated upto high school level. 8 were educated upto intermediate. 34 were educated upto degree level or above.

Graph 6C **Graph 6c**

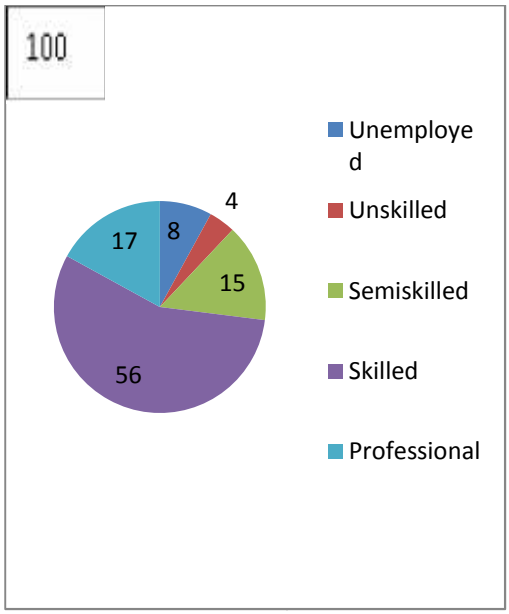


Graph 6C and 6c shows the education status of the conventional sutures group. The graph shows that 1 out of 50 of study population was illeterate. 5 were educated upto primary school level. 6 were educated upto high school level. 16 were educated upto intermediate level.22 were educated upto degree level or above.

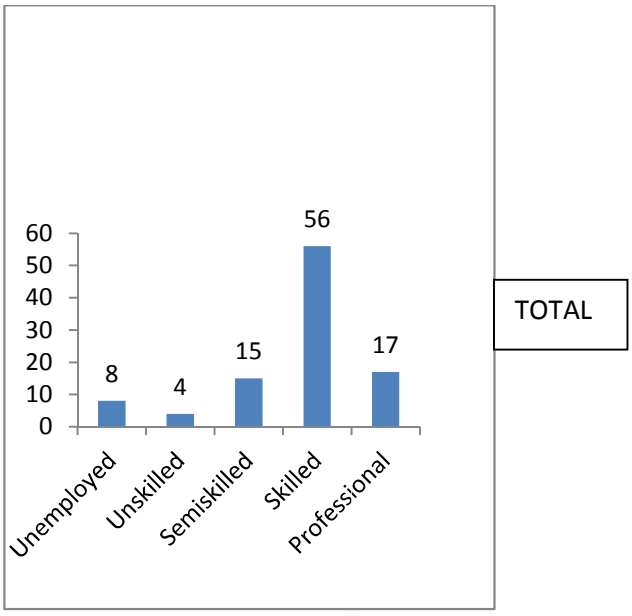
TABLE 10:EMPLOYMENT STATUS

EMPLOYMENT STATUS	STAPLES	CONVENTIONAL METHOD	TOTAL
UMEMPLOYED	3	5	8
UNSKILLED	-	4	4
SEMI SKILLED	8	7	15
SKILLED	31	25	56
PROFESSIONAL	8	9	17
GRAND TOTAL	50	50	100

Graph 7A

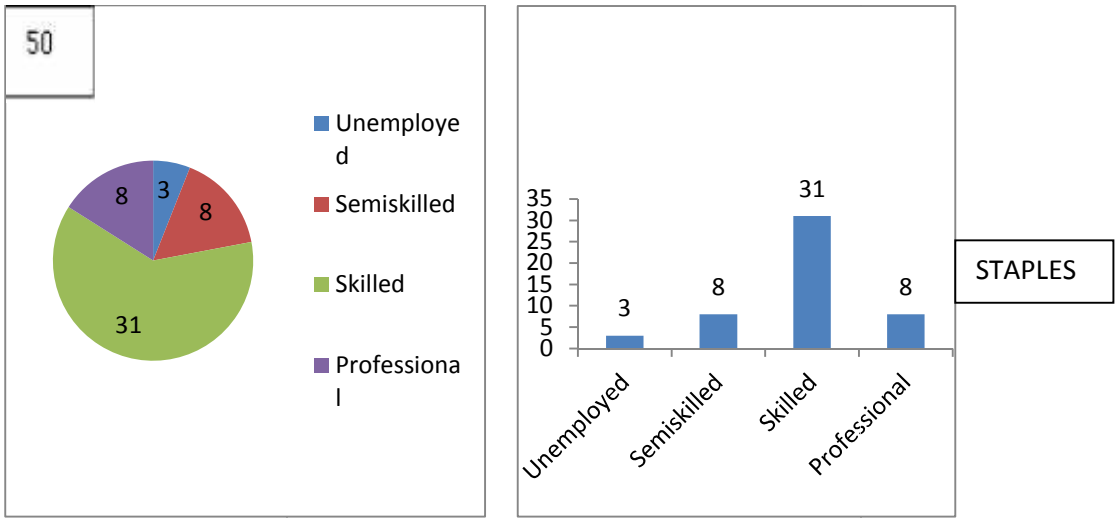


Graph 7a

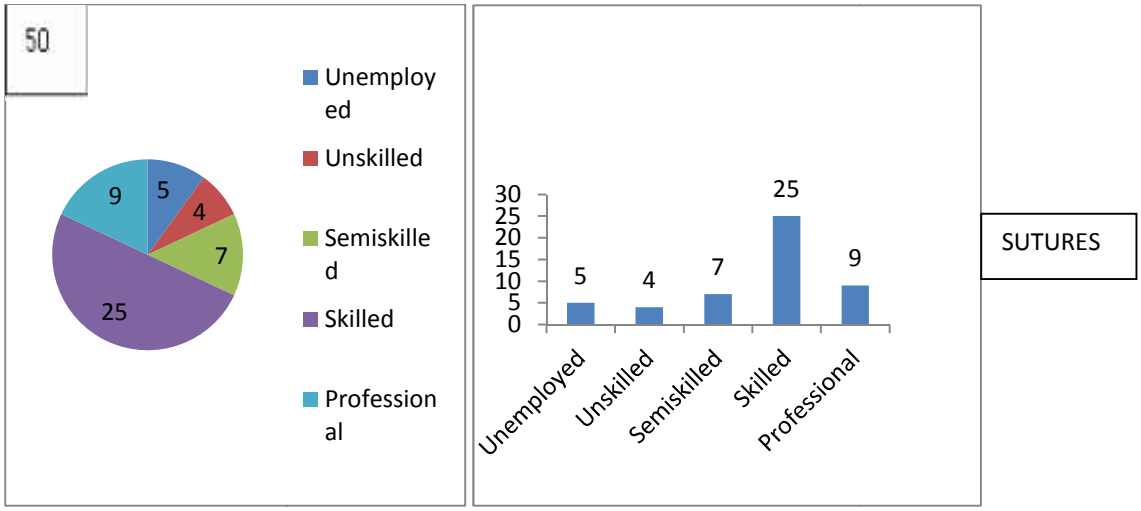


Graph 7A and 7a shows the occupation of the study population. The bar chart and pie chart show that majority i.e 56% of the study population were skilled. 4% were involved in unskilled labour and 15% in semi-skilled jobs. A small percentage i.e 8% were unemployed and 17% were in professional group.

Graph 7B **Graph 7b**



Graph 7B and 7b shows the occupation of the staples group. The bar chart and pie chart show that majority i.e 31 out of 50 were skilled. 8 were involved in semiskilled labour and 8 in professional jobs.3 were unemployed.



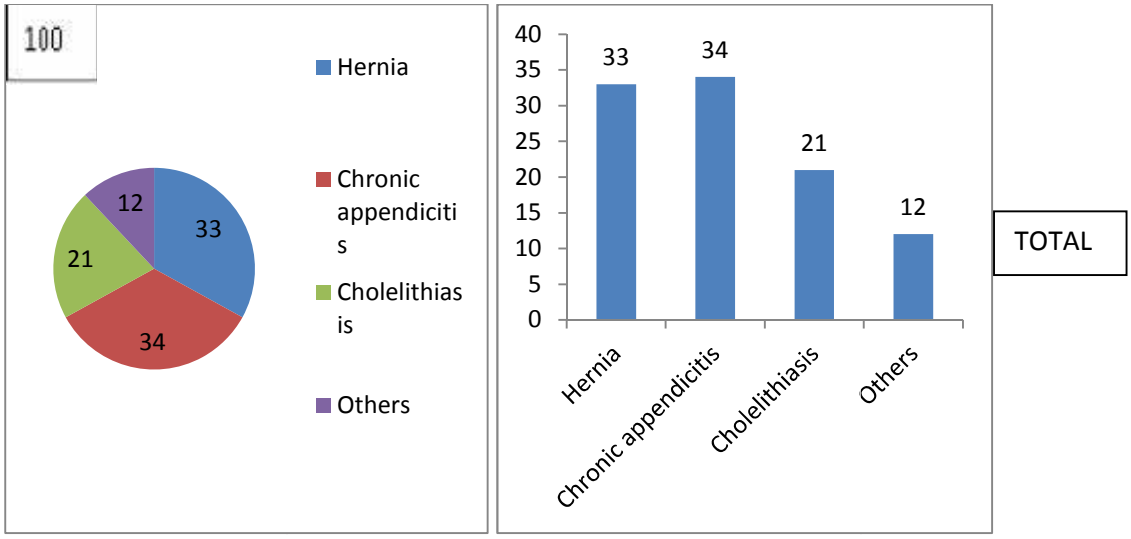
Graph 7C **Graph 7c**

Graph 7C and 7c shows the occupation of the conventional sutures group. The bar chart and pie chart show that majority i.e 25 out of 50 were skilled. 7 were involved in semiskilled labour and 9 in professional jobs.5 were unemployed and 4 were unskilled.

TABLE 11:DIAGNOSIS

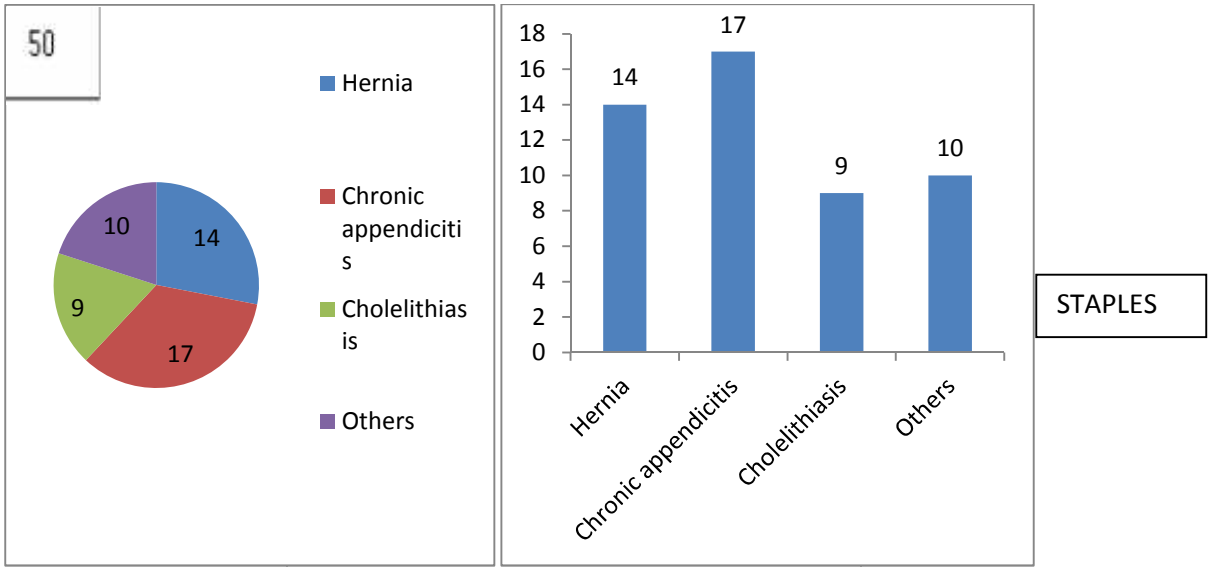
DIAGNOSIS	STAPLES	CONVENTIONAL METHOD	TOTAL
HERNIA	14	19	33
CHRONIC APPENDICITIS	17	17	34
CHOLELITHIASIS	9	12	21
LYMPHADENOPATHY	-	-	-
OTHERS	10	2	12
GRAND TOTAL	50	50	100

Graph 8A **Graph 8a**



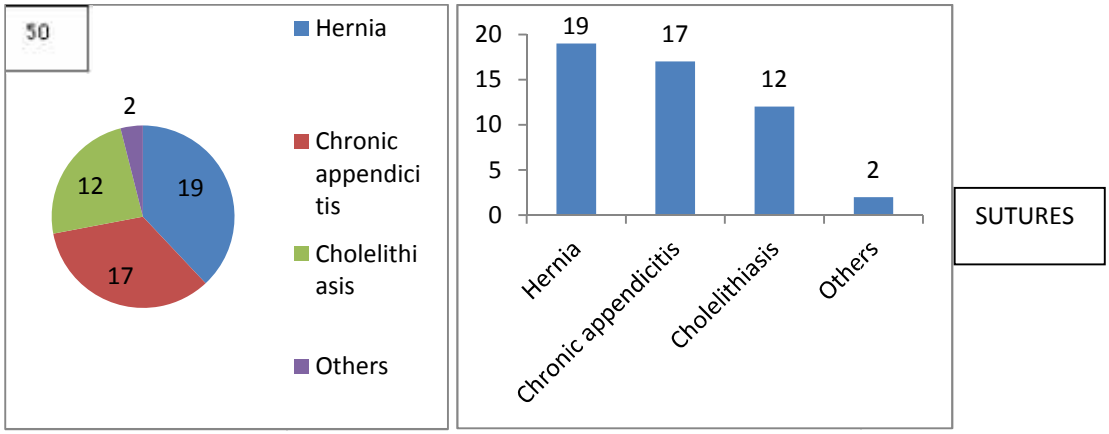
Graph 8A and 8a shows the final diagnosis in the study population.The graph shows majority of the patients had hernia(34%) and chronic appendicitis(33%). 21% of patients had cholelithiasis for which cholecystectomy was done.12% of the patients were diagnosed to have other disorders.

Graph 8B **Graph 8b**



Graph 8B and 8b shows the final diagnosis in the staples group.The graph shows majority of the patients had chronic appendicitis(17 out of 50) and hernia(14 out of 50). 9 patients had cholelithiasis for which cholecystectomy was done.10 patients were diagnosed to have other disorders mentioned above.

Graph 8C **Graph 8c**

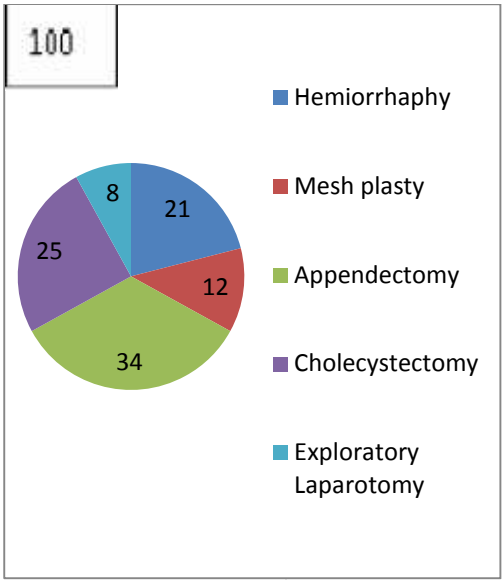


Graph 8C and 8c shows the final diagnosis in the conventional sutures group.The graph shows majority of the patients had hernia(19 out of 50) and chronic appendicitis(17 out of 50). 12 patients had cholelithiasis for which cholecystectomy was done.2 patients were diagnosed to have other disorders mentioned above.

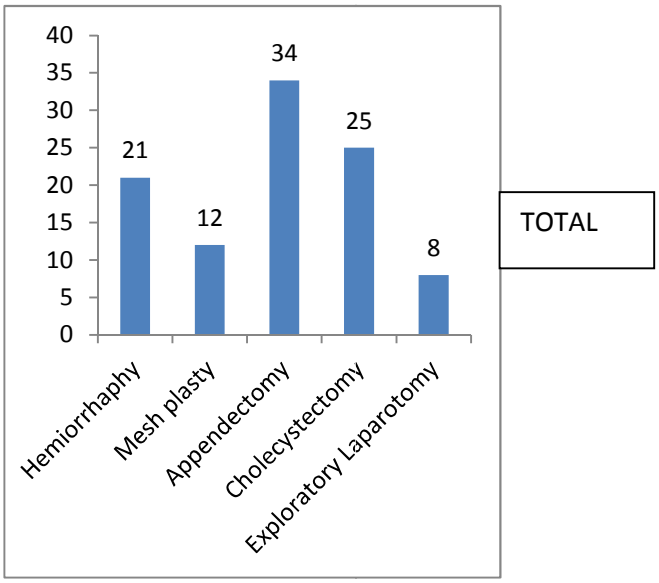
TABLE 12:PROCEDURE

PROCEDURE	STAPELS	CONVENTIONAL METHOD	TOTAL
HERNIORRHAPHY	8	13	21
MESH PLASTY	6	6	12
APPENDECECTOMY	17	17	34
CHOLECYSTECTOMY	13	12	25
EXPLORATORY LAPAROTOMY	6	2	8
GRAND TOTAL	50	50	100

Graph 9A

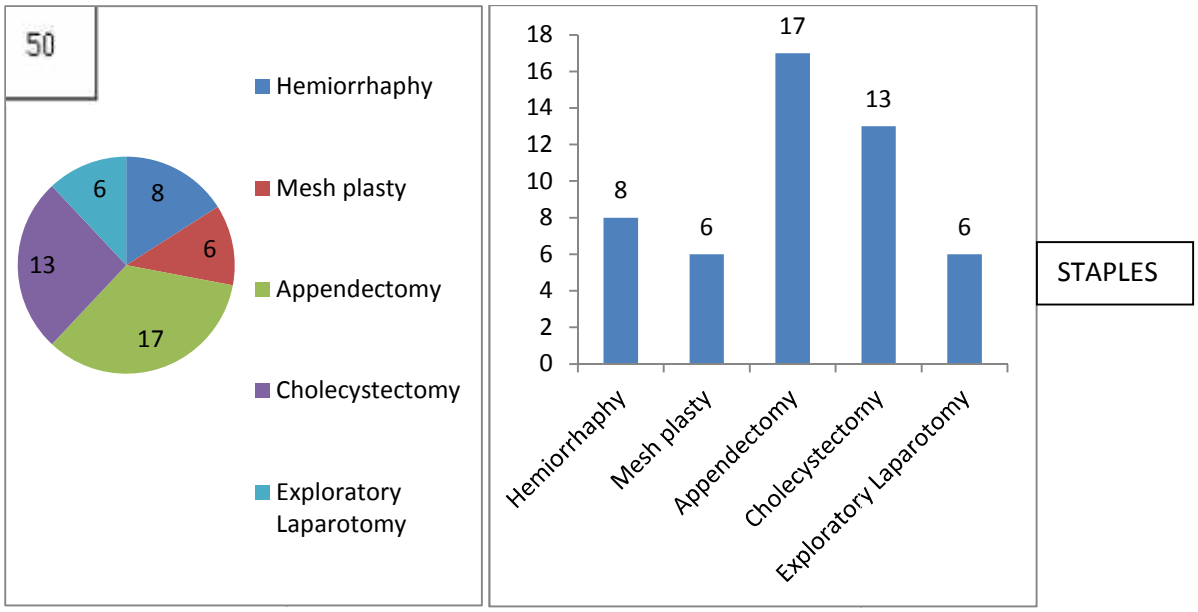


Graph 9a



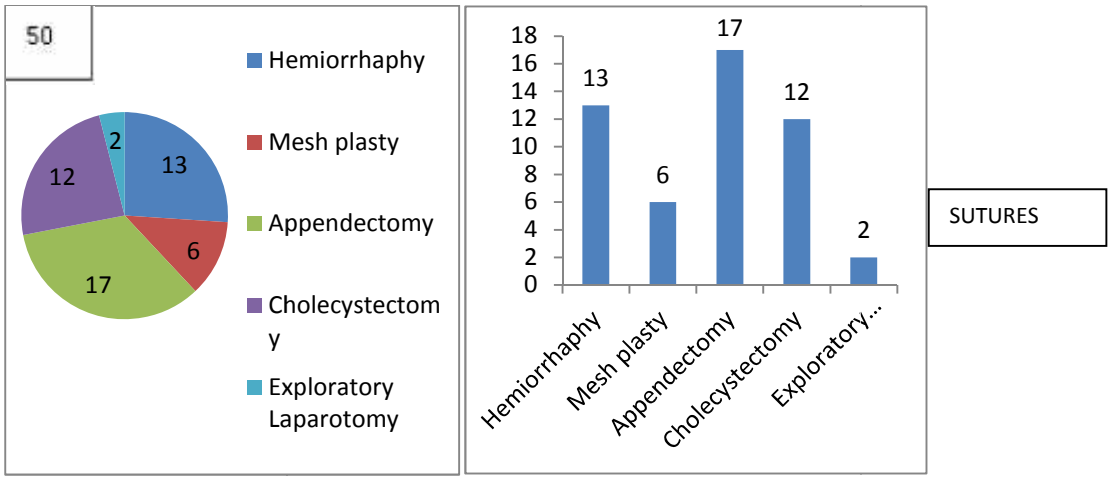
Graph 9A and 9a shows the procedure conducted on the study population.The graphs show that major patients are diagnosed to have chronic appendicitis and are operated for the same i.e appendecectomy(34%) and next to it are the group of patients diagnosed to have cholelithiasis and are subjected to cholecystectomy(25%).21% underwent herniorrhaphy and 12% underwent mesh plasty and 8% underwent exploratory laparotomy.

Graph 9B **Graph 9b**



Graph 9B and 9b shows the procedures conducted on staples group.17 out of 50 underwent appendecectomy and 13 out of 50 underwent cholecyctectomy.8 patients underwent herniorrhaphy and 6 patients each underwent mesh plasty and exploratory laparotomy.

Graph 9C **Graph 9c**



Graph 9C and 9c shows the procedures conducted on conventional sutures group.17 out of 50 underwent appendecectomy and 13 out of 50 underwent herniorrhaphy.12 patients underwent cholecystectomy and 6 patients underwent mesh plasty and 2 patients underwent exploratory laparotomy.

TABLE 13: WOUND COMPLICATIONS

STAPLES GROUP

3 patients had post operative wound inflammation,out of which 2 patients developed wound infection in the form of purulent discharge on 6th post operative day.1 patient went on to develop wound gape.

CONVENTIONAL SUTURE GROUP

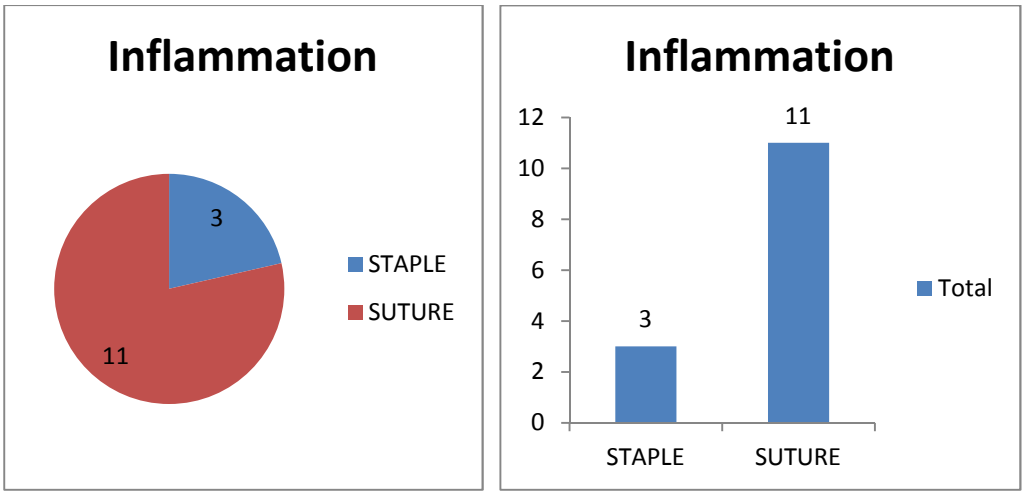
11 patients developed wound inflammation out of which 5 patients developed wound infection and 3 patients had gaping of wound. P value calculated using Mann-Whitney test.

P value was 0.0026 which was very significant.

COMPLICATIONS	STAPLES	SUTURES	TOTAL
Inflammation	3	11	14
Infection	2	5	7
Gape	1	3	4

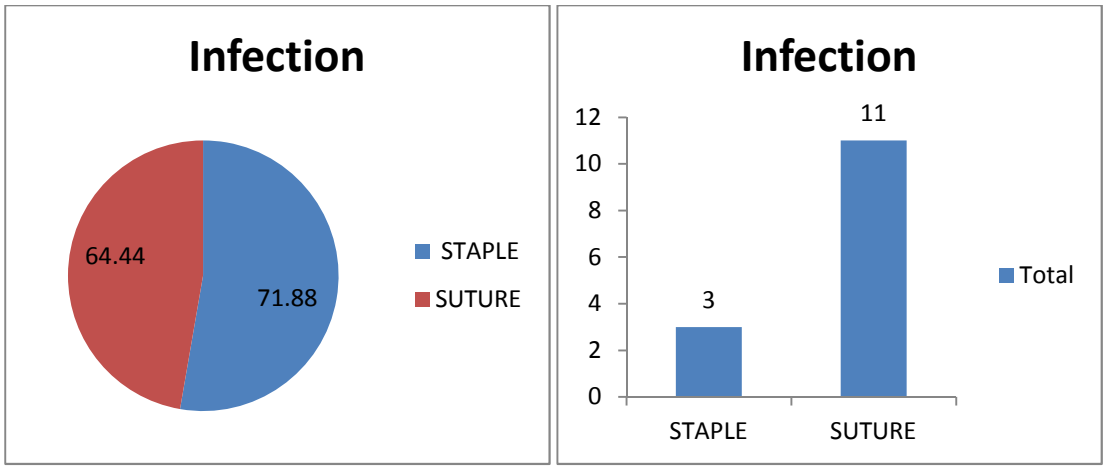
P=0.0026 (V S)

Graph 10A **Graph 10A**



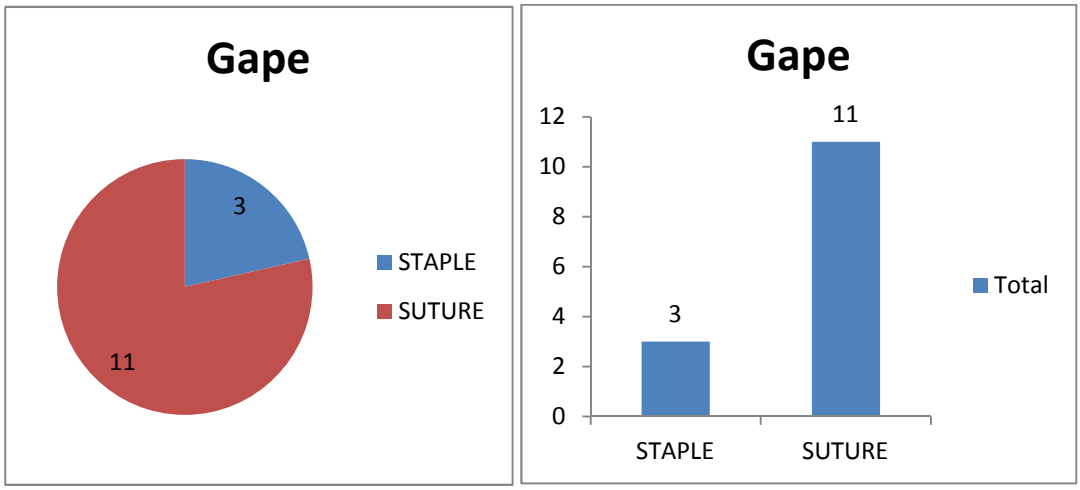
Graph 10A and 10Ab : Showing Inflammation In Study Population

Graph 10B **Graph 10b**



Graph 10B and 10b: Showing Infection In Study Population

Graph 10C **Graph 10c**



Graph 10C and 10c : Showing Gape In Study Population

TABLE 14:COSMETIC EVALUATION

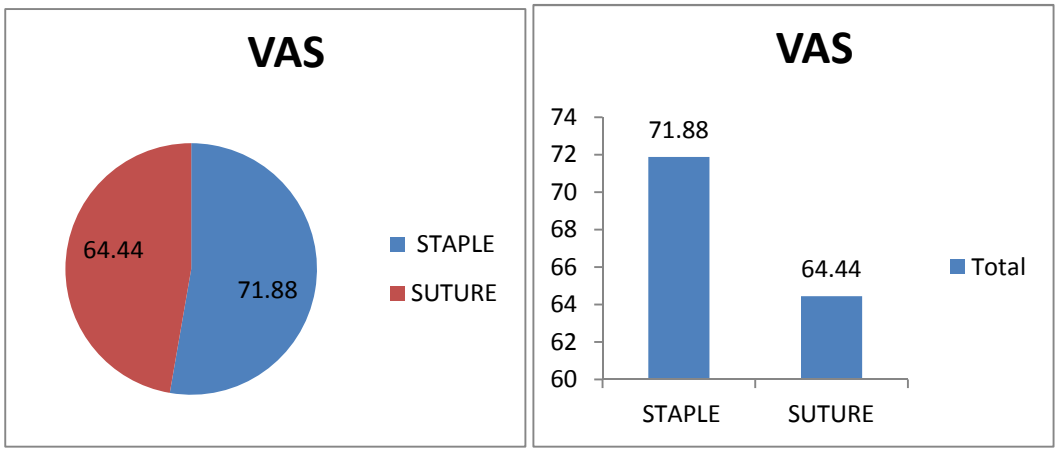
Patients were followed up after discharge at 8th to 10th post operative day for removal of staples. Cosmetic evaluation was done at 1 month follow up. No patients were lost to follow up.

Average VAS of patients in staple group at the end of one month was 71.88(±5.50) while the average for suture group was 64.44(±6.17). P value calculated using Student's Unpaired 'T' test.

P value was <0.0001 which was highly significant.

COSMETIC OUTCOME	STAPLES	SUTURES	P VALUE
VAS	71.88	64.44	<0.001(H S)
SD	5.50	6.17	

Graph 11A **Graph** 11a



Graph 11A and 11a : Showing cosmesis In Study Population

DISCUSSION

Wound closure is as important as any other action performed by the surgeon. And apart from the need for producing a healthy and strong scar, it is the surgeon's responsibility to ensure its aesthetically pleasing physical appearance. Skin staples are an alternative to regular sutures in offering this advantage.

Sutures are used to facilitate the process of wound healing by

1) Closing dead space within wound

2) Supporting wounds until their tensile strength is increased

3) Approximating skin edges.

Sutures initiate a foreign body response (i.e tissue reaction). The initial tissue reaction is attributed to the injury inflicted by the passage of suture and needle and reaction to the suture material itself. The reaction of living tissue to injury or foreign bodies is called inflammation. The inflammatory response usually peaks between 2 to 7 days after implantation. The longer a suture mass stays in the human body, the more likely it is to produce undesirable tissue reactions.

For the surgeon, a scar may be the only trademark of the surgical procedure performed, as FitzGibbon has stated, "By your scars you will be judged."

(FitzGibbon, 1968).

There are many factors that affect the cosmetic outcome of scars.

The following factors are important in comparing the various methods that are available.

- Incidence of complications (for example, infection)
- Cosmetic results

- Patient comfort and acceptability
- Ease of post-operative wound care (dressing, wound inspection), ease of dealing with complications should they occur, and ease of removal
- Time taken to close the wound

Although sutures are inexpensive, they typically take longer to place, and there is also risk of needle stick injury to the surgeon and operating staff.

The problem associated with suturing of the wound is

- Needle stick injuries to the surgeon
- Stitch abscess may develop.
- Injury to the blood vessels in the skin resulting in haematoma.

In the present study,100 patients underwent abdominal wound closure. Out of the 100, 50 underwent closure of skin with skin staples while the remaining 50 patients had their skin closed with non-absorbable sutures. There was no significant difference between the results of application of staplers or sutures at various anatomic regions. The commonest region of the surgical wounds in this study was Mcburney's 17 in each group and inguinal, 14 in staples and 19 in suture group, The regional distribution of surgical wounds in the staples group was mid line 10, subcostal 9and among the suture group midline 02 and subcostal 12.

The comparison of these two groups were done in relation to :

1) Post operative complications
2) Cosmetic outcome

WOUND COMPLICATIONS :

The primary objective of our study was to measure the incidence of post- operative wound infection.

Wound complications included :

- Inflammation
- Infection
- Wound gape

Inflammation was defined as the presence of redness and tenderness at the site of incision. In our study, 11 patients had wound inflammation in the suture group as compared to 3 in stapled group. The difference was found to be statistically very significant (p value =0.0026)

Infection of the wound is the presence of serosanguinous discharge or frank pus. It was present in 2 patients of the stapled group and 5 patients of the suture group. Wound gape was seen in 1 patient of the stapled group and 3 of the vertical mattress sutured group which was found to be significant.

Patients with wound infection had their discharge sent for culture & sensitivity and antibiotics were instituted as per the report. Secondary suturing was done in 2 patients of the suture group. In the other 2 patients, 1 each in staple and suture groups, the wounds healed with regular dressings. All of the patients were evaluated 1month after discharge.

There is a uniform agreement that skin wounds closed by staples exhibit a superior

resistance to infection than skin wounds contaminated by the least reactive suture ·

The superior resistance of stapled wounds to infection as compared with the resistance of sutured wounds was confirmed by the experimental study of Stillman and colleagues. In contaminated wounds in mice, stapled woun-ds displayed a lower incidence of infection than wounds approximated by either percutaneous sutures (4-0 silk, 4-0 monofilament nylon, and 4-0 polyglycolic acid suture) or subcuticular sutures (4-0 polyglycolic).

No difference was found with regard to wound infection in a randomised trial conducted by Eldrup et al when they compared stapler with conventional skin closure .

COSMESIS :

All the patients were followed up 1 month after discharge for evaluation of the scar. A senior surgeon who was blinded to the method of closure evaluated it.

No Patients were lost to follow up. Cosmetic outcome for the remaining patients were evaluated based on

Visual analogue score :

VAS obtained by analysis of month post-operative photographs, revealed cosmetic results between the two groups- 71.88(±5.50) for staples and 64.44(±6.17) for suture group, which was statistically highly significant (p value = <0.0001)

George TK et al and Macgregor FB et al studied wound closure in the accident and emergency department and found that stapled closure promotes wound edge eversion, formation of an incomplete loop with decreased tissue strangulation, and lack of residual cross marks

In a study comparing staples closure with nylon wound closure in head and neck surgeries by Meiring et al showed that the cosmetic result of staples is as good as if not better than that with nylon sutures

Lubowski D et al compared stapled and sutured abdominal wound closure which resulted in almost equal cosmetic scores for vertical wounds .

No significant difference in wound appearances was found in a study conducted by R Bhatia et al in closure of palmar skin following Duyputrens contracture

Medina dos Santos et al have compared the cosmetic results of staplers with noncontinuous nylon sutures[7]. They have observed that the wounds closed with staplers were cosmetically superior in 80% of the cases. There are no studies available in the literature comparing the results of application staplers to various anatomic regions. Though Ranaboldo and Rowe-Jones have compared the results of stapler with subcuticular absorbable sutures for laparotomy wounds and divided them into lower and upper abdominal regions, no mention was made by them regarding the appearance of the scar at various sites[6]. There was no significant benefit of staplers over subcuticular sutures in their study.

In the present study, the time taken to complete wound closure with the use of staplers as compared to sutures was not done.

In the study by Ranaboldo et al, the rate of wound closure was 8 seconds/cm with stapler and 12.7 seconds/cm with sutures[6]

Kanagaye observed that staplers were six times faster than standard sutures[4].

Eldrup et al analyzed 137 patients and concluded that mechanical sutures took one third of the time taken by conventional sutures[5].

Meiring et al have recorded that there was 80% time saving, whereas Harvey and Logan have reported 66.6% time saving with the use of staplers[8.9].

Medina dos Santos et al found in a prospective trial that the mean skin closure time with staple was 5 minutes and 25 minutes with nylon suture[7].

In a study done by J. H. Wolterbeek et al, they compared various methods of skin closure in infrainguinal bypass surgeries and came to a conclusion that time needed for wound closure is significantly reduced using metallic staples.

Ritchie AJ et al carried out a prospective double blind randomised study comparing staples versus sutures in the closure of scalp wound and found that stapling was significantly faster and less painful[80]

COST FACTOR:

The cost of staplers used in this study PROXIMATE PLUS MD (Ethicon Endo-Surgery) is Rs 695 per stapler and reuse is not recommended even after resterilization. Ethylon sutures cost approximately Rs. 120 and are 6 times cheaper than the disposable skin stapler.

A Prospective study done by dos Santos et al concluded that even though stapled closure was faster it was found to be costlier [69]

Orlinsky et al did a cost analysis of stapling versus suturing for skin closure and concluded that stapling is less costly than suturing and that the advantage appears to increase as laceration or wound length increases[87]

LIMITATIONS :

- Sample size was small
- Long term follow up of at least 1 year is required for cosmetic evaluation, which was not possible in our study.

Skin staples have several advantages over conventional sutures. They are quick and easy to use. Cosmetically, they produce good wound eversion and have a minimal crosshatch scar. Skin staples are relatively inert and can be left in situ for a longer period of time without any complications and in addition, patient can take a bath in the early postoperative period[22].

To summarize, considerable alteration has taken place from the conventional skin suture technique and switch over to the new era of cosmesis, in the forum of skin stapling to achieve a near virgin scar less skin.

CONCLUSION

Several methods of skin closure are available to close the skin incisions in place of sutures like staples, clips, steristrips and glue adhesives.

Wound infection is a great hazard in abdominal skin closure as it can lead to disastrous complications.

Cosmesis is essential and important aspect in this day of modern surgical practice. A cosmetic scar gives satisfaction to the patient and also to the surgeon.

Preventing wound infection is necessary as it may lead not only to an ugly scar but also occurrence and recurrence of hernia.

In our study, comparision of abdominal skin closure with staples and vertical mattress sutures was done. We found that:

- Incidence of post operative wound infection was less with skin staples.
- Skin staples provided better cosmesis than the vertical mattress skin closure.

Hence, we conclude that the use of skin staples in low tension incision is easy, associated with low incidence of wound complications, provides good cosmetic outcome and also takes considerably less time for skin closure and thus recommend its use more frequently especially for closure of long and multiple incisions.

SUMMARY

100 cases of abdominal skin closure were studied to compare the result of stainless steel skin staples and conventional vertical mattress sutures using Ethylon as closure techniques.

Equal number of 50 cases were randomly selected and divided in both groups..

Patients' aged more than 40 years formed the maximum number of this study(59%).

Patients with appendicitis (34%) were predominant.

- The wound complications of each group was as follows,

11 Patients had wound inflammation in the suture group as compared to 3 patients in stapled group.

Infection was present in 2 patients of the stapled group and 5 patients of the suture group. Wound gape was seen in 1 patient of the stapled group and 3 patients of the Ethylon-sutured group. Overall complication rate was seen in 3 patients in stapled group and 11 patients in Ethylon group P value was 0.0026. The statistical difference in wound complication was very significant.

The cosmetic outcome between the two groups were comparable, Skin staples average VAS: 71.88(±5.50) ; Suture group average VAS: 64.44(±6.17); P value=<0.0001 is highly significant.

Cost of skin staples is Rs 695 and that of Ethylon sutures is around Rs 120. The cost of skin staples per patient is more than suture, and also requires a specialized instrument for staple extraction it might be inconvenient and expensive. Thus using skin staplers for skin closure of low-tension wounds (inguinal hernia surgeries) is safe, less time consuming has good cosmetic results as compared to conventional vertical mattress using Ethylon.

BIBLIOGRAPHY

1) Doctor H.G.: Surgeons and sutures. 2nd edition, Ethicon, USA, 1999.
2) Townsend CM Jr., Beauchamp DR, Evers MB, Mattox KL. The biological basis of modern surgical practice. 16th Edition, Harcourt Asia Pvt. Ltd., Singapore. 2001, 260-268.
3) Russel R C G. Sutures in Surgery in Recent Advances in Surgery, Volume 12, Ed Russel R C G. 1-15.
4) Kanagaye JT, Vance CW, Chan L, Schonfeld N. Comparison of skin stapling devices and standard sutures for pediatric scalp lacerations: a randomized study of cost and time benefits. J Pediatr 1997; 130:813.
5) Eldrup J, Wied U, Anderson B. Randomised trial comparing Proximate stapler with conventional skin closure. Acta Chirurg Scand 1981; 147:501-502.
6) Ranaboldo CJ, Rowe-Jones DC. Closure of laporatomy wounds: skin staples versus sutures. Br.J.Surg. 1992; 79:1172-1173.
7) Medina dos Santos LR, Freitas CAF, Hojaji FC et al. Prospective study using skin staplers in head and neck surgery. AM J Surg. 1995; 170-451-452.
8) Meiring L, Cilliers K, Barry R, Nel CJC. A comparison of a disposable skin stapler and nylon sutures for wound closure. S.Afr. Med. J 1982; 62:371-372.
9) Harvey CF , Logan J. A prospective trial of skin staples and sutures in skin closure. Ir J Med Sci. 1986; 155:194-196.
10) Orlinsky M, Goldberg RM, Chan L, Puertos A, Slager HL. Cost analysis of stapler versus suturing for skin closure. Am J Emerg Med 1995; 13:77-81.
11) Corson JD, Williamson RCN. Surgery. Mosby London. 2000. Cherry GW, Hughes MA, Ferguson MWJ, Leaper DJ. Wound healing. In Oxford Text Book of Surgery, 2nd Edition. Morris PJ, Wood WC (Eds.) Oxford University Press, Oxford. 131-139.

12) Russel R.C.G. Noraman WG Clips bulstrode Arnold London. 2000, Bailey & Love's short practice of surgery 23rd edition. Arnold London page 31-39.

13) Gillbert HW, Everett WG Clips or sutures for herniorrhaphy wounds. Br J Clin Pract 1990; Aug; 44(8) : 306-308.

14) Edlich RF, Becker DG, Thacker JG, et al scientific basis for selecting staple and tape skin closures. Clin Plast Surg 1990 Jul;17(3): 571-578.

15) Brickman KR, Lambert RW. Evaluation of skin stapling for wound closure in the emergency department, Ann Emerg Med 1989 Oct;18(10): 1122-1125.

16) Stockley I, Elson RA. Skin closure using staples and nylon sutures: a comparison of results, Ann R Coll Surg Engl 1987 Mar;69(2): 76-78.

17) Swanson NA, Tromovitch TA. Suture materials, 1980s : Properties, uses, and abuses, Int J Dermatol 1982 Sep ; 21(7) : 373-378.

18) Wilton Van Winkle, Jr. M.D. and Thomas N. Salthouse Biological Response to Sutures and Principles of Suture Selection, Post Graduate Surgery, Lectures.

19) Burke JF, Infection, in Hunt TK, Dunphy JE (eds): Fundamentals of wound Management, New York, Appleton – Century – Crofts, 1979, pp 170-241.

20) Moutas GL, Yeadon A: Does the choice of suture material affect the incidence of wound infection? Br J Surg 1975; 62:952-955.

21) Johnson A, Rodeheaver GT, Durand LS, et al: Automatic disposable stapling devices for wound closure. Ann Emerg Med 1981; 10:631-635.

22) Stillman RM, Bella FJ, Seligman SJ, Skin Wound Closure: The effect of various wound closure methods on susceptibility to infection. Arch Surgery, 1980; 115:674-675.

23) Van Winkle W Jr; Hastings JC: Consideration in the choice of suture material for various tissues. Surg Gynecol Obstet 1972; 113-126.

24) Huskisson EC. Measurement of pain, Lancet 1974;ii: 112731.

25) Coupland RM. Sutures versus staples in skin flap operations. Ann R Coll Surg Engl 1986: 68-2-4.

26) Gatt D. Quick CRE, Owen – Smith MS. Staples for wound closure: a controlled trial. Ann R Coll Surg Eng 1982; 67:318-20.

27) Rintou R.F., Waston ACH Farqua Harson Text Book of Operative Surgery. Churchill Living Stone page 1-12.

28) Chummy S. Sinnatamby, Lasts Anatomy, Regional and Applied 10th Edition, Churchill Living Stone page 1-3.

29) Stockley I. Elson RA. Skin Closure using staples and nylon Sutures: a comparison of results. Ann R Coll Surg Engl 1987:69:76-8.

30) Johnson A, Rodeheaver GT, Durand LS, Edgerton MT, Edition RF. Automatic disposable stapling devices for wound closure. Ann Emerg Med 1981; 10:631

31) Bennett RG. Selection of wound closure materials. J Ann Acad Dermatol 1988:18:619-37.

PROFORMA

Title:" Staple versus conventional suture for abdominal skin wound closure- a randomised control trial"

ID No.

S	V	C	S			

Date of admission_____
Date of interview_____
Date of discharge_____

IP No.

1. Name:_____
   _____
   _____

2. Age: 1: <20 years 2: 20-40 years 3: >40 years

3. Sex: 1-Male 2-Female

4. Address: 1-Belgaum 2-Outside Belgaum

5. Occupation: 1-Unemplyoed
   2-Unskilled
   3-Semi-skilled
   4-Skilled
   5-Professional

6. Education: 1-Illiterate
   2-Primary (1st-7th std)
   3-High school (8th -10th std)
   4-Intermediate
   5-Degree and above

7. Socio-economic status:
   1-Low 2-Middle 3-High

Screening

8. H/o Diabetes: 1-Yes 2-No
9. If answer to 8 is yes, current status: 1-Under control 2-Uncontrolled
   3-Not applicable
10. On medication for diabetes: 1-Yes 2-No 3-Not applicable

11. Retroviral illness (HIV I and II): 1-Positive 2-Negative

12. H/o Hypertension? 1-Yes 2-No
13. If Yes to Q12, current status: 1-Controlled 2-Uncontrolled
3-Not applicable

14. H/o recent intake of steroids : 1-Yes 2-No

15. If answer to 14 is yes, duration of intake:

1. less than 6 months 2. 6 to12 months 3. >12 months

4. Not applicable

16. H/o serious systemic illness: 1-Yes 2-No

17. If answer to 16 is yes, which system involvement:

1-GIT 2-Renal and genitourinary 3-Respiratory 4-Cardiac
5-CNS 6-Immune system related 7-Others 8-Not applicable

18. Level of hemoglobin: 1: Less than 10gm% 2: 10 gm% 3: >10gm%

19. Applicant willing to give consent? 1-Yes 2-No

20. Final result
1-Ineligible 2-Eligible but refused 3-Eligible and participating

21. Chief complaint: 1. Abdominal pain 2. Vomiting 3. Sensation of mass/dragging sensation4. Swelling in one abdominal quadrants 5. Loose stools 6. Fever 7. Others 8. More than 1 complaint

22. Duration of complaint: 1: <1 week 2: 1-4 weeks 3: >4 weeks

23. Received any treatment elsewhere for same complaint(s):
1-Yes 2-No

24 If yes to Q.23, Surgical or medical treatment? 1-Surgical 2-Medical

25. Outcome of treatment? 1-Not improved 2-Improved
3-Improved with recurrence of symptoms
4-Not applicable

26. Final diagnosis at current admission: 1-Hernia 2-Chronic appendicitis 3-Cholelithiasis

4-Lymph node 5. Others

27. Surgery planned: 1-Herniorapy 2-Meshplasty 3-Appendicectomy
4-Cholecystectomy 5-Exploratory Laparotomy
6-Others ☐

28. Method of wound closure A or B? 1-A 2-B ☐

29. Score on Day 3: (0-5) ☐

30. Score on day 7: (0-5) ☐

31. Change in score between day 3 and 7: (-5 to +5) ☐

32. Effective reduction: 1. <50% 2. 50% or more
(Refer to observation findings for details of effective reduction) ☐

33. Purulent/serosanguinous discharge from day 3 to day 7:
(Indicating infection) ☐
1-Present 2-Absent

34. If yes to Q33, overall discharge scoring: 1. <5 2. 5 or more 3. Not applicable
(Refer to observation findings for details of scoring for discharge) ☐

Observation findings

	Post operative day				
Score	3	4	5	6	7
0					
1					
2					
3					
4					
5					

Change in score between day 3 and day 7 (range -5 to +5): _____

Key:
0= No features of inflammation
1=Redness
2=Redness + Edema
3=Redness + Edema + Tenderness
4=Above features + local rise of temperature
5=Above features + swelling

Effective reduction in score : 1. <50% 2. 5% or more

	Post operative day				
Score	3	4	5	6	7
0					
1					
2					

0 = No discharge
1 = 0< (quantity of discharge) <5 ml
2 = 5 ml or more

Total score at end of day 7 (range from 0-10)	
Overall score rating: 1. <5 2. 5 or more	

Cosmetic Evaluation (At 1 month)

- Visual Analogue Scale (VAS) – / 100

Summary

- Type of closure
- Time taken for closure
- Complications
- Cosmesis

ANNEXURE III – PHOTOGRAPHS

Photograph 1: Showing Stapler Device

Photograph 2: Showing Staple Extractor

Photograph 3: Showing Ethylon Sealed Pack

Photograph 4: Showing Ethylon Suture

METHOD OF WOUND CLOSURE USING STAPLES

Closure Of The Roof Top Incision With Staples

Photograph 5a: Approximation Of Edges With Forceps

Photograph 5b: Showing Application Of Stapler

Photograph 5c: Showing Application Of Staples

Photograph 5d: Showing Rooftop Incision After Staple Application

METHOD OF WOUND CLOSURE USING ETHYLON

Photograph 6a: Showing Midline Incision Closure With Ethylon

Photograph 6b: After Closure With Vertical Mattress Using Ethylon

POST OPERATIVE FOLLOW UP FOR STAPLES METHOD OF CLOSURE

Photograph 7 : Day 3

Photograph 8: Day 7

Photograph 9: Day 10

POSTOPERATIVE FOLLOW UP OF VERTICAL MATTRESS CLOSURE

Photograph 10 : Day 3

Photograph 11 : Day 7 Showing Serousanguinous Discharge

Photograph 12 : Day 10 Showing Gaping

CLOSURE OF VARIOUS INCISIONS WITH STAPLES

Photograph 13 : Appendicectomy

Photograph 14 : Hernia

Photograph 15 : Midline

Photograph 16 : Kocher's Incision

CLOSURE OF VARIOUS INCISIONS WITH CONVENTIONAL MATTRESS SUTURES

Photograph 17: Showing Appendectomy

Photograph 18: Hernia

Photograph 19: Midline Incision

Photograph 20: Showing Kocher's Incision

SVCS no.	IP no.	Age	Sex	Address	Occcupation	Education	Socio-Economic Status	Diagnosis	Surgery	Method of wound closure	D-3	D-7	Change	VAS
1	400506	2	1	2	4	4	1	2	3	2	0	2	2	64
2	400537	1	1	1	4	4	1	2	3	2	0	0	0	70
3	405046	2	1	2	5	5	2	1	2	2	0	2	2	63
4	479206	3	2	2	4	5	2	3	4	2	0	1	1	69
5	408049	3	1	2	4	4	2	2	3	2	0	2	2	64
6	408975	2	1	2	5	5	2	3	4	2	0	3	3	59
7	409876	3	1	2	4	4	2	1	2	2	0	0	0	72
8	413847	3	1	2	4	4	1	1	2	2	0	0	0	71
9	412950	3	2	1	3	4	2	2	3	2	0	0	0	70
10	412902	3	1	2	4	3	1	1	2	2	0	0	0	71
11	409835	2	1	1	4	5	2	3	4	2	0	0	0	69
12	412699	3	1	2	4	2	1	1	2	2	0	1	1	64
13	401462	1	2	1	1	2	1	2	3	2	0	0	0	71
14	401125	3	1	1	3	5	2	3	4	2	0	2	2	59
15	413755	3	2	1	2	1	1	1	2	2	0	1	1	61
16	414122	3	1	1	4	5	2	1	1	2	0	1	1	62
17	415117	3	1	1	3	3	1	3	4	2	0	3	3	51
18	416960	2	1	2	5	5	2	3	4	2	0	2	2	61
19	417028	1	1	1	4	3	2	2	3	2	0	0	0	72
20	417775	2	2	1	3	4	2	2	3	2	0	0	0	71
21	418072	2	1	2	4	5	2	3	4	2	3	4	1	61
22	418571	2	2	1	4	4	2	2	3	2	0	0	0	69
23	420178	2	1	2	4	5	2	2	3	2	0	0	0	70
24	420261	3	1	2	2	2	1	1	1	2	0	5	5	50
25	420129	2	1	1	4	5	2	2	3	2	0	3	3	57
26	420181	2	1	2	3	4	2	2	3	2	0	3	3	60
27	420203	3	1	2	4	5	2	2	3	2	0	3	3	61
28	420150	2	1	2	4	4	2	1	1	2	0	3	3	65
29	421214	1	1	2	2	3	1	2	3	2	0	0	0	69
30	421241	2	1	1	4	5	2	1	1	2	0	3	3	58
31	420173	3	1	2	4	4	2	1	1	2	0	0	0	70
32	423514	3	1	2	4	4	2	1	1	2	0	3	3	50
33	423246	1	1	2	1	5	2	2	3	2	0	0	0	71
34	422305	3	1	1	4	5	2	3	4	2	1	4	3	53
35	422454	1	1	1	1	4	1	2	3	2	0	0	0	69
36	423367	3	1	1	5	5	2	2	3	2	0	0	0	71
37	423301	3	1	1	5	5	3	3	4	2	0	0	0	73
38	424437	2	1	2	4	5	2	3	4	2	1	4	3	57
39	423000	1	1	1	1	2	1	2	3	2	0	0	0	68
40	475941	3	1	1	4	4	2	5	5	2	2	4	2	61

41	477064	3	2	2	1	3	2	3	4	2	1	2	2	63
42	478960	3	2	1	2	2	1	1	1	2	0	1	1	66
43	473056	3	1	2	3	4	1	1	1	2	0	0	0	71
44	478076	2	1	1	5	5	3	1	1	2	0	1	1	62
45	473202	3	1	1	5	5	2	1	1	2	0	0	0	67
46	474040	3	2	2	4	4	2	1	1	2	0	1	1	66
47	474536	3	2	2	5	5	3	3	4	2	2	4	2	60
48	474685	3	2	1	3	3	1	1	1	2	0	0	0	59
49	475624	3	2	1	5	5	3	5	5	2	2	2	0	61
50	471012	3	1	1	4	5	2	1	1	2	0	0	0	70
51	394462	2	1	2	5	5	3	5	5	1	0	0	0	67
52	400032	3	1	1	5	5	2	5	5	1	0	1	1	65
53	405446	3	1	2	4	5	2	3	4	1	0	0	0	71
54	405984	3	2	1	3	3	2	3	4	1	0	1	1	69
55	407782	3	2	2	3	3	2	3	4	1	0	0	0	74
56	407914	2	1	2	4	4	3	2	3	1	0	0	0	78
57	407871	3	1	2	5	5	3	3	4	1	0	0	0	79
58	407994	3	1	2	4	5	2	1	2	1	0	0	0	82
59	409012	2	1	2	4	5	3	1	2	1	0	0	0	80
60	408975	2	1	2	4	5	2	3	4	1	0	0	0	79
61	409802	3	1	2	5	5	2	3	4	1	0	0	0	75
62	401559	3	1	1	4	5	3	3	5	1	0	0	0	73
63	413978	1	1	2	3	3	2	2	3	1	0	0	0	72
64	413948	2	2	2	4	5	2	3	4	1	0	1	1	71
65	409844	3	1	2	4	5	2	1	2	1	0	0	0	73
66	414508	2	1	2	5	5	2	2	3	1	0	0	0	72
67	414602	3	1	1	5	5	2	5	4	1	0	0	0	77
68	416113	2	1	2	5	5	2	2	3	1	0	0	0	79
69	416058	2	1	1	4	5	2	1	2	1	0	0	0	80
70	416988	3	2	2	3	3	2	2	3	1	0	0	0	75
71	416968	3	2	2	3	3	2	1	2	1	0	0	0	76
72	415831	3	1	1	4	5	2	1	2	1	0	0	0	70
73	41813	2	1	1	4	5	2	2	3	1	1	3	4	65
74	418503	2	1	2	4	5	2	2	3	1	0	0	0	69
75	420075	1	1	2	1	2	2	2	3	1	0	0	0	70
76	42126	3	1	1	5	5	3	2	3	1	0	0	0	71
77	424372	3	1	2	4	5	2	1	1	1	0	0	0	73
78	423306	1	1	2	1	3	2	2	3	1	0	0	0	69
79	424740	3	1	1	4	5	2	2	3	1	1	3	2	59
80	425079	1	1	1	1	3	2	2	3	1	0	0	0	71
81	425433	3	1	2	4	5	2	1	1	1	0	1	1	79
82	426376	3	1	2	4	5	2	1	1	1	0	0	0	77

83	426707	2	2	1	3	4	2	2	3	1	0	1	1	76
84	426674	3	2	1	4	5	2	5	4	1	0	0	0	75
85	426612	3	1	2	4	4	2	5	4	1	0	0	0	74
86	427073	3	2	1	4	5	2	5	4	1	0	1	1	73
87	426983	3	2	1	4	5	3	5	4	1	0	0	0	72
88	427159	3	2	1	4	5	2	2	3	1	1	3	2	51
89	427891	2	2	2	4	5	2	2	3	1	0	0	0	71
90	425682	3	1	2	4	5	3	1	1	1	0	0	0	70
91	442825	3	1	2	4	4	2	5	5	1	0	1	1	69
92	470987	2	2	1	4	5	3	2	3	1	0	0	0	67
93	471592	3	2	2	3	4	3	3	4	1	0	1	1	68
94	472487	2	2	2	4	5	2	2	3	1	0	0	0	69
95	472737	3	1	1	3	4	2	1	1	1	0	0	0	71
96	473431	3	2	1	4	5	2	1	1	1	0	0	0	72
97	47433	3	1	1	4	4	2	5	5	1	0	1	1	65
98	472216	3	1	1	4	5	3	5	5	1	0	0	0	71
99	474707	3	1	1	4	5	2	1	1	1	0	0	0	72
100	475900	2	2	2	4	4	2	1	1	1	0	1	1	68

KEY TO MASTER CHART

SVCS : Staples versus conventional suturing

IP no : Inpatient number

AGE – 1: >20 years

2: 20 to 40 years

3: > 40 years

SEX – 1: Male

2: Female

ADDRESS – 1: Belgaum

2: Outside Belgaum

OCCUPATION - 1: Unemplyoed

2: Unskilled

3: Semi-skilled

4: Skilled

5: Professional

EDUCATION -1: Illiterate

2: Primary (1st-7^{th} std)

3: High school (8^{th} -10^{th} std)

4: Intermediate

5: Degree and above

SOCIOECONOMIC STATUS – 1: Low

2: Middle

3: High

DIAGNOSIS – 1: Hernia

2: Appendicitis

3: Cholelithiasis

4: Lymph node

5: Others

SURGERY – 1: Hernioraphy

2: Meshplasty

3: Appendicectomy

4: Cholecystectomy

5: Exploratory Laparotomy

6: Others

METHOD OF WOUND CLOSURE – 1: Group A (Staples)

2: Group B (Suture)

D-3: Post-operative day 3

D-7: Post-operative day 7

0: No features of inflammation

1: Redness

2: Redness + Edema

3: Redness + Edema + Tenderness

4: Above features + local rise of temperature

5: Above features + swelling

Change: Difference in score between day 3 and day 7

VAS : Visual analogue score

ANNEXURE-I

CONSENT FORM

ANNEXURE-II

DATA COLLECTION INSTRUMENT

ANNEXURE-III

PHOTOGRAPHS

ANNEXURE-IV

MASTERCHART

CONSENT FOR PARTICIPATION IN RESEARCH

INFORMED CONSENT

TITLE OF THE STUDY:

"Staple versus conventional suture for abdominal skin wound closure-a 1yr randomised control trial"

PRINCIPAL INVESTIGATOR: REG. NO. BH0110004

INTRODUCTION AND PURPOSE:

PROCEDURE:

I request you to kindly participate in the study titled **"comparision of staple versus conventional suture for abdominal skin wound closure-a 1yr randomised control trial at DR.PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTRE"**

BENEFITS:

1) LOW RATE OF WOUND INFECTION
2) COSMETICALLY BETTER

RISKS: NIL

VOLUNTARY PARTICIPATION/WITHDRAWAL:

Taking part in this study is voluntary. I may choose not to take part in this study, or if I decide to take part I can later change my mind and withdraw from the study. My decision will not change the present or future health care or other services that I receive. The study doctor or the sponsor may stop my participation in this study. I will tell of any important new findings that may change my willingness to continue to take part. If I choose not to take part in the study I will receive the standard treatment for patients with my condition.

COSTS:

NO EXTRA COST

COMPENSATION:

In the event that I become injured as a result of taking part in this study, treatment will be offered to me, No reimbursement, compensation or free medical care is given.

CONFIDENTIALITY:

All information collected about me during the course of the study will be kept confidential to the extent permitted by the law. The code numbers will identify me in this research record. Information from this study may be published but my identity will be confidential in any publication.

HOW WILL THE RESULTS OF STUDY BE USED?

Results will help the surgeons and also the patients to choose appropriate technique of skin closure which can reduce the rate of post operative wound infection and also which is cosmetically better.

QUESTION:

If any enquiries in the future or in case of research related injury illness, you may contact following person.

. **REG. NO. BH0110004**

CONSENT TO PARTICIPATE IN RESEARCH STUDY:

I voluntarily agree to take part in this study by signing on the line below. I may withdraw at any time. I am not giving up any of my legal rights by signing this form. My signature below indicated that I have read this entire consent form or it has been read to me, and has been explained to me in my vernacular language and had all my questions answered. I will be given a copy of this consent form.

Signature /Left Thumb print of the Participant or legally authorized representative.

Participant's Name : …….

Signature/ Left Thumb

impression. : …….

Name of the legally authorized representative :……

Signature/ Left Thumb

impression. : …….

Witness's Name : …….

Signature/ Left Thumb

impression.

: ……....

Investigators name and Signature : …….

Date : …….

Place : ……..