



Use of Tissue adhesives versus Sutures on Minor surgery for incision closure

Randomized controlled trial

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“You got a dream, you got to protect it. People can't do something themselves, they want to tell you that you can't do it. You want something? Go get it. Period.”

Will Smith – Pursuit of Happiness(2006)

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ABSTRACT

TITLE

Use of Tissue adhesives versus Sutures on minor surgery for incision closure

BACKGROUND

Sutures, staples and adhesive tapes have been used for many years as methods of wound closure, but tissue adhesives have entered clinical practice more recently. Closure of wounds with sutures enables the closure to be meticulous, but the sutures may show tissue reactivity and can require removal. Tissue adhesives offer the advantages of an absence of risk of needlestick injury and no requirement to remove sutures later. Initially, tissue adhesives were used primarily in emergency room settings, but this review looks at the use of tissue adhesives in the operating room/theatre where surgeons are using them increasingly for the closure of surgical skin incisions.

Nowadays, Minor surgery represents almost 40% of all surgical procedures developed during the care process of Plastic Surgery. This type of surgery includes procedures such as the removal of skin lesions for pathological analysis result as basal cell carcinoma, squamous cell carcinoma, melanomas, lipomas, small skin tags, xanthelasma, naevus, sebaceous cyst, seborrheic wart, readjustment of previous scars. The proportion of wound breaking (dehiscence), the wound infection, the cosmetic appearance, the patient satisfaction, the description of costs of procedures are also analysed in order to provide up-to-date data of the effects of both different techniques for incision closure. Finally this study aims to optimize the resources and the time on Minor Surgery.

OBJECTIVES

To determine the effects of tissue adhesives compared with conventional skin closure techniques for the closure of surgical wounds.

METHODS

332 patients admitted to Hospital doctor Josep Trueta and Hospital Santa Caterina to perform a Minor Surgery procedure. Patients will be divided in two groups and one of those following interventions for closure of surgical incisions on minor surgery will be used: 1. Tissue Adhesives 2. Conventional skin closure (sutures). The main goal of study is to determine the effectiveness of tissue adhesives compared with conventional skin closure techniques. Finally the proportions of wound breaking (dehiscence), the wound infection, the cosmetic appearance, the patient satisfaction, the description of costs of procedures are also determined.

KEYWORDS

Tissue Adhesives, Sutures, Conventional Skin Closure, Minor Surgery, Incision Closure, Dehiscence, Wound Infection, Cosmetic Appearance, Costs of Procedures

INTRODUCTION

WOUND HEALING PROCESS:

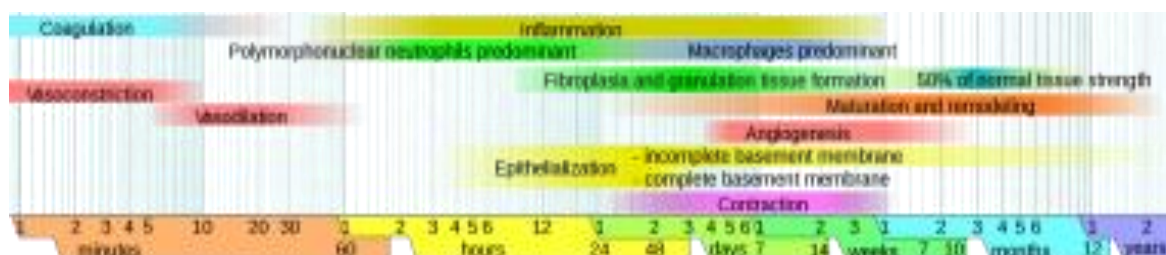
Wounds can heal by second intention, or they can be closed by a variety of methods. Although the skill and technique of the surgeon are important, so is the choice of wound closure materials.(1)

The purpose of these materials is to maintain wound closure until a wound is strong enough to withstand daily tensile forces and to enhance wound healing when the wound is most vulnerable.(2)

In order to fully appreciate the essentials of a wound closure, it is first important to understand the process of wound healing. Healing occurs in 4 stages—homeostasis, inflammation, proliferation, and remodeling:(3)

- The homeostasis phase begins immediately after injury.
- The inflammation stage begins shortly after injury. In this stage, mobilization of the components of the immune system remove damaged tissue and bacteria from the wound.
- The proliferative stage is the tissue-formation stage in which reepithelialization, angiogenesis, and fibroblast proliferation and migration predominate.
- During the final stage (remodeling), the extracellular matrix, which is composed of fibronectin, hyaluronic acid, proteoglycans, and type III collagen, is deposited and constantly altered with the final accumulation of mature type I collagen. This stage may occur for as long as 6-12 months after wounding.

Wound strength gradually increases throughout the healing process, reaching about 20% of the preinjury strength at 3 weeks. Post injury skin strength ultimately only reaches 70-80% of that of normal skin.(4)



1-WOUND HEALING PHASES. IMAGE COURTESY OF MIKAEL HÄGGSTRÖM, MEDICAL GALLERY OF MIKAEL HÄGGSTRÖM 2014

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SUTURES:

In the past the options for wound closure have been largely limited to sutures (needle and thread), with other alternatives such as staples, adhesive tapes and tissue adhesives entering clinical practice more recently.(5)

Traditional methods of surgical incision closure have been used for many years. However, these techniques are not without some problems and it is therefore important to consider new developments that may offer advantages for the patient. The most common device for incision closure is the suture.(6)

As a method for closing cutaneous wounds, the technique of suturing is thousands of years old. Although suture materials and aspects of the technique have changed but the **primary goals** remain the same:

- Closing dead space
- Supporting and strengthening wounds until healing increases their tensile strength
- Approximating skin edges for an aesthetically pleasing and functional result
- Minimizing the risks of bleeding and infection

At the same time we know sutures are not perfect and no one suture possesses or can allow achieving all desirable's goals/characteristics.

The choice of suture technique depends on the following factors:

- Type and anatomic location of the wound
- Thickness of the skin
- Degree of tension
- Desired cosmetic result

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CLASSIFICATION OF SUTURE MATERIALS:(2)

- **Absorbable:** most used polyglactin (vicryl) and polyglycolic (Dexon)
Absorbable sutures are defined by the loss of most of their tensile strength within 60 days after placement. They are used primarily as buried sutures to close the dermis and subcutaneous tissue and reduce wound tension.
- **Non-absorbable:** most used natural silk and synthetic as polyamide (nylon) polyester (Dacron) and polypropylene (Prolene)
No absorbable sutures should be just tight enough to approximate and not strangulate tissues.

TABLE 1				
PARTIAL LISTING OF COMMON SUTURE TYPES				
Suture Type	Absorbable	Non-absorbable	Monofilament	Multifilament
Chromic Gut (Ethicon) (Kendall)	●			●
Vicryl (Ethicon)	●			●
PDS (Ethicon)	●		●	
Monocryl (Ethicon)	●		●	
Nylon (Ethicon) (Kendall)		●	●	
Prolene (Ethicon)		●	●	
Vetafil		●		●
Dexon (Kendall)	●			●
Polysorb (Kendall)	●			●
Biosyn (Kendall)	●		●	
Maxon (Kendall)	●		●	
Surgilene (Kendall)		●	●	
Novafil (Kendall)		●	●	
Silk (Ethicon) (Kendall)		●		●

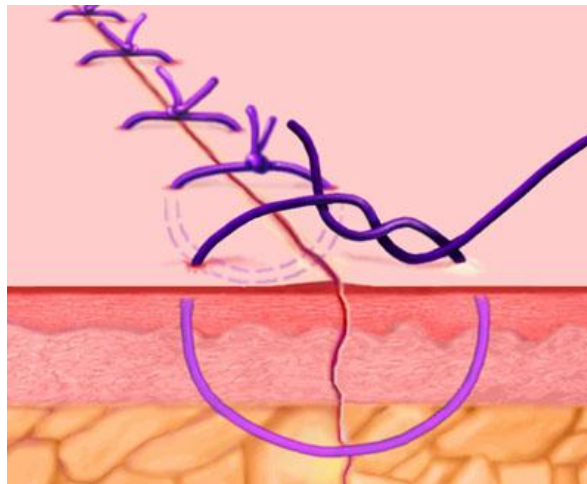
2-HTTP://GEEKYMEDICS.COM/WP-CONTENT/UPLOADS/2015/02/SUTURE-MATERIALS-5.JPG

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SUTURE TECHNIQUES:

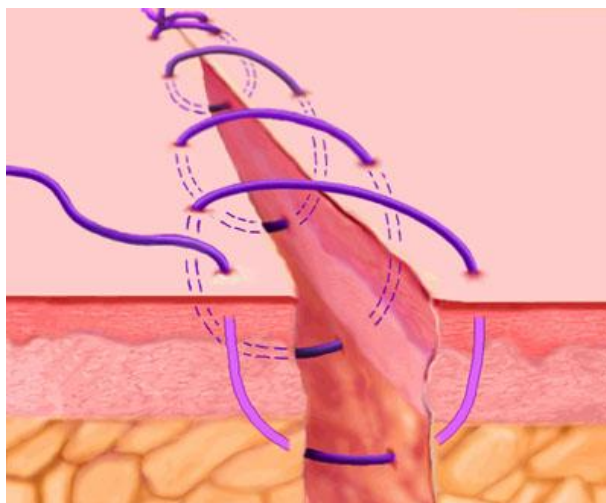
As it was mentioned before, a good suturing technique should eliminate dead space in subcutaneous tissues, minimize tension that causes wound separation. It involves correct wound placement with respect to relaxed tension lines. The baselines of suture techniques are mainly described by simple interrupted suture and simple running suture:

-Simple interrupted suture-easy to place, greater tensile strength, less potential for causing wound edema and impaired cutaneous circulation. Interrupted sutures also allow the surgeon to make adjustments as needed to properly align wound edges as the wound is sutured. Disadvantages include greater length of time required for their placement, greater risk of crosshatched marks across the suture line.



3-SIMPLE INTERRUPTED SUTURE-[HTTP://RESIDENTNET.COM/IMAGES/INTERR.JPG](http://residentnet.com/images/interr.jpg)

-Simple running suture - useful for long wounds, in which wound tension has been minimized, may also be used to secure a split- or full-thickness skin graft, less scarring occurs with running sutures than with interrupted sutures because fewer knots are made with simple running sutures. Disadvantages include possible crosshatching, the risk of dehiscence if the suture material ruptures, difficulty in making fine adjustments along the suture line.(7)



4-SIMPLE RUNNING SUTURE-[HTTP://RESIDENTNET.COM/IMAGES/RUNNING.JPG](http://residentnet.com/images/running.jpg)

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TISSUE ADHESIVES:

Now talking about tissues adhesives and brief explanation what is the nowadays panorama.

Suturing is the most common method used to repair lacerations and incisions. Although wound closure with sutures is safe and effective, it usually requires the painful injection of a local anesthetic, is time-consuming, is operator dependent, requires specialized instruments, carries the risk of a needle stick to the practitioner, and requires a return visit for suture removal.(8)

The ideal method of laceration and incision closure should be simple, safe, rapid, inexpensive, painless, bactericidal, and result in optimal cosmetic appearance of the scar. The cyanoacrylate tissue adhesives offer many of these characteristics. (9)



5-DERMABOND PRINEO-[HTTP://WWW.ETHICON.COM/SITES/DEFAULT/FILES/PRODUCTS/WC/DERMABOND_PRINEO_883X602.PNG](http://www.ethicon.com/sites/default/files/products/wc/DERMABOND_PRINEO_883X602.PNG)

Skin adhesives have been used in variety of different specialties to close skin wounds. Traumatic lacerations encountered in the emergency department are commonly repaired with skin glue. Surgical wounds are traditionally closed with sutures (polydioxanone, polypropylene) and imply rapid wound healing by apposing the epidermal and dermal tissue layers. (10)

First developed in 1949, the cyanoacrylate adhesives are applied topically to the outermost skin layer. The cyanoacrylates are supplied as monomers in a liquid form. On contact with tissue anions, they polymerize, forming a strong bond that holds the apposed wound edges together. For surgical wounds cyanoacrylate sets quickly, often in less than 1 minute. (11)

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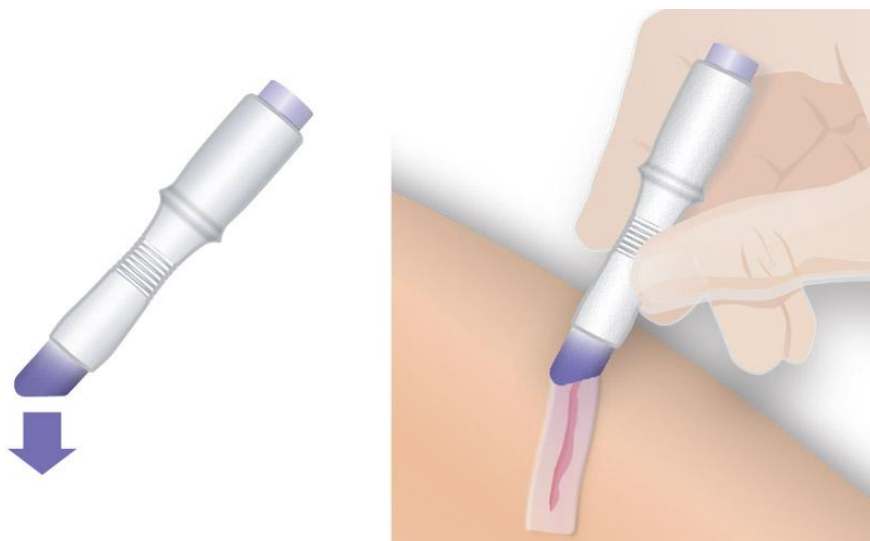
The cyanoacrylate adhesives usually slough off with wound reepithelialization within 5 to 10 days and do not require removal.(12)

The perceived speed of application and ease of use has meant that tissue adhesives have gained popularity but their widespread application was limited as a result of concerns over toxicity such as skin irritation and respiratory problems. These issues have largely been resolved with further advances in pharmaceutical formulations.(8)



6-HISTOACRYL-[HTTP://WWW.NORENGROS.NO/NORENGROS/FRONTEND/MEDIABANK/3/30724/10062-1050052_L.JPG](http://www.norengros.no/norengros/frontend/mediabank/3/30724/10062-1050052_L.JPG)

Cyanoacrylate is the generic name for fast-acting cyanoacrylate-based glues such as ethyl-2-cyanoacrylate, n-butyl-cyanoacrylate, and 2-octyl cyanoacrylate; the latter is commonly used in medical glues such as Indermil, Histoacryl, Dermabond, Nexaband, and Traumaseal. (13)



7-SURGISEAL STYLUS-[HTTP://WWW.KEBOMED.CO.UK/IMG/UPLOADS/33/SURGISEAL_STYLUS2.JPG](http://www.kebomed.co.uk/img/uploads/33/surgiseal_stylus2.JPG)

JUSTIFICATION

Sutures, staples and adhesive tapes have been used for many years as methods of wound closure, but tissue adhesives have entered clinical practice more recently.(11) Closure of wounds with sutures enables the closure to be meticulous, but the sutures may show tissue reactivity and can require removal. Tissue adhesives offer the advantages of an absence of risk of needle stick injury and no requirement to remove sutures later.(14)

The use of adhesives has increased in providing increased ease of use and speed as key advantages regarding the use of sutures(15). Besides these important advantages the use of tissue adhesives reveals a clear superiority on the satisfaction of patients regarding the use of this technique(16).

Considering that the use of sutures are based on the introduction of the occurrence of foreign material so the rate of incisions becoming infected in surgical wound are relatively superior in sutures to the use of tissue adhesives.(17)(18)(19)

At cosmetic level is another important study in minor surgery some references demonstrate the best cicatrization and appearance of the scar that is formed in the post-surgical period(20)(21)(22)

Another important aspect is the relative cost of the materials used in the closure of surgical wounds .In this case tissue adhesives have a higher cost doubling the cost of the use of sutures for closing incisions but can offers an advantage that the use of the adhesive not require a post-surgical control to review the incision and consequent removal of non-absorbable suture points.(11)(15)

The most important aspect that determines the safety of use of the adhesive versus suture is wound dehiscence among the literature published to date is determined that the use of adhesive is safe and that the variable does not vary significantly dehiscence independently from its method of closure of surgical wounds.(11)(23)(24)

So, why is important to study the use Tissue adhesives versus Sutures on Minor surgery?

Minor surgery represents an important volume of surgeries performed by plastic surgeons. Time is an important factor because today hospitals are overwhelmed. Managers only think about the cost effectiveness in clinical practice.

Therefore Minor surgery works on small surgical fields where close smaller surgical wounds where the execution time is lower and volume of patients are higher maintaining a concentrated work. All this leads to an accumulation of Surgeries that take years to be realized. To get an idea currently waiting time waiting for organization of a proceeding as to the removal of nevus is between one and two years.

Reviewing the literature publish to date I found that tissue adhesives has been used in a large number of procedures as brain surgery, spinal surgery, hernia, thyroidectomy incision closure, coronary artery bypass graft surgery, simple traumatic laceration in children. On the

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other hand I couldn't find any specific study that determines the effectiveness of tissues adhesives compared to sutures on Minor surgery.

For all these reasons mentioned above I think it is in the area of Minor Surgery that the introduction of tissue adhesives would more advantageous and would be considered in addition to a safe and viable alternative to sutures, a real gold standard in incisions correctly SELECTED explain later the second which inclusion criteria.

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HYPOTHESIS

The main hypothesis of this study is that there is not a significant difference on dehiscence between patients treated with Tissue Adhesives and patients treated with conventional skin closure techniques on minor surgery.

Secondary hypotheses are the following:

- Less proportion of wound becoming infected using Tissue adhesives versus conventional skin closure with sutures
- Better cosmetic appearance for patient and plastic surgeon at or after 3 months of minor surgery using Tissues adhesives versus conventional skin closure with sutures
- Better satisfaction for patients using Tissue adhesives compared with conventional skin incision closure
- Less comparative cost of full-complete procedure (materials/follow-up consultation/possible complications) using Tissue adhesives versus conventional skin closure with sutures

In summary, knowing the tissue adhesives proprieties our hypothesis is that tissue adhesives are a safe alternative to conventional skin closure using suture as standard choice on minor surgery.

OBJECTIVES

MAIN OBJECTIVE

In this study the main objective is to compare the proportion of wounds breaking down (wound dehiscence) after using tissue adhesives versus sutures for closure of surgical incisions on minor surgery

SECONDARY OBJECTIVES

- To compare the proportion of wounds becoming infected using TA versus suture for closure of surgical incisions on minor surgery
- To compare the cosmetic appearance at or after 3 months by investigator and patient where both have used a validated measure using TA versus for closure of surgical incisions on minor surgery
- To compare patients satisfaction with skin incision closure technique (TA versus sutures on minor surgery)
- To compare relative cost of full-complete procedure (materials+-visit) required for skin incision closure techniques (TA versus Sutures on minor surgery)

METHODS

STUDY DESIGN

The study will be a multicentre, randomized, controlled, open-label, parallel-group and non-inferiority clinical trial designed to evaluate the efficacy and safety of Tissue Adhesives versus Sutures for closure of surgical incisions on Minor Surgery. The study will be conducted in the Plastic Surgery department of Hospital Universitari Josep Trueta (HUIT), Girona and Hospital St. Caterina, Salt.

Subjects will be randomized in a 1:1 ratio to Tissue Adhesives or Sutures for closure of surgical incisions on Minor Surgery.

The estimated time to perform the study and showing the final results and conclusions is two years.

STUDY POPULATION

This is a multicentre study, the sample will be extracted from the patients scheduled to perform Minor surgery procedures at Josep Trueta Hospital and St Caterina Hospital.

INCLUSION CRITERIA

Patients must meet all this following criteria to enter in this study:

- Tension free area on surgical incision
- No previous procedure performed on surgical incision location
- Linear surgical incision
- Size of surgical incision less than 5cm

EXCLUSION CRITERIA

Patients meeting any single exclusion criteria will be excluded from the study:

- Contused, stellate, puncture, infected, heavily contaminated or devitalized wounds
- Surgical incisions above crossing-joints, muco-cutaneous junctions and hair-bearing areas
- Patients with keloid formation
- Previous procedure performed on surgical incision location

SAMPLE SIZE

Accepting an alpha risk of 0.05 and a beta risk of 0.20 in a bilateral contrast, we need 166 patients in each group to perceive a minimum relative risk of 0.15 (332 subjects in total). We have estimated that the tax of follow up loses will be 20%, taking into account those patients that will not come to the follow up visits and those patients who will die because of their underlying disease. The sample size has been obtained with the program GRANMO Calculator. The POISSON approximation has been used.

Acknowledging the numbers of Minor Surgery procedures performed in the Hospital Dr Josep Trueta and Hospital of St. Caterina which is around 300 cases per year we will need at least 2 years to reach the sample size confirm or refuse our hypothesis with a high level of evidence and publish our research findings.

STUDY INTERVENTIONS

Patients who respect inclusion and exclusion criteria will receive one of those followings interventions for closure of surgical incisions on minor surgery:

- Surgical skin incision closure with tissue adhesive “surgiseal stylus” (2-octyl cyanoacrylate)
- Surgical skin incision closure with conventional closure system such as sutures (subcutaneous-intradermique-superficial)

STUDY VARIABLES

INDEPENDENT VARIABLES

- Surgical skin closure with tissue adhesive
- Surgical skin closure with conventional skin closure such as sutures

DEPENDENT VARIABLES

- Wounds breaking down (wound dehiscence)
- Wounds becoming infected
- Cosmetic appearance at or after three months by investigator and patient
- Patient satisfaction with skin incision closure technique
- Cost of full-complete procedure of each skin incision closure technique

Co-variables

A complete understanding of the anatomy and physiology of the skin, the phases of the healing process, the types of wounds, and the options for wound repair is essential for recognizing factors that may complicate or delay wound healing. This way we consider as co-variables the various factors that may delay or impede healing-local and systemic that also they could be interpreted as confounding factors.

- Age-The main features of cutaneous wound healing in older people include: an altered inflammatory response; decreased collagen synthesis and increased degradation; delayed angiogenesis; and slower reepithelialization. The changes associated with age may predispose older people to the deleterious effects of ischemia and other factors that impair wound healing.(25)
- Skin lesion location- the site of incision closure is obviously an important factor against the cicatrization because it's not the same an incision closure in the back or joint that is an high tension area than an tension free area.(26)
- Wound/Incision closure size-Perhaps the most important element of the initial assessment in terms of predicting subsequent healing and hard to-heal status, is to carefully map and measure the wound.(27)
- Skin lesion- Another element is the aetiology of skin lesion because this is determines what type of incision closure would be performed.(27)(26)
- Comorbidities- Patients with hard-to-heal wounds may have a number of comorbid conditions that affect incision closure process. Diabetes is a significant factor and can affect healing process.(28)(27)

MEASURE INSTRUMENTS

The measure instruments that will be used in the study are the following:

Wound dehiscence----Wound dehiscence is one of the most common complications of surgical wounds, involving the breaking open of the surgical incision along the suture and in this case we will consider as wound dehiscence a separation of wound edges more than 2cms at follow-up visit at 7-14 days after minor surgery (yes or no).

Wound infection----- follow up at 7-14days after procedure with wound culture test to find and identify germs that may be growing on the wound. A sample of skin, tissue, or fluid is collected from the affected area and placed in a container with a substance (called growth medium or culture medium) that helps organisms grow (yes or no).

Wound cosmetic appearance---follow-up after 3 months ---This assessment must be performed by a plastic surgeon using standard VANCOUVER SCALE. To patient evaluation must use the Visual Analogue Scale (A sheet of paper on which a 10 – centimeter line is drawn and

divided into 10 equal parts from which the parents were asked to assess their level of satisfaction). Zero represented the worst scar the parents could ever imagine while 10 represented the finest. (Annex IV-V)

Patient satisfaction about the technique performed---- follow after 3 months –this assessment must be done by the patients and where they could show in the POSAS questionnaire their satisfaction about procedure used. (Annex I)

Costs of full-complete procedures on trial ---- record the data about each patient and what method of procedure including the price of stuff used. We need take in account all of this including follow-up consultation and possible complications as dehiscence and infection. This way we could get the final numbers about how much we need to perform using one method or the other one. The prices used will be consulted according DOGC (Diari Oficial de la Generalitat de Catalunya).

METHODS OF DATA COLLECTION

The data will be collected from the electronic medical records, anthropometric measures, and medical visits of the participating patients and will be reflected in the trial database. Moreover, information will be collected in a Patient Data Sheet (Annex VI) during the period of clinical trial at following times:

- Trial entry and randomization
- At day of admission – before and after surgery
- During the post-surgical period (7th-14th post-surgical day and 3rd month by POSAS questionnaire-VANCOUVER scar scale-VISUAL analogue scale)

The Patient Data Sheet will include different sections, each one for each appointment in which specific data will be collected. In each appointment, the person who will collect the data will have to write his/her surname and the date when the data is collected. All data should be introduced to a computer database after each appointment in order to have two copies of the Patient Data Sheet.

Data will be collected by the study team that will include four plastic surgeons and two nurses. Each member will be previously taught and trained so to know the questionnaire, the methodology of collecting data and how and when each item should be collected.

ENROLLMENT AND RANDOMIZATION PROCESS

All patients with scheduled minor surgery procedure admitted in the Hospital Josep Trueta and Hospital St. Caterina will be assessed to participate in the study. After it has been verified that they are eligible per inclusion and exclusion criteria, they will be enrolled in the study once have signed the informed consent.

The randomization process will be conducted by the main investigator by simple randomization. Enrolled participants will be randomly assigned at a 1:1 ratio between Tissue Adhesive versus Standard Skin closure (sutures) by using cards in sequentially numbered, sealed opaque envelopes. Each patient will be assigned an identification number obtained by a number code generator to maintain personal data confidentially.

Plastic surgeons will be also randomized in order to decrease inter-surgeon variation.

Subjects withdrawn from the study will not be replaced.

EXECUTION PLAN AND SCHEDULE EVENTS

1-At the first visit on plastic surgery department the surgeon must analyze what kind of procedure will perform at future minor surgery procedure.

2-Once a time plastic surgeon has an idea what type of incision closure could perform according the skin lesion at this moment he must consider if the wound meet the inclusion and exclusion criteria to enter on trial.

3-That patients who meet the criteria must be informed about the current trial by the explanation of plastic surgeon and corresponding information sheet.

4-After this even in the same visit if the patient accepts enters on clinical trial he must read and sign the informed consent.

5-Once we have informed consent signed patient could enter on our database.

6-At this point the randomization process will be conducted by the main investigator by simple randomization. Enrolled participants will be randomly assigned at a 1:1 ratio between Tissue Adhesive versus Standard Skin closure (sutures). Each patient will be assigned an identification number obtained by a number code generator.

7-Day of Procedure and data collection according procedure realized and data about patient

8-Post surgical period at 7-14day – evaluation of the wound closure and detecting if exist dehiscence or the wound become infected.

9-Post surgical period at 3months after minor surgery – evaluation of remain variables as cosmetic appearance and satisfaction of patient.

STATISTICAL ANALYSIS

In the univariate analysis, we will define variables as categorical or continuous. - Categorical variables are Wound dehiscence and wound infection. Each categorical variable will be described as percentages and proportions. - Quantitative variables are cosmetic appearance (evaluated by VANCOUVER SCAR SCALE and Visual analogue scale—0-10) and Patient satisfaction according to POSAS questionnaire and Costs of procedures. Each quantitative variable will be described as means +/- standard deviation assuming a normal distribution.

In the bivariate analysis, the comparison between the independent and the dependent variables, as they are both categorical, will be realized with the relative risk or with a Chi Square test or a Fisher's exact test. For the comparison between the independent and the secondary dependent variables, Student's t-test will be used as the independent is a categorical variable and the secondary dependent variables are quantitative.

In the multivariate analysis, we will use a type of probabilistic statistical classification model such a logistic regression adjusted for all the co variables.

IBM SPSS Statistics will be the software package that will be used for statistical analysis. To manage computed data, Microsoft Excel tool will be used. We will considerate all variables statistically significant if p value <0.05.

ETHICAL ASPECTS

This trial is designed in accordance with the medical ethics requirements defined on the World Medical Association Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects (last revised in October 2013) and it has been approved by the Clinical Research Ethics Committee (CEIC) of the Hospital Universitari de Girona Dr. Josep Trueta.

As it is now recommended, the trial has also been registered with an International Standard Randomized Controlled Trial Number (<http://www.controlled-trials.com>) and has been submitted to ClinicalTrials.gov (<http://clinicaltrials.gov>).

The information will be confidential, guaranteeing the anonymity of the patients involved in the study under the Organic Law of Data Protection 15/1999. In addition, patients will be informed about the interventions (ANNEX II) and they must sign an informed consent (ANNEX III) before being included in the trial.

STUDY LIMITATIONS AND BIASES

The main limitation of the study is that is an open-label trial. That means the patient, plastic surgeons and the study team will know in which incision closure technique group is the patient include.

Plastic surgery has only four surgeons and Plastic surgery department is full of work performing a lot head cancers and over booked performing breast cancer reconstruction and head-neck surgery.

Four plastic surgeons will participate in the surgeries so it may be a limitation as the surgeon experience and technique can be a factor that may be determinant of the results. To avoid inter-surgeon variation, they will be randomly assigned and they will perform a similar amount of surgeries.

Data collection may be another limitation as six study members are involved in it. To avoid mistakes and missing data, all members will be previously trained to use the Patient Data Sheet correctly.

In statistics, a covariate is a variable that is possibly predictive of the outcome under study. A covariate may be of direct interest or it may be a confounding or interacting variable. In order to minimize the effects of age-comorbidities-location-size-aetiology on our research findings we will use a type of probabilistic statistical classification model such a logistic regression adjusted for all the co variables.

Lost to follow-up may be a limitation in the study but we expected it will be minimum as most of the appointments are part of the medical care.

The study will be performed in a small Health Area of Catalonia with a small number of patients which may be difficult to extrapolate to other regions or countries. However, randomization of patients and using validated questionnaires increases reliability to extrapolate outcomes to other regions or countries.

WORK PLAN

PERSONNEL OF THE RESEARCH TEAM

The research team will be composed by four plastic surgeons, two nurses, a computer engineer and a statistical specialist.

STUDY STAGES

The study has been designed in four stages that are described below:

STAGE1- COORDINATION

- Obtaining the ethical approval from the Clinical Research Ethics Committee (CREC). The general coordinator of the study (chief of plastic surgery) will be the responsible of this activity.
- Informative meeting. The chief of plastic surgery department will explain all the objectives to the rest of the research team. The chronogram of the study will be done and tasks will be distributed.
- Database elaboration. The Statistical specialist will be in charge to create a database in order to ease data extraction and data management.

STAGE 2-STUDY CONDUCTED

- Patient recruiting, randomization, coding and data collection from procedures and follow up consultation
- Doctors will recruit patients during 6months and after that; the Statistical specialist will randomize and give a code to each one of them. Data will be introduced in the database after each appointment
- Data cleansing from database and data quality assurance and control. The Statistical specialist will be responsible for maintaining a good quality of data and make sure all the information of each patient is correctly introduced in the database.

STAGE 3- DATA ANALYSIS AND INTERPRETATION

- Statistical analysis. Data will be analyzed using the appropriate statistical tests by the Statistical specialist.
- Interpretation and discussion of the results. The results will be interpreted and discussed by the plastic surgeons, nurses and Statistical specialist.

STAGE 4- PUBLICATION AND DISSEMINATION OF THE RESEARCH FINDINGS

- Publication of the results. Articles will be written and we will also attempt to publish them in a plastic surgery journal.
- Dissemination of the findings. We will attempt to assist to conferences about Incision closure techniques to present the results.

USE OF TISSUE ADHESIVES VERSUS SUTURES ON MINOR SURGERY FOR INCISION CLOSURE

ACTIVITY	TASK	JAN-MAR 2016	ABR-2016 ABR-2017	MAY-JUL 2017	SEPT-OCT 2017	NOV-DEC 2017
COORDINATION PHASE	First research team meeting					
	Ethical approval from the clinical research ethics committee					
	Database elaboration					
STUDY CONDUCTED DATA EXTRACTION AND PROCESSING DATABASE	Patient recruiting					
	Statistical randomization					
	Data collection from appointments					

USE OF TISSUE ADHESIVES VERSUS SUTURES ON MINOR SURGERY FOR INCISION CLOSURE

ACTIVITY	TASK	JAN-MAR 2016	ABR-2016 ABR-2017	MAY-JUL 2017	SEPT-OCT 2017	NOV-DEC 2017
DATA ANALYSIS AND INTREPRETATION	Review of data collected from appointments					
	Statistical analysis					
	Interpretation and discussion of the results					
PUBLICATION AND DISSEMINATION OF RESEARCH FINDINGS	Publication of the results in a plastic surgery journal					
	Scientific diffusion at plastic surgery meetings and conferences					

BUDGET AND AVAILABLE MEANS TO CARRY OUT THE PROJECT

The appointments and surgeries will not be included in the budget because they are part of the National Health System.

On the other hand it's important to know the prices of **a standard incision closure** versus use of tissue adhesive for you have an idea for incision closure generally **you use 2types of sutures and minimum cost goes around 2euros to 6 Euros(medium 4eur)**. To this price we need to add the price of **follow-up consultation** to quite the suture points and check the wound if it's ok that cost around 60euros. Now analyzing the prices by **using tissue adhesive** the price is a little bit higher and **goes around 8eur** per unit but using this method we **don't need a follow up** consultation and you save time and personnel.

We will hire a statistical specialist in order to randomize and code patients, do data quality control, statistical analysis, discussion and publication of the results. The estimated salary will be 30€ per hour and approximately 30 hours of statistical support will be needed. Then, the estimated cost will be 900€.

Translation of evaluations tools (POSAS-VAS-VANCOUVER) TO CATALAN AND SPANISH WILL HAVE A COST OF 50EUR each.

USE OF TISSUE ADHESIVES VERSUS SUTURES ON MINOR SURGERY FOR INCISION CLOSURE

SERVICES AND DISPOSABLE ITEMS	ITEM	QUANTITY	DESCRIPTION	PRICE	COST
	Conventional Method for incision closure	166	Absorbable suture +- Non-absorbable suture	4EUR	664EUR
	Tissue adhesive	166	Surgiseal is the brand used at our hospital	8EUR	1.328EUR
	Follow up evaluation 3 months	332	Consultation/evaluation for cosmetic appearance and satisfaction	60EUR	19.920EUR
	Statistical specialist	1	Statistical analysis	30EUR/30Hour	900EUR
	Translation of evaluations tools VAS/VANCOUVER/POSAS	3	Translate to Spanish and Catalan	50EUR/each questionnaire	150EUR
	Trial Insurance	332	Each patient must have and individual insurance		XXXXXXEUR
				TOTAL	22.962EUR

PUBLICATION AND DISSEMINATION COSTS	ACTIVITY	COST
	Publication of research findings	1.000EUR
	Travel costs-coordination and investigators meetings	3.000EUR
TOTAL		4.000EUR

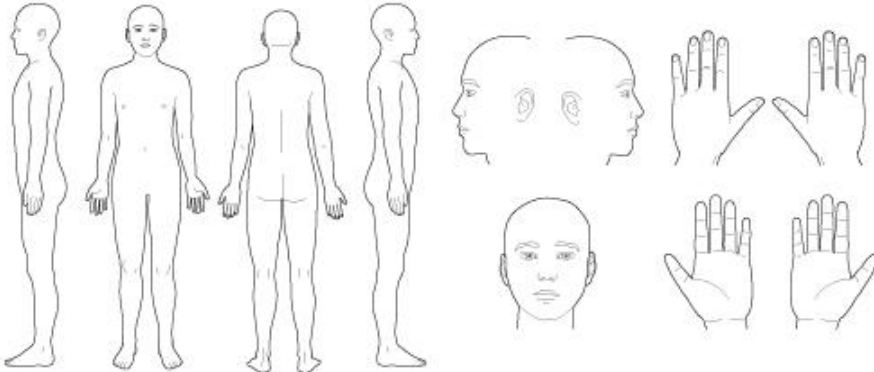
TOTAL AMOUNT AND AID CLAIMED	26.962EUR
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ANNEXES

ANNEX I- POSAS PATIENT EVALUATION

POSAS Patient scale
The Patient and Observer Scar Assessment Scale v2.0 / EN

Date of examination: _____ Name of patient: _____
Observer: _____
Location: _____ Date of birth: _____
Research / study: _____ Identification number: _____



1 = no, not at all yes, very much = 10
1 2 3 4 5 6 7 8 9 10

HAS THE SCAR BEEN PAINFUL THE PAST FEW WEEKS? ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

HAS THE SCAR BEEN ITCHING THE PAST FEW WEEKS? ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

1 = no, as normal skin yes, very different = 10

IS THE SCAR COLOR DIFFERENT FROM THE COLOR OF YOUR NORMAL SKIN AT PRESENT? ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

IS THE STIFFNESS OF THE SCAR DIFFERENT FROM YOUR NORMAL SKIN AT PRESENT? ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

IS THE THICKNESS OF THE SCAR DIFFERENT FROM YOUR NORMAL SKIN AT PRESENT? ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

IS THE SCAR MORE IRREGULAR THAN YOUR NORMAL SKIN AT PRESENT? ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

1 = as normal skin very different = 10
1 2 3 4 5 6 7 8 9 10

WHAT IS YOUR OVERALL OPINION OF THE SCAR COMPARED TO NORMAL SKIN? ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

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8-[HTTP://WWW.POSAS.ORG/WP-CONTENT/UPLOADS/POSASV2-0_PATIENTSCALE-EN1.JPG](http://www.posas.org/wp-content/uploads/POSASV2-0_PATIENTSCALE-EN1.JPG)

ANNEX II- INFORMATION SHEET FOR PARTICIPANTS

Hospital Dr. Josep Trueta, Av. França s/n 17007 Girona	INFORMACIÓN AL PACIENTE	Use of Tissue Adhesive versus Sutures on Minor surgery for incision closure
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HOJA DE INFORMACIÓN AL PACIENTE

Usted, está invitado a participar en un estudio clínico sobre el cierre de incisiones quirúrgicas en la cirugía menor ambulatoria. El período de duración del estudio será de dos años durante el cual se recogerán datos clínicos, coincidiendo con los controles de salud con el departamento de cirugía plástica.

La Cirugía Menor Ambulatoria incluye una serie de procedimientos quirúrgicos sencillos y generalmente de corta duración, realizados sobre tejidos superficiales y/o estructuras fácilmente accesibles, bajo anestesia local, que tienen bajo riesgo y tras los que no son esperables complicaciones postquirúrgicas significativas.

Las patologías más habituales que se tratan con cirugía menor son: drenaje o desbridamiento de infecciones de la piel, abscesos, forúnculos o panadizos, exéresis de hidradenitis crónica, xantelasmas, quistes sebáceos, lipomas, verrugas, quistes epidérmicos, fibromas, papilomas y moluscos, queratosis seborreica, tumores epidermoides, cuerpo extraño, úlceras, abscesos, paroniquias, exéresis de la uña, reconstrucción de heridas, desbridamientos de heridas, quemaduras, úlceras o tejidos desvitalizados, entre otras.

Finalmente debe registrarse adecuadamente el procedimiento realizado por Cirugía Menor en la historia clínica y asegurar la recogida de muestras y su análisis anatómico-patológico, garantizando al paciente un seguimiento postquirúrgico apropiado.

El propósito de este estudio consiste en comparar dos enfoques de atención médica, en pacientes que están solicitados para una intervención quirúrgica de cirugía menor ambulatoria. Se comparará el enfoque actual que remonta a la utilización de suturas para el cierre de heridas quirúrgicas con un nuevo enfoque según características pre determinadas de las incisiones quirúrgicas en el que se caracteriza por el uso de adhesivos tisulares.

Que son los adhesivos tisulares?

Los adhesivos tisulares o pegamentos de tejidos son sustancias o materiales que se usan en medicina para cerramiento de laceraciones o heridas traumáticas o quirúrgicas (incisiones) como alternativa al uso de suturas, grapas o cintas adhesivas que son los métodos tradicionales.

Son sustancias que polimerizan en contacto con los tejidos y esta polimerización puede unir los tejidos y actuar como sellante.

Se usan como alternativa aceptable a la sutura quirúrgica para cierre de heridas o incisiones pequeñas o sencillas de piel en áreas con poca tensión. Ofrecen la ventaja para el paciente de que son menos dolorosas y que no hay material que retirar posteriormente y para el cirujano no existe riesgo de lesión por pinchazo. Se han utilizado principalmente en el servicio de urgencias y en niños, pero los estudios señalan que los cirujanos pueden considerar el uso de adhesivos tisulares para el cierre de incisiones en el quirófano en todo tipo de procedimientos.

En este estudio clínico participaran 436 pacientes que se encuentran citados para un procedimiento de cirugía menor ambulatoria.

Después del procedimiento quirúrgico se citara usted para consultas posteriores con la intención de evaluar la incisión quirúrgica. En este momento se necesitara que usted nos ofrezca su valoración cuanto al aspecto de la cicatriz quirúrgica que será valorado por una escala analógica visual y también su valoración en forma de cuestionario relativamente a la sanitación del procedimiento realizado.

Este estudio clínico es voluntario y no remunerado, si usted acepta participar en él se incorporado en uno de los grupos de estudio de forma aleatoria.

Como a resultado del estudio, esperamos tener un mejor conocimiento de cómo evolucionan al largo del tiempo las incisiones quirúrgicas segundo el procedimiento usado para el cierre quirúrgico. Estos resultados pueden ser útiles también para el diseño de nuevas metodologías y posibilidades terapéuticas.

La información recogida en este estudio será introducida en una base de datos computarizada (en un ordenador) para su análisis. Los resultados de este estudio se utilizarán para su presentación en congresos médicos o la publicación en revistas científicas.

Todos los datos de carácter personal e información recogida o generada en el estudio quedan protegidos de acuerdo con la legislación vigente sobre protección de datos de carácter personal (Ley Orgánica 15/1999 de 13 de diciembre). Nadie, excepto su médico y el personal directamente relacionado con este estudio, podrá conocer la identidad. Únicamente las autoridades sanitarias pueden tener acceso a las secciones relevantes del estudio, si así lo solicitaran.

Su participación en este estudio es voluntaria, por lo que, aunque inicialmente aceptara participar, usted podrá solicitar a los responsables del estudio, en cualquier momento y sin necesidad de especificar el motivo, el eliminación de todas las muestras recogidas que se encuentren almacenados y de la información relacionada con las mismas, sin que ello repercuta en sus cuidados médicos.

Por favor, no dude en hacernos cualquier pregunta al respecto.

Teléfono de contacto: **972 94 02 00** (de 9:00 a 15:00h).

ANNEX III- INFORMED CONSENT FOR PARTICIPANTS

Hospital Dr. Josep Trueta, Av. França s/n 17007 Girona	CONSENTIMENT O INFORMADO	Use of Tissue Adhesive versus Sutures on Minor surgery for incision closure
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CONSENTIMIENTO POR ESCRITO DEL PARTICIPANTE

TITULO DEL ESTUDIO: Use of tissue adhesives versus sutures on minor surgery for incision closure

Yo.....

Confirmo que:

He leído la hoja de información que se me ha entregado.

He podido hacer preguntas sobre el estudio.

Han respondido mis preguntas de manera satisfactoria.

He recibido suficiente información sobre el estudio.

He hablado con (nombre del investigador / cirujano plástico / enfermero):

.....

Comprendo que la participación es voluntaria, y que puedo retirarme del estudio cuando quiera, sin que ello repercuta en los cuidados médicos y sin dar explicaciones.

USE OF TISSUE ADHESIVES VERSUS SUTURES ON MINOR SURGERY FOR INCISION CLOSURE

En consecuencia,

Doy mi conformidad para entrar en este estudio.

Sí----- No-----

Permito al personal del estudio que consulte la mi historia clínica con la finalidad de verificación de los datos.

Sí----- No-----

Permito que todos los datos sobre el procedimiento y la demás información recopilada durante el estudio realizado sean utilizados en investigaciones futuras en el ámbito de Cirugía Plástica y Reparadora.

Sí----- No-----

Firma del participante: -----

Firma del investigador: -----

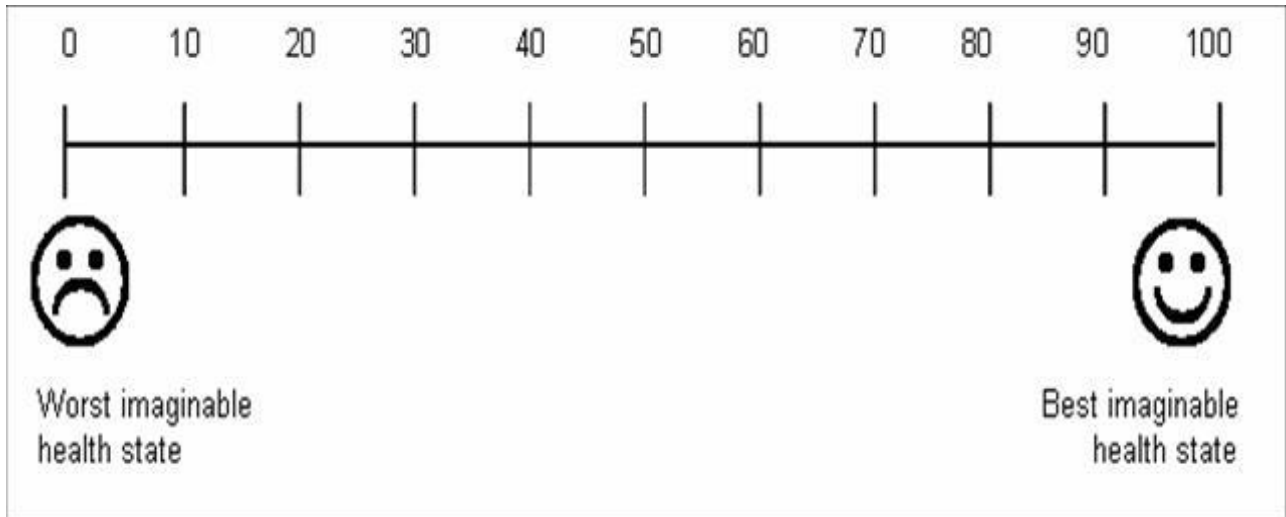
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ANNEX IV- VANCOUVER SCAR SCALE-COSMETIC APPEARANCE EVALUATION (OBSERVER)

9-VANCOUVER		SCAR	SCALE-
Feature		Score	
Vascularity	Normal		0
	Pink		1
	Red		2
	Purple		3
Pigmenta- tion	Normal		0
	Hypo-pigmentation		1
	Mixed-pigmentation		2
	Hyper-pigmentation		3
Pliability (Elasticity)	Normal		0
	Supple (flexible with minimal resistance)		1
	Yielding (giving way to pressure)		2
	Firm (inflexible, not easily moved, resistant to manual pressure)		3
	Banding (rope-like tissue that blanches with extension of the scar)		4
	Contracture (permanent shortening of scar, producing deformity or distortion)		5
Height	Flat		0
	< 2 mm		1
	2-5 mm		2
	> 5 mm		3
Pain	None		0
	Occasional		1
	Requires medication		2
Itchiness	None		0
	Occasional		1
	Requires medication		2

[HTTP://WWW.JKMS.ORG/SEARCH.PHP?WHERE=AVIEW&ID=10.3346/JKMS.2014.29.S3.S249&CODE=0063JKMS&VMODE=PUBR
EADER](http://www.jkms.org/search.php?where=aview&id=10.3346/jkms.2014.29.s3.s249&code=0063jkms&vmode=publisher)

ANNEX V- VISUAL ANALOGUE SCALE-COSMETIC APPEARANCE EVALUATION (PATIENT)



10-VISUAL ANALOGUE SCALE-[HTTP://EDOC.HU-BERLIN.DE/UMACJ/1/CHATTERJEE-HELEN-1/XML/CHATTERJEE1.JPG](http://EDOC.HU-BERLIN.DE/UMACJ/1/CHATTERJEE-HELEN-1/XML/CHATTERJEE1.JPG)

ANNEX VI-PATIENT DATA SHEET

PATIENT DATA SHEET	
PROJECT TITLE	USE OF TISSUE ADHESIVES VERSUS SUTURES ON MINOR SURGERY FOR INCISION CLOSURE

PATIENT INFORMATION	
IDENTIFICATION NUMBER (CODE)	DATE OF BIRTH
EMAIL	TELF
SEX	MALE FEMALE

ANTHROPOMETRIC MEASURES		
HEIGHT (M)	WEIGHT (KG)	BMI

PERSONAL-SURGICAL ANTECEDENTS	
ALLERGIES	
REGULAR MEDICATION	
CORMOBILITIES	

USE OF TISSUE ADHESIVES VERSUS SUTURES ON MINOR SURGERY FOR INCISION CLOSURE

APPOINTMENT 1- FIRST VISIT		
DOCTOR SURNAME		
DATE		
DESCRIPTION OF SKIN LESION		
	YES	NO
PATIENT HAS READ THE INFORMATION SHEET		
PATIENT HAS SIGNED THE INFORMED CONSENT		

APPOINTMENT 2- SURGERY DAY	
DOCTOR SURNAME	
DATE	
DESCRIPTION OF PROCEDURE	
INCISION CLOSURE TECHNIQUE	
DATE OF SCHEDULE NEXT VISIT	
INDICATIONS TO THE PATIENT	

APPOINTMENT 3- 7-14TH DAY POST-SURGICAL VISIT	
DOCTOR SURNAME	
DATE	

DESCRIPTION OF EVOLUTION OF INCISION CLOSURE
--

	YES	NO
DEHISCENCE		
INFECTION		
OTHER COMPLICATIONS		
IF YES --- DESCRIBE IT		

USE OF TISSUE ADHESIVES VERSUS SUTURES ON MINOR SURGERY FOR INCISION CLOSURE

APPOINTMENT 4- ESTIMATED 3MONTHS AFTER SURGICAL PROCEDURE	
DOCTOR SURNAME	
DATE	

DESCRIPTION OF EVOLUTUION OF INCISION CLOSURE
--

	YES	NO
COMPLICATIONS		
IF YES --- DESCRIBE IT		

VARIABLE	METHOD	RESULT
COSMETIC APPEARENCE		
	VANCOUVER SCAR SCALE	
	VISUAL ANALOGUE SCALE	
PATIENT SATISFACTION		
	POSAS QUESTIONNAIRE	