"A COMPARATIVE STUDY OF SURGICAL STAPLES AND SUBCUTICULAR SUTURES FOR SKIN CLOSURE IN CESAREAN DELIVERY."

By

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DISSERTATION SUBMITTED TO SRI DEVARAJ URS ACADEMY OF HIGHER EDUCATION AND RESEARCH, KOLAR, KARNATAKA

In partial fulfillment of the requirements for the degree of

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IN
OBSTETRICS AND GYNAECOLOGY

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DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled **"A COMPARATIVE STUDY OF SURGICAL STAPLES AND SUBCUTICULAR SUTURES FOR SKIN CLOSURE IN CESAREAN DELIVERY**. **"** is a bonafide and genuine research work carried out by me under the guidance of **Dr.MUNIKRISHNA. M**, Professor & Head, Department of Obstetrics and Gynaecology, Sri Devaraj Urs Medical College, Kolar, in partial fulfillment of University regulation for the award "**M.S. DEGREE IN OBSTETRICS AND GYNAECOLOGY**", the examination to be held in April 2017 by SDUAHER. This has not been submitted by me previously for the award of any degree or diploma from the University or any other university.

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LIST OF ABBREVIATIONS

β-TGH	-	Beta thromboglobulin
FGF	-	Fibroblast growth factor
FGF-7	-	Fibroblast growth factor-7
IL-8	-	Interleukin -8
KGF	-	Keratinocyte growth factor
MCP-1	-	Monocyte chemotactic protein -1
PDS	-	Polydioxanone
PDGF	-	Platelet-derived growth factor
PF-4	-	Platelet factor -4
POSAS	-	Patient and Observer Scar Assessment Scale
TGF-β	-	Transforming growth factor- β
VEGF	-	Vascular endothelial growth factor
GCSF	-	Granulocyte colony stimulating factor
IV	-	Intravenous
VAS	-	Visual analogue scale

ABSTRACT

Background: Cesarean delivery is one of the most common major surgical procedures in women worldwide. As the rate of cesarean deliveries increases, so do the associated complications. Wound complications occur in 2.5%–16% of cesarean deliveries. Although several factors contribute to cesarean wound complications, the optimal method of skin closure to minimize these complications is unknown

Aims and Objectives: To study the wound complications with the use of subcuticular sutures and staples. To compare the wound complications with the use of subcuticular sutures and staples.

Methodology: A Hospital based Randomized control Study was conducted during October 2014 to September 2016. A total of 228 pregnant women coming to R L Jalappa Hospital fulfilling the inclusion criteria undergoing cesarean delivery were included in the study. A detailed history and general physical, systemic, abdominal and per vaginal examination were done on admission. Patients were then grouped into two groups 114 subjects each by simple randomization table for surgical staples or subcuticular sutures for skin incision closure after obtaining informed consent. Standard steps of cesarean section with Pfannenstiel incision were followed, and the skin closure was done by either using surgical staples or subcuticular skin sutures. Postoperatively patients were followed up till four weeks and following outcomes were noted in each group of cases wound infection which includes surgical site infection requiring antibiotic, presence of hematoma, presence of seroma, skin separation 1 cm or more, re-closure of the skin incision required, readmission for wound concern. The other outcome measures were operation time, duration of skin suturing, length of hospital stay.

Results:. The baseline characteristics of the randomized groups including Age, BMI, medical co-morbidities and prior cesarean (64.9% vs. 63.2%) were similar between study groups. Out of the total 228 subjects, 45.6% and 54.4% were primigravida and multi- gravida in suture group and 41.2% and 58.8% were primigravida and multi-gravid in stapler group ($p>0.05$). Skin closure time was significantly less in stapler group as compared to suture group (1.44 min vs. 10.75 minutes; $p<0.01$). Mean pain score was significantly high in stapler group (6.83 vs. 4.82; p-<0.05) at 4^{th} post-op day. Tenderness and Induration at 4^{th} post-op day were significantly more in stapler group (43.9% vs. 19.3% and 29.8% vs. 3.5%; $p<0.05$) respectively. Complaint of cellulitis and serous discharge was also more common in stapler group ($p<0.05$). Mal-approximation of the wound was seen in 19.3% patients of stapler group compared to none in suture group ($p<0.05$). Mean hospital stay was significantly more in stapler group as compared to suture group (7.33 vs. 4.64 days; $p<0.01$)

Conclusion: The use of staples for cesarean delivery closure is associated with an increased risk of wound infection rates, pain scores, malapproximation of the wound edges and increased hospital stay compared to subcuticular suture group.

Thus we recommend the use of subcuticular sutures rather than surgical staples for skin closure after cesarean section

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INTRODUCTION

Cesarean delivery is one of the most common major surgical procedures in women worldwide. In India, 27% of all deliveries were performed by cesarean section per year, in the United States, the prevalence is 33% per year, and in China, the rate is as high as 46%.[1]

As the rate of cesarean deliveries increases, so do the associated complications. Wound complications occur in 2.5%–16% of cesarean deliveries.[2] Although several factors contribute to cesarean wound complications, the optimal method of skin closure to minimize these complications is unknown.[3] The ideal method of skin closure should be rapidly accomplished, result in minimal wound complications and postoperative pain, and produce cosmetic results that are acceptable to women.[4]

The two most common techniques used for skin closure after cesarean delivery are subcuticular skin suture and surgical staples. Until recently there has been little documentation regarding the best cesarean skin closure material.[5] It has been postulated that sutures act as a foreign body and damage tissue leading to increased infections.[6] Initial small studies regarding cesarean skin closure materials examined operative time, pain scores, cosmesis scores and patient satisfaction and yielded contradictory findings.[7,8] One randomized controlled trial of wound disruption and infection (evaluated by phone interview supplemented with record review) at 2-4 weeks as the primary outcome and suggested increased rates with staple compared with suture closure.[9] Several studies, since have compared subcuticular sutures with staples for the closure of the skin after cesarean delivery, but with differing outcome measures and follow-up times and conflicting results regarding cosmetics, pain, and infection.[10-12] The only conclusive finding is that staples significantly reduce the time of skin closure. A recent Cochrane review also concluded that there were insufficient data to recommend any technique or materials for CS wound closure.[13] Despite being the most common major obstetric operation performed annually, there is a paucity of data to guide best practices for closure of the cesarean delivery skin incision.[1]

In developing country like India where infection rates associated with pregnancy are high, due to the poor nutritional status of mothers. Most Cesarean sections in our set up are done for fetal distress, previous cesarean section, prolonged labor and cephalopelvic disproportion, but no standard method has been followed for skin closure after cesarean. Also, there is no study done in a rural setup in this regard. Hence we planned this study to compare the wound complication rates with the use of subcuticular sutures and surgical staples for skin closure after cesarean section.

AIM AND OBJECTIVES

1. To study the wound complications with the use of subcuticular sutures.
2. To study the wound complications with the use of staples.
3. To compare the wound complications with the use of subcuticular sutures and staples.

REVIEW OF LITERATURE

HISTORICAL ASPECT OF SUTURES

The history of surgical sutures is more than 2,000 years old. It is not clear when mankind learned to use strings or animal parts to ligate bleeding vessels or approximate tissues.[14]

The earliest recording of a "wound healing man" is in a cave drawing in Spain dating back some 20,000-30,000 years. This is one of the first recordings of wounds from the Stone Age. From the earliest recorded history, it is clear that the Assyrians knew about healing not just from an observational point of view but also regarding practical management.[15]

The ancient Egyptians were the first civilization to have trained physicians to treat physical ailments. Medical papyri such as Edwin Smith papyrus(circa 1600BC) and the Earls Papyrus(circa 1534 BC) provided detailed information on management of disease, including wound management with the applications of various potions and grease to help to heal(Breasted,1930; Bryan 1930).[16]

The Sushruta script also includes a description of how insects have been applied in the healing of wounds. The earliest type of clip was based on the mandibles of certain ants. It described how wounds in connection with the bowels caused so much juice that they were difficult to close.

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 Burchellii are particularly significant. Its Mandibles would close the wound, and the body of the ant would then be pinched off. Contemporary clips work as the same principles, but this method is still practiced in some South American tribes.[14]

The edges were approximated, and black ants were applied to the wound. As soon as their mandibles were closed on the two edges of the wound the ant's heads were snipped off and left in situ.[17]

The Father of Medicine Hippocrates, who lived nearly 2,500 years ago wrote several accounts on wound healing and was aware of the importance of infection about wound healing. He understood the concept of primary and secondary wound healing, using antiseptics such as wine. In only a few hours, wine can eliminate certain types of bacteria such as cholera vibrios, E Typhi, S aureus and E Coli.[15]

Celsus wrote about suture in the treatise De medicine, describing the suture of the soft tissue with the human hair. He also described small metal clips similar to Michel clips of today.[18]

Over the centuries, different materials were used that were derived from a variety of sources like metals (gold, silver, and tantalum), plant material (linen and cotton) and animal products (horsehair, silk, intestinal tissue, and tendons).

In 30 AD, the Romans described the use of suture and staples and the use of silk and catgut in 150 [AD]. Before the ending of the first millennium, Avicenna described monofilament the use of pig bristles for Suturing wounds.[19] J. Marion Sims,[20] (1813-1883) also called the father of gynecology was the first person to find the surgical cure for fistulas, His technique using silver wire sutures to repair a fistula was successful, and this was reported in 1852. Surgical and Suture techniques evolved further in the 1800s with the development of sterilization procedures. Finally, modern methods of manufacturing and classification of sutures (using United States Pharmacopeia) created uniformly sized sutures.

Catgut and silk are the natural materials that were the mainstay of suturing products, and they remain in use even today. Catgut is the oldest suture that is derived from the sheep intestine. The name derived from "kit gut" which referred to the strings of the musical instruments known as the kit. The term has evolved into catgut over the years.[21]

The first synthetic suture materials were developed in the 1950's, and further advancements have led to the creation of different forms used today.

WOUND HEALING

Biology of wound healing

Wound healing, the body's response to injury is an essential and primitive process standard to all multicellular organism wherein a principle type of cell assumes embryonic features, undergoes migration, divides and then differentiates to produce an extracellular matrix in a seemingly less than optimal or hostile environment.[22]

TYPES OF HEALING [23]

1. Primary intention

Most wounds heal by primary intention where the wound edges are brought together (opposed) and then held in place by mechanical means shortly after injury (adhesive strips, staples or sutures), provides the wound time to heal and gain enough strength to withstand stress without support. It is also the way most surgical wounds heal.

Typically such wound is created in aseptic conditions with minimal bacterial contamination and a minor amount of tissue damage. They have accurately opposed and sutured wound edges. Epithelization and contraction have little role in this type of healing.

2. Secondary Intention

Healing happens when the wound is left open because of the presence of infection, extreme trauma or skin loss, and wound edges come closer naturally using granulation and contraction.[24]

There are three main reasons why wound will undergo this form of healing - wound infection, substantial tissue damage or lack of skin edge apposition. Repair of this kind is also encountered following ulceration, abscess formation, major superficial wounds or tissue infarction. Healing by secondary intention allows the natural process to occur without surgical closure. Wound contraction is the most important factor that aids secondary healing.

3. 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.

Phases of wound healing (Figure 1 & 2)**:**

1. Lag phase/inflammatory or exudative phase

- Inflammation of wound and mobilization of the cells that will synthesize granulation tissue.
- The lag phase was so entitled not because it is a period of inactivity in wound repair, but merely because there is no significant increase in the mechanical strength of the wound.

2. Proliferative or granulation phase

- Granulation tissue is formed, collagen and mucopolysaccharides are produced by the granulation tissue which increases the mechanical strength of the wound.

3. Wound contraction (matrix formation) or remodeling phase

- Cells in the wound decrease in number, but there is extensive remodeling of wound collagen and a further increase in the mechanical strength of the wound.

Inflammation/ Exudative phase (2-5 days)[25,26]

0-48 hours post injury, bleeding is the first response. Platelet attracted in this process promote hemostasis by accelerating fibrin deposition and formation of a platelet plug. Platelet also releases cytokines, which recruit neutrophils, and include the chemokines interleukin -8(IL-8), platelet factor -4(PF-4), and beta thromboglobulin (β-TGH), as well as transforming growth factor- β(TGF-β) and platelet-derived growth factor(PDGF). Neutrophils are not required for routine repair in the absence of infection but aid in initial removal of the fibrin clot. After 24 hours, monocytes start to infiltrate the wound, largely under the influence of cytokines TGF β and PDGF and the chemokine, monocyte chemotactic protein -1(MCP-1). Monocytes have two primary roles within the wound; first to continue cleaning debris from the site of injury, and second to produce further cytokines that attract those cell types capable of laying down granulation tissue, that is, fibroblasts and endothelial cells. During this period there is also the proliferation of epithelial cells at the epidermal, dermal junction, which migrates toward the midline and forming a thin epidermal layer under the surface clot.

Proliferative or Granulation phase (2 days -3 weeks):[25,26]

This phase of healing is also typified by the gradual appearance of granulation tissue, which consists of newly developed blood vessels with surrounding fibroblasts and additional elements of the extracellular matrix, creating a pink, velvety appearance. Collagen deposition from fibroblasts is largely under the control of TGF-β whereas neovascular development is started by fibroblast growth factor(FGF) and vascular endothelial growth factor(VEGF) all factors secreted by monocytes At the end of fifth-day neovascularization is maximal with an increase of granulation tissue which begins to fill the defect.

Formation of granulation tissue

New stroma, begins to invade the wound space approximately four days after injury. A number of new capillaries endow the new stroma with its granular appearance. Fibroblasts, macrophages, and blood vessels move into the wound space at the same time. The macrophages provide a continuing source of growth factor necessary to stimulate fibroplasia and angiogenesis; the fibroblast produces the new extracellular matrix required to support cell ingrowth and blood vessels carry oxygen and nutrients necessary to maintain cell metabolism.

Growth factor specially platelet-derived growth factor and TGFβ stimulate fibroblasts to proliferate and migrate into the wound space. The structural molecules of the extracellular matrix which is formed newly are termed as the Provisional matrix, contributes the formation of granulation tissue by providing a conduit for cell migration. These molecules includes:

1. Fibrin
2. Fibronectin
3. Hyaluronic acid

The appearance of fibronectin and the appropriate receptors that bind fibronectin fibrin or both on fibroblasts appear to be the rate-limiting step in the formation of granulation tissue.[27] The fibroblasts are responsible for the synthesis, deposition, and remodeling of extracellular matrix. Conversely, the extracellular matrix can have a feedback effect on the ability of fibroblasts to remodel.

Cell movement into a cross-linked fibrin requires an active proteolytic system that can cleave a path for cell migration. A variety of fibroblast-derived enzymes including plasminogen activator and collagenases are potential candidates for this task.

After migration into wounds, fibroblast commences the synthesis of extracellular matrix. The provisional matrix is gradually replaced with a collagenous matrix. Once a significant amount of collagen matrix has been deposited the fibroblasts stop producing collagen and fibroblast abundant granulation tissue starts getting superseded by a relatively acellular scar. Dysregulation of these processes occurs in fibrotic disorders such as keloid formation.

Neovascularization

The newly formed blood vessels are necessary to maintain the newly formed granulation tissue. Angiogenesis is a complex process that relies on extracellular matrix in the wound bed as well as mitogenic stimulation and migration of endothelial cells.

Induction of angiogenesis has been attributed to molecules like TGF-β, angiogensin, angiotropin and vascular endothelial growth factor. Low oxygen tension and high lactic acid may also stimulate angiogenesis. Many of these molecules mentioned above appear to induce angiogenesis by stimulating the production of:

a. Basic fibroblast growth factor-active during first three days of repair.
b. Vascular-endothelial cell growth factor-critical during formation of granulation tissue on days through to 7.

Mechanism

The injury causes the destruction of tissue and hypoxia. Angiogenesis factors such as fibroblast growth factor are immediately released from macrophages. Proteolytic enzymes released into the connective tissue degrade extracellular matrix proteins. Fragments of these proteins recruit peripheral blood monocytes to the site of injury, where they become activated macrophages and release angiogenesis factors. These factors stimulate endothelial cells to release plasminogen activator and procollagenases, which in concert get activated and digest basement membranes. The fragmentation of the basement membrane allows endothelial cells stimulated by angiogenesis factors to migrate and form new blood vessels at the injured site. Once the wound is filled with granulation tissue angiogenesis ceases and many of the new blood vessels disintegrate as a result of apoptosis.[28]

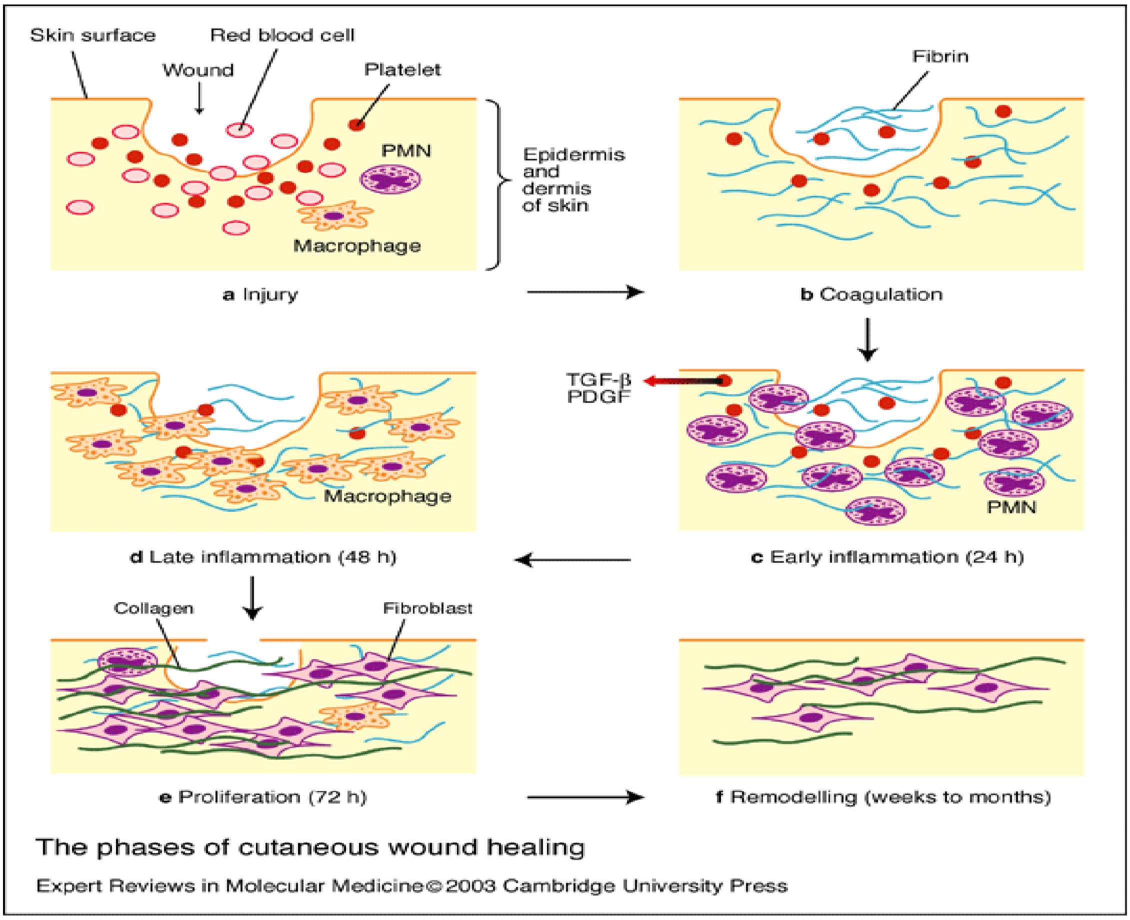
1) Epithelization[25,26]

Three-Five days post injury –epithelial proliferation (epithelialisation) continues beneath the surface clot (scab) with subsequent surface keratinization. Keratinocyte growth factor (KGF)- an alternative designation is fibroblast growth factor-7(FGF-7)- is secreted by dermal cells and has been implicated in epithelial proliferation.

2) Remodeling (3 weeks-2 years)

Two weeks post injury-granulation tissue begin to be remodeled, and its vascularity decreases as the amount of collagen increases. Maturation of the scar occurs over the next six months and is characterized by further remodeling. Collagen produced from fibroblasts is initially laid down in a vertical manner but gradually changes its orientation to align across a defect, leading to increased wound strength.

A healed skin wound will never achieve the tensile strength found previously in the undamaged skin. Following wounding, only sutures provide the initial strength of skin, and only 10% of the original tissue strength is regained one week following injury. By the third week 20%of the strength is gained during which time fibrillar collagen has accumulated relatively rapidly and has been remodeled by contraction of the wound. Thereafter the rate at which wounds gain tensile strength is slow, reflecting a much slower rate of accumulation of collagen and more extensive collagen remodeling with the formation of larger collagen bundles and number of intermolecular crosslinks are increased. Nevertheless, wounds never attain the same tensile strength as uninjured skin. At maximal strength, the scar is only 70% as strong as normal skin this process usually takes three to four months.



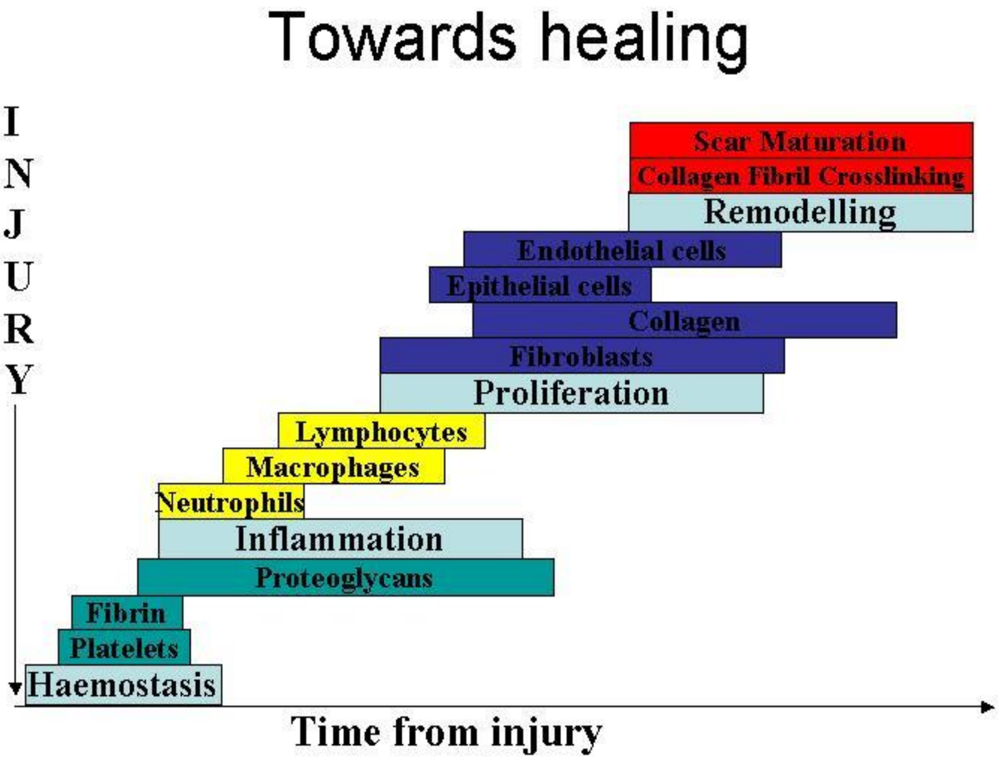


Figure 1 & 2. Phases of Wound Healing

Cells involved in wound healing (Table 1)

Cell type	**Function related to wound healing**
Platelet	-Involved in thrombus formation -Granules are rich source of inflammatory mediators including cytokines -The major initial stimulus for inflammation.
Neutrophils	-The first cell to infiltrate site of injury -Phagocytosis and intracellular killing of invading bacteria.
Monocytes/ Macrophages	-Phagocytose and destroy invading bacteria -Clear debris and necrotic tissue -Rich source of inflammatory mediators including cytokines. -Stimulate fibroblast division, collagen synthesis, and angiogenesis.

Growth Factors Involved In Wound Healing (Table 2)

Growth Factors	Major source	Functions related to wound healing
VEGF	Platelets, Neutrophiles	-Stimulates angiogenesis in granulation tissue -Stimulates formation of collateral blood vessels in peripheral vascular disease.
FGF	Fibroblasts, Endothelial cells, Smooth muscle cells, macrophages; also brain, pituitary.	-The proliferation of epithelial cells and fibroblasts; matrix deposition; wound contraction, angiogenesis.
KGF	Fibroblasts	Proliferation and migration of keratinocytes
EGF	Platelets, Macrophages, Keratinocytes	-Differentiation, proliferation migration and adhesion of keratinocytes Formation of granulation tissue
PDGF	Platelets, Fibroblasts, Macrophages, Endothelial cells	-Stimulates production of neutrophils -Enhances the function of neutrophils and monocytes -Promote proliferation of keratinocytes
GCSF	Monocytes, Fibroblasts, Lymphocytes	-Promote proliferation of keratinocytes -Stimulates production of neutrophils -Enhances function of neutrophils and monocytes.

Factors affecting wound healing:

Many factors influence surgical site healing and determine the potential for an incidence of infection. The level of bacterial burden is the most significant risk factor. The healing of closed surgical wounds depends on many factors, one of the most complex of which is technique and expertise.[29-31]

1. Surgical technique and principles

Keeping tissue trauma to a minimum promotes faster healing. A good surgical technique includes gentle handling of tissues, meticulous hemostasis, and prevention of dead space and avoidance of tissue necrosis resulting from excessive use of surgical diathermy or ligatures. Ischemic tissue wound hematoma or collection of serous discharge are exquisite media for growth of bacteria.

2. Choice of closure material

When an incision is closed, marked biochemical changes are observed in normal tissue. As far as sutures are concerned, most important are the active collagenolysis that causes it to soften in first few postoperative days. This lytic process is enhanced if the wound becomes infected. If sutures are to hold securely, they should be placed well back from the wound edge to avoid this zone. Properties of suture materials[32]

1. Tensile strength
2. Knot strength
3. Elasticity
4. Memory

Qualities of the ideal suture include the following:

1) Strong

2) Handles easily

3) Forms secure knots

4) Causes minimal tissue inflammation

5) Does not promote infection

6) Able to stretch to accommodate wound edema.

7) Can recoil to its original strength with wound contraction.

8) Inexpensive

The choice of suture materials in primary wound healing may have a significant bearing of the success of subsequent wound repair. A thorough understanding, of the composition of various layers of skin and subcutaneous tissue and a fair idea of the physical and chemical properties of currently available suture materials, are fundamental to the proper selection and placement of sutures in a skin wound.

Staples: They are reported to be easy to use and to save considerable operating time. Furthermore, the use of stapling devices abolishes the risk of needle sticking injury.[33] Staples are formed from high-quality stainless steel and are available in regular and wide sizes. Staples are relatively easy to place and shorten the closure time by 70 to 80 %. [34] The primary utility of staples is in closure of wounds under high tension on the trunk, extremities, and scalp.

Advantages of staples include decreased the risk of tissue strangulation, infection, improved wound eversion and minimal tissue reactivity. Disadvantages include the need for a second operator to evert and re-approximate skin edges during staple placement, the greater risk of cross hatch marking and the cost is usually more than that of suture material.[35]

Clinical studies have found that for scalp, neck, trunk and extremities staple produces a cosmetic result that is identical to that from sutures. Several studies have been conducted to compare the use of staples on nylon sutures on the trunk, head, and neck gives comparable cosmesis.

3. Blood Supply

A good blood supply is a basic factor in the success of wound repair. It is essential for the supply of oxygen and other nutrients required in the cellular and biochemical process of repair, and it is necessary for the removal of wound metabolites. Any factor causing increased mechanical tension in the wound will have the adverse effect on the blood supply. Extrinsic forces cause wound tension by distracting the wound edges. Intrinsic wound tension results from an increase in the volume of the wound contents following suture. It can also occur in the presence of wound infections, hematomas, and seromas.

4. Mechanical Stress

Extrinsic forces affecting wound tension can cause disruption, or it may be a consequence of the excessive movement of the wound edges.

The wound is a result of physical disruption of skin one of the major obstacles to the establishment of infection by bacterial pathogens in internal tissues. When bacteria breach this barrier infections can result.[36] The most common underlying event for all wound is trauma, which may be accidental or intentionally induced.[37]

Host defense against invading bacteria is markedly impaired by the presence of foreign body in the tissues, and it has been shown experimentally that suture increases the risk of infection in the wounds with critical bacterial contamination. Despite recent advances in surgical technique sterilization, procedure and prophylactic antimicrobial therapy, prevention of infection is of paramount importance.[38]

5. Operative Time

The duration of surgery is one factor that influences the wound infection rate. A procedure that takes longer than two hours leads to higher infection rates.[39]

6. Infection Rate

Wounds do not provide identical conditions, and therefore different wounds support diverse communities of micro-organisms.[40] Acquisition of microbial species by wounds can lead to three clearly defined outcomes:

- Contamination
- Colonization
- Infection

Contamination

All wounds can acquire microorganisms, but if suitable physical conditions and nutrition are not available for each microbial species or they are not able to successfully invade host defenses, they will not multiply or persist; the presence of microorganisms is transitory so that wound healing won't be delayed.

Colonization

Microbial species successfully grow and divide, but do not cause damage to host or initiate wound infection.

Infection

Microbial growth, multiplication, and invading host tissue lead to cellular injury and overt host immunological reactions. Local factors also increase the risk of infection.

Foreign body present in tissues markedly impairs host defense against invading bacteria. The presence of silk sutures, the number of microorganisms needed to cause an infection is reduced from 10^5-10^{12} bacteria per gram.[41]

Anantakrishnan et al.[42] found increased bacteria adherence to silk suture. GL Mouzas et al. there were more cases of infection in patients who were sutured with silk as compared to daxone and nylon. The braided nature of silk suture allows surface debris and bacterial accumulation resulting in inflammation of surrounding wound.

Clean contaminated wounds which are closed by staples have a greater resistance to infection than wounds closed with suture.[43] Staple closure is accomplished with significantly less damage to wound defenses than with the least reactive suture. The infection rate in these wounds correlated with the wound bacterial counts. Sutured wounds exhibited the highest bacterial counts followed by staples wounds.[44]

Complications of Wound Healing [21]

1. Wound dehiscence (bursting)

It occurs in the first few weeks after surgery before substantial completion of collagen cross-linking. Excessive wound tension, a sudden increase in mechanical stress, poor nutritional status (hypoproteinemia, Vit C deficiency) result in weak scars and increase the likelihood of dehiscence.

2. Hypertrophic scars and keloid

Results from post-traumatic tissue overproduction of connective tissue leading to firm raised flesh

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, Acnevulgaris, Acneconglobata, Hydradenitis suppurtiva, Pilonodal cyst and foreign body reactions.
6. Certain infections – Herpes zoster, small pox, Vaccinia.
7. Certain connective tissue diseases: Ehler – Danlos Syndrome, Rubinstein – Taybi syndrome, pachyderma periostosis, scleroderma.

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

4. Neoplasia: An enhancement in the rate of cell turnover increases the likelihood of tumor indication.

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

CLOSURE OF SKIN WOUNDS WITH SUTURES

Indications

Sutures are appropriate when the depth of the wound will lead to excess scarring if the wound edges are not adequately opposed. Typically this is true whenever the laceration extends through the dermis. Clean, uninfected lacerations on any part of the body in healthy patients may be closed primarily for up to 18 hours following the injury without a significant increase in the risk of wound infection.[45]

Contraindications

Concern about wound infection is the main reason not to close a wound primarily.[45] Wounds that have been grossly contaminated, which cannot be completely removed, infected tissue, or noncosmetic wounds that have come to medical attention late should be allowed to heal by granulation (secondary intention) after appropriate cleansing. In addition, patients with risk factors for proper wound healing (e.g., immunocompromise, peripheral arterial disease, diabetes mellitus) may warrant delayed primary closure depending upon the age of the wound (e.g., >6 hours old) or wound site (e.g., hands or feet).

WOUND PREPARATION

Wound irrigation, foreign body removal, and necrotic tissue debridement are the primary preventative measures against tissue infection.

Debridement has been considered by many to be equally or more important than irrigation in the management of the contaminated wound.

SUTURE MATERIALS

Terminology

A number of terms are used to describe the properties of various types of sutures.

- The physical configuration of a suture represents whether it is monofilamentous (Prolene or Ethilon) or multifilamentous (silk). Multifilamentous sutures come in braided and twisted types. Braided types are usually easier to handle and tie, but can harbor bacteria between strands which grows and multiplies causing higher infection rates.
- Tensile strength is defined as the amount of weight required to break a suture divided by its cross-sectional area. The specification for suture strength is the number of zeros. The higher the number of zeros (1-0 to 10-0), the smaller the size of a suture and lower the strength.
- Knot strength is the measure of the amount of force required to cause a knot to slip and is directly proportional to the coefficient of friction for a given material.
- Elasticity refers to the suture's inherent ability to hold its original form and length after being stretched. This allows the suture to expand with wound edema or to retract and maintain wound edge apposition during wound contraction. Plasticity of a material means, when stretched, does not return to original length.
- Memory is closely related to plasticity and elasticity. It relates to the inherent ability of material to go back to its former shape after being manipulated and is

often a reflection of its stiffness. A suture with a high level of memory is stiffer, harder to handle, and more susceptible to becoming untied than a suture with little memory. Polypropylene (Prolene) is a good example of a suture with a high level of memory.[46]

ABSORBABLE SUTURES

An absorbable suture is defined as one that will lose most of its tensile strength within 60 days after implantation beneath the skin surface.[47] The most commonly used today are the synthetic sutures (polyglactin 910 [Vicryl], polyglycolic acid [Dexon], polydioxanone [PDS], and polytrimethylene carbonate [Maxon]) (table 3). Catgut is still used frequently in pediatric wound closures. Fast Absorbing Gut is ideal for percutaneous facial closures and Chromic Gut can be utilized for laceration repair under splints or casts.

The ideal absorbable suture has low tissue reactivity, high tensile strength, slow absorption rates, and reliable knot security. Classically, absorbable sutures were only used for deep sutures. However, many have advocated the use of absorbable sutures for percutaneous closure of wounds in adults and children.[48-51]

- Fast-absorbing gut for percutaneous closure of some facial lacerations is reasonable, particularly if suture removal will be traumatic. Subcutaneous sutures with a synthetic absorbable suture improve wound tension providing support to the healing wound once the gut has dissolved.
- Vicryl Rapide or Chromic Gut is ideal for percutaneous closure of lacerations underneath casts or splints but is limited for facial use due to their longer absorption times.

- Chromic gut or Vicryl works well for a single or layered closure of tongue or mucosa lacerations.
- Vicryl or Monocryl is ideal for dermal closure of deep facial lacerations.
- Nail bed closure is best done with chromic gut or Vicryl.

Table 3. Absorbable Sutures

Suture material	Knot security	Wound tensile strength	Security (days)*	Tissue reactivity	Anatomic site
Fast-absorbing gut	Poor	Least	4 to 6	Most	Face
Vicryl Rapide	Good	Fair	5 to 7	Minimal	Face, scalp, under cast/splint
Surgical gut	Poor	Fair	5 to 7	Most	Face (rarely used)
Poliglecaprone 25 (Monocryl)	Good	Fair	7 to 10	Minimal	Face, consider in contaminated wounds needing deep closure
Chromic gut	Fair	Fair	10 to 14	Most	Mouth, tongue, nailbed
Polyglactin (Vicryl)	Good	Good	30	Minimal	Deep closure, nailbed, mouth
Polyglycolic acid (Dexon)	Best	Good	30	Minimal	Deep closure
Polydioxanone (PDS)	Fair	Best	45 to 60	Least	Deep closure
Polyglyconate (Maxon)	Fair	Best	45 to 60	Least	Deep closure

* Retention of 50 percent of tensile strength.

Catgut

Catgut is a natural product derived from sheep or cattle intima. Plain catgut retains significant tensile strength for only five to seven days. Chromic gut is treated with chromium salts to resist body enzymes, thus delaying absorption time. Chromic gut retains tensile strength for 10 to 14 days.[46]

The primary use of chromic gut is to close lacerations in the oral mucosa. Chromic gut is more rapidly absorbed in the oral cavity than most synthetic sutures, making it ideal for this environment. Chromic Gut is also used at our institution for skin closure on fingertip lacerations with or without concurrent nail bed injuries. It is less optimal for use in dermal (subcutaneous) and muscle layer closures because of increased tissue reactivity.[52]

The fast-absorbing gut is a newer material not treated with chromic salts. It is heat-treated to accelerate tensile strength loss and absorption. It is used primarily for epidermal suturing, where sutures are only required for five to seven days.[53] The use of this fast-absorbing suture was studied in 654 wounds during plastic surgery procedures. The suture was adequately dissolved in the majority of cases during follow-up visits at four to six days.[49] The fast-absorbing gut is ideal for suturing facial lacerations when tissue adhesives cannot be used, or suture removal will be difficult. However, care must be taken to be gentle with tying knots when using the smaller (6-0) fast-absorbing gut, due to its low tensile strength. It is reasonable to reinforce this suture with skin tapes. The use of 5-0 fast absorbing gut is reasonable for facial closures due to improved tensile strength.

Polyglactin 910 (Vicryl)

Introduced in 1974, Vicryl is a lubricated, braided synthetic material with excellent handling and smooth tie-down properties. It retains significant tensile strength for three to four weeks. Complete absorption occurs in 60 to 90 days. It has decreased tissue reactivity compared with catgut as well as improved tensile strength and knot strength.[46] Vicryl is an ideal choice for subcutaneous sutures.

Vicryl Rapide

Vicryl Rapide has properties similar to fast-absorbing gut. It is the fastest absorbing synthetic suture and is indicated only for use in superficial soft tissue approximation of the skin and mucosa. All of its tensile strength is lost by 10 to 14 days, and the suture begins to "fall off" in 7 to 10 days as the wound heals.[53-54]

Poliglecaprone 25 (Monocryl)

Monocryl is a monofilament suture that has superior pliability for easier handling and tying of knots. Its monofilament quality gives it a theoretical advantage over braided sutures for contaminated wounds requiring deep sutures. This suture is often used by plastic surgeons for facial lacerations closed with subcuticular running sutures. All of its tensile strength is lost by 21 days postimplantation.[53]

Polyglycolic acid (Dexon)

Introduced in 1970, polyglycolic acid was the first synthetic absorbable suture to become available. It is a braided polymer, is less reactive than gut sutures, and has excellent knot security. It maintains at least 50 percent of its tensile strength for 25 days.[55]

The main drawback is a high friction coefficient causing "binding and snagging" when wet. Newer forms of this suture have been developed, Dexon Plus and Dexon II, which have an added synthetic coating to improve handling properties while maintaining knot security.[46]

Polydioxanone (PDS)

PDS is a synthetic monofilament polymer marketed as having improved tensile strength compared with Vicryl. It retains the majority of its tensile strength at five to six weeks. Because it is a monofilament, it has the theoretical advantage of creating a lower potential for infection. In addition, it appears to have a lower friction coefficient and better knot security than Vicryl. A disadvantage of using PDS is that it is more difficult to use than the braided synthetics because of intrinsic stiffness. In addition, it costs about 14 percent more than either Dexon or Vicryl.[46]

Polytrimethylene carbonate (Maxon)

Maxon is a synthetic monofilament. It was developed to combine the excellent tensile strength of PDS with improved handling properties. The majority of its tensile strength is present at five to six weeks. It has minimal tissue reactivity, great first-throw holding capacity, and smoother knot tie-down than Vicryl. The only disadvantage is the approximate 7 percent increased cost compared with Vicryl or Dexon.[46]

NON-ABSORBABLE SUTURES

Knot security, tensile strength, tissue reactivity, and workability of the various nonabsorbable sutures used for skin closure are provided in the table (table 4).

Table 4. Non-Absorbable Sutures

Suture material	Knot security	Wound tensile strength	Tissue reactivity	Workability	Anatomic site
Nylon (Ethilon)	Good	Good	Minimal	Good	Skin closure anywhere
Polybutester (Novafil)	Good	Good	Minimal	Good	Skin closure anywhere
Polypropylene (Prolene)	Least	Best	Least	Fair	Skin closure anywhere. Blue dyed suture useful in dark-skinned individuals.
Silk	Best	Least	Most	Best	Rarely used

Silk

Silk is a natural product that is renowned for its ease to handle and tie. It has the lowest tensile strength of any nonabsorbable suture. It is rarely used for suturing of minor wounds because stronger synthetic materials are now available.

Nylon (Dermalon, Ethilon)

Nylon was the first synthetic suture introduced; it is popular due to its high tensile strength, excellent elastic properties, minimal tissue reactivity, and low cost.

Its main disadvantage is prominent memory that requires an increased number of knot throws (three to four) to hold a suture in place.[55]

Polypropylene (Surgilene, Prolene)

Polypropylene is a plastic, synthetic suture that has low tissue reactivity and high tensile strength similar to nylon. It is slippery and requires extra throws to secure the knot (four to five). Prolene is especially noted for its plasticity, allowing the suture to stretch to accommodate wound swelling. When wound swelling recedes, the suture will remain loose. The cost of Prolene is approximately 13 percent more than nylon.[55] Prolene can be purchased in a blue color, which can be advantageous in localizing sutures in the scalp and dark-skinned individuals.

Polybutester(Novafil)

Polybutester suture is composed of a monofilament synthetic copolymer with tensile strength and healing properties similar to nylon and polypropylene.[56] Polybutester also handles well but has greater elasticity than either nylon or polypropylene. Its use may be associated with decreased potential for suture marks because of its ability to expand if wound edema occurs.[57]

SUTURE SELECTION

In a meta-analysis of 19 trials (1748 patients) comparing the efficacy of nonabsorbable sutures with absorbable sutures for skin closure of surgical and traumatic lacerations, absorbable and nonabsorbable sutures had similar cosmetic outcomes and no significant difference for wound infection or wound dehiscence although follow-up was insufficient in several studies.[58] Thus, the type of suture material should be individualized for patients based upon clinician discretion.

NEEDLES

Choosing the proper needle can be confusing because of varying nomenclature. The two most prominent manufacturers of suture, Ethicon and Davis and Geck, use different terminology for their needles.[46] The basic anatomy of a needle remains the same, however:

- The eye is the end of the needle attached to the suture. All sutures used for acute wound repair are swaged (i.e., the needle and suture are connected as a continuous unit).
- The body of the needle is the portion that is grasped by the needle holder during the procedure. The body determines the shape of the needle and is curved for cutaneous suturing. The curvature may be one-fourth, three-eighths, one-half, or five-eighths circle. The most commonly used curvature is the three-eighths circle, requiring only minimal pronation of the wrist for large and superficial wounds. The one-half and five-eighths circles were devised for suturing in confined spaces, such as the oral cavity.
- The point of the needle extends from the extreme tip to the maximum cross section of body. For soft tissue and fascia, the taper needle, round in cross section, is ideal.
- Needle points are also available in cutting, conventional cutting, or reverse cutting form:
- **Cutting** – Cutting needles have at least two opposing cutting edges. Cutting needles are ideal for skin sutures that must pass through dense, irregular, and relatively thick dermal connective tissue.

- **Conventional cutting** – Conventional cutting needles have a third cutting edge on the inside concave curvature of the needle. This needle type may be prone to cutout of tissue because the inside cutting edge cuts toward the edges of the incision or wound.
- **Reverse cutting** – Reverse cutting needles have a third cutting edge located on the outer convex curvature of the needle, which theoretically reduces the danger of tissue cutout.[53] Reverse cutting needles should be used for thick skin like the palm and soles.

Standard skin needles (FS series, CE series) are suitable for the scalp, trunk, and extremities. Finer sutures on the face require a smaller and more sharply honed needle (P, PS, PC, and PRE series).[59]

SUTURING TECHNIQUES

Percutaneous skin closure

The simple interrupted suture is used to close most uncomplicated wounds. For proper healing, the edges of the wound must be everted. This is best accomplished using the following technique:

- The needle should penetrate the skin surface at a 90-degree angle.
- The suture loop should be at least as wide at the base as it is at the skin surface.
- The width and depth of the suture loop should be the same on both sides of the wound.
- The width and depth of the suture loop should be similar to the thickness of the dermis and will, therefore, differ from wound to wound, according to the anatomic location.

The number of sutures needed to close a wound varies depending upon the length, shape, and location of the laceration. In general, sutures are placed just far enough from each other so that no gap appears in the wound edges. A useful guideline is that the distance between sutures is equal to the bite distance from the wound edge.[54]

Dermal closure

The dermal or buried suture approximates the dermis just below the dermal-epidermal junction, which minimizes skin tension and closes dead space. Removing tension from a wound allows percutaneous sutures to be tied loosely and removed sooner, thereby improving the cosmetic result.

Absorbable suture material must be used for dermal or buried sutures. The knot should be buried away from the skin surface of the wound so that it will not interfere with epidermal healing. This can be accomplished by inverting the suture loop using the following technique:

- The needle should be inserted in the dermis and directed toward the skin surface, exiting near the dermal-epidermal junction on the same side.
- The needle should then be inserted on the opposite side of the wound near the dermal-epidermal junction, directly across from the point of exit.
- The suture loop should be completed in the dermis, directly opposite the origin of the loop, and the knot tied.

Dermal sutures do not increase the risk of infection in clean, uncontaminated lacerations.[60] However, animal studies suggest that deep sutures should be avoided in highly contaminated wounds.[61] There should be no more than three knots per suture, and the fewest number of sutures possible should be placed.

Alternative suture techniques

Running suture

A running suture is used for rapid percutaneous closure of longer wounds. It provides even distribution of tension along the length of the wound, preventing excess tightness in any one area. This technique is best reserved for wounds at low risk of infection with edges that align easily.

The closure is started with the standard method of a percutaneous simple interrupted suture, but the suture is not cut after the initial knot is tied. The needle is then used to make repeated bites, starting at the original knot by making each new bite through the skin at an angle of 45 degrees to the wound direction. The cross stays on the surface of the skin will be at an angle of 90 degrees to the wound direction. The final bite is made at an angle of 90 degrees to the wound direction to bring the suture out next to the previous bite. The last bite is left in a loose loop, which acts as a free end for tying the knot. A disadvantage to this suture is if the stitch breaks or if the physician wants to remove only a few sutures at a time.[55]

Subcuticular running suture

The subcuticular running suture is often used by plastic surgeons to close straight lacerations on the face. An absorbable suture, such as Monocryl or Vicryl, is used. The suture is anchored at one end of the laceration and then a plane is chosen in the dermis or just deep to the dermis in the superficial subcutaneous fascia. Mirror image bites are taken horizontally in this plane for the full length of the laceration. The final bite leaves a trailing loop of suture so a final knot can be tied. The wound is then reinforced with adhesive tape.[55]

Vertical mattress

The vertical mattress suture is recommended for wounds under tension and for those with edges that tend to invert.[62]

Horizontal mattress

A horizontal mattress suture can also be used to achieve wound eversion in areas of high skin tension.[55]

AFTERCARE

Dressing and bathing

Most wounds should be covered with an antibiotic ointment and a nonadhesive dressing immediately after laceration repair. Evidence for this approach is as follows:

- A trial of 426 patients with wounds that received care within 12 hours found that treatment with topical bacitracin zinc (e.g., Bacitracin®) or combination ointment containing neomycin sulfate, bacitracin zinc, and polymyxin Bsulfate (e.g., Neomycin®) significantly reduced the rates of wound infection when compared to a petroleum ointment control (5 to 6 percent versus 18 percent).[63]

The dressing should be left in place for 24 hours, after which time most wounds can be opened to air. Wounds closed with nonabsorbable (e.g., nylon, polypropylene) suture may be gently cleaned with mild soap and water or half-strength peroxide after 24 hours to prevent crusting over the suture knots. An antibiotic ointment can be applied to the wound as well, with instructions to use the cream two times per day at home until suture removal. In contrast, absorbable sutures rapidly break down when exposed to water and should be kept dry.

Patients with non-absorbable sutures (e.g., nylon, polypropylene sutures) may be allowed to shower or wash the wound with soap and water without risking increased rates of infection or disruption of the wound based on the following studies:

- A trial of 857 patients who underwent minor skin excisions found that allowing bathing more than 12 hours after suture placement without antiseptic or dressing use was not inferior to keeping the wound dry and covered (infection rate 8.4 versus 8.9 percent, respectively).[67]
- An observational study of 100 patients who underwent primary excision of skin or soft-tissue lesion or local flap closure and began washing their wounds twice daily within 24 hours of surgery found no wounds developed infection or dehiscence.[68]

Prophylactic antibiotics

Proper wound preparation is the essential measure for preventing wound infection after suturing simple lacerations.

A meta-analysis of seven trials (1701 total patients with a total of 110 wound infections) found that prophylactic antibiotics in healthy patients with wounds, other than bite wounds, were not associated with a significantly lower chance of wound infection (summary odds ratio for the risk of infection in patients receiving antibiotics: 1.2, 95% CI: 0.8-1.7).[69,70]

Follow-up visits

Most clean wounds do not need to be seen by a physician until suture removal unless signs of infection develop. Highly contaminated wounds should be viewed for follow-up in 48 to 72 hours. It is imperative that clear discharge instructions are given to every patient regarding signs of wound infection.

STAPLERS [72]

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 significant advances came from Russia after World War II in 1939. The instrument was brought to the US by Ravitch, who research and development refined the tool to the current state and the widespread 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.[73]

The development of disposable skin staplers has been made this method of wound closure an increasingly popular technique. Numerous studies have confirmed the speed and efficacy of stapling compared with suture repair.

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. Furthermore, the use of stapling devices abolishes the risk of needle sticking injury.[74] Staples are formed from high-quality stainless steel and are available in regular and wide sizes.

Composition

Staples are composed of a cross member that lays on the surface of skin perpendicular to skin, legs that are vertically placed in the skin and tips that secure the staples parallel to the cross member. Staples are relatively easy to place and shorten the closure time by 70 to 80%.[75] The primary utility of staples is in closure of wounds under high tension on the trunk, extremities, and scalp. Several studies have been conducted to compare the use of staples on nylon sutures on trunk head and neck, these revealed comparable cosmetic results.

John T Kanagaye et al. at the Children's Hospital, Los Angles, USA, following a study, showed 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.[76]

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 significant disadvantages of additional expense, as the cost was forty-seven times higher than that of the suture with Dermalon.[77]

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.[78]

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 select patients with a large number of wounds; however, the additional cost would not be justified for small sutures.[79]

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, and does not increase the incidence of complications, although the slightly higher cost was involved.[80]

Advantages & Disadvantages

They are best avoided in the face and hand. Skin staplers are quick and easy to use, but an assistant is usually required to hold the skin edges accurately with forceps or skin hooks. The application is then aligned on the wound, often there is an arrow or mark to assist, and the trigger is pulled. In one action staple is driven into the tissues and closed. For removal, a special extractor is required. Which bends the staple back with its original configuration where upon it can be withdrawn.[81] Stapler's closure also causes considerably less damage to wound defenses than closure with least reactive non-absorbable suture. Standard suturing causes significantly more necrosis than stapling in mucocutaneous flaps.[82]

CLOSURE OF SKIN WOUNDS WITH STAPLERS

Indications

For many minor wounds, suturing is the standard method of closure. Staples are an acceptable alternative for linear lacerations through the dermis that have straight, sharp edges and is located on the scalp, trunk, arms, and legs.[83-86]

Scalp lacerations are particularly suitable for closure with staples. For these injuries, randomized trials suggest that closure of scalp wounds with staples is faster and less costly than with similar infection rates, healing time, and cosmetic outcomes when compared to sutures.

Because staples can be placed more rapidly than can sutures,[87,88] they are especially useful in mass casualty situations.[83] In such circumstances, staples may be safer because the risk of accidental needle-stick injury is eliminated.[89]

Contraindications

Because staples do not permit meticulous cosmetic repair, the clinician should avoid staple use on the face or neck.[85,86] Also, discomfort makes staples a poor choice for wound closure in the hands or feet. Staples should not be used in patients who may require computed tomography or magnetic resonance imaging as part of their acute care because they produce scan artefacts and may be avulsed by the powerful magnetic field.

PREPARATION

Analgesia

Local anesthesia using topical agents (e.g., lidocaine-epinephrine-tetracaine [LET] gel) and infiltrative anesthesia (e.g., buffered lidocaine) provide adequate pain control in most patients. In children, anxiety and pain response may often be decreased with distraction techniques and use of a child life specialist.

Wound assessment and irrigation

Wound irrigation, foreign body removal, and necrotic tissue debridement should occur before staple placement. The preparation of a skin wound for closure is discussed in greater detail separately.

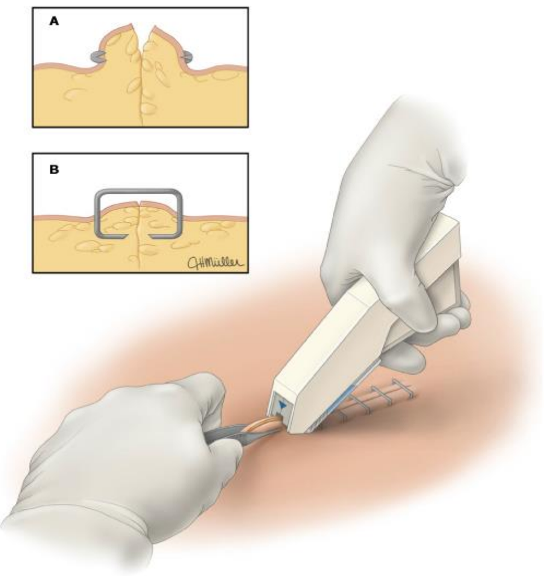
Materials Required

- Sterile gloves for the provider
- Sterile 4 x 4-inch gauze, tubular gauze bandage, and tape for dressing
- Sterile drapes
- Irrigation solution (e.g., sterile normal saline)
- 30 to 60 mL syringe with 18 to 19 gauge IV catheter or irrigation device with splash shield (e.g., Zerowet)
- Staple device
- Skin forceps
- Antibiotic ointment
- Staple remover

PROCEDURE

After wound assessment and preparation with appropriate local anesthesia, the clinician performs staple closure as follows (figure 3): [90]

Figure 3. Placement of Skin Staples



Place the stapler perpendicular to and centered over the wound while everting the wound edges (figure A above) with forceps (preferable) or thumb and forefinger. While pinching the edges of the wound together, gently squeeze the stapler handle to eject the staple into the skin. If the stapler does not automatically release, then release the staple from the stapler by pulling the stapler back. When correctly placed, the crossbar of the staple is elevated a few millimeters above the skin surface (figure B above).

Staple placement

- Approximate the adjacent skin margins with eversion of the skin edges using Adson forceps (forceps with teeth) or the thumb and forefinger. Eversion is necessary to avoid the tendency of the stapler to invert the edges of the wound, which can cause a less aesthetically pleasing scar. Eversion of the wound edges by an assistant may permit more accurate staple positioning.

- Place the stapler firmly on the skin surface but without indenting the skin.
- Align the center mark on the stapler with the center of the wound margin.
- Gently squeeze the stapler handle to eject the staple into the skin.
- If the stapler does not automatically release, then release the staple from the stapler by pulling the stapler back. When correctly placed, the crossbar of the staple is elevated a few millimeters above the skin surface.
- Place staples about 0.5 to 1 cm apart.
- Place enough staples to allow for proper apposition of the wound edges.

Wound care

After the wound is stapled, apply an antibiotic ointment to minimize dressing adherence, and either cover the wound with a sterile dressing (e.g., leg, arm, and trunk wounds) or leave it open to the air (e.g., scalp wounds). The patient may remove the dressing and gently clean the wound in 24 to 48 hours. The patient may then continue wound care until the staples are removed as follows:

- Apply antibiotic ointment daily to the wound.
- Apply a dressing to the wound, unless it was originally left open.
- Do not soak the wound (e.g., swimming, bathing), although showering is acceptable

The interval between application and removal of the staple is the same as that for standard suture placement and removal.

Staple removal

The procedure for staple removal is as follows:

- Position the prongs of the staple remover under the staple.
- Depress the handle of the staple remover so that the staple is bent outward in the midline, easing it out of the skin.

Some patients describe a pinching sensation during removal.[84] If the patient is following up elsewhere for staple removal, provide a staple remover to the patient to ensure that the follow-up provider has the proper equipment.

COMPLICATIONS

Complications related to staple closure occur infrequently and at a rate that appears equivalent to that of sutured wounds.[87,90]

- **Scarring** – As with sutures, staples can cause scarring. In patients who scar easily, the scar that results from staples may be more pronounced than one produced by sutures particularly if the staples are left in place for prolonged periods (>5 to 15 days, depending upon the location).[83,91]
- **Difficult removal** – Embedding of the staples in the skin and rotation of the staples may lead to difficulty in removal. Proper depth and symmetry of initial staple placement, as well as timely removal, should avoid this problem in most patients.[92]

For partially embedded staples, the remover can be placed as far under the staple as possible and toggled back and forth until the staple loosens. On occasion, it is easier to grasp and toggle the staple with a hemostat.

Rarely, staples may become completely lodged within the skin. In this situation, radiographs may be necessary to determine the orientation of the buried staple. After local anesthesia, an incision can be made over the embedded staple so that removal can occur.

- **Wound dehiscence** – Wound dehiscence may occur if hemostasis is not ensured before staple placement or if the wound is not opposed completely during closure.[93]

CAESAREAN SECTION: STAPLES VS SUBCUTICULAR SUTURE

Postoperative wound complication is one of the most common complications of caesarean delivery. Although rarely life-threatening, wound separation and infection are associated with significant psychological stress for patients and increased cost to the health care system.[94,95] Whereas the beneficial effects of interventions such as preoperative antibiotics for preventing wound infection have been established,[96] the role of wound closure technique is less clear. In addition to preventing wound complications, the desirable wound closure technique should be fast and simple to perform, cost-effective, and result in minimal pain while maximizing wound cosmesis and patient satisfaction.[97]

Staple closure gained popularity in the 1980s when initial studies in general surgery demonstrated shorter operating times and reduction in wound infection.[98] It was hypothesized that staples might cause less damage to the wound's defences than sutures that act as foreign bodies.[99] Subsequent RCTs in general surgery failed to confirm a beneficial effect of staple closure for preventing wound infections.[100,101]

The findings of a comparative review of Staples vs sutures, by Tuuli et al.[6] showed that staple closure is associated with shorter operating times but higher risk of wound complications. The results was contrary to the conventional wisdom that interrupted closure techniques should be used for skin closure of clean contaminated wounds such as cesarean incisions.[102] The near-universal use of preoperative antibiotics at caesarean delivery reduces wound infection rates overall,[96] but whether the apparent superiority of subcuticular suture is attributable to Staples being metallic or subcuticular suture achieving better wound coaption is unclear. Tuuli et al. proposed that the continuous nature of subcuticular suture and its concealment below the skin without connection to the external environment reduces the entry of bacteria, thus reducing wound separation and infection. Two other reviews[103,104] evaluated studies that compared staples to subcuticular suture closure for transverse caesarean delivery incisions. The Cochrane review in 2003 included only the study by Frishman et al.[7] and concluded that there is insufficient evidence to recommend one skin closure method over the other.[103]

Altman et al.[104] reviewed skin closure techniques for Pfannenstiel incisions. That review was performed before the three recent RCTs were published[8-9] and included animal, general abdominal, gynecologic and obstetric surgical procedures. Although no meta-analysis was performed, the authors concluded that there is insufficient evidence to guide surgeons in their choice of skin closure technique after caesarean delivery and other procedures using Pfannenstiel incisions.[104]

Ranabaldo and Rowe-Jones compared sutures with staples and subcuticular 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.[10]

Gaertner et al. studied the role of skin and subcutaneous space closure in caesarean section on the cosmetic appearance of the scar and the patients' satisfaction. 153 patients undergoing caesarean section without prior abdominal delivery were included and randomly assigned in a non-blinded study to four different combinations of skin and subcutaneous tissue closure. The scar was assessed after a period of at least four months by a self-developed protocol, and the patient was asked to complete a survey regarding her satisfaction with the scar. One hundred patients were eligible for long-term evaluation of the scar. Skin closure by either staples or intracutaneous suture in combination with closure or non-closure of the subcutaneous space has a comparable outcome in view of cosmetic outcome and patient satisfaction. The study concluded that all four methods of skin closure seem to be a reasonable choice in caesarean section because they have comparable cosmetic outcome, do not differ on the patients' satisfaction and bear comparable costs.[106]

Cromi et al. compared the scar quality associated with different types of wound closure methods after cesarean section (CS). Patients were randomized to have skin closure following CS with either staples or 3 different types of subcuticular sutures. Scar quality was evaluated 2 and 6 months postoperatively. The Vancouver Scar Scale, the Patient and Observer Scar Assessment Scale (POSAS), and a visual analog scale were used as scar assessment tools. Of the 180 patients who were recruited, 123 successfully completed the study. No difference in both subjective and objective scar rating was detected across groups at either 2 months or 6 months. In the overall study population, objective scores correlated with patient rating, and correlation was strongest between the observer and patient components of the POSAS ($r = 0.48$). They concluded that in women undergoing CS, stapled wounds and those closed with subcuticular sutures result in equivalent cosmetic appearance of the scar.[10]

Frishman GN et al. compared skin closure with staples and subcuticular suture. Obstetric patients undergoing caesarean section with a Pfannenstiel incision were prospectively randomized to skin closure with staples or subcuticular suture. Pain and cosmesis were assessed postoperatively. Patients reported significantly less pain following subcuticular closure at both the time of discharge ($p \le .01$) and the postoperative visit ($p \le .002$). Incisions closed with subcuticular suture were found to be more cosmetically attractive by both patients ($p = .04$) and physicians ($p = .01$) at the postoperative visit. They concluded that Pfannenstiel skin incisions closed with subcuticular closure following caesarean section result in less postoperative discomfort and are more cosmetically appealing at the six-week postoperative visit as compared to incisions closed with staples.[7]

Johnson A et al. conducted a study to monitor surgical site infection after caesarean section. Data were collected prospectively for 715 patients undergoing a Caesarean section procedure for 35 weeks during the latter months of 2002 and the first quarter of 2003. Of these, 80 (11.2%) patients developed an SSI, 57 (71%) of which were detected by post-discharge surveillance. Risk factors associated with infection were analyzed. The choice of subcuticular suture rather than staples to close the surgical site was associated with a significantly lower incidence of infection ($p=0.021$).[105]

Basha et al. conducted a study to determine the wound complication rates and patient satisfaction for subcuticular suture vs. staples for skin closure at cesarean delivery. This was a randomized prospective trial. Subjects who underwent cesarean delivery were assigned randomly to stainless steel staples or subcuticular 4.0 Monocryl sutures. The primary outcomes were composite wound complication rate and patient satisfaction. A total of 435 patients were assigned randomly. Staple closure was associated with a 4-fold increased risk of wound separation (adjusted odds ratio [aOR], 4.66; 95% confidence interval [CI], 2.07-10.52; $p < .001$). Having a wound complication was associated with a 5-fold decrease in patient satisfaction (aOR, 0.18; 95% CI, 0.09-0.37; $p < .001$). After confounders were controlled for, there was no difference in satisfaction between the treatment groups (aOR, 0.71; 95% CI, 0.34-1.50; $p = .63$). Authors concluded that use of staples for cesarean delivery closure is associated with an increased risk of wound complications. The occurrence of a wound complication is the most important factor that influenced patient satisfaction.[9]

Figueroa D et al. compared the risk of cesarean wound disruption or infection after closure with surgical staples compared with subcuticular suture. Women with viable pregnancies at 24 weeks of gestation or greater undergoing scheduled or unscheduled cesarean delivery were randomized to wound closure with surgical staples or absorbable suture. Staples were removed at postoperative days 3-4 for low transverse incisions and days 7-10 for vertical incisions. Standardized wound evaluations were performed at discharge (days 3-4) and 4-6 weeks post-operatively. The primary outcome was a composite of wound disruption or infection within 4-6 weeks. Secondary outcomes included operative time, highest pain score on analog scale, cosmesis score, and patient scar satisfaction score. Of 398 patients, 198 were randomized to staples and 200 to suture (but four received staples). Baseline characteristics including body mass index, prior cesarean, labor, and type of skin incision were similar by group. The primary outcome incidence at hospital discharge was 7.1% for Staples and 0.5% for suture; $p <0.001$ (RR 14.1; 95% CI 1.9-106). Of 350 (87.9%) with follow up at 4-6 weeks, the cumulative risk of the primary outcome at 4-6 weeks was 14.5% for staples and 5.9% for suture; $p=0.008$ (RR 2.5; 95% CI

1.2-5.0). Operative time, pain scores at 72-96 hours and at 6 weeks, cosmesis score, and patient satisfaction score did not differ by group. They concluded that Staples closure compared with suture is associated with significantly increased composite wound morbidity after cesarean delivery.[108]

Assadi S et al. conducted a single-center randomized controlled trial that included women with viable pregnancies (≥24 weeks) undergoing cesarean delivery at Motahary University Hospital, Urmia, Iran from April to November 2014. All cesarean types were included: scheduled or unscheduled and primary or repeat cesareans. Women were excluded for the following reasons: inability to obtain informed consent, immune compromising disease (e.g. AIDS), chronic steroid use, diabetic mellitus and BMI≥30. Of 266 women, 133 were randomized to staples and 133 women to suture group. The mean±SD age of the staples group was 27.6±5.4 years, and mean±SD age of suture was 28.7±5.9 years. Multiparity is the most frequent in both groups that by using Chi-square test, no significant differences were observed between the two groups (p=0.393). The most frequent indication for cesarean section in both groups was history of cesarean section in staple 40 cases (30.1%) and suture 32 cases (24.1%). The survey was conducted using the Chi-square test was not significant (p=0.381). Pain at 6 weeks postoperatively was significantly less in the staple group (p=0.001). Operative time was longer with suture closure (4.68±0.67 versus 1.03±0.07 minute, p<0.001). The Vancouver scar scale score was significantly less in suture closure (6.6±0.8 versus 7.5±0.9, p=0.001). Wound disruption was significantly less in suture closure (3.8% versus 11.3%, p=0.017). They concluded that staple group had low pain and operation time but had a significant wound disruption and scar. The patients who have suffered a significant wound disruption were affected by age (p=0.022) and BMI (p=0.001) at compared those who were not affected by factors such as age or high BMI as risk factors for open surgical wound.[109]

Tulli et al. in their review concluded that the two techniques appear equivalent in terms of postoperative pain, cosmesis, and overall patient satisfaction. They recommend that subcuticular suture generally be used for transverse skin closure after caesarean delivery to minimize wound complications.[6]

Rousseau et al. sought to compare postoperative pain according to the skin closure method (subcuticular sutures vs staples) after an elective term cesarean section. A randomized controlled trial of 101 women was performed. Women were randomly assigned to subcuticular sutures or staples. Operative technique and postoperative analgesia were standardized. Stratification was used for primary vs repeat cesareans. Analog pain and satisfaction scales ranging from 0-10 were completed at postoperative days 1 and 3, and at 6 weeks postoperatively. A digital photograph of the incision was taken at 6 weeks postoperatively and evaluated by 3 independent blinded observers. Pain at 6 weeks postoperatively was significantly less in the staple group (0.17 vs 0.51; $p = .04$). Operative time was shorter in that group (24.6 vs. 32.9 minutes; $p < .0001$). No difference was noted for incision appearance and women's satisfaction. They concluded that Staples are the method of choice for skin closure for elective term cesareans in our population.[8]

Aabakke AJ et al. compared subcuticular sutures with staples for skin closure after cesarean delivery in a randomized trial in which each woman was her own control. Women undergoing cesarean delivery (primary, n=32; repeat, n=31) were randomized to side distribution of skin closure methods with one side of the skin incision closed with staples and the other side closed with subcuticular suture. The primary outcome was the overall preferred side of the scar 6 months postoperatively. Additional outcomes were women's preferred method of closure and cosmetically preferred side of the scar, difference in objective cosmetic scores (assessed by two plastic surgeons), and pain between the two sides of the scar and infection rate. Significantly more women preferred the stapled side, both overall (odds ratio [OR] 2.55; 95% confidence interval [CI] 1.18–5.52) and cosmetically (OR 2.67; 95% CI 1.24–5.74), and reported staples as their preferred technique (OR 2.00; 95% CI 1.10–3.64). There were no significant differences in pain scores at any time. One plastic surgeon preferred the stapled side (OR 2.8; 95% CI 1.01–7.78) and scored it significantly higher on a cosmetic visual analog scale (p=.031); the other found no significant difference. There were four (6.8%) cases of infection—three on the sutured side and one bilateral. They concluded that staples were preferred to subcuticular suture for skin closure by women after cesarean delivery.[107]

MATERIAL AND METHODS

Study Design

Hospital based Randomized control Study

Study Duration

October 2014 to September 2016

Study Area

Department of Obstetrics and Gynecology, R.L. Jalappa Hospital and Research Centre attached to Sri Devaraj Urs Academy of Higher Education and Research, Tamaka, Kolar, Karnataka.

Sample Size Calculation

Calculation based on the formula:

$$n = f(\alpha/2, \beta) \times [p1 \times (100 - p1) + p2 \times (100 - p2)] / (p2 - p1)^2$$

Where

α= significance level is 5% (two sided)

β= Power taken as 90%

p1= wound complication in stapler group =22% [9]

p2= wound complication in subcuticlar suture group =9% [9]

Using the above formula, sample size is estimated to be 110 in each group. So, final sample size is 220 subjects undergoing cesarean delivery.

Inclusion Criteria

1. Primary or repeat cesarean section
2. Gestation > 28 weeks
3. Pfannenstiel skin incision

Exclusion Criteria

1. Pre-pregnancy diabetes mellitus
2. Premature rupture of membranes
3. Immunocompromised status
4. Body weight more than 80kg
5. Hemoglobin less than 10gm%

Study Methodology

A total of 228 pregnant women in the study period came to R L Jalappa Hospital fulfilling the inclusion criteria undergoing cesarean delivery were included in the study. A detailed history and general physical, systemic, abdominal and per vaginal examination were done on admission.

Patients were then grouped into two groups 114 cases each by simple randomization table for surgical staples or subcuticular sutures for skin incision closure after obtaining informed consent.

Standard aseptic precautions were taken, and prophylactic antibiotic Ceftriaxone 1gm IV is given for all patients. Standard steps of cesarean section with Pfannenstiel incision were followed, and the skin closure was done by either using surgical staples which are made of stainless steel or subcuticular skin sutures using poliglecaprone 25, 3-0 suture. Subcuticular fat is closed if more than 2 centimeters. The metallic staples were removed on the 6th day while the subcutaneous sutures were left in situ. Postoperatively patients were followed up to two and four weeks.

During follow-up, the following outcomes were noted in each group of cases wound infection which includes surgical site infection requiring antibiotic, presence of hematoma, presence of seroma, skin separation 1 cm or more, re-closure of the skin incision required, readmission for wound concern. The other outcome measures were duration of skin suturing, postoperative pain on postoperative day 4 and 7 on Visual analogue scale (VAS), duration of skin suturing, the length of hospital stay.

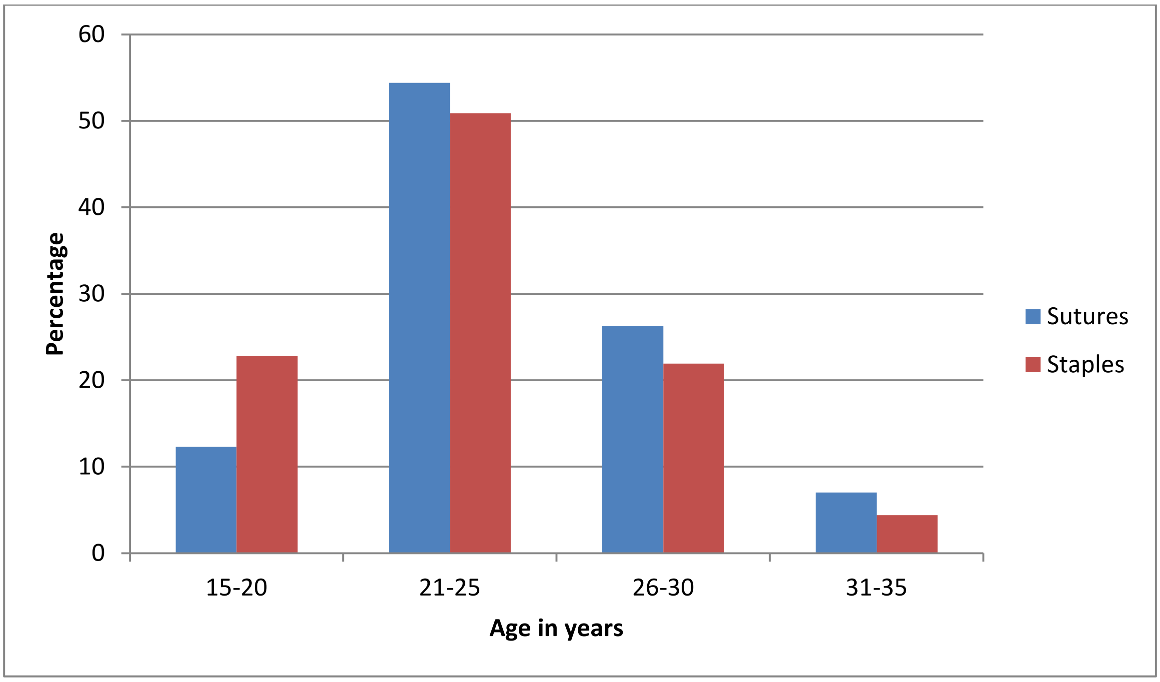
Statistical Analysis

All the collected data was entered in Microsoft Excel sheet and then transferred to SPSS software version 21 for analysis. Qualitative data was presented as frequency and percentages and Quantitative data was presented as mean and SD. Appropriate statistical tests were applied based on type and distribution of data. A p-value < 0.05 was taken as level of significance

RESULTS

Table 5. Age distribution

Age years	Group			
	Sutures		Staples	
	n=114	%	n=114	%
15-20	14	12.3	26	22.8
21-25	62	54.4	58	50.9
26-30	30	26.3	25	21.9
31-35	8	7.0	5	4.4
p- value - 0.181				

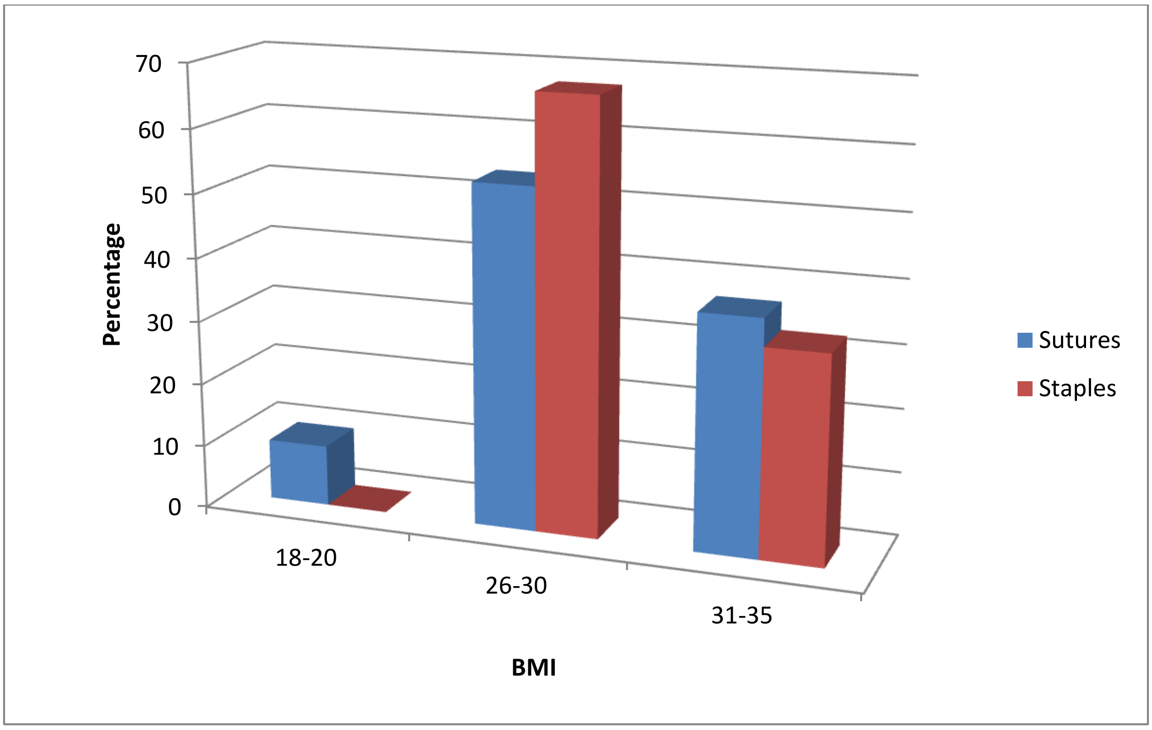


Graph no1: Bar diagram showing age distribution

Age distribution was comparable in both groups with most of the subjects in both groups were between 21-30 years (80.7% in subcuticular sutures vs. 72.8% in skin staples; $p>0.05$).

Table 6. BMI distribution

BMI (Kg/m2)	Group			
	Sutures		Staples	
	n=114	%	n=114	%
18-25	11	9.6	0	0.0
26-30	61	53.5	77	67.5
31-35	42	36.8	37	32.5
p- value < 0.01				

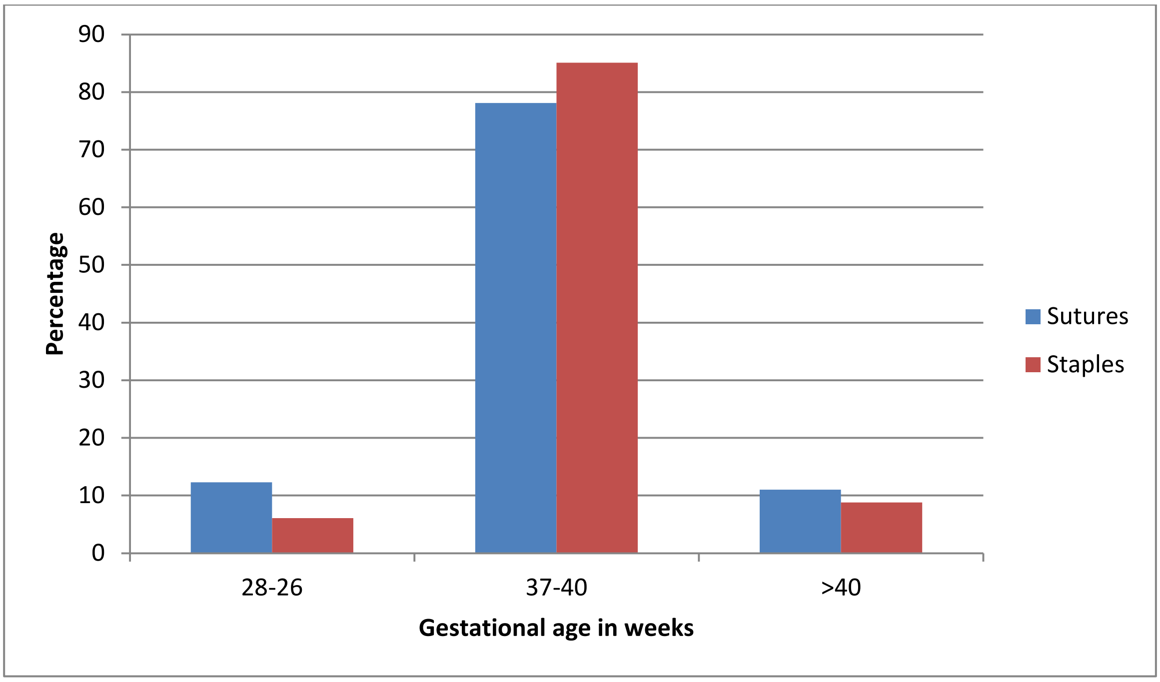


Graph no2: Bar diagram showing BMI distribution

Staple group have BMI of > 25 kg/m^2 while BMI above 30 kg/m^2 was seen in 34.6% subjects. BMI < 25 kg/m^2 was observed in 9.6% subjects of suture group while > 30 kg/m^2 was observed in 36.8% (p<0.05)

Table 7: Gestation Age distribution

Gestation Age (weeks)	Group			
	Sutures		Staples	
	n=114	%	n=114	%
28-36	14	12.3	7	6.1
37-40	89	78.1	97	85.1
> **40**	11	9.6	10	8.8
p- value - 0.256				

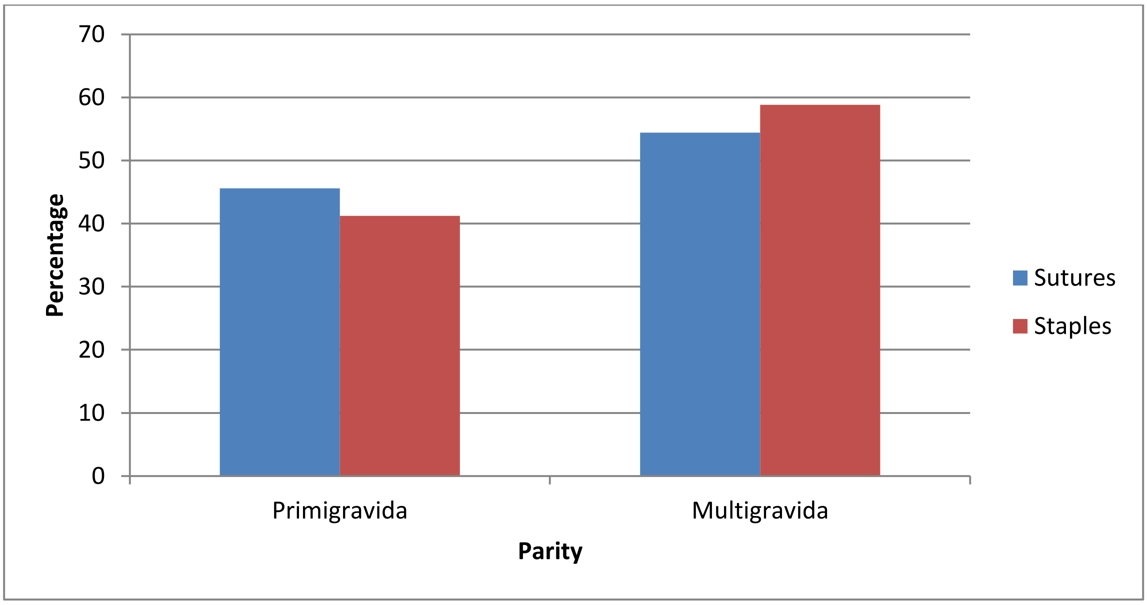


Graph no3: Bar diagram showing gestation Age distribution

Gestation age was comparable in both groups with most of the subjects in both groups delivered between 37-40 weeks (78.1% in subcuticular sutures vs. 85.1% in skin staples; p>0.05).

Table 8: Parity distribution

Parity	Group			
	Sutures		Staples	
	n=114	%	n=114	%
Primigravida	52	45.6	47	41.2
Multigravida	62	54.4	67	58.8
Total	114	100	114	100
p- value - 0.593				

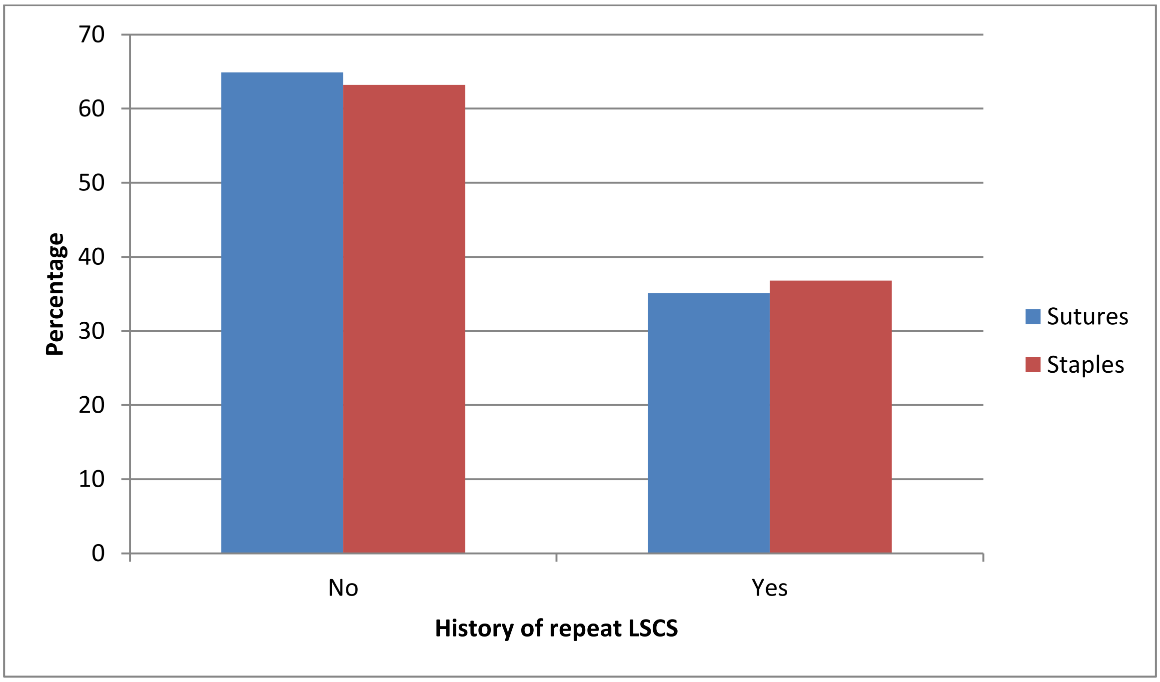


Graph no4: Bar diagram showing parity distribution

Out of the total 228 cases, 45.6% and 41.2% were primigravida and 54.4% and 58.8% were multigravida in suture and stapler group respectively (p>0.05)

Table 9: Repeat LSCS

Repeat LSCS	Group			
	Sutures		Staples	
	n=114	%	n=114	%
No	74	64.9%	72	63.2%
Yes	40	35.1%	42	36.8%
Total	114	100.0%	114	100.0%
p- value - 0.89				

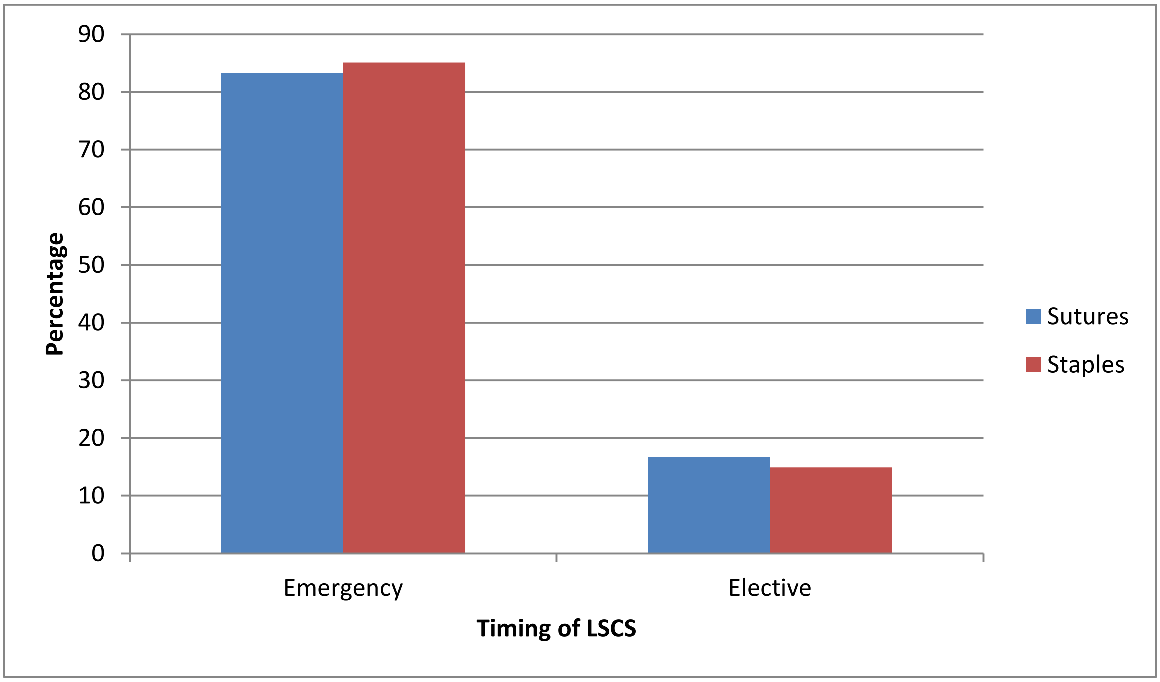


Graph no5. Bar diagram showing history of repeat LSCS

History of previous LSCS was given by 35.1% and 36.8% subjects in suture and stapler group respectively (p>0.05).

Table 10: Type of LSCS distribution

LSCS	Group			
	Sutures		Staples	
	n=114	%	n=114	%
Emergency	95	83.3	97	85.1
Elective	19	16.7	17	14.9
Total	114	100	114	100
p- value - 0.856				

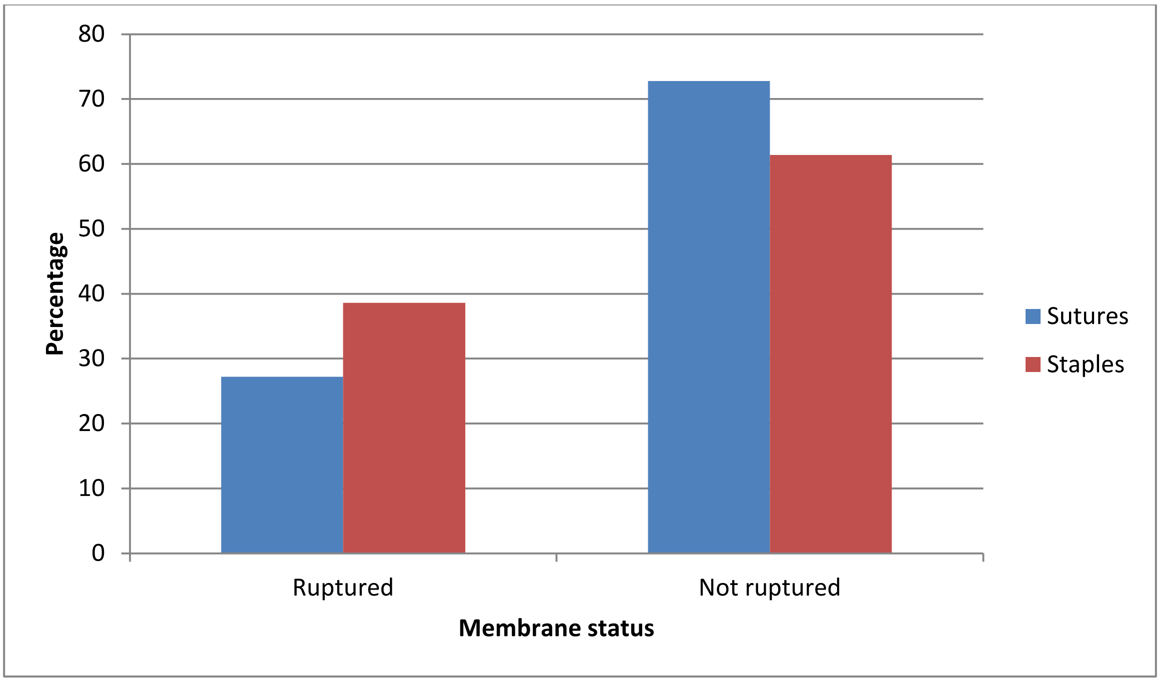


Graph no6: Bar diagram showing type of LSCS distribution

Emergency LSCS was done in 83.3% and 85.1% cases of suture and stapler group respectively (p>0.05).Elective LSCS was done in 16.7% and 14.9% cases of suture and stapler group respectively (p>0.05).

Table 11: Membrane status

Bag of Membranes	Group			
	Sutures		Staples	
	n=114	%	n=114	%
Ruptured	31	27.2	44	38.6
Not Ruptured	83	72.8	70	61.4
Total	114	100	114	100
p- value - 0.067				

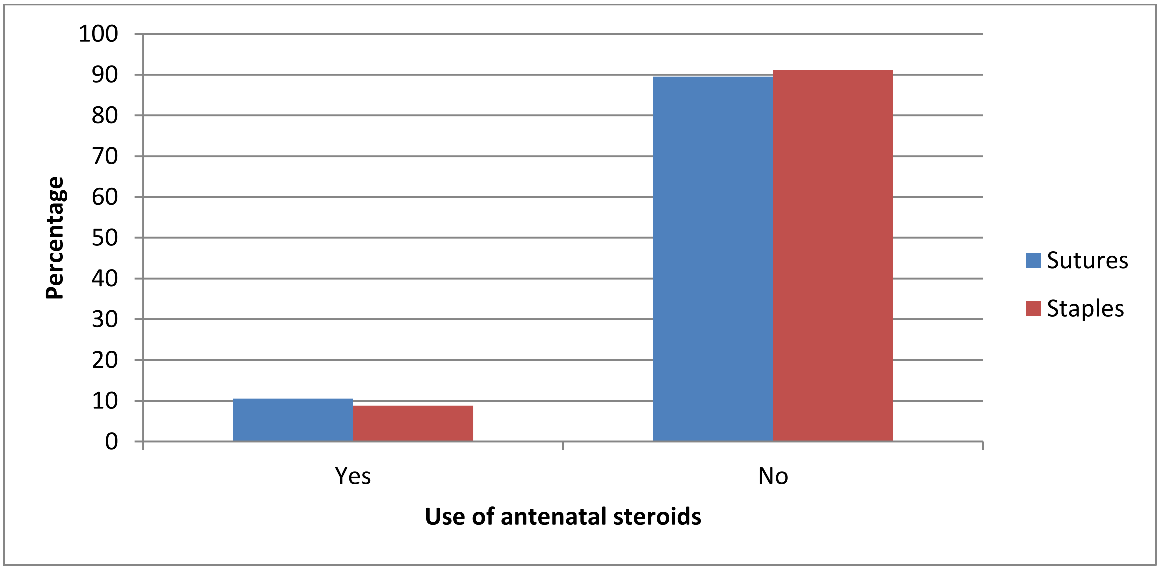


Graph no7: Bar diagram showing membrane status

Ruptured bag of membranes was encountered in 27.2% cases of suture group compared to 38.6% in staple group (p>0.05).

Table 12: Use of Antenatal Steroids

Antenatal Steroids	Group			
	Sutures		Staples	
	n=114	%	n=114	%
Yes	12	10.5	10	8.8
No	102	89.5	104	91.2
Total	114	100.0	114	100.0
p- value - 0.823				

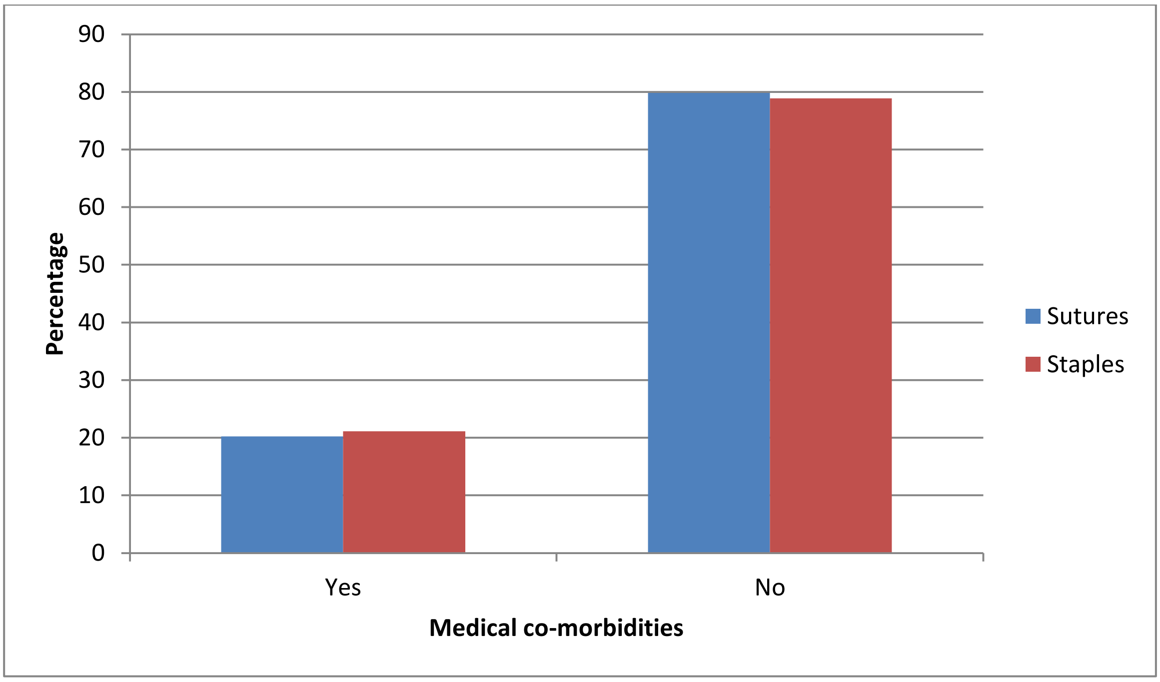


Graph no8: Bar diagram showing use of Antenatal Steroids

10.5% and 8.8% subjects required antenatal steroids in suture and stapler group respectively (p>0.05).

Table 13: Medical Co-morbidities

Medical Co-morbidities	Group			
	Sutures		Staples	
	n=114	%	n=114	%
Yes	23	20.2	24	21.1
No	91	79.8	90	78.9
Total	114	100	114	100
p- value - 1.0				

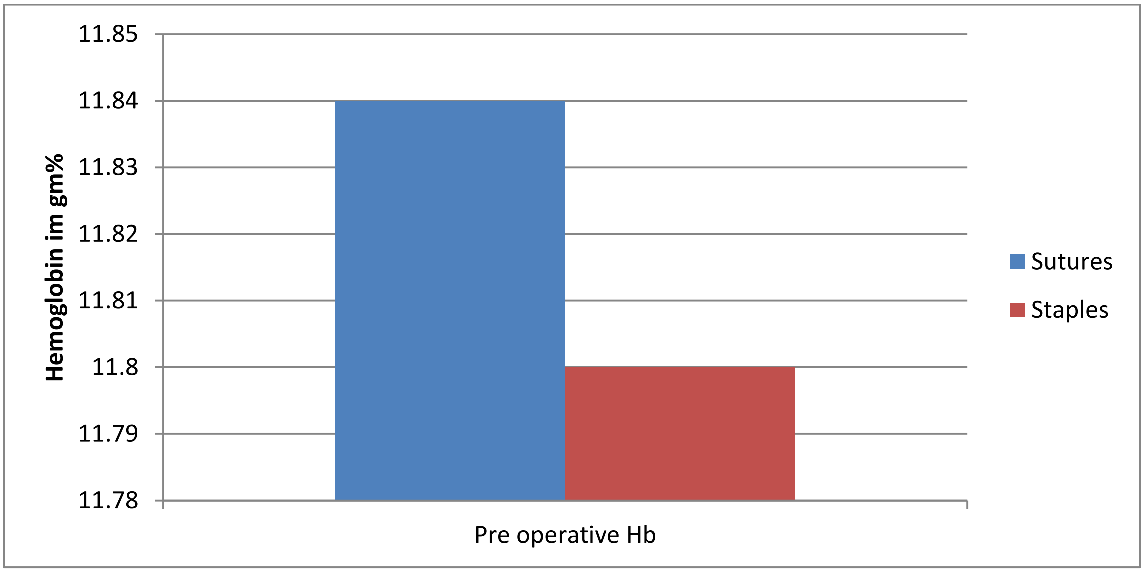


Graph no9: Bar diagram showing medical Co-morbidities

A total of 20.2% and 21.1% subjects had associated medical complications in suture and stapler group respectively (p>0.05).

Table 14: Pre-operative Haemoglobin levels

Variables	Group	Mean	SD	SEM	p- value
Pre-op Hb (gm /dl)	Suture	11.84	1.18	0.11	0.8
	Stapler	11.80	1.04	0.10	

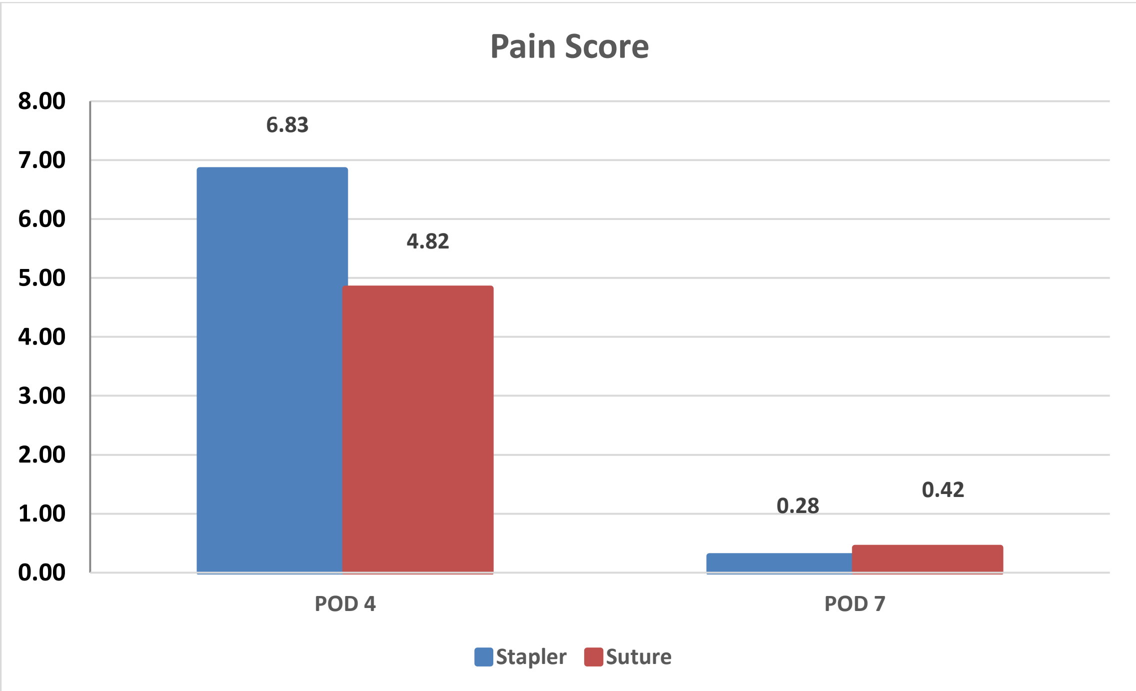


Graph no10: Bar diagram showing pre-operative Haemoglobin levels

Mean pre-op hemoglobin level were comparable between both groups (11.80 vs. 11.84 gm%; p->0.05)

Table 15: Comparison of mean pain scores on post-op day 4 and 7 on VAS among study groups

Pain Score	Group	Mean	SD	SEM	p- value
POD 4	Suture	4.82	0.99	0.09	< 0.01
	Stapler	6.83	0.97	0.09	
POD 7	Suture	0.42	0.50	0.05	0.026
	Stapler	0.28	0.45	0.04	

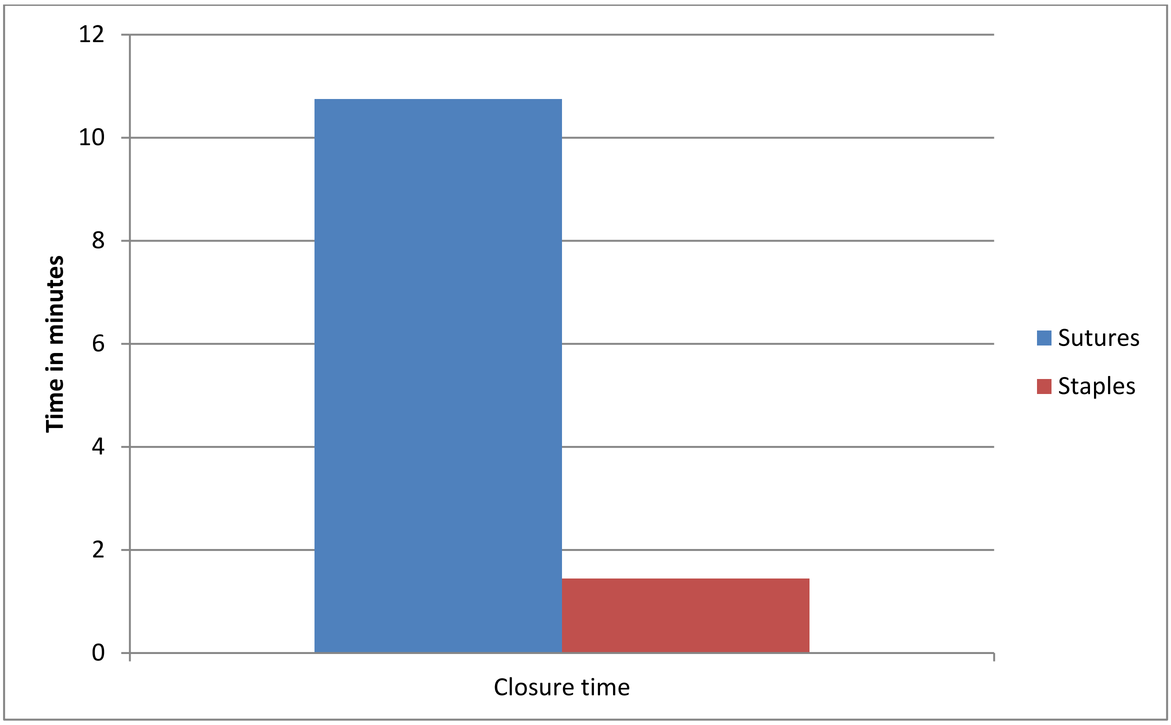


Graph no11: Bar diagram showing comparison of mean pain scores on post-op day 4 and 7 on VAS among study groups

Mean pain score was significantly high in stapler group (6.83 vs. 4.82; p-<0.05) at 4th post-op day while it was slightly higher in subcuticular suture group on day 7 with no significant p value (0.42 vs. 0.28; p>0.05).

Table 16: Mean closure time among study groups

Variables	Group	Mean	SD	SEM	p-value
Closure Time (mins.)	Suture	10.75	1.21	0.11	< 0.01
	Stapler	1.44	0.35	0.03	



Graph no 12: Bar diagram showing mean closure time among study groups

Mean closure time was significantly less in stapler group as compared to suture group (1.44 min vs. 10.75 minutes; $p<0.01$)

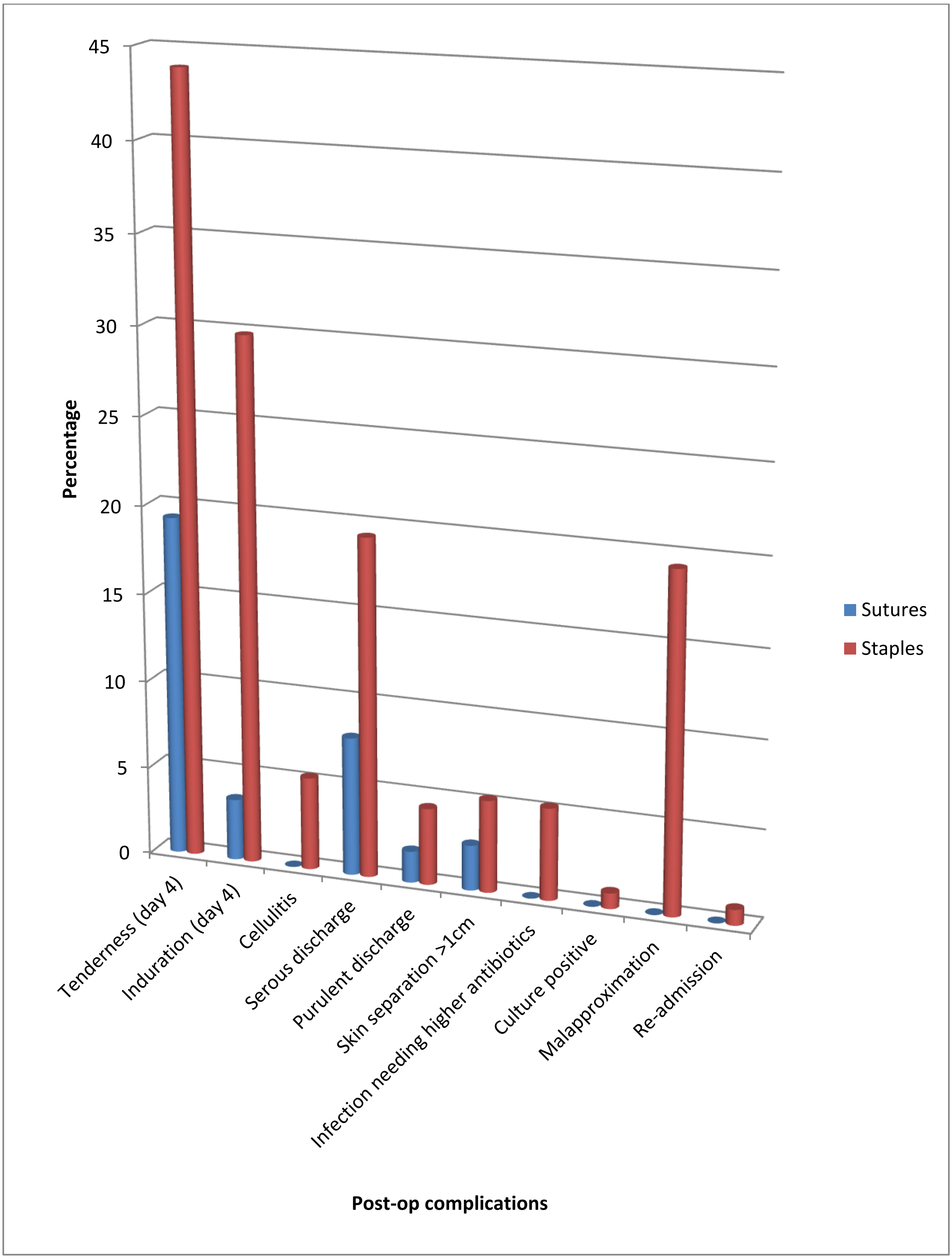
Table 17: Comparison of study groups based on post-op Complications

Post-op Complications	Group				p- value
	Sutures		Staples		
	n=114	%	n=114	%	
Tenderness (day 4)	22	19.3	50	43.9	**< 0.01**
Induration (day 4)	4	3.5	34	29.8	**< 0.01**
Cellulitis	0	0.0	6	5.3	**0.029**
Serous Discharge	9	7.9	22	19.3	**0.019**
Purulent discharge	2	1.8	5	4.4	**0.446**
Skin Separation > 1 cm	3	2.6	6	5.3	**0.499**
Infection needing higher Antibiotics	0	0	6	5.3	**0.029**
Culture positive	0	0	1	0.9	**1.0**
Mal-approximation	0	0	22	19.3	**< 0.01**
Re-admission for wound disruption	0	0	1	0.9	**1.0**

Tenderness and Induration at 4th post-op day was significantly more in stapler group (43.9% vs. 19.3% and 29.8% vs. 3.5%; $p<0.05$). Complaint of cellulitis and serous discharge was also more common in stapler group ($p<0.05$). Mal-approximation of the wound was seen in 19.3% patients of stapler group compared to none in suture group ($p<0.05$).

Purulent discharge and Skin separation of >1cm were seen more in the staples groups with no significant p value ($p>0.05$).

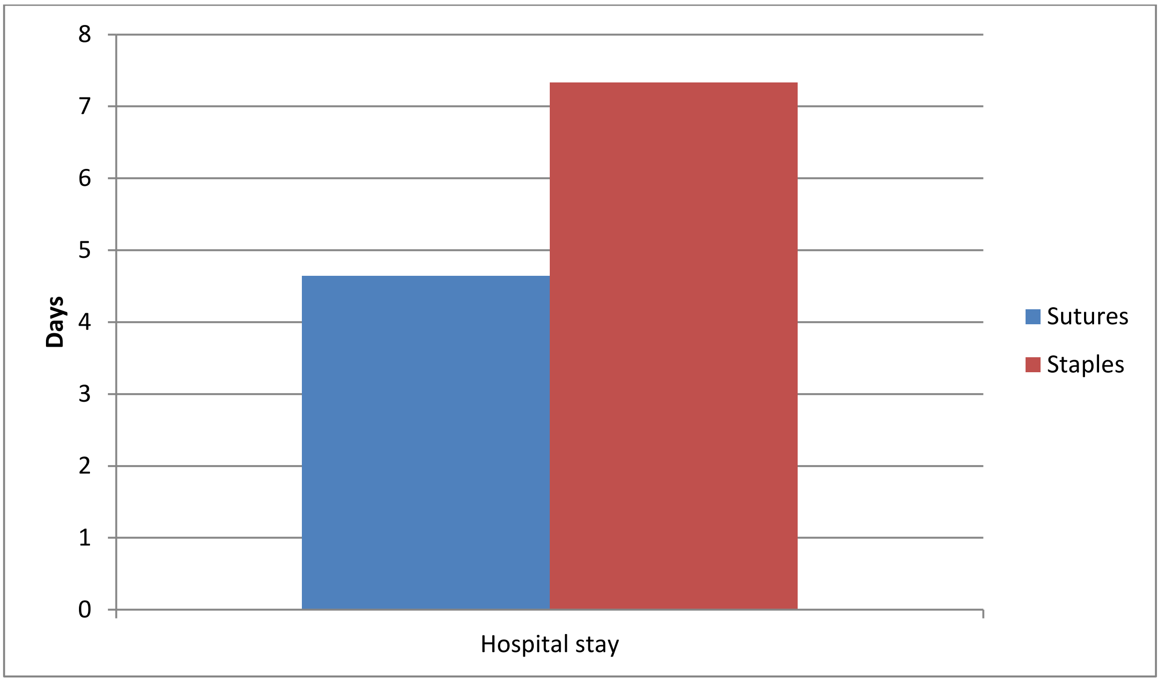
Infection needing higher antibiotics , culture positive swabs and Re-admission for wound disruption were none in suture groups and were few in staple groups with no significant p value (p>0.05).



Graph no13: Bar diagram showing comparison of study groups based on post-op complications

Table 18: Hospital stay

	Group	Mean	SD	SEM	p-value
Hospital Stay (days)	**Suture (n=114)**	4.64	1.00	0.09	**< 0.01**
	Stapler (n=114)	7.33	2.16	0.20	



Graph no14: Bar diagram showing hospital stay

Mean hospital stay was significantly more in stapler group as compared to suture group (7.33 vs. 4.64 days; p<0.01)

Figure no 4: Subcuticular sutures

Figure no 5: Surgical staples

Figure no 6: Skin closed with subcuticular sutures.

Figure no 7: Skin closed with metallic stples.

Figure no 8: Clean wound closed with subcuticular sutures on postoperative day 7

Figure no 9: Clean wound closed with surgical skin staples on postoperative day 7

Figure no 10: Serous discharge from the wound closed with surgical staples at post operative day 6

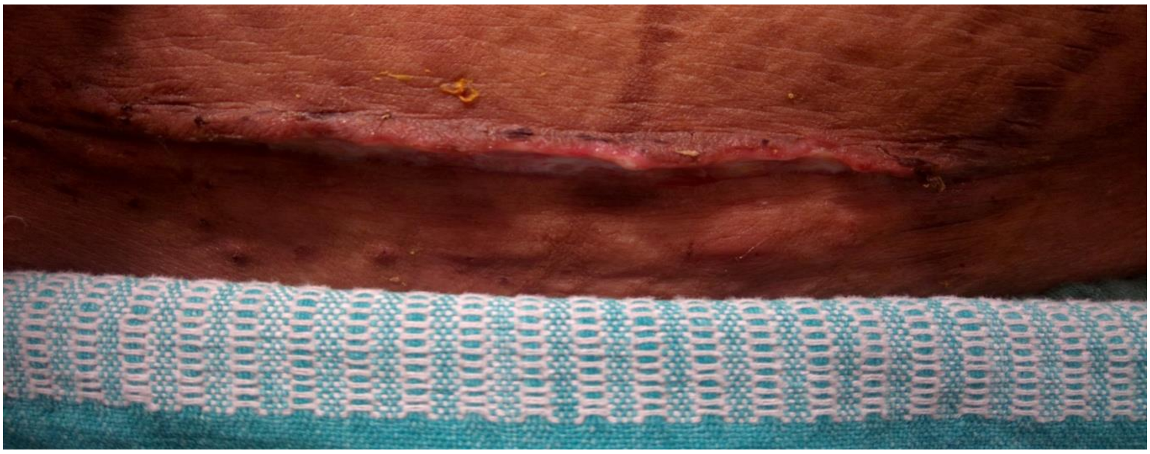


Figure no 11: Serous discharge and malapproximation of the wound edges closed with surgical staples on post operative day 6

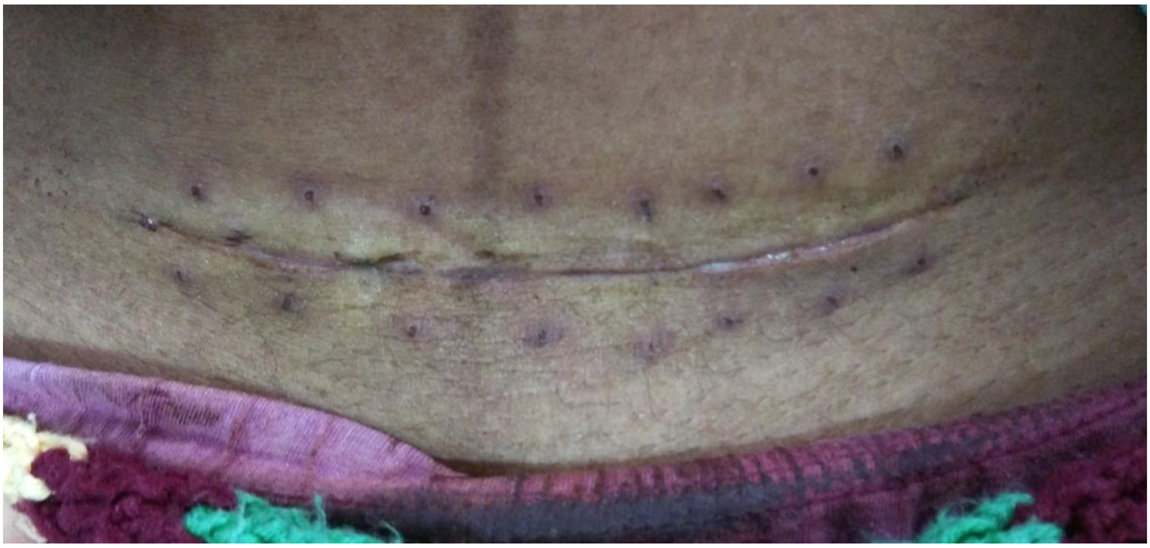


Figure no 12: Malapproximation of the wound edges closed with surgical staples on post operative day

DISCUSSION

A Hospital based Randomized control Study was conducted with the aim of comparing the wound complication rates with the use of subcuticular sutures and surgical staples for skin closure after cesarean section.

Overall, we observed in the present study, that surgical staples were significantly associated with a higher incidence of cumulative wound morbidity than absorbable sutures after cesarean delivery. The difference was mainly due to more infections and wound disruptions among staples group.

The baseline characteristics of the randomized groups including age, BMI, medical co-morbidities and prior cesarean (64.9% vs. 63.2%) were similar between study groups. The mean age of the study groups was 23.65 and 24.46 years in stapler and suture group respectively ($p>0.05$).

In a similar study by Assadi et al.,[109] the mean age of the staples group was 27.6±5.4 years and mean age of suture was 28.7±5.9 years. In another study by Figueroa et al.,[108] the baseline characteristics of the randomized cohort including BMI (≈36 kg/m2), race/ethnicity (predominantly African American) and prior cesarean (47-49%) were similar between study groups with mean age of the study group was 26.7 and 24.6 years in stapler and suture group respectively (p-0.622) with the history of LSCS observed in 64.9% vs. 63.2% subjects.

Out of the total 228 subjects, 45.6% and 54.4% were primigravida and multigravida in suture group and 41.2% and 58.8% were primigravida and multigravid in stapler group ($p>0.05$).

Similarly, multiparity is most frequently observed in both groups by Assadi et al.[109] and no significant differences was noted between the two groups (p=0.393). In a study by Figueroa et al., about 45.6% and 41.2% cases were primigravidas.[108]

Skin closure time was significantly less in stapler group as compared to suture group (1.44 min vs. 10.75 minutes; p<0.01).

Similar to other studies, a study by Figueroa et al. a 4-minute lower median procedure time was observed with stapler group.[108] Assadi et al. also found operative time to be longer with suture closure (4.68±0.67 versus 1.03±0.07 minute, p<0.001).[109] Rousseau et al. also observed operative time to be longer in the suture group (24.6 vs. 32.9 minutes; p < .0001).[8] Our results were also consistent with recent reports of shorter operative time with staple closure [6,8,9,110]

Study	Closure Time (min.)	
	Staples	Sutures
Frishman et al.[7]	**0.78**	**10.08**
Assadi et al.[109]	**1.03**	**4.68**
Our study	**1.44**	**10.75**

Table no 19: Epidemiological Studies comparing mean closure time.

Mean pain score was significantly high in stapler group (6.83 vs. 4.82; p-<0.05) at 4th post-op day while it was slightly higher in suture group at day 7 with no significant p value (0.42 vs. 0.28; p>0.05).

Frishman GN et al. compared pain and cosmesis in cesarean section patients with skin closure via staples or subcuticular suture. Patients reported significantly less pain following subcuticular closure at both the time of discharge ($p <$ or $= .01$) and the postoperative visit ($p < 0.01$).[7] Rousseau et al. in a similar study observed that pain at six weeks postoperatively was significantly less in the staple group (0.17 vs. 0.51; $p = .04$).[8] In another study, Aabakke AJ et al. observed no significant differences in pain scores at any time between the study groups.[107] Similarly, pain scores at 72-96 hours and six weeks did not differ significantly in a study by Figueroa et al.[108] Assadi S et al. [109] observed in their study that pain at six weeks postoperatively was significantly less in the staple group ($p=0.001$).

Study	Pain Score
Frishman et al.[7]	Suture superior
Assadi S et al. [109]	Staple superior
Rousseau et al.[8]	Staple superior
Cromi et al.[10]	Equivalent
Tuuli et al.[6]	Equivalent
Our study	Sutures superior

Table no 20: Epidemiological Studies comparing pain scores.

Tenderness and Induration at 4th post-op day were significantly more in stapler group (43.9% vs 19.3% and 29.8% vs 3.5%; $p<0.05$) respectively. Complaint of cellulitis and serous discharge was also more common in stapler group ($p<0.05$). Mal-approximation of the wound was seen in 19.3% patients of stapler group compared to none in suture group ($p<0.05$). Mean hospital stay was significantly more in stapler group as compared to suture group (7.33 vs. 4.64 days; $p<0.01$)

Our findings are consistent with various recent studies in which staple closure was associated with significantly higher self-reported wound morbidity compared with suture, a finding observed in both meta-analyses.[6,9,10,101,104]

The higher hospital stay in staple group in our study can be attributed to the increased complication rates seen in subjects where staples were used for skin closure.

Assadi S et al. also observed wound disruption to be significantly less in suture closure (3.8% versus 11.3%, p=0.017).[109] Figueroa et al. observed the incidence of wound infection at hospital discharge as 7.1% for staples and 0.5% for suture (p <0.001; RR 14.1; 95% CI 1.9-106)[108] Basha et al. in their study observed that staple closure was associated with a 4-fold increased risk of wound separation (adjusted odds ratio [aOR], 4.66; 95% confidence interval [CI], 2.07-10.52; p < .001).[9]

Study		Wound morbidities	
		Staples	Sutures
Frishman et al.[7]		8.0%	0.0%
Johnson et al. [105]		13.0%	7.9%
Gaertner et al.[106]		5.9%	8.2%
Rousseau et al.[8]		0.0%	2.1%
Cromi et al.[10]		3.2%	2.2%
Basha et al.[9]		21.8%	8.2%
Figueroa et al.[108]		7.1%	0.5%
Assadi et al.[109]		11.3%	3.8%
Our study	Tenderness (day 4)	43.9%	19.3%
	Induration (day 4)	29.8%	3.5%
	Mal-approximation	19.3%	0

Table no 21: Epidemiological Studies comparing wound morbidities.

CONCLUSION

The use of staples for cesarean delivery closure is associated with an increased risk of wound infection rates, pain scores, malapproximation of the wound edges and increased hospital stay compared to subcuticular suture group.

Thus we recommend the use of subcuticular sutures rather than surgical staples for skin closure after cesarean section.

SUMMARY

A Hospital based Randomized control Study was conducted during October 2014 to September 2016 at Department of Obstetrics and Gynecology, R.L. Jalappa Hospital and Research Centre attached to Sri Devaraj Urs Academy of Higher Education and Research, Tamaka, Kolar, Karnataka. The aim was to study and compare the wound complication rates with the use of subcuticular sutures and surgical staples for skin closure after cesarean section. A total of 228 pregnant women coming to R L Jalappa Hospital fulfilling the inclusion criteria undergoing cesarean delivery were included in the study. A detailed history and general physical, systemic, abdominal and per vaginal examination were done on admission. Patients were then grouped into two groups 114 subjects each by simple randomization table for surgical staples or subcuticular sutures for skin incision closure during cesarean section after obtaining informed consent. Both the groups were compared on the basis of various operative parameters and complication rate. The following observations were made.

1. Age distribution was comparable in both groups with most of the subjects in both groups were between 21-30 years (80.7% vs. 72.8%; $p>0.05$).
2. Staple group have BMI of > 25 kg/m^2 while BMI above 30kg/m^2 was seen in 34.6% subjects. BMI < 25 kg/m^2 was seen in 9.6% subjects of suture group while > 30kg/m^2 was observed in 36.8% ($p<0.05$)
3. Gestation age was comparable in both groups with most of the subjects in both groups delivered between 37-40 weeks (78.1% vs. 85.1%; $p>0.05$).
4. Out of total 228 subjects, 45.6% and 54.4% were primigravida and multigravida in suture group respectively, and 41.2% and 58.8% were primigravida and multigravida in stapler group respectively($p>0.05$).

5. 10.5% and 8.8% cases required ante-natal steroids in suture and stapler group respectively ($p>0.05$).
6. 20.2% and 21.1% cases had medical co-morbidities in suture and stapler group respectively ($p>0.05$).
7. Emergence LSCS was required in 83.3% and 85.1% subjects of suture and stapler group respectively ($p>0.05$).
8. History of previous LSCS was given by 64.9% and 63.2% subjects in suture and stapler group respectively ($p>0.05$).
9. Ruptured bag of membranes was encountered in 72.8% subjects of suture group compared to 61.4% in staple group ($p>0.05$).
10. Skin closure time was significantly less in stapler group as compared to suture group (1.44 min vs. 10.75 minutes; $p<0.01$).
11. Mean pain score was significantly high in stapler group (6.83 vs. 4.82; p-<0.05) at 4th post-op day.
12. Tenderness and Induration at 4th post-op day was significantly more in stapler group (43.9% vs. 19.3% and 29.8% vs. 3.5%; $p<0.05$).
13. Complaint of cellulitis and serous discharge was also more common in stapler group ($p<0.05$).
14. Mal-approximation of the wound was seen in 19.3% patients of stapler group compared to none in suture group ($p<0.05$).
15. Mean hospital stay was significantly more in stapler group as compared to suture group (7.33 vs. 4.64 days; $p<0.01$)

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KEYS TO MASTER CHART

GA – Gestational age

BMI – Body mass index

LSCS – Lower segment caesarean section

Pre op Hb – Preoperative haemoglobin

POD – Postoperative day

Mins – Minutes

Sec – Seconds

CPD – Cephalopelvic disproportion

TMSL – Thick meconium stained liquor

NRNST – Non reactive non stress test

IUGR – Intra uterine growth restriction

DTA – Deep transverse arrest

CASE PROFORMA

NAME: **AGE:** **Yrs**
SEX: **IP NO :**

OCCUPATION:
DOA:

ADDRESS:
DOD:

EDUCATION:

HUSBANDS OCCUPATION:

SOCIOECONOMIC STATUS:

CHIEF COMPLAINTS:

HISTORY OF PRESENT ILLNESS:

OBSTETRIC HISTORY:

Marital life:

Consanguinity :

Obstetric formula:

Details of previous pregnancy:

Details of present pregnancy:

MENSTRUAL HISTORY

Last menstrual period: **Age of menarche:**

Expected delivery date: **Past menstrual cycles:**

Period of gestation:

Period of gestation according to early scan:

PAST HISTORY:

H/O HTN/DM/BA/RHD/TB/DENGUE/MALARIA/BLOOD DYSCRASIAS

blood transfusions:

Others: **H/O Surgeries**

PERSONAL HISTORY:

Sleep and appetite: **Diet:**

Bowel and bladder: **Addictions:**

FAMILY HISTORY:

DRUG HISTORY:

GENERAL EXAMINATION:

Built: **Nourishment:**

Ht: cms Wt: kgs BMI:

Pallor: Icterus: Cyanosis: Clubbing: Lymphadenopathy: Pedal oedema:

VITALS:

Pulse rate:

Respiratory rate:

Blood pressure

Temperature:

SYSTEMIC EXAMINATION:

Cardiovascular system:

Respiratory system:

Central nervous system:

PER ABDOMEN:

PER SPECULUM:

PER VAGINUM:

PROVISIONAL DIAGNOSIS:

INVESTIGATIONS:

Blood group and Rh typing:

CBC: HB:	**HIV:**	**RBS:**
PCV:	**HbsAG:**	**Urine routine & microscopy:**
RBC:	**VDRL:**	
WBC:		
PLT:		

OBSTETRICS SCAN:

Others:

MODE OF DELIVERY:

INDICATION:

SKIN CLOSED WITH SUBCUTICULAR SUTURES/ SKIN STAPLES:

SKIN CLOSURE TIME:

DELIVERY DETAILS:

Date:	**APGAR SCORE:**
Time:	**I min:**
Sex:	**5 min:**
Birth weight:	

MATERNAL COMPLICATIONS: **FETAL COMPLICATIONS:**

TREATMENT GIVEN:

POST OPERATIVE WOUND: POD4

POD 7

POST OPERATIVE PAIN SCORE : POD 4

POD 7

WOUND MORBIDITIES:

INFECTION NEEDING HIGHER ANTIBIOTICS:

CONDITION AT DISCHARGE:

Mother: **Baby:**

INFORMED CONSENT

STUDY TITLE: “A COMPARATIVE STUDY OF SURGICAL STAPLES AND SUBCUTICULAR SUTURES FOR SKIN CLOSURE IN CESAREAN DELIVERY. ”

- INVESTIGATOR: Dr.Apoorva I
  Under the guidance of Dr. Munikrishna. M
- ADDRESS : Department of OBG,
  Sri Devaraj Urs Medical College, Kolar
- PLACE OF STUDY : R.L. Jalappa Hospital and Research Centre, attached to Sri Devaraj Urs Academy of Higher Education and Research, Tamaka, Kolar,

Patient Information:

- We are doing this study the wound complications associated with subcuticilar sutures and skin staples.
- I understand the wound complications like cellulitis, serous discharge, purulent discharge, skin sepatation, seroma, hematoma infection needing higher antibiotic, wound disruption which might result after using staples/subcuticular sutures.
- If you agree to participate in this research study, the information will be kept confidential. You will not have to incur any additional expenditure. We will publish the results without revealing your name and identity. If you are not willing to participate in this research, it will not affect your treatment.

I__________________ Participant hereby give consent to participate in the study mentioned above.

I have been explained that:

1) I understand the wound complications like cellulitis, serous discharge, purulent discharge, skin sepatation, seroma, hematoma

infection needing higher antibiotic, wound disruption which might result after using staples/subcuticular sutures.

2) The data generated from my clinical examination and laboratory tests and other reports will be used in the study (which may be substantially published or used for further research) without revealing my identity in any manner.
3) I do not suffer any adverse health consequences by my participation in the study.
4) I am free to withdraw from the study anytime.

- I affirm that I have been given full information about the purpose of the study and the procedure involved and have been given ample opportunity to clarify my doubts. In giving my consent, I have not faced any trouble. I have been informed that not withstanding this consent given, I can withdraw from the study at any stage.

Signature of participant   Signature of witness

Name of participant   Name of witness