Universitat de Girona
Facultat de Medicina

FINAL DEGREE PROJECT

COSMETIC OUTCOME OF NONABSORBABLE CONTINUOUS INTRADERMAL SUTURES VERSUS SKIN STAPLES FOR SKIN CLOSURE FOLLOWING A PAROTIDECTOMY FOR BENIGN PAROTID TUMORS IN ADULTS

OPEN-LABEL RANDOMIZED CONTROLLED TRIAL

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I would like to extend my deepest gratitude to my clinical tutor, Manel Gorina, for his patience and effort in guiding me throughout this project.

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I must also thank the Oral and Maxillofacial Surgery Department of Hospital Josep Trueta for embracing me and making me feel part of the team during my clinical practices and the Universitat de Girona for all these years.

Thank you Mireia and Cristina, for being my "partners in crime" and making it easier every step of the way.

And last but not least, I would like to thank my parents and Carles for their unconditional love and support, all this would have been impossible without you.

PERSONAL MOTIVATION

From a very young age I was introduced into the world of aesthetic medicine which gave me the opportunity to see with my own eyes the amount of people that struggle with their appearance and how it affects their life. After nearly six years of medical studies, I also learned about and witnessed, many patients being treated of life-threatening conditions. The idea of a healthy patient that is simply unsatisfied with his or her image became obscure and eventually, even absurd. Nevertheless, at some point, a new concept was introduced into my vocabulary, “quality of life”, a term that was heard from many but applied by few. It became clear to me that the cosmetic outcome is, sometimes, not a redundant desire but rather an answer to an important health concern that can have implications for psychological happiness and quality of life, equivalent to, or perhaps greater than any other medical intervention.

The face is undoubtedly one of the most exposed features of the human body. Whether it's a curled lip or a high cheekbone, we all make quick social judgements based on strangers' faces. During my stay at the Oral and Maxillofacial Surgery Department, I was able to confirm every theory I had on the importance of one’s appearance. Even if most, especially oncologic, patients at fist say that they will not be bothered by a scar, once the surgery is performed, they come to the follow-up sessions with questions on how long will it take to disappear and what can they do to improve it. Therefore, it is clear that people do care and even if scarring may be skin deep, its impact goes deeper still.

With this being said, I was motivated to study the cosmetic outcome of the facial surgeries and how or what could be done to improve it. After talking the idea through with my clinical tutor, we decided to limit the study population to those patients with benign parotid tumors who are scheduled to undergo a parotidectomy via modified Blair incision (MBI). This would allow me to avoid many confounding variables (wound related factors that affect the healing process) that could alter the results of the trial. While it might not be my final goal, sometimes you need to start small to reach the big one.

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1. ABBREVIATIONS

AE: Adverse Events

BMI: Body Mass Index

CC: Clinical Coordinator

CEIC: Clinical Research Ethics Committee

CT: Computed Tomography

DAS59: Derriford Appearance Scale 59

DM: Diabetes Mellitus

ECA: External Carotid Artery

ECM: Extracellular Matrix

EJV: External Jugular Vein

FDA: Food and Drug Administration

FNAC: Fine-Needle Aspiration Cytology

GAN: Great Auricular Nerve

HCP: Health Care Professionals

HUJT: Hospital Universitari Josep Trueta

IAPSM: International Advisory Panel on Scar Management

MBI: Modified Blair Incision

MFI: Modified Facelift Incision

MI: Main Investigator

MRI: Magnetic Resonance Imaging

POSAS: Patient - Observer Scar Assessment Scale

QOL: Quality Of Life

RAHI: Retroauricular Hairline Incision

ROS: Reactive Oxygen Species

SPSS: Statistical Package for Social Sciences

US: Ultrasound

VAS: Visual Analog Scale

VEGF: Vascular Endothelial Growth Factors

VI: V-shaped Incision

WMA: World Medical Association

2. ABSTRACT

BACKGROUND: Scars are an inevitable result of a surgical procedure that have a great physical and psychological repercussion on patients. Although sutures are still considered as the standard of care in closing cutaneous wounds, staples are being commonly used as an alternative in head and neck cancer surgery. However, if a more agreeable aesthetic result is wished to be achieved, an intradermal suture is more suited for skin closure. Unfortunately, despite the increasing emphasis on scar cosmesis, there is very little reliable comparative data on which to base closure method selection.

OBJECTIVES: Our main objective is to prove that nonabsorbable continuous intradermal sutures will provide a better cosmetic outcome, that being a less visible scarring tissue, when compared to skin staples used for skin closure following a parotidectomy via modified Blair incision (MBI) for benign parotid tumors in adults. When it comes to secondary objectives, we will assess psychosocial and quality of life impact during the postoperative period, wound closure time, post-surgical complications and satisfaction with the incision closure method, all while comparing both techniques.

DESIGN: This research is designed as a single-institution, prospective, open-label, randomized clinical trial carried out, from September 2022 to September 2027, at the Oral and Maxillofacial Surgery Department of Hospital Universitari Josep Trueta (HUJT).

PARTICIPANTS: All the patients at HUJT with suspected benign parotid tumors (pleomorphic adenoma and Warthin tumors) on preoperative examination, who are scheduled to undergo a parotidectomy via MBI and are at least 18 years old.

METHODS: A total of 220 patients will be recruited. Each participant will be assigned with a numeric code and randomized into two groups according to the skin closure method: (A) nonabsorbable continuous intradermal sutures and (B) skin staples. All the data about study variables and covariables will be collected (14 days, 6 and 12 months after the surgery) and analyzed to determine its statistical significance.

KEYWORDS: Benign Parotid Tumors, Complications, Cosmetic Outcome, Modified Blair Incision, Nonabsorbable Continuous Intradermal Sutures, Parotidectomy, Quality Of Life, Satisfaction, Scars, Skin Closure, Skin Staples, Wound Closure Time.

3. INTRODUCTION

3.1. PAROTIDECTOMY

INTRODUCTION

A parotidectomy is a head and neck surgery that consists in partially or completely removing the parotid gland. This surgical procedure has a vast variety of indications that include congenital malformations, inflammations, infections, malignant or benign neoplasms; being the latest the most common. Despite of the indication, one should take into considerations that a parotidectomy is a laborious operation that requires competent professionals, considering the anatomical proximity of the gland to the facial nerve. For this reason, prior to the surgery it is important to identify all the anatomical landmarks in order to avoid any functional and/or aesthetic complications that could have a colossal impact on patient's quality of life (QOL) (1).

ANATOMY AND PHYSIOLOGY

The parotid gland is the largest major salivary gland in the human species. Its name comes from the Greek term *parotis* (*para*- meaning "beside" and *ot*- meaning "ear") which can be translated as "a tumor behind the ear". This gland is mainly serous, therefore its saliva is rich with amylase (enzyme that catalyzes the hydrolysis of amylum into carbohydrates) and its consistency tends to be very liquid (1,2). The location, structure and relations of the parotid gland can be seen in *Figure 1*.

Location

This lobular gland is located in the lateral side of the face where it occupies an irregular space confined by the masseter muscle (anterior border), the sternocleidomastoid muscle (posterior border), the external auditory meatus and zygomatic arch (superior border) and the mandibular angle (inferior border). The gland is divided into superficial and deep lobes by the facial nerve. The superficial lobe of the parotid is subjacent to the skin and subcutaneous tissue, however, in normal conditions it does not protrude and therefore its form is not visible to the naked eye. The whole surface of the gland is encapsulated with the parotid fascia which origins from the upper layer of the deep cervical fascia (1,3,4).

Structure and Relations

The Stenson's duct is the excretory duct of the parotid gland. It emerges from the anteroinferior surface of the gland and runs forward along the masseter muscle for about 7cm. When the duct reaches the anterior border of the masseter it deepens and, surrounded by the buccal fat bad, passes through the buccinator muscle. Finally, after outlining the cheek mucosa, it opens into the mouth vestibule through the parotid papilla, at the level of the upper second molar (1,2,4).

The arterial blood supply is provided by the external carotid artery (ECA), either by the posterior auricular artery or some small branches that originate within the gland from the ECA itself. Within the gland the ECA divides into its terminal branches, the superficial temporal and maxillary arteries. The venous blood drainage is regulated by the superficial temporal and maxillary veins, that together form the retromandibular vein and then drain into the external jugular vein (EJV). The lymphatic drainage is regulated by the parotid lymph nodes (superficial and deep) which ultimately drain to the cervical chain (1,2,4).

The parotid gland receives both autonomic and sensory innervation. The autonomic parasympathetic innervation is provided by the glossopharyngeal nerve (CN IX) and its main purpose is to stimulate the saliva production whereas the sympathetic innervation is provided by the periarterial nerve plexuses and its main purpose is to inhibit the saliva secretion via vasoconstriction. The afferent sensory fibers of the gland's fascia are transmitted via auriculotemporal nerve, a branch of the mandibular nerve (CN V3).

It is important to highlight that there are some nervous structures that, despite not innervating the gland, are considered important anatomical landmarks that should be properly identified in order to avoid any devastating complication. On one hand, the facial nerve (CN VII) that after emerging from the stylomastoid foramen, forms the posterior auricular branch and then passes through the parotid gland to form the parotid plexus that later divides into five major facial branches (from superior to inferior: temporal branch, zygomatic branch, buccal branch, marginal mandibular branch and cervical branch), the function of which is to innervate the muscles of facial expression.

On the other hand, the great auricular nerve (GAN; originated from C2-C3) that advances parallel to the EJV and separates into an anterior and posterior branch at the level of the parotid gland; the injury of this nerve causes the loss of sensation in the skin at the angle of the mandible, upper neck and the inferior half of the external ear (2,3).

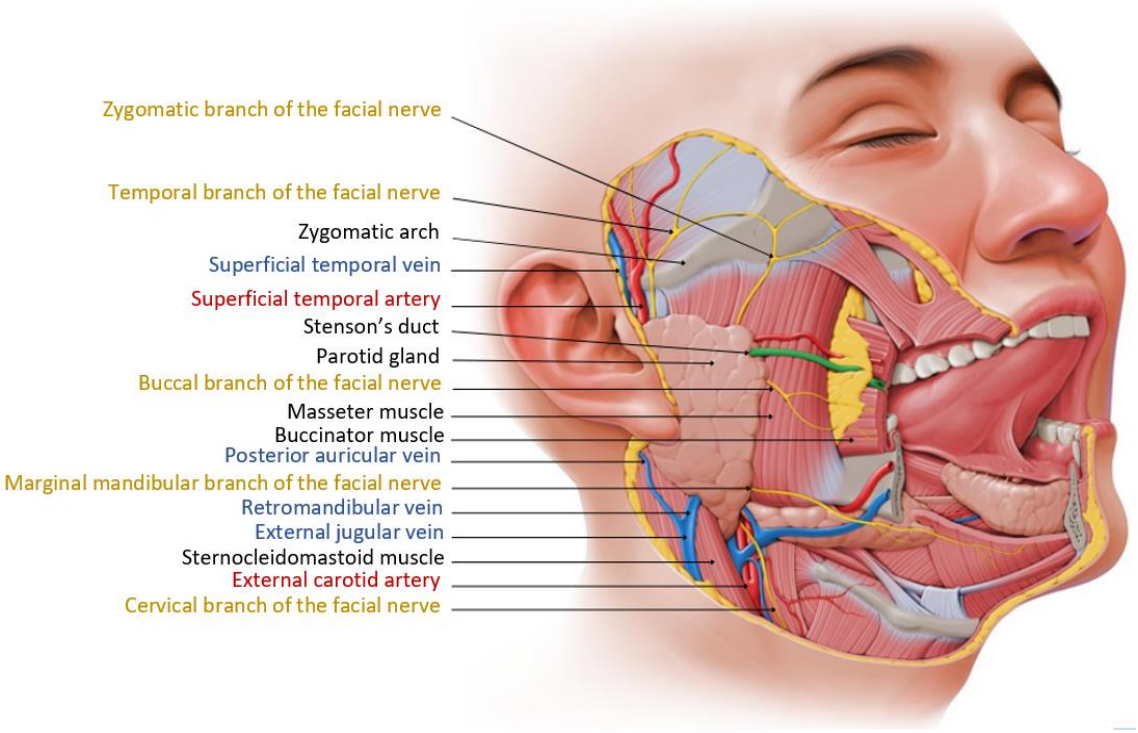

Figure 1: Location, structure and relations of the parotid gland.

INDICATIONS AND CONTRAINDICATIONS

Indications

Nowadays, the most common indication for parotidectomy is the extirpation of a parotid tumor. Generally speaking, salivary gland tumors are rare, accounting for approximately 3% of head and neck tumors, and less than 1% of all tumors overall. Out of all the salivary gland tumors the parotid ones are the most frequent, they represent around 80% of the cases. In 75-80% of cases, these neoplasms are benign, with the pleomorphic adenoma (71%) and Warthin tumor (22%) being the most frequent. As for the malignant tumors, the mucoepidermoid and adenoid cystic carcinoma are the two most common. Other indications include resistant chronic parotitis, recurrent sialadenitis, caseating granulomas, toxoplasmosis, branchial cleft cyst, symptomatic lymphoepithelial cyst, tuberculosis, etc. (1).

Contraindications

On the whole, the are no contraindications to performing a parotidectomy however a patient can be denied the surgery if not considered medically fit for general anesthesia (hypersensitivity or history of adverse reactions to anesthesia; untreated diabetes, heart disease, hypertension, kidney failure, etc.) (1,5).

PROCESS

Preoperative evaluation

Prior to the surgery every patient should be thoroughly evaluated; medical history should be retrieved and a complete physical examination performed. Most patients are admitted after noticing an asymptomatic enlarging lump on the lateral part of the face; others might present discomfort and even pain, however, its presence is not predictive of malignant histology. During the physical evaluation, the oral cavity and the facial nerve functions should be examined. Facial paralysis, trismus and/or sensory loss are considered as red flags, and therefore indicate a worse state of the patient's health. Finally, US-guided fine-needle aspiration cytology (FNAC) and MRI should be performed in order to obtain the final diagnosis and elaborate a preoperative planning.

Once established the diagnosis, the patient must be assessed about the risks of the surgery: pain, swelling, bleeding, infection, temporary or permanent facial paralysis, Frey's syndrome (neurological disorder that causes excessive sweating while eating), salivary fistula, aesthetic deformity and/or scarring at the surgery site. A written consent must be completed and signed, both by the patient and the professional (6,7).

Surgical technique

The surgery is performed under general anesthesia with the endotracheal tube positioned in the contralateral oral cavity and secured with tape. Occasionally, an intraoperative electrophysiological facial nerve monitoring is used. Following all standard patient preparation and surgical protocols, the intended surgical site is marked using a skin marker. Surgical field is scrubbed with an antiseptic solution and transparent drapes are placed in way that allows a clear vision of the hemiface and neck (1,6).

Several surgical incisions have been described to perform a parotidectomy, some of the most recognized are: modified Blair incision (MBI), modified facelift incision (MFI), retroauricular hairline incision (RAHI) and V-shaped incision (VI) (*Figure 2*). Although no significant differences (surgical time, drainage volume, surgical complications, etc.) were found between these techniques the MBI was established as the most common parotidectomy method (8,9). A MBI is planned in a preauricular fold coursing around the ear lobe and into an upper neck fold below the jaw line. This S-shaped incision provides an excellent exposure of the parotid gland without putting at risk the blood supply of the flap (6,10).

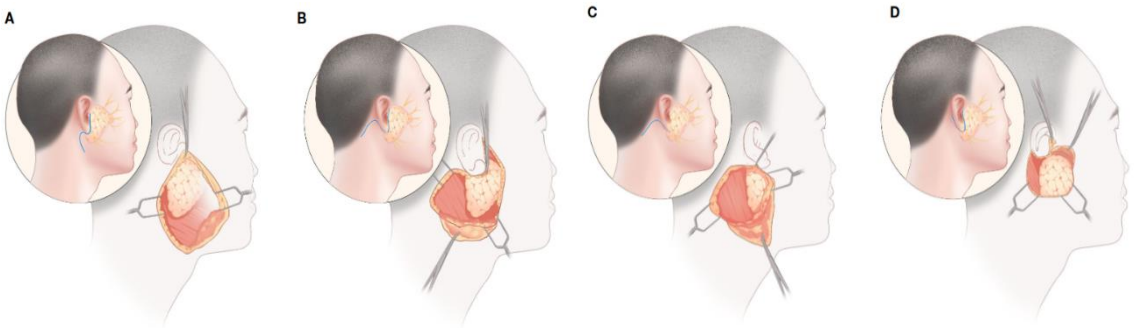

Figure 2: Parotidectomy via four incisions: (A) modified Blair incision, (B) modified facelift incision, (C) retroauricular hairline incision, (D) V-shaped incision. Extracted from (8).

Once the skin flap is elevated, the main trunk of the facial nerve should be identified and carefully divided in order to preserve its integrity. The exposed tumor should be removed completely, along with normal parotid parenchyma within at least 1 cm from the capsule of the tumor. After an accurate hemostasis, a suction drain must then be inserted and left in place until the output is less than 15-30cc in 24 hours (1,9).

To achieve a proper dead space closure and provide a minimal tension a deep absorbable suture is placed through subcutaneous tissue and deep dermis. This tissue approximation is crucial for achieving an appropriate support for the upper layers. Finally, the epidermal layer is closed with sutures, skin staples or both (1,11).

3.2. WOUND HEALING PROCESS

INTRODUCTION

A skin wound can be defined as a disruption of the epidermal layer, therefore wound healing refers to the restauration of the anatomical integrity of the skin. Adult skin heals by scarring, which restores the barrier function of the skin, protecting it from dehydration and infection (12). This dynamic process consists of three overlapping, highly organized and intertwined phases (inflammation, proliferation, maturation and remodeling) that begin immediately after an injury and might take years to culminate (*Figure 3*). For obtaining full recovery these phases must progress without any interruptions, aberrancies or prolongations otherwise it would lead to abnormal wound healing, excessive production of extracellular matrix (ECM) and finally fibrosis (13,14).

It is speculated that over 15% of the wounds become chronic, making them a very challenging problem for both the patient and the physician (15). It is important to underline that beyond the physical, mental, and social aspects, productivity loss in the workforce together with expensive medical treatments, wound management creates an economic burden on the health care system (16).

WOUND HEALING PHASES

Inflammatory phase (immediately upon injury through day 10)

This phase includes hemostasis and inflammation. Immediately upon injury, the skin initiates clotting cascades to provide temporary fibrin clot plug and, at the same time, triggers the temporal vasoconstriction to prevent further bleeding (17). Immediately after the clot is formed, a cellular distress signal is sent. As the inflammatory mediators (interleukins, fibroblasts, prostaglandins, growth factors, etc.) accumulate, the nearby blood vessels vasodilate to facilitate cellular transit. Within the first 24 hours the neutrophils are drawn into the injured area and the phagocytosis begins. The phagocytic cells release reactive oxygen species (ROS) and proteases for digesting local bacteria and debriding necrotic tissues. Approximately 48-96 hours after the injury, monocytes arrive and transform into macrophages. Similarly to the neutrophils, the activated macrophages release numerous enzymes and cytokines that promote cell proliferation and synthesis of ECM (17,18).

Proliferative phase (day 10 through day 30)

This phase is characterized by the re-epithelialization, neovascularization and formation of granulation tissue. The epithelization begins in the early stages and is stimulated by several inflammatory and growth factors. Keratinocytes, both local and those differentiated from the stem cells, migrate to the wound edge and begin proliferating and sending out projections to reestablish a protective barrier (17). Simultaneously, the local hypoxia and vascular endothelial growth factors (VEGF) initiate an angiogenic and vasculogenic response to provide an adequate blood supply and therefore, ensure the nutrient delivery as well as gas and metabolite exchange (15). The final step is the formation of granulation tissue which can take days or weeks to complete. Fibroblasts migrate into the wound and begin synthesizing a provisional ECM composed of collagen, glycosaminoglycans, and fibronectin. Additionally, the fibroblasts start differentiating into myofibroblasts initiating wound contraction (13,18).

Maturation and remodeling phase (day 30 through year 1)

This phase begins around the second week and can last up to 12 months. This phase is characterized by the apoptosis of granulation tissue and an organized deposition of collagen which results in flattening of the scar and fading of the initial redness (18). Collagen type III is replaced by stronger collagen type 1 and realigned along tension lines. For at least 4-5 weeks the collagen synthesis continues and the tensile strength gradually increases. Nevertheless, the collagen in the scar will never become as organized as the one of uninjured skin. Wound strength also never returns to 100%; at 1 week, the wound has only 3% of its strength whereas at 3 months and beyond, approximately 80% (17).

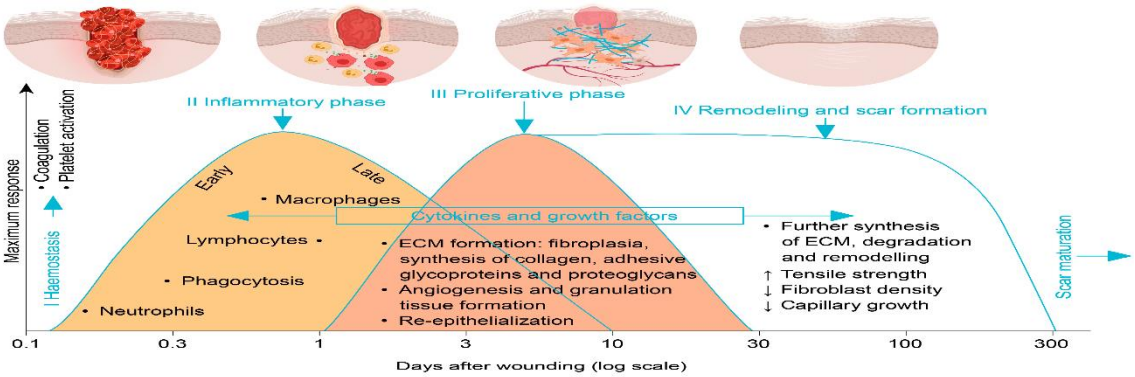

Figure 3: Wound healing timeline with important processes and actors. Extracted from (19).

IMPAIRED WOUND HEALING

Factors that complicate or delay wound healing

Many factors can lead to impaired healing and many are closely related. Generally, these factors can be classified into local (those that influence the characteristics of the wound itself) and systemic (those that influence the patient's ability to heal) (14,18).

- **Local:** Location, size, hypoxia, edema, infection, necrosis, foreign bodies, previous irradiation, incision location and its correlation with tension lines (Langer's lines).
- **Systemic**: Age (>60 years), sex hormones (estrogen improves wound healing), stress (stress up-regulates glucocorticoids and reduces the levels of the proinflammatory cytokines), diabetes mellitus (DM), immunodeficiencies (systemic lupus erythematosus, scleroderma, vascular pathology, etc.), obesity, malnutrition, medications (chronic corticosteroid use, chemotherapy), alcoholism and smoking.

Complications of a surgical wound

- **Infection:** Invasion of tissues by pathogens, their multiplication, and the reaction of host tissues to the infectious agent and the toxins they produce. Surgical site infection (SSI) is defined as an infection that is present up to 30 days after a surgical procedure if no implants are placed (20).
- **Hematoma:** Collection of extravasated blood, usually clotted.
- **Seroma:** Collection of clear serous fluid composed of blood plasma. Infected seromas can lead to the formation of abscesses (collection of pus).
- **Dehiscence:** Separation of the layers of a surgical wound; it may be partial (superficial disruption) or complete (total disruption).
- **Necrosis:** Passive process resulting in a breakdown of ordered structure and function following irreversible traumatic damage.
- **Hypertrophic scars and/or keloids:** Fibrotic disorders characterized by a continuous localized inflammation with disproportionate collagen synthesis, abnormal collagen replacement and exaggerated ECM accumulation (17,21).
- **Chronic wounds (vascular, diabetic and pressure ulcers):** Wounds that do not follow the normal healing process and show no signs of effective healing within 3 months after the tissue injury (19).

3.3. SUTURES

INTRODUCTION

A surgical suture is a medical device used to hold body tissues together and approximate wound edges after an injury or surgery. Its application involves using a needle with an attached length of thread. Nowadays, there are approximately 5,269 different types of sutures, including antibiotic-coated and knotless ones (21) (*Table 1*).

There is often more than one appropriate method of closure, however, when selecting the most accurate suture, one must consider several factors (14,21):

- **Wound characteristics:** Location (skin itself varies throughout the body in terms of thickness, elasticity/degree of tension, speed of healing and tendency to scar), size, hypoxia, edema, infection, necrosis, foreign bodies, etc.
- **Patient's characteristics:** Age, sex, health status (DM, immunodeficiencies, etc.).
- **Suture material properties:** Handling characteristics, tensile strength, size, etc.
- **Surgeon's personal preference and experience.**

SUTURE MATERIAL PROPERTIES

The ideal suture should have good handling characteristics, adequate tensile strength, suitable size, convenient configuration, adequate knot strength, minimal tissue reaction, low capillarity and fluid absorption and ability to hold wound edges (21,22).

- **Handling characteristics**
  - **Elasticity**: Ability of a material to return to its original length after stretching. High elasticity will allow the suture to stretch with wound edema but return to its original length and form once swelling has subsided.
  - **Plasticity**: Capacity of a suture to be permanently molded or altered. Highly plastic sutures may become too loose when wound edema subsides and fail to correctly approximate wound edges.
  - **Memory / Suture stiffness**: Capacity of a suture to assume a stable linear configuration after removal from packaging and after stretching. Sutures with significant memory are not pliable, which makes them difficult to work with, and significant memory necessitates additional knots.
- **Tensile strength**: Force that a suture will withstand before breaking.

- **Size**: Diameter of the suture; described from 11-0 (smallest) to 7 (largest). When selecting suture size, it is recommended to always use the one most comparable with the natural strength of the tissue.
- **Knot security:** Quality of a suture that allows it to be tied securely with a minimum number of throws per knot. Greater knot strength minimizes the risk of dehiscence.
- **Tissue reactivity**: Inflammatory response, that interferes with wound healing and increases the risk of infection. An ideal suture stimulates minimal tissue reaction and does not create a situation favorable to bacterial growth. Therefore, suture material should be sterile, non-electrolytic, non-allergenic and non-carcinogenic.
- **Capillarity and fluid absorption**: Ability of transporting and absorbing liquids along the suture strand and, therefore, spreading microorganisms.
- **Configuration**: Suture material may be composed either of a single (monofilament; lower risk of infection but poor handling and knot security) or multiple filaments (multifilament; higher risk of infection but easier to handle and tie).
- **Absorption / biodegradability**: Degradation and uptake of the suture by the tissue. An absorbable suture undergoes absorption within 60 days; it is generally used for buried sutures that approximate deep tissues. A non-absorbable is resistant to absorption; it is commonly used externally and will eventually be removed.
- **Origin**: Natural (e.g., silk or gut) or synthetic (e.g., nylon or monocryl).

SURGICAL SUTURE	PROPERTIES					
	Configuration		Absorption		Origin	
	Monofilament	Multifilament	Absorbable	Non-absorbable	Natural	Synthetic
Gut: plain and chromic	X		X		X	
Collagen; plain and chromic	X		X		X	
Polydioxanone (PDS)	X		X			X
Polyglyconate (Maxon)	X		X			X
Polyglecaprone (Monocryl)	X		X			X
Polyglycolic acid (Dexon)	X	X	X			X
Polyamide (Ethilon)	X	X		X		X
Polypropylene (Prolene)	X			X		X
Polybuyester (Novafil)	X			X		X
Polyester	X	X		X		X
Polyglactic 910 (Vicryl)		X	X			X
Silk		X		X	X	
Linen		X		X	X	
Cotton		X		X	X	
Stainless steel	X	X		X		X

Table 1: Classification of surgical suture thread. Extracted from (22).

SUTURING TECNIQUES

The choice of suture and technique depends on many factors, nevertheless, the primary goals are 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, and minimizing the risks of bleeding and infection (23).

Most suture techniques can either be interrupted or continuous/running (24,25):

- **Interrupted sutures**: The approximation of the tissue is tied with a knot and the suture is cut. The following sutures are placed roughly 5mm apart. Such sutures provide great tensile strength and have less potential to cause wound edema and impaired circulation. Also, in case of infection, the entire length of sutures would not need to come out. Disadvantages include longer placement time and greater risk of crosshatched marks across the suture line.
- **Continuous/running suture**: It is similar to the simple interrupted suture; however, after tying the first knot, the suture is not cut and the bites are continued on each side of the incision. Such sutures can be quickly applied and spread the tension along the wound. Disadvantages include the risk of dehiscence if the suture material ruptures and difficulty in making fine adjustments along the suture line.

Depending on the layers and wound characteristics sutures can be classified into (25,26):

- **Simple**: The needle penetrates into the dermis or subcutaneous tissue and then passes to the opposite side of the wound and exits through the epidermis. This is the most commonly used suture technique (*Figure 4*).

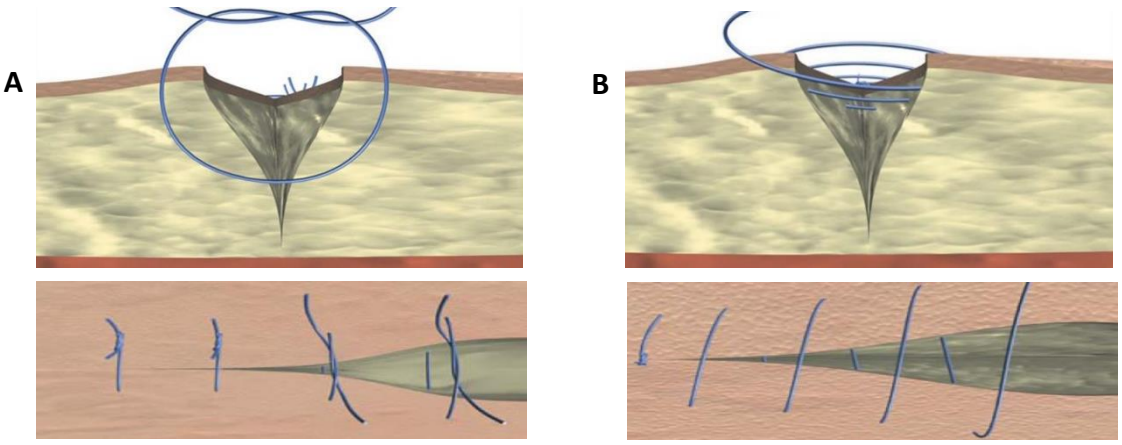

Figure 4: (A) Simple Interrupted Suture and (B) Simple Continuous/Running Suture. Extracted from (26).

- **Intradermal/Subcuticular:** The needle is inserted into the superficial dermis and is brought out at the same level of the opposite side. Such technique provides an excellent way to achieve accurate skin edge apposition without external sutures or cross-hatching and thus has the ability to produce better aesthetic results. The knots can be either external or buried (the knot protrudes to the inside) (*Figure 5A*).

- **Subcutaneous**: The needle is inserted into the subcutaneous tissue and is brought out at the same level of the opposite side. Such technique is performed to release tension from the wound surface in order to ease the healing of the skin (*Figure 5B*).

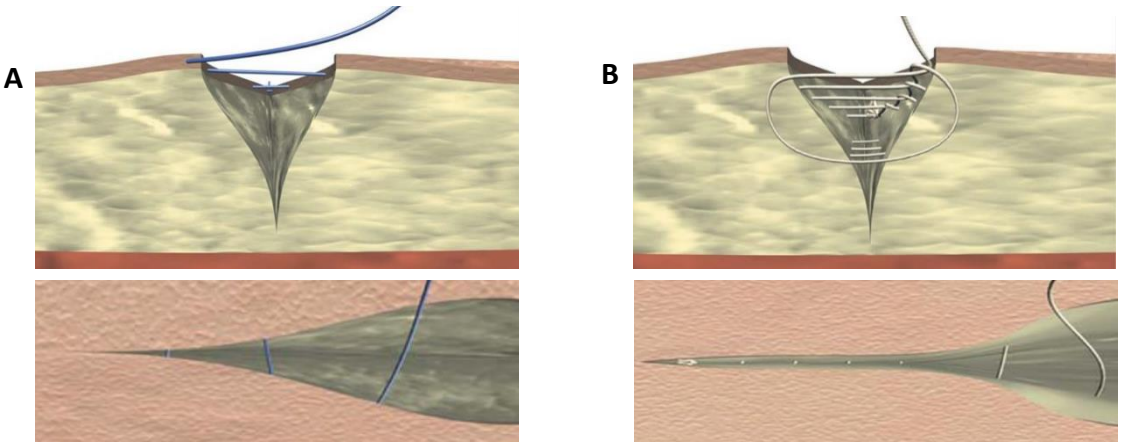

Figure 5: (A) Intradermal/Subcuticular Continuous/Running Suture and (B) Subcutaneous Continuous/Running Suture. Extracted from (26).

- **Mattress**: The needle is inserted as per the simple suture and then reinserted in the emerged side back to the original side. Mattress sutures can be applied as vertical (reinserted deeper) or horizontal (reinserted on the same level) subtypes. Such technique minimizes the tension, promotes the eversion of the wound edges and allows a better closure of deeper wounds.

- **Other**: Corner (used for irregular edges), Algoewer, Donati, figure of eight, frost/suspension, etc.

SUTURES ACCORDING TO ANATOMIC LOCATION

Numerous options for skin closure have become available in the last years. It is essential to choose a method suited to each patient and wound, mainly its length and location (*Table 2*). One must keep in mind that with proper execution, several methods can achieve similar, high-quality results (21).

ANATOMIC LOCATION		SUTURE CHOICE ACCORDING TO ANATOMIC LOCATION OF WOUND	
		Skin closure	**Deep closure**
Scalp		Vicryl simple continuous suture Prolene simple interrupted suture	Vicryl simple interrupted suture
Face		Monocryl, Nylon, Vicryl or Gut simple interrupted suture Monocryl simple continuous suture	Vicryl simple interrupted suture Vicryl, Monocryl or Prolene continuous subcuticular suture
Ears	**Anterior**	Monocryl or Nylon simple interrupted suture	------
	Lobe	Monocryl or Nylon simple interrupted suture	Vicryl simple interrupted suture
	Posterior	Monocryl or Nylon continuous horizontal mattress suture	------
Eyelids		Monocryl or Prolene simple continuous suture Nylon simple interrupted suture	------
Neck		Monocryl simple continuous suture	Vicryl simple interrupted suture Vicryl, Monocryl or Prolene continuous subcuticular suture
Breasts		Monocryl simple continuous suture Nylon simple interrupted suture	Vicryl simple interrupted suture Quill, Vicryl, or Prolene continuous subcuticular suture
Areola		Monocryl simple continuous suture	Vicryl simple interrupted suture
Presternal		Monocryl simple continuous suture	Vicryl simple interrupted suture
Abdomen		Monocryl simple continuous suture	Vicryl simple interrupted suture Monocryl or Prolene continuous subcuticular suture
Back		Monocryl simple continuous suture Nylon simple interrupted suture	Vicryl simple interrupted suture
Arm and forearm		Monocryl simple continuous suture Nylon simple interrupted suture	Vicryl simple interrupted suture
Hand	**Back**	Nylon simple interrupted suture	------
	Palm	Nylon simple interrupted suture with vertical mattress sutures	------
Leg and thigh		Monocryl simple continuous suture Nylon simple interrupted suture	Vicryl simple interrupted suture
Foot		Nylon simple interrupted suture	------

Table 2: Suture choice according to anatomic location of wound. Extracted from (21).

3.4. SKIN STAPLES

INTRODUCTION

Surgical staples are a medical device used to hold body tissues together and approximate wound edges after an injury or surgery, both internal and external. Staples are usually applied using a stapler that can either be disposable or reusable. Both types are generally loaded with disposable cartridges. If the staples must be removed, a specialized staple remover should be used (24).

Surgical staples offer a great alternative for sutures when dealing with liner lacerations, especially if located on the scalp, abdomen or extremities. Staples are cost-effective, require minimal training, have similar healing times and infection rates as sutures and, most importantly, are rapidly placed making them immensely useful in situations of active bleeding or for reducing the amount of time a patient is under anesthesia. Nevertheless, they also cause more discomfort and are less aesthetically pleasing (24).

STAPLES FABRICATION MATERIALS

The surgical staples can be categorized based on their fabrication material:

- **Metal:** Currently available surgical metal staples are primarily made up of stainless steel, titanium, magnesium and zinc. Although there are many restrictions on their use due to corrosion and having a high X-ray absorption coefficient (they result in artifacts in the different radiological imaging systems such as MRI and CT), metal-based staples are still preferred by the physicians for their characteristics (high tensile strength, sufficient elasticity, biocompatibility, etc.). It is important to highlight that all metal staples include a certain percentage of nickel which means it must be determined whether a patient has a nickel allergy and, if so, any possible side effects need to be discussed prior to the surgery (27).
- **Polymers**: The most commonly used biodegradable polymers are poly-galactic acid, poly-lactic acid, poly-dioxanone, poly-lactic-co-glycolic acid, cellulose, etc. Absorbable staples do not interfere with radiological imaging systems and offer an effective alternative in case the patient is allergic to metal-based staples or in situations where staples cannot be removed (21,27).

STAPLES SIZE AND FORM

Another crucial aspect for efficient staples functioning is their design. Optimal staple geometry parameters (size and form) lead to sufficient strength, satisfactory homeostasis and minimal tissue damage whereas any uncontrolled deformation has a significant impact on the staple failure and its biodegradation process (27).

According to the U.S. Food and Drug Administration (FDA) different staple sizes should be used depending upon the tissue types (27) (*Table 3*).

TISSUE TYPE	STAPLE HEIGHT		COLOR CODE
	Open stage	Closed stage	
Thick	4.1 mm	2.0 mm	Green
Moderate	3.8 mm	1.8 mm	Gold
Normal	3.5 mm	1.5 mm	Blue
Vascular	2.5 mm	1.0 mm	White
Mesentery	2.0 mm	0.75 mm	Grey

Table 3: Staples sizes concerning different tissue types. Extracted from (27).

Nowadays, two major forms of staple designs, U-shaped and B-shaped, are available due to their dispenser simplicity and usage facility. Nevertheless, some other designs such as circular, D-shaped, and modified U-shaped are also accessible. In any case, the intended design of the staple should be such that it can hold the edges of the wound effectively and simultaneously resist the outward tensions (27).

4. JUSTIFICATION

Scars are an inevitable result of a surgical procedure that have a great repercussion on patients, yet, in most occasions, they are tacitly assumed as a secondary aspect, especially when caused by cancer treatment surgeries. Any permanent mark on one's physique, remains a fear amongst many, not so much for the physical impairment it causes, but rather the aesthetic change and the psychological burden it carries. With the rise of social media and new beauty standards, knowledge of the psychological and QOL consequences of scars has never been more relevant. Finally, one must underline that, despite the increasing emphasis on scar cosmesis, there is very little reliable comparative data on which to base closure method selection (28,29).

Much is being learned about factors that contribute to impaired wound healing and clinicians now understand that certain techniques may allow a more rapid and aesthetic healing (30). Sutures are still considered as the standard of care in closing cutaneous wounds, especially those that require meticulous repair (21). However, for most linear, non-facial lacerations, skin staples have been found to be a faster, easier and more cost-effective option. Other studies suggested that, despite the advantages, staples can contribute to an increased risk of infection as well as poor scar formation (31).

Although, in most cases, the decision of the skin closure technique lies with the surgeon, it is important to take into consideration not only wound characteristics but also patient's opinion and/or preferences. For example, despite the simple interrupted suture being the most commonly used technique, if a more agreeable aesthetic result is wished to be achieved, an intradermal suture is more suited for skin closure (21).

A great number of papers have been published comparing sutures and skin staples, yet most are centered in proving the superiority of the latest; by doing so, they tend to provide little and/or unspecific data about sutures. Many use "conventional sutures" as comparison; others unify different techniques into the general term of "sutures" or simply state suture material and not the technique. Additionally, the variables that these articles most frequently asses are: surgical site infection, complications, wound closure time, cost and surgery satisfaction; leaving little data to the cosmetic outcome (32–35).

Articles that actually compare intradermal sutures and skin staples are mostly centered on obstetric, abdominal or orthopedic surgeries. Last but not least, a part from the cesarian closure, very few actually perform the study on the same wound (36–39).

As staples are being commonly used as an alternative to suturing for incision closure in head and neck cancer surgery and given the lack of clear evidence in the literature, this study aims to determine whether nonabsorbable continuous intradermal sutures, used for skin closure following a parotidectomy for benign parotid tumors, will provide better cosmetic outcome, that being less visible scarring tissue, compared to skin staples. Additionally, we expect this suturing technique to achieve more favorable psychosocial and QOL impact during the postoperative period, fewer post-surgical complications and for the patient to be more satisfied with the incision closure method; all while not significantly increasing the wound closure time. If the hypotheses of this study prove to be correct it will provide enough evidence to validate it as the reference technique**.**

5. HYPOTHESES

5.1. MAIN HYPOTHESIS

The main hypothesis of this study is that when comparing nonabsorbable continuous intradermal sutures and skin staples for skin closure, following a parotidectomy via modified Blair incision (MBI) for benign parotid tumors, the first method will provide better **cosmetic outcome**, that being a less visible scarring tissue.

5.2. SECONDARY HYPOTHESES

The secondary hypotheses include:

- Nonabsorbable continuous intradermal sutures used for skin closure, following a parotidectomy via MBI for benign parotid tumors, have a more favorable **psychosocial and QOL impact** during the postoperative period.
- The nonabsorbable continuous intradermal sutures will not significantly increase the **wound closure time**, following a parotidectomy via MBI for benign parotid tumors, when comparing to skin staples.
- The patient will experience fewer **post-surgical complications** (infection, hematoma, seroma, dehiscence, necrosis, etc.) when using nonabsorbable continuous intradermal sutures for skin closure, following a parotidectomy via MBI for benign parotid tumors.
- The patient will experience more **satisfaction with the incision closure method** (less postoperative pain, less difficulty of maintaining hygiene, less pain on removal and more overall comfort) when using nonabsorbable continuous intradermal sutures for skin closure, following a parotidectomy via MBI for benign parotid tumors.

6. OBJECTIVES

6.1. MAIN OBJECTIVE

The main objective of this study is to evaluate the **cosmetic outcome**, that being the visible scarring tissue graded by several scar assessment tools, of nonabsorbable continuous intradermal sutures when compared to skin staples used for skin closure following a parotidectomy via modified Blair incision (MBI) for benign parotid tumors.

6.2. SECONDARY OBJECTIVES

The secondary objectives include:

- To determine whether nonabsorbable continuous intradermal sutures used for skin closure, following a MBI parotidectomy for benign parotid tumors, have a more favorable **psychosocial and QOL impact** during the postoperative period.
- To register and compare the **wound closure time** of nonabsorbable continuous intradermal sutures and skin staples used for skin closure following a parotidectomy via MBI for benign parotid tumors.
- To assess whether the patient experiences fewer **post-surgical complications** (infection, hematoma, seroma, dehiscence, necrosis, etc.) when using nonabsorbable continuous intradermal sutures for skin closure, following a parotidectomy via MBI for benign parotid tumors.
- To analyze whether the patient experiences more **satisfaction with the incision closure method** (less postoperative pain, less difficulty of maintaining hygiene, less pain on removal and more overall comfort) when using nonabsorbable continuous intradermal sutures for skin closure, following a parotidectomy via MBI for benign parotid tumors.

7. MATERIALS AND METHODS

7.1. STUDY DESIGN AND SETTING

This research will be carried out at the Oral and Maxillofacial Surgery Department of HUJT as a study protocol for a single-institution, prospective, open-label, randomized clinical trial designed to evaluate the cosmetic outcome, that being the visible scarring tissue, of nonabsorbable continuous intradermal sutures when compared to skin staples used for skin closure following a parotidectomy via MBI for benign parotid tumors.

The estimated time to perform this study and obtain results is 3 years and 9 months.

7.2. STUDY POPULATION

The study population will include all the patients at HUJT with suspected benign parotid tumors (pleomorphic adenoma and Warthin tumors) on preoperative examination, who are scheduled to undergo a parotidectomy via MBI and are at least 18 years old.

All the previous data concerning this type of surgery will be excluded.

7.3. STUDY SUBJECTS

INCLUSION CRITERIA

- Patients, with suspected benign parotid tumors on preoperative examination, who are scheduled to undergo a parotidectomy via MBI and are at least 18 years old.

EXCLUSION CRITERIA

- Patients who had previous surgery and/or radiotherapy on the incision location.
- Patients who have history of hypertrophic scars and/or keloids.
- Patients who have a medical disorder that could affect wound healing (uncontrolled diabetes mellitus, immunodeficiencies, obesity class II or III, severe malnutrition, history of long-term immune-modulator therapy).
- Patients who have history of adverse reactions to the materials used in the study.
- Patients diagnosed with malignant parotid tumors on postoperative examination.

PARTICIANT WITHDRAWAL OR TERMINATION

All participants are free to decide to withdraw the study at any time. When taken such decision, participants must communicate their decision to the research team, or one of the physicians responsible for the study. Furthermore, a patient will be considered to have dropped out of the study if, after several attempts to contact him/her, he/she does not attend the follow-up sessions. Patients who present exclusion criteria, either newly developed or not recognized at first, will also be excluded of the study.

In case of withdrawal or death, no extra patients will be added to the clinical trial, since all patients who are part of the study are already included in the statistical analysis.

7.4. STUDY SAMPLE

SAMPLE SELECTION

A non-probabilistic consecutive sampling method will be followed in the Oral and Maxillofacial Surgery Department of HUJT. All the patients meeting the inclusion and not meeting the exclusion criteria will be offered to participate in the study.

SAMPLE SIZE

For the estimation of the sample size we have relied on the recommendations of experts of HUJT as well as the 6 month results of POSAS scale retrieved from an analogous study that compared cosmetic outcomes of skin closure after cesarean delivery (38).

In this clinical trial, GRANMO software was used to calculate the sample size. In a bilateral test, accepting an alpha risk of 0.05 and a beta risk of 0.2, a total of 220 subjects are necessary (110 in each group) to recognize as statistically significant a difference greater than or equal to 3 units. The common standard deviation is assumed to be 7.5. A 10% drop-out rate has been anticipated.

ESTIMATED TIME OF RECRUITMENT

Taking into account the number of patients scheduled to undergo a parotidectomy for a benign parotid tumor (80 patients per year), we estimate to recruit all the participants in 2 years and 9 months, and to collect the data during the following year.

SAMPLE RANDOMIZATION

Consenting patients to will be assigned with a numeric code (numbers from 1 to 220). To reduce the bias of selection, a software will be used to create two groups distributed, in a 1:1 ratio, according to the method that will be used to perform the skin closure:

- **Group A / Study group:** Nonabsorbable continuous intradermal sutures.
- **Group B / Control group:** Skin staples.

MASKING TECHNIQUES

This study is designed to be open-label trial, which means that both the health practitioner and the patient are aware of the treatment. Such research makes the masking impossible, however, in order to reduce the detection bias, an additional blinded outcome assessment will be performed. An independent observer (plastic surgeon trained in the use of the scar assessment scales), who will be unaware of the closure method, will analyze the results and will therefore provide a more objective result. The statistician will also be unaware of the intervention each patient received.

7.5. STUDY VARIABLES

INDEPENDENT VARIABLES / INTERVENTION

The independent variables of this study refer to the methods that will be used to perform skin closure following a parotidectomy via MBI for benign parotid tumors:

- **Group A / Study group:** Nonabsorbable continuous intradermal sutures.
- **Group B / Control group:** Skin staples.

DEPENDENT VARIABLES / OUTCOME

Main dependent variable

- **Cosmetic outcome:** Wound healing is a complex and imperfect process that results in a wide range of visible scars. For this study, several specific assessment tools were chosen to monitor the changes in scar quality over time. At each scheduled session, the scar appraisal will incorporate the following: (1) scar photography; (2) scar classification proposed by the International Advisory Panel on Scar Management (IAPSM); (3) scar rating using a Patient - Observer Scar Assessment Scale (POSAS);

(4) scar overall satisfaction assessed by a Visual Analog Scale (VAS) (see *7.7 Measurement Tools*). The primary outcome measure will be POSAS mean scores obtained 6 months after the surgery. The secondary outcome measures will include POSAS mean scores obtained 14 days and 12 months after the surgery as well as patient's scar overall satisfaction assessed by a VAS.

Secondary dependent variables

- **Psychosocial and QOL impact:** Psychological happiness and QOL provide a meaningful way to determine the impact of health care. The Derriford Appearance Scale (DAS59) was selected for this study because it is a highly sensitive instrument with which to measure the effectiveness of cosmetic surgical interventions for appearance (see *7.7 Measurement Tools*).
- **Wound closure time:** In this study the timing will only refer to the incision closure process. In this study, wound closure time will be rounded to the nearest minute and obtained from the patient's clinical chart.
- **Post-surgical complications:** Complications such as infection, hematoma, seroma, dehiscence, necrosis, etc. are known to have a considerable impact on the recovery of the patient and may cause increased morbidity, delayed discharge, increased costs and decreased satisfaction. In this study, the previously mentioned complications will be categorized as a dichotomous yes/no variables and will be obtained from the patient's clinical chart.
- **Satisfaction with the incision closure method:** In this study, variation in patient's satisfaction with the incision closure will be evaluated with four items: postoperative pain, difficulty of maintaining hygiene, pain of removal and overall comfort. All of them will be assessed by VAS (see *7.7 Measurement Tools*).

POTENTIAL CO-VARIABLES

- **Age:** Expressed in years at the moment of treatment. The answer will be extracted from the ID card or any other official document and collected into the "Data Collection Sheet" (*Annex 3*).
- **Sex:** Categorized as a dichotomic male/female covariate. The answer will be extracted from the ID card or any other official document and collected into the "Data Collection Sheet" (*Annex 3*).
- **Body Mass Index (BMI):** Categorized in six weight statuses: (I) Underweight, (II) Normal, (III) Overweight, (IV) Obesity class I, (V) Obesity class II and (VI) Obesity class III. The answer will be calculated by the physician (body mass divided by the square of the body height) and collected into the "Data Collection Sheet" (*Annex 3*).
- **Socioeconomic status:** Categorized in five social classes based on the occupation according to Domingo et al (40). The answer will be asked to the patient and collected into the "Data Collection Sheet" (*Annex 3*).
- **Ethnicity:** Categorized in five groups: (I) African, (II) Asian, (III) Caucasian, (IV) Latin-American and (V) others. The answer will be given by the patient and collected into the "Data Collection Sheet" (*Annex 3*).
- **Concomitant diseases or disorders:** Categorized as a dichotomic yes/no covariate; if answered "yes" the patient will be asked to indicate which ones. The answer will be asked to the patient and collected into the "Data Collection Sheet" (*Annex 3*).
- **Smoking:** Categorized in three groups: (I) Non-smokers, (II) Smokers (considering those who smoke at the time of the diagnosis or 28 days prior) and (III) Ex-smokers (considering those who smoked during their lifetime but haven't smoked during the past 28 days). The answer will be asked to the patient and collected into the "Data Collection Sheet" (*Annex 3*).
- **Alcohol consumption:** Categorized in three groups: (I) Non-consumer, (II) Moderate consumer (20-40g/day in women and 50-60g/day in men), and (III) High consumer (>40g/day in women and >60g/day in men). The answer will be asked to the patient and collected into the "Data Collection Sheet" (*Annex 3*).

Study variables and co-variables can be seen in *Table 4*.

VARIABLES AND CO-VARIABLES		MEASUREMENT TOOL	TYPE OF DATA	CATEGORIES / VALUES
Independent variable	Type of intervention	Patient's clinical chart	Qualitative	Type of intervention
Main dependent variable	Cosmetic outcome	Photography	---	---
		IAPSM classification	Qualitative	Scar category
		POSAS scale	Quantitative continuous	Scale
		VAS scale	Quantitative discrete	Scale
Secondary dependent variables	Psychosocial and QOL impact	DAS59 scale	Quantitative continuous	Scale
	Wound closure time	Patient's clinical chart	Quantitative continuous	Minutes
	Post-surgical complications		Qualitative	Presence / Absence
	Satisfaction with the incision closure method	VAS scale	Quantitative discrete	Scale
Co-variables	Age	Data collection sheet	Quantitative continuous	Number of years
	Sex		Qualitative	Male / Female
	Body Mass Index		Qualitative	I. Underweight II. Normal III. Overweight IV. Obesity class I V. Obesity class II VI. Obesity class III
	Socioeconomic status		Qualitative	Class I to V
	Ethnicity		Qualitative	I. African II. Asian III. Caucasian IV. Latin-American V. Other
	Concomitant diseases or disorders		Qualitative	Yes / No
	Smoking		Qualitative	I. Non-smokers II. Smokers III. Ex-smokers
	Alcohol consumption		Qualitative	I. Non-consumers II. Moderate consumers III. High consumers

Table 4: Study variables and co-variables.

7.6. STUDY INTERVENTION

All the patients, with suspected benign parotid tumors (pleomorphic adenoma and Warthin tumors) on preoperative examination, who fulfilled and consented for the study will be submitted to a parotidectomy via MBI. All the incisions and wound closures will be performed by or under the direct supervision of the same surgeon.

Following all standard patient preparation and surgical protocols, the intended surgical site will be marked using a skin marker. This will not only confirm the correct laterality of the incision but also guide the posterior skin closure. Incisions will be made taking great care to hold the scalpel at 90º to the skin so that perfect apposition of the skin edges could be achieved at the end of the operation.

Once the surgery is performed, a surgical drain will be placed for avoiding the formation of dead space, hematoma, and subsequent infection. The incision closure will be executed in layers. The deeper layers will be closed two times with a buried 3-0 vicryl simple interrupted suture in both groups. In the study group, the surgeon will close the skin layer with a **nonabsorbable continuous 3-0 prolene intradermal suture** while an assistant surgeon everts and approximates the wound edges using Adson's tissue forceps. In the control group, the skin will be closed with **stainless steel staples** (it is important that all the patients receive the same type of staples) by placing a disposable stapler along the wound edges.
The time taken to close the skin will be measured using the theatre timer.

In both groups, once the closure is completed, the wound will be dressed by the application of an antiseptic cream and a strip of sterile gauze. The dressing will be changed every 24h. Additionally, all patients will be given i.v. antibiotics for a period of 5-7 days. The surgical drains will be kept until the drain content is minimal (less than 15-30cc in 24 hours). After an interval of 14 days the sutures will be removed in a conventional manner whereas the staples will be removed using a staple remover.

Patients will be assessed for complications on daily basis until discharge. At each follow-up session, the study variables will be graded by the patient and an independent observer; both unaware of each other's grading.

7.7. STUDY MEASUREMENT TOOLS

EQUIPMENT

- **Digital camera**: Medical photography can be used to assess, quantify, and monitor response to treatment. In this study, a digital camera will be acquired and used as one of the tools to evaluate the cosmetic outcome of the incision closure methods.
- **Theatre timer**: Wound closure time is one of the secondary variables in this study. For obtaining accurate results a timer will be used to keep track of the time needed to perform the wound closure.

SCALES AND SURVEYS

- **IAPSM scar classification** (41; *Annex 4.1.*): This classification categorizes the scars as normal immature, normal mature, hypertrophic, minor and major keloid.
- **POSAS** (42; *Annex 4.2.*): This scale comprises two numerical scales, each uses a 10-point scoring system, summed to obtain a total score from 6 to 60, with 6 representing normal skin with no associated symptoms.
  - Patient Scar Assessment Scale (PSAS) consists of 6 items on scar-related pain, itchiness, color, stiffness, thickness and irregularity.
  - Observer Scar Assessment Scale (OSAS) consists of 6 items on scar-related vascularization, pigmentation, thickness, relief, pliability and surface area.
- **VAS** (42; *Annex 4.3.*): This scale uses a 10-point scoring system, with 0 representing the worst and 10 the best experience. In this study, it will be used to determine the overall satisfaction of the cosmetic outcome and the satisfaction with the incision closure method (based on postoperative pain, difficulty of maintaining hygiene, pain of removal and overall comfort).
- **DAS59** (43; *Annex 4.4.*): This scale contains 59 self-report items, each scored from 0 to 3, intended to assess the turmoil of everyday life, lowered self-esteem, problems with personal relations, and psychological distress associated with a perceived problem of appearance. A higher score is associated with a greater degree of image-related distress and dysfunction and therefore indicates worse QOL.

7.8. STUDY CIRCUIT AND DATA COLLECTION

The diagnosis of the parotid tumor will be the first step of the study circuit. It will include a detailed anamnesis, a physical examination, a US-guided fine-needle aspiration cytology (FNAC) and an MRI. Once obtained all the results, if the tumor is benign, the doctor will communicate the patient his/her diagnosis and will explain the study after making sure the inclusion and exclusion criteria are met (*see 7.3. Study Subjects*).

Following the study explanation, the doctor will handle the patient an electronic tablet where he/she will find the Information Form and the Informed Consent Form (*Annexes 1 and 2*). If the patient agrees to participate in the study, he/she will have to sign the Informed Consent Form. A numerical code will be assigned to every patient so as to preserve their anonymity during the rest of the clinical trial. Afterwards, the physician will fill out the Data Collection Sheet (*Annex 3*).

Study randomization will be performed, dividing all the patients into two intervention groups. Group's A skin closure will be performed with nonabsorbable continuous intradermal sutures whereas group's B with skin staples (*see 7.3. Study Sample*).

Prior to the surgical intervention, an anesthesiology evaluation will be performed. After the preoperatory exams, the patient will receive the intervention (*see 7.6. Intervention*) that was assigned to him/her according to the group he/she has been randomized into. The description of the surgery and the timing of the incision closure will be registered in the patient's clinical chart.

After the surgery, all patients will be hospitalized and evaluated daily, with the purpose of ruling out acute post-surgical complications and providing the maximum comfort. Once the patient is discharged, he/she will be scheduled with several follow-up visits with the Head and Neck Functional Unit during which the study variables will be graded by the patient and an independent observer; both unaware of each other's grading.

The first follow-up session will take place 14 days after the surgery, on the day of suture/skin staples removal. Once the surgeon removes the wound closure materials, the patient will be asked to move into the adjacent consulting room where the patient and an independent observer will carry out the evaluation of the following variables:

cosmetic outcome, psychosocial and QOL impact, post-surgical complications and satisfaction with the incision closure method. The next follow-up sessions will take place 6 and 12 months after the surgery and will only assess the cosmetic outcome and psychosocial and QOL impact. All answers will be stored in the hospital database.

As stated in *7.5. Variables*, the cosmetic outcome will be assessed with scar photography, IAPSM scar classification, POSAS scar rating, and a VAS for scar overall satisfaction; the psychosocial and QOL impact will be determined by DAS59; and the satisfaction with the incision closure method will be evaluated with VAS.

The participant flow chart through the trial can be seen in *Figure 6.*

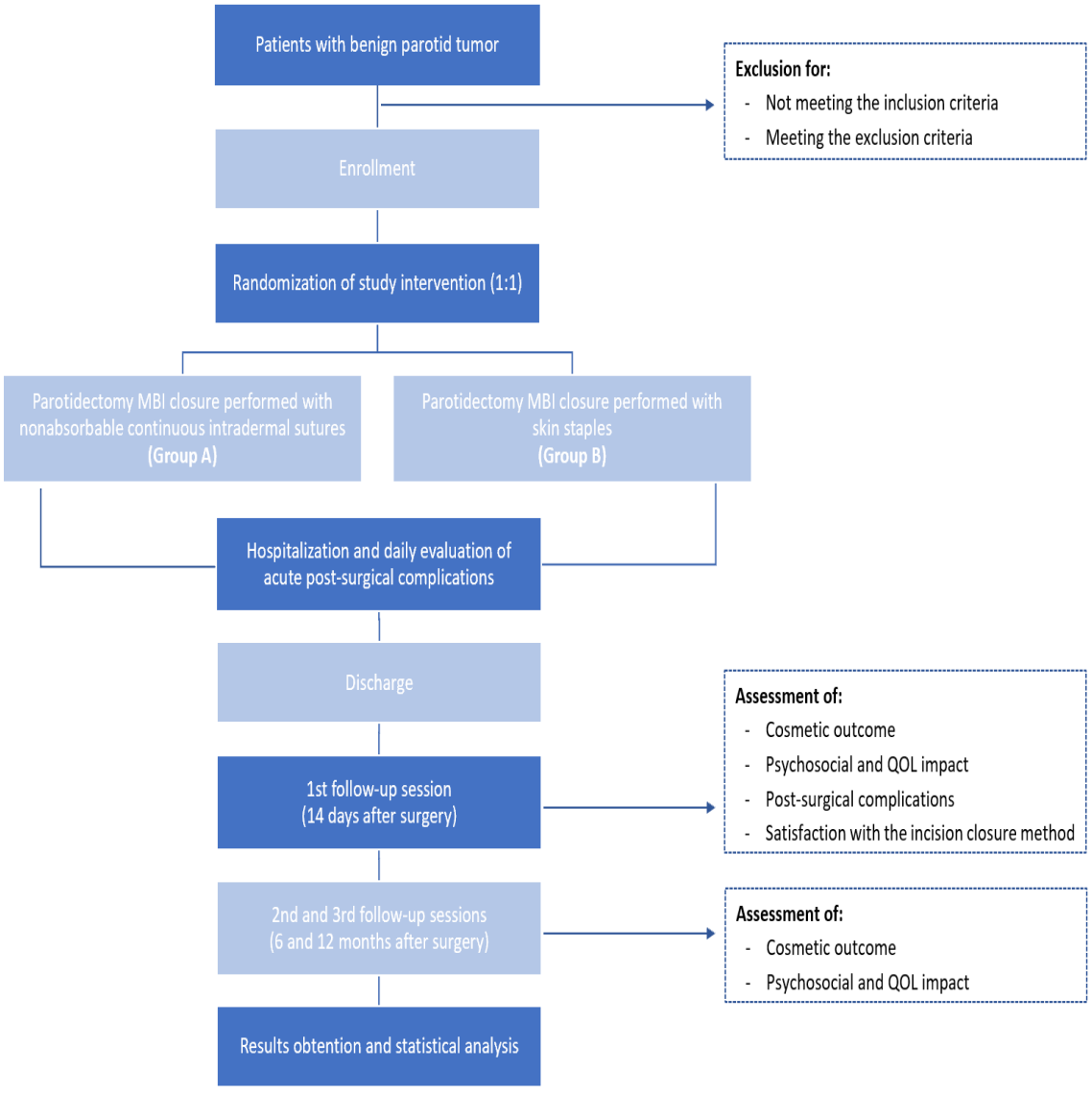

Figure 6: Participant flow chart through the trial.

7.9. STUDY SAFETY

In this study, safety will be treated in high consideration. For promoting trust and enthusiastic participation in the on-going trial the following measures will be taken:

- **Equivalent treatment options:** Both techniques that will be compared in this study have been widely studied and are being used in daily basis. A great number of papers exist that prove that both methods can achieve high-quality results in terms of wound complications, length of hospital stay, pain control, etc. Doing one or the other procedure will not affect the patient's morbidity and/or mortality being the parotidectomy the curative procedure and not the incision closure.
- **Control of complications:** Before signing the consent, all patients will be informed of the possible complications from the procedure. It is important to highlight that both study and control group will be equally exposed to those derived from the curative surgery and as for the complications directly associated with the incision closure, this study does not expect there to be a significant difference between the two methods. Throughout the trial, the physicians will record and document all adverse events (AE). An AE will be considered serious when it requires hospitalization or its prolongation, results in persistent or significant disability or incapacity, results in a congenital anomaly or birth defect, is life-threatening, or results in death. All serious AE will be reported to the research team not later than within 24 hours.
- **Pain management:** Being pain a subjective experience, its management should be appropriate to the patient's needs. All subjects of this study will receive unprejudiced and nondiscriminatory pain control medication that will be chosen according to the WHO analgesic ladder. This study expects there to be a significant difference between the two methods, with nonabsorbable continuous intradermal suture being less painful in terms of overall comfort and pain of removal.

8. STATISTICAL ANALYSIS

The statistical analysis will be performed by a statistical analyst, blinded to the study groups, with the Statistical Package for Social Sciences (SPSS) software version 25 (IBM, Armonk, NY, US) for Windows®.

For all the results, a confidence interval of 95% will be assumed and a $p<0.05$ will be considered statistically significant.

8.1. DESCRIPTIVE ANALYSIS

In this analysis, variables and covariables will be defined as quantitative or qualitative (*see 7.5. Variables; Table 4*). Quantitative variables and covariables will be described using mean and standard deviations for the continuous ones; and median and range for the discrete ones. Qualitative variables and covariables will be described with proportions and percentages.

8.2. BIVARIATE INFERENCE

The association between the type of intervention and the quantitative variables and covariables will be contrasted using a **T-Student test** or **Mann-Whitney's test** depending if they follow or not a parametric distribution, respectively.

The effect of the intervention on the qualitative variables and covariables will be assessed by the **Chi Square test or Fisher's exact test.**

8.3. MULTIVARIATE ANALYSIS

Even though we expect our groups to be balanced in terms of covariates thanks to the randomization process, if the appearance of a cofounding is suspected during the statistical analysis, the associations between the dependent and independent variables will be adjusted to avoid possible confusion.

For controlling all the co-variates, several analysis techniques will be used. On one hand, **multiple linear regression** will be used to assess the effect of the intervention on the quantitative variables. On the other hand, **logistic regressions** will be used to assess the effect of the intervention on the qualitative variables.

9. ETHICAL AND LEGAL CONSIDERATONS

This study will be conducted according to the ethical principles for medical research involving human subjects, established and defined in the Declaration of Helsinki which was developed by World Medical Association (WMA) in 1964 and reviewed in 2013.

The **justice** principle will be taken into consideration since every patient meeting the inclusion and not meeting the exclusion criteria will be asked to enroll on the trial, without any discrimination. The **autonomy** principle will be respected as the enrollment will be completely voluntary and only those signing the Informed Consent Form (*Annex 2*) will participate. Also, patients will have access to the Information Form (*Annex 1*) which they can read and evaluate if they are interested in participating or not. It is expected that the **non-maleficence** principle will be respected because, according to the available bibliography, doing one or the other procedure will not affect the patient's morbidity and/or mortality being the parotidectomy the curative procedure. Finally, the principle of **beneficence** will be respected by achieving a better cosmetic outcome of the incision and therefore, improving the QOL of the patient.

This protocol has also been developed according to the Spanish legal precepts of:

- "*Real Decreto 1090/2015, de 4 de diciembre, por el que se regulan los ensayos clínicos con medicamentos, los Comités de Ética de la Investigación con medicamentos y el Registro Español de Estudios Clínicos*".
- "*Ley 14/2007, de 3 de julio, de Investigación Biomédica*".
- "*Ley 41/2002, de 14 de noviembre, básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica*".
- "*Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales*".

Before beginning the study, its protocol will be submitted to the Clinical Research Ethics Committee (CEIC) of HUJT for its evaluation. All the recommendations will be considered, and relevant modifications will be made to get its approval.

The research team will assert that all data is published with transparency and clarity.
All investigators involving the study will have to declare no conflict of interest.

10. WORK PLAN AND CHRONOGRAM

10.1. PERSONNEL OF THE RESEARCH TEAM

The whole study will have an estimated duration of 3 years and 9 months. The personnel essential in the different stages of the clinical trial include:

- **Main investigator (MI):** Person responsible for elaborating the protocol, assembling the team and making sure that everything needed for the project is ready.
- **Clinical coordinator (CC):** Person responsible for data recollection and its presentation to the statistician. The CC will also have direct contact with the MI in case any complications appear throughout the trial.
- **Health care professionals (HCP):** Surgeons and nurses from Oral and Maxillofacial Surgery Department of HUJT responsible for collecting the patients' data and carrying out the interventions.
- **Other personnel:** Independent observer (plastic surgeon trained in the use of the scar assessment scales), statistical analyst and IT personnel.

10.2. STUDY STAGES

STAGE 0: STUDY DESIGN (September 2022 - November 2022)

- **Activity 1:** Bibliographic research. Systematic literature search on the following topics will be carried out: parotidectomy, wound healing, sutures and staples. It is important to make an inquiry about the already existing studies related to the incision closure techniques.
- **Activity 2:** Protocol elaboration. Objectives, hypothesis, variables and methodology will be accurately elaborated.

STAGE 1: ETHICAL EVALUATION (December 2022 - January 2023)

- **Activity 3:** CEIC evaluation and approval. The protocol will be submitted to the CEIC of HUJT for its revision and approval. Once approved, the protocol will be adapted to the CEIC contributions.
- **Activity 4:** Liability insurance acquisition.

STAGE 2: STUDY COORDINATION (February 2023 - March 2023)

- **Activity 5:** Research team meeting. The MI will choose a CC and a work chronogram will be prepared with all the phases detailed. A general coordination meeting will be held to explain and discuss the design, objectives and methods of the trial.
- **Activity 6:** Formation sessions. All the participant professionals will be trained on what information they have to request and how to collect it. Additionally, all the surgeons will attend a workshop to unify their techniques and discuss their different approaches.

STAGE 3: FIELD WORK AND DATA COLLECTION (April 2023 - December 2026)

- **Activity 7:** Recruitment and randomization. A consecutive non-probabilistic recruitment will be performed will be used for the sample selection. Only patients meeting inclusion criteria and not meeting exclusion criteria, and having the informed consent signed, will be included in the trial. They will be randomly assigned to one of the intervention groups.
- **Activity 8**: Intervention and discharge. The intervention will be performed and patients will be hospitalized. The timing of the incision closure will be registered in the patient's clinical chart. An assessment of acute complications will be done daily during the hospital stay. Once the patient is discharged, he/she will be scheduled with several follow-up visits during which the study variables will be graded by the patient and an independent observer; both unaware of each other's grading.
- **Activity 9:** Follow-up sessions. The first follow-up session will take place 14 days after the surgery, on the day of suture/skin staples removal. On this session, the following variables will be evaluated: cosmetic outcome, QOL impact, post-surgical complications and satisfaction with the incision closure method. The next follow-up sessions will take place 6 and 12 months after the surgery and will only assess the cosmetic outcome and psychosocial and QOL impact.
- **Activity 10:** Data collection. Trained personnel will register all the information collected in every visit in the patients' clinical chart. The CC will assemble all the information and upload it into the study database.

STAGE 4: DATA ANALYSIS AND INTERPRETATION (January 2026 - April 2027)

- **Activity 11:** Statistical analysis. A statistician, who will be masked for intervention groups, will perform a statistical analysis once all the data has been collected.
- **Activity 12:** Results and conclusions. The final statistical analysis will be interpretated by the MI and the CC. Then, discussion and conclusions from the previous analyses will be elaborated.

STAGE 5: DATA PUBLICATION AND DISSEMINATION (March 2027 - September 2027)

- **Activity 13:** Article publication. The MI will write the final article. It will be edited and supervised by English correctors and published afterwards.
- **Activity 14:** Article dissemination. The results will be exhibited in national and international conferences and congresses of Oral and Maxillofacial Surgery.

Clinical trial chronogram can be seen in *Table 5*.

STAGE AND ACTIVITY		YEARS AND MONTHS															
		2022				2023											
		S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
STAGE 0																	
A1	Bibliographic research	■	■	■													
A2	Protocol elaboration	■	■	■													
STAGE 1																	
A3	CEIC evaluation and approval				■	■											
A4	Liability insurance acquisition.					■											
STAGE 2																	
A5	Research team meeting						■										
A6	Formation sessions							■									
STAGE 3																	
A7	Recruitment and randomization								■	■	■	■	■	■	■	■	■
A8	Intervention and discharge								■	■	■	■	■	■	■	■	■
A9	Follow-up sessions								■	■	■	■	■	■	■	■	■
A10	Data collection								■	■	■	■	■	■	■	■	■
STAGE 4																	
A11	Statistical analysis																
A12	Results and conclusions																
STAGE 5																	
A13	Article publication																
A14	Article dissemination																

STAGE AND ACTIVITY		2024											
		J	F	M	A	M	J	J	A	S	O	N	D
STAGE 0													
A1	Bibliographic research												
A2	Protocol elaboration												
STAGE 1													
A3	CEIC evaluation and approval												
A4	Liability insurance acquisition.												
STAGE 2													
A5	Research team meeting												
A6	Formation sessions												
STAGE 3													
A7	Recruitment and randomization	■	■	■	■	■	■	■	■	■	■	■	■
A8	Intervention and discharge	■	■	■	■	■	■	■	■	■	■	■	■
A9	Follow-up sessions	■	■	■	■	■	■	■	■	■	■	■	■
A10	Data collection	■	■	■	■	■	■	■	■	■	■	■	■
STAGE 4													
A11	Statistical analysis												
A12	Results and conclusions												
STAGE 5													
A13	Article publication												
A14	Article dissemination												

STAGE AND ACTIVITY		2025											
		J	F	M	A	M	J	J	A	S	O	N	D
STAGE 0													
A1	Bibliographic research												
A2	Protocol elaboration												
STAGE 1													
A3	CEIC evaluation and approval												
A4	Liability insurance acquisition.												
STAGE 2													
A5	Research team meeting												
A6	Formation sessions												
STAGE 3													
A7	Recruitment and randomization	■	■	■	■	■	■	■	■	■	■	■	■
A8	Intervention and discharge	■	■	■	■	■	■	■	■	■	■	■	■
A9	Follow-up sessions	■	■	■	■	■	■	■	■	■	■	■	■
A10	Data collection	■	■	■	■	■	■	■	■	■	■	■	■
STAGE 4													
A11	Statistical analysis												
A12	Results and conclusions												
STAGE 5													
A13	Article publication												
A14	Article dissemination												

STAGE AND ACTIVITY		2026												2027								
		J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S
STAGE 0																						
A1	Bibliographic research																					
A2	Protocol elaboration																					
STAGE 1																						
A3	CEIC evaluation and approval																					
A4	Liability insurance acquisition.																					
STAGE 2																						
A5	Research team meeting																					
A6	Formation sessions																					
STAGE 3																						
A7	Recruitment and randomization																					
A8	Intervention and discharge																					
A9	Follow-up sessions	■	■	■	■	■	■	■	■	■	■	■	■									
A10	Data collection	■	■	■	■	■	■	■	■	■	■	■	■									
STAGE 4																						
A11	Statistical analysis													■	■							
A12	Results and conclusions															■	■					
STAGE 5																						
A13	Article publication																	■	■	■		
A14	Article dissemination																				■	■

Table 5: Clinical trial chronogram.

11. BUDGET

11.1. PERSONNEL EXPENSES

The main research team (MI, CC and HCP) will be composed by employees of HUJT and, therefore, won't imply an additional cost.

An independent observer (plastic surgeon trained in the use of the scar assessment scales) will be hired to carry out the evaluation of the outcome variables of each patient. His/her will work for 35€/hour, during approximately 150 hours. This will cost 5.250€.

A qualified statistician will also be hired in order to randomize and code patients, as well as to perform the final statistical analysis from the collected data. His/her will work for 25€/hour, during approximately 100 hours. This will cost 2.500€.

11.2. INSURANCE EXPENSES

In case the CEIC considers this clinical trial to be invasive, an insurance will be hired to cover any possible adverse effects that could result from patients' participation in the study. Its estimated cost is 4.400€. The precise cost will be confirmed at the time of the study kick-off once known the changes to the protocol made by the CEIC advice.

11.3. EXECUTION EXPENSES

Material for the bibliography research has not represented an additional expense. Also, the surgical procedures, imaging techniques and anatomopathological exams are a part of the routine management for parotid tumors, so they will not add any cost.

Therefore, the additional expenses of this study will be composed by:

- **Sutures**: Deep layer sutures cost around 10€/unit and skin layer sutures around 5€/unit. Their approximate cost is 25€/patient.
- **Electronic tablet**: The tablet will allow reading the Information Form, signing the Informed Consent Form and filling out the Data Collection Sheet as well as the scales and surveys (*Annexes 1-4*). Its approximate cost is 300€.
- **Digital camera**: The camera will allow evaluating the cosmetic outcome of the incision closure methods. Its approximate cost is 400€.

11.4. TRAVEL AND COORDINATION EXPENSES

One research team meeting and two formation sessions will take place during our clinical trial. Nevertheless, as this is a single-institution study no additional travel and /or coordination expenses are expected.

11.5. PUBLICATION AND DISSEMINATION EXPENSES

Once the study has ended, and the extraction and interpretation of results has been performed, it will be published as a journal article. Taking into account the English correction (500€) and the preparation of the Open Access (1.800€), the estimated subtotal cost of the publication fees is budgeted on 2.300€.

11.6. DISSEMINATION EXPENSES

In order to disseminate the results of our clinical trial to the scientific community, we will attend national and international congresses of Oral and Maxillofacial Surgery. The admission fees are estimated in 500€ for the national and 800€ for the international congress, approximately.

Budget summary can be seen in *Table 6.*

ITEM		COST	AMOUNT	SUBTOTAL
Personnel expenses	Independent observer	30€/hour	150 hours	4.500€
	Statistician	30€/hour	100 hours	3.000€
Insurance expenses	Liability insurance	20€/patient	220 patients	4.400€
Execution expenses	Sutures	25€/patient	110 patients	2.750€
	Electronic tablet	300€/unit	1 unit	300€
	Digital camera	400€/unit	1 unit	400€
Publication expenses	English correction	500€	1	500€
	Open Access	1.800€	1	1.800€
Dissemination expenses	National congress	500€	1	500€
	International congress	800€	1	800€
TOTAL COST				**18.950€**

Table 6: Budget summary.

12. FEASIBILITY

We have considered this study feasible from different perspectives:

Being a single-institution study, it makes it easy to control the different activities that will be performed at every stage of the trial. Additionally, because all the interventions and follow-up sessions will take place in HUJT we can rely that the hospital itself will provide most of the equipment and staff.

Apart from the independent observer and the statistician, no additional personnel will be hired. The main research team will be formed by a group of prepared professionals who have already specialized in the field of interest and, more importantly, are habituated to work together. Even so, all participants, will attend to a general coordination meeting and will receive a workshop to unify their techniques and discuss their different approaches.

Although the hospital would be able to assume the costs and responsibility of any complication that could result from patients' participation in the study, a liability insurance will be acquired to cover any possible adverse effects.

Two gadgets will be acquired for this study, a digital camera and an electronical tablet. While at first sight it might seem as an unnecessary investment, we believe it will not only prove useful but also reduce the costs of this study. The tablet will be used both by the professionals and the patients to fill out all the documents of this study; if we consider the cost of printing all the files it will easily surpass the price of both devices.

A total of 220 patients must be recruited for this study, which means that 2 years and 9 months will be needed to achieve the sample. An additional year will be needed to perform the final evaluation. We believe, that such period will not allow the studied techniques to be become outdated. Furthermore, despite the prospective format we do not expect to have high withdrawal rate. Nevertheless, we must disclose that the sample is calculated based on the ideal health care situation and we must assume that now, due to the Covid-19 pandemic many non-essential surgeries are still being postponed.

13. STUDY LIMITATIONS AND BIASES

Throughout the design process of this clinical trial protocol, the following limitations and biases have been detected and will be taken into consideration:

- Being a small study conducted in a **single institution** implies a **longer duration to achieve the correct sample size** and, sometimes, even if the goal sample size is estimated properly, it may not prove feasible to enroll the target number of patients. However, we believe that the duration of the present trial will not allow the studied techniques to be become outdated and will also serve for a future multi-centric study that would allow enhancing the statistical power by increasing the sample size and reducing the recruitment time.

- Due to the **prospective format** of the clinical trial, there is a **risk of withdrawals** during the follow-up period. This risk has been assessed at the time of the sample size determination with a 5% of drop-out rate. The sample size has been increased for covering for those who will potentially drop-out. Furthermore, telephone calls will be made to those patients that were absent on their follow-up visits and a research team member will encourage them to pursue in the study.

- The **consecutive non-probabilistic recruitment method** used for the sample selection in this trial may lead to a **selection bias**, as it is not the perfect method to obtain a representative sample of the population. Nevertheless, due to the low incidence of benign parotid tumor, designing it otherwise wouldn't be as beneficial. To minimize this bias, a randomization of the intervention will be performed to distribute patients between equitable groups.

- As a result of this trial being **open-label**, it is impossible to mask patients and surgeons, a fact that can lead to a **detection bias**. To minimize this possible bias, a number of actions will be taken: every patient will be assigned a numeric code so that he/she cannot be identified; an independent observer will be recruited and the participants will be told not to reveal the type of intervention received; finally, the statistical analyst will also be unaware of the intervention each patient received.

- In this study, the intervention is an **operator-dependent procedure** and, therefore there's a chance of **intra and intervariability** not only between professionals from the same hospital but also between hospitals. To avoid this possible variability, all the incisions and wound closures, in this study, will be performed by or under the direct supervision of the same surgeon and prior to that, all surgeons will receive a workshop to unify their techniques and discuss their different approaches.

- An additional limitation to keep in mind, presented in all clinical trials, is the **external validity**. Even though, we believe that this study could be extrapolated to our population, further multi-centered studies should be carried out in the future to reduce this limitation. Regarding internal validity, all the covariates will be controlled, and taken into account, in the statistical analyses. Furthermore, the randomization provides two highly comparable groups of subjects at baseline.

14. CLINICAL AND HEALTHCARE IMPACT

Scars are an inevitable result of the surgical procedure that have a great cosmetic and psychological repercussion on patients. In most occasions, the scar is tacitly assumed as a secondary aspect, especially when the operation is due to cancer treatment.

Studies such as ours, aim to highlight the fact that cosmetic outcome an important health concern that can have implications for psychological happiness and QOL. We believe that this clinical trial will have a significant clinical and healthcare impact as it will give and objective conclusion whether nonabsorbable continuous intradermal sutures achieve a greater cosmetic outcome, that being the less visible scarring tissue, when compared to skin staples used for skin closure following a parotidectomy via MBI for benign parotid tumors.

Another point worth mentioning is that sometimes, it is thought that the financial cost of wound management, surgical or not, only refers to the cost of the materials (sutures and/or staples, dressings, topical antiseptics, etc.) used, however, that is almost never the case. Part of the cost relates to health care professionals' time which includes not only the intervention but also the post-operatory procedures. We believe that by achieving a better cosmetic outcome we would also be able to reduce additional follow-up visits and scar revision procedures (surgical and non-surgical techniques that attempt to minimize a scar so that it is less conspicuous and blends in with the surrounding skin) and, by doing so, cut down total expenses.

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16. ANNEXES

ANNEX 1: INFORMATION FORM

FULLA D'INFORMACIÓ PER AL PACIENT SOBRE L'ESTUDI

Nom de l'estudi: Resultat estètic de sutures intradèrmiques continues no absorbibles versus grapes cutànies pel tancament de la pell després d'una parotidectomia per a tumors parotidis benignes en adults.

Hospital: Hospital Universitari Josep Trueta (HUJT)

Investigador principal: Dr. Manel Gorina Faz i estudiant Veronika Ranneva.

Benvolgut/da,

Ens dirigim a vostè per proposar-li participar en un estudi d'investigació dut a terme en el servei de Cirurgia Oral I Maxil·lofacial de l'Hospital Universitari Doctor Josep Trueta. Aquest estudi ha sigut aprovat pel Comitè d'Ètica i Investigació Clínica de l'hospital i per l'Agència Espanyola del Medicament i Productes Sanitaris.

La nostra intenció és que vostè entengui el motiu pel qual es realitza aquest estudi i què implica formar-ne part, per tal que pugui decidir voluntàriament si desitja participar-hi. Per això, li preguem que es prengui el temps necessari per llegir detingudament i comprendre aquest resum informatiu sobre el nostre estudi. No cal que decideixi avui la seva participació, i, en cas que sorgeixi qualsevol dubte, el nostre equip estarà pendent i el respondrà, posant a la seva disposició tota la informació necessària.

DESCRIPCIÓ I OBJECTIUS DE L'ESTUDI

Les cicatrius són un resultat inevitable d'un procediment quirúrgic que tenen una gran repercussió física i psicològica per els pacients. Tot i que les sutures encara es consideren l'estàndard de cura en el tancament de ferides cutànies, les grapes s'utilitzen habitualment com a alternativa en la cirurgia del càncer de cap i coll. Tanmateix, si es vol aconseguir un resultat estètic més agradable, una sutura intradèrmica és més adequada per al tancament de la pell. Malauradament, malgrat l'èmfasi creixent en l'impacte cosmètic de les cicatrius, hi ha molt poques dades comparatives fiables sobre les quals basar la selecció del mètode pel tancament de les incisions quirúrgiques.

L'objectiu principal del nostre projecte és demostrar que les sutures intradèrmiques contínues no absorbibles proporcionaran un millor resultat estètic, sent aquest un teixit cicatricial menys visible, en comparació amb les grapes utilitzades pell tancament de la pell després d'una parotidectomia mitjançant una incisió de Blair modificada (MBI) per a tumors parotidis benignes. Quan es tracta d'objectius secundaris, avaluarem l'impacte psicosocial i de la qualitat de vida durant el postoperatori, el temps de tancament de la ferida, les complicacions post-quirúrgiques i la satisfacció amb el mètode de tancament de la incisió, tot comparant ambdues tècniques.

METODOLOGIA I INTERVENCIÓ

En aquest estudi participaran un total de 220 pacients. Cada participant serà assignat un codi numèric i distribuït aleatòriament en un dels dos grups de l'estudi (grup A i B):

- Als pacients del grup A se'ls farà un tancament de la incisió amb sutures intradèrmiques contínues no absorbibles
- Als pacients del grup B se'ls farà un tancament de la incisió grapes de pell.

En ambdós grups, un cop finalitzat el tancament, la ferida es curarà amb l'aplicació d'una crema antisèptica i una tira de gasa estèril. L'embenat es canviarà cada 24h. A més, a tots els pacients se'ls administrarà i.v. antibiòtics durant un període de 5-7 dies. Els drenatges quirúrgics es mantindran fins que el contingut del drenatge sigui mínim (menys de 15-30cc en 24 hores). Després d'un interval de 14 dies, tant les sutures com les grapes es trauran de manera convencional.

Els pacients seran avaluats per complicacions diàriament fins a l'alta. En cada sessió de seguiment (14 dies, 6 i 12 mesos després de la cirurgia), les variables d'estudi seran qualificades pel pacient i un observador independent (cirurgià plàstic format en l'ús de les escales d'avaluació que s'utilitzaran en aquest estudi).

BENEFICIS I RISCS DE L'ESTUDI

Creiem que aquest assaig clínic tindrà un impacte assistencial important ja que donarà una conclusió objectiva si les sutures intradèrmiques contínues aconsegueixen un millor resultat estètic, és a dir una cicatriu menys visible, en comparació amb les grapes de pell utilitzades habitualment pel tancament de la incisió d'una parotidectomia. Per tant, el principal benefici que s'espera per als pacients participants en aquest estudi és aconseguir disminuir no només el deteriorament funcional que comporta tenir una cicatriu, sinó també la carrega psicològica que comporta.

Pel que fa als riscos, no es preveu cap risc afegit respecte la tècnica convencional. A més, per assegurar no perjudicar la salut dels pacients participants, els individus seran seleccionats mitjançant uns criteris d'inclusió i exclusió estrictes.

ALTERNATIVES AL PROCEDIMENT

Si el pacient decideix no participar en l'assaig clínic, serà el tancament de la incisió després de la parotidectomia serà realitzada de forma convencional, és a dir, amb grapa o amb sutura simple i grapa.

En referència al seguiment, el pacient que decideixi no participar a l'estudi rebrà també la mateixa atenció que aquell que sí hi participi, amb les visites de seguiment adequades. L'únic procediment del qual estaran exempts pel fet de no entrar a l'assaig clínic és l'emplenament de les escales i/o qüestionaris.

CONFIDENCIALITAT

Des del principi de la seva participació en aquest estudi, totes les dades personals que es recullin seran gestionades i emmagatzemades amb total confidencialitat, ajustant-se a la legislació actual de la Llei Orgànica 3/2018, de 5 de desembre, de Protecció de dades personals i garantia dels drets digitals. Aquesta informació serà identificada amb un número i només s'utilitzarà amb fins d'investigació.

L'accés a la informació només serà disponible per a investigadors i altres autoritats sanitàries. El pacient té el dret de poder consultar la informació recopilada sobre ell i corregir-la en cas d'error. Garantim que cap informació personal serà publicada.

DIFUSIÓ DELS RESULTATS

Quan hagi finalitzat l'estudi i s'hagin extret conclusions, la intenció és publicar aquests resultats obtinguts en revistes científiques. D'aquesta manera, altres centres assistencials i pacients en la mateixa situació podran beneficiar-se'n. Tal i com s'ha comentat anteriorment, en aquestes publicacions no constarà cap dada personal.

PARTICIPACIÓ I COMPENSACIÓ ECONÒMICA

Els investigadors d'aquest estudi no obtenen benefici econòmic.

La seva participació com a pacient en aquest estudi és estrictament voluntària, pel que si decideix participar no rebrà cap tipus de compensació econòmica, però tampoc li suposarà cap despesa. En cas de no voler participar, tampoc li suposarà cap canvi en quant a la seva atenció mèdica per l'equip d'especialistes.

Si vostè decideix participar, haurà de firmar la fulla de consentiment informat conforme dóna la seva aprovació. També està vostè en el seu dret de sortir de l'estudi si en qualsevol moment del seu transcurs així ho decideix, no alterant això tampoc la seva atenció mèdica, tot i que li demanem que ho comuniqui a algun dels professionals del servei de Cirurgia Oral I Maxil·lofacial de l'Hospital Universitari Doctor Josep Trueta.

Abans de decidir sobre la seva participació, vostè és lliure de demanar una segona opinió a altres professionals mèdics si així ho requereix

RESPONSABILITAT I ASSEGURANÇA

Els promotors d'aquest estudi tenen contractada una pòlissa d'assegurança per a la seva realització, tal i com s'estableix en la legislació. En cas de perjudici o detriment de la seva salut com a conseqüència de la seva participació en aquest estudi, se li proporcionarà la indemnització corresponent.

CONTACTE

En cas de qualsevol dubte abans, durant o després de la realització d'aquest estudi, podrà posar-se en contacte sempre que ho necessiti amb: _____.

ANNEX 2: INFORMED CONSENT FORM

DOCUMENT DE CONSENTIMENT INFORMAT DEL PACIENT.

Jo, _____, amb document d'identificació personal (DNI/NIE) _____, declaro que:

- He llegit i entès tota la informació que apareix a la fulla d'informació per al pacient.
- Estic satisfet amb la quantitat d'informació que se m'ha proporcionat.
- He pogut exposar qualsevol dubte que m'hagi sortit, i me l'han resolt adequadament.
- Entenc els potencials riscs i beneficis derivats de participar en aquest estudi.
- No he ocultat informació essencial sobre el meu cas, els meus hàbits o règim de vida, que poguessin ser rellevants als metges que m'atenen.
- Comprenc que la meva participació és voluntària i no remunerada.
- Comprenc que les meves dades i proves seran confidencials.

Sé, per altra banda, que m'intervindrà el facultatiu que, dins de les circumstancies de l'equip mèdic en el dia de la intervenció, sigui el més adequat per al meu cas. Per tot això, **DONO EL MEU CONSENTIMENT PER A PARTICIPAR EN L'ESTUDI**, així com per què, els investigadors del projecte puguin posar-se en contacte amb mi en un futur si es considera oportú. En el cas que, durant la intervenció, el cirurgià trobi aspectes de la meva malaltia que li exigeixin o li aconsellin modificar el procediment inicialment projectat, podrà fer-ho de la maner que millor convingui a la meva salut.

A més, comprenc que tot i haver firmat el consentiment informat, puc revocar-lo en qualsevol moment i que això no suposarà un perjudici en el meu tractament ni en la meva assistència sanitària.

Signatura del/la pacient **Signatura de l'investigador**

☐ Accepto

☐ No accepto

Lloc i data: _____, ____ de _____ de l'any _____

REVOCACIÓ DEL CONSENTIMENT INFORMAT

Jo, _____, amb document d'identificació personal (DNI/NIE) _____, revoco el consentiment prèviament signat per a la participació en l'assaig clínic: *Resultat estètic de sutures intradèrmiques continues no absorbibles versus grapes cutànies pel tancament de la pell després d'una parotidectomia per a tumors parotidis benignes.*

Signatura del/la pacient **Signatura de l'investigador**

☐ Accepto

☐ No accepto

Lloc i data: _____, ____ de _____ de l'any _____

ANNEX 3: DATA COLLECTION SHEET

FULLA DE RECOLLIDA DE DADES DE LES VARIABLES DEMOGRÀFIQUES I EPIDEMIOLÒGIQUES DELS PACIENTS PARTICIPANTS A L'ESTUDI.

Hospital: Hospital Universitari Josep Trueta (HUJT)

Codi numèric assignat: _____

Lloc i data: _____, ____ de _____ de l'any _____

- **Data de naixement (dia/mes/any):** ____ / ____ / _____
- **Sexe:** ☐ Home
  ☐ Dona
- **Índex de Massa Corporal (IMC), kg/m²**
  - ☐ **Baix pes**: IMC <18.5
  - ☐ **Pes normal:** IMC 18.5-24.9
  - ☐ **Sobrepès:** IMC 25-29.9
  - ☐ **Obesitat classe I:** IMC 30-34.9
  - ☐ **Obesitat classe II:** IMC 35-39.9
  - ☐ **Obesitat classe III:** IMC ≥40
- **Estatus socioeconòmic:**
  - ☐ **Classe I**: Directius de l'Administració pública i d'empreses de 10 o més assalariats. Professions associades a titulacions de 2n i 3r cicle universitari.
  - ☐ **Classe II:** Directius d'empreses amb menys de 10 assalariats. Professions associades a una titulació de 1r cicle universitari. Tècnics. Artistes i esportistes
  - ☐ **Classe III:** Empleats de tipus administratiu i professionals de suport a la gestió administrativa i financera. Treballadors dels serveis personals i de seguretat. Treballadors per compte propi. Supervisors de treballadors manuals.
  - ☐ **Classe IV:** Treballadors manuals qualificats o semi-qualificats.
  - ☐ **Classe V:** Treballadors no qualificats
- **Ètnia**:
  - ☐ **Africana**
  - ☐ **Asiàtica**
  - ☐ **Caucàsica**
  - ☐ **Llatí-Americana**
  - ☐ **Altres**: _____

- **Malalties o trastorns concomitants:**
  - ☐ Si (indiqui quines: _____)
  - ☐ No

- **Hàbit tabàquic**:
  - ☐ **No fumador**
  - ☐ **Fumador**: Si fuma actualment o fa menys de 28 dies que ha deixat de fumar.
  - ☐ **Ex-fumador**: Si ha fumat al llarg de la seva vida però fa més de 28 dies que ha deixat de fumar

- **Consum d'alcohol**:
  - ☐ **No consum**
  - ☐ **Consum moderat**: 20-50g/dia en dones i 40-60g/dia en homes
  - ☐ **Consum elevat:** >40g/dia en dones i >60g/dia en homes

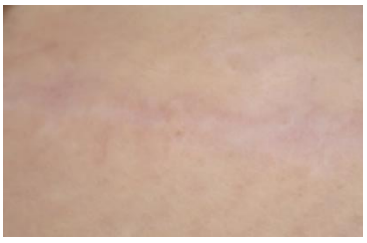
- Grams d'alcohol = (Volum en mil·lilitres x Graduació beguda x 0,8) / 100.
- 10 grams d'alcohol són aproximadament 1 canya de cervesa o 1 got de vi o 1 copa de cava o ½ got de licor.

ANNEX 4: MEASURMENT SCALES AND SURVEYS

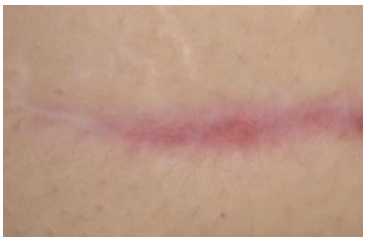
ANNEX 4.1: INTERNATIONAL ADVISORY PANEL ON SCAR MANAGEMENT (IAPSM) SCAR CLASSIFICATION.

This classification categorizes the scars as:

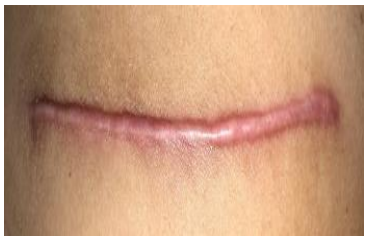
- **Normal mature**: Light-colored, flat scar.
- **Normal immature**: Red, slightly elevated scar in the process of remodeling. Many of these will mature normally over time and become flat, and assume a pigmentation that is similar to the surrounding skin, although they can be paler or slightly darker.
- **Hypertrophic**: Thin, elevated and sometimes itchy scar confined to the border of the original surgical incision. These scars may increase in size rapidly for 3-6 months and then after a static phase, begin to regress. They generally mature to have an elevated, slightly rope-like appearance with increased width, which is variable. The full maturation process may take up to two years.
- **Minor keloid**: Thick, elevated and itchy scar that extends over the border of the original surgical incision. These scars may develop up to 1 year after injury and do not regress on their own. There may be a genetic abnormality involved in keloid scarring. Typical sites include earlobes.
- **Major keloid**: Thick, large, elevated, itchy and possibly painful scar that extends over the border of the original surgical incision. These scars continue to spread over years.



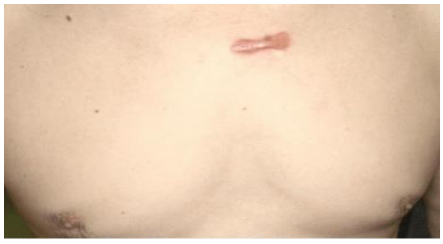
Normal mature



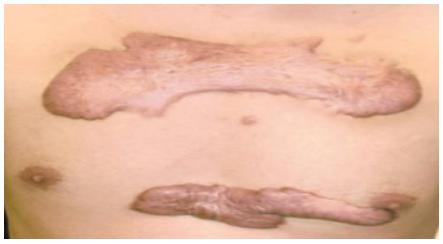
Normal immature



Hypertrophic



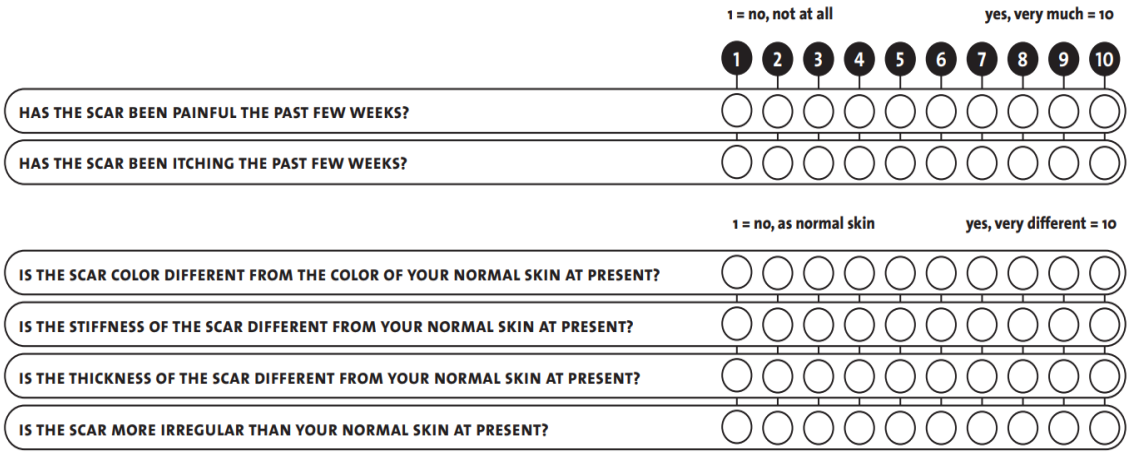
Minor keloid



Major keloid

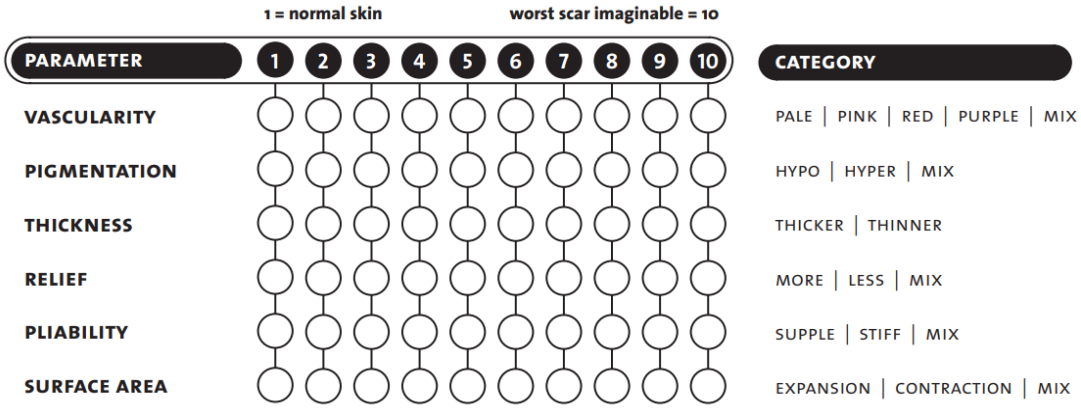
POSAS Patient scale

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



POSAS Observer scale

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



Explanation

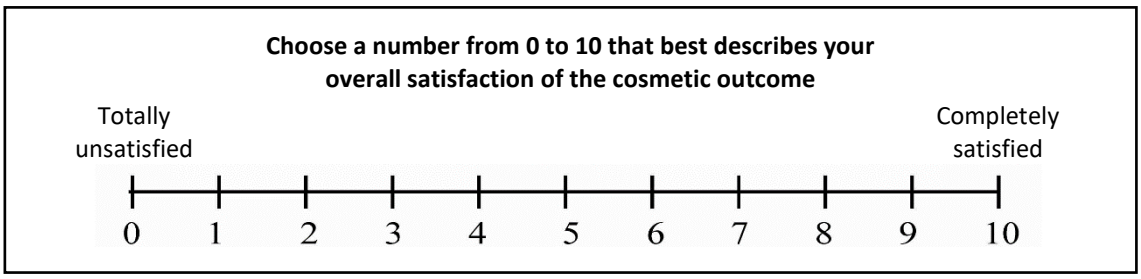
The observer scale of the POSAS consists of six items (vascularity, pigmentation, thickness, relief, pliability and surface area).
All items are scored on a scale ranging from 1 ('like normal skin') to 10 ('worst scar imaginable').
The sum of the six items results in a total score of the POSAS observer scale. Categories boxes are added for each item. Furthermore, an overall opinion is scored on a scale ranging from 1 to 10.
All parameters should preferably be compared to normal skin on a comparable anatomic location.

Explanatory notes on the items:

- **VASCULARITY** Presence of vessels in scar tissue assessed by the amount of redness, tested by the amount of blood return after blanching with a piece of Plexiglas
- **PIGMENTATION** Brownish coloration of the scar by pigment (melanin); apply Plexiglas to the skin with moderate pressure to eliminate the effect of vascularity
- **THICKNESS** Average distance between the subcutical-dermal border and the epidermal surface of the scar
- **RELIEF** The extent to which surface irregularities are present (preferably compared with adjacent normal skin)
- **PLIABILITY** Suppleness of the scar tested by wrinkling the scar between the thumb and index finger
- **SURFACE AREA** Surface area of the scar in relation to the original wound area

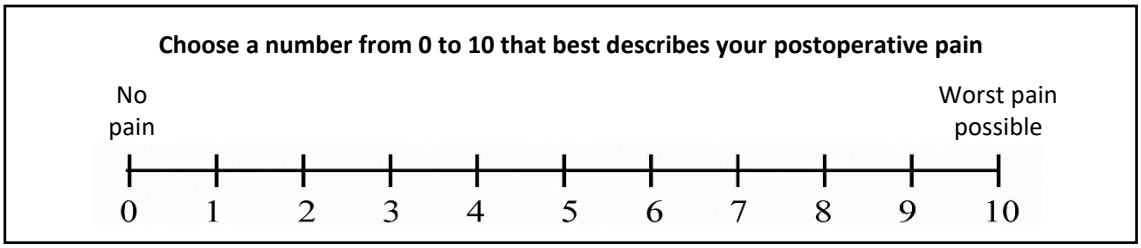
ANNEX 4.3: VISUAL ANALOG SCALE (VAS)

Overall satisfaction of the cosmetic outcome

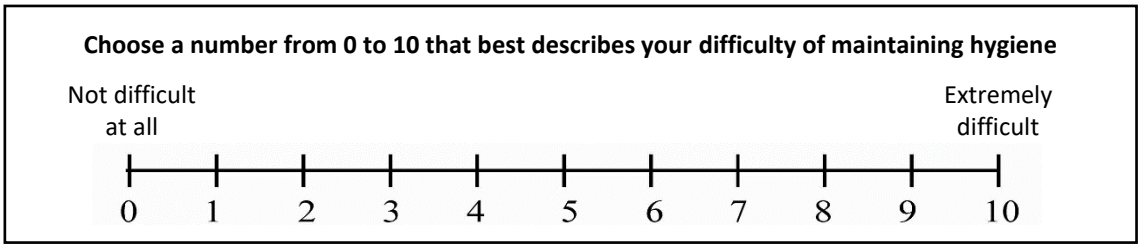


Satisfaction with the incision closure method

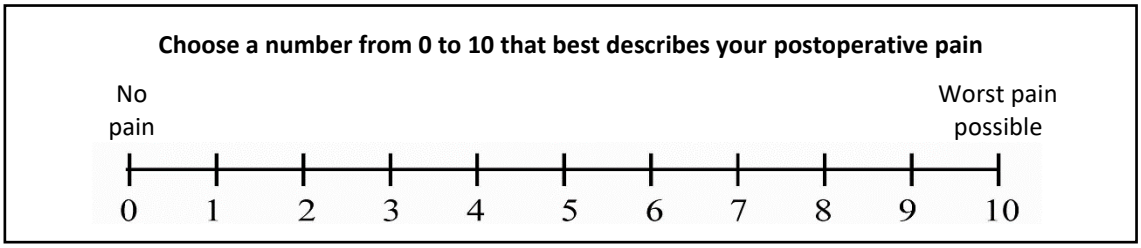
- **Postoperative pain**



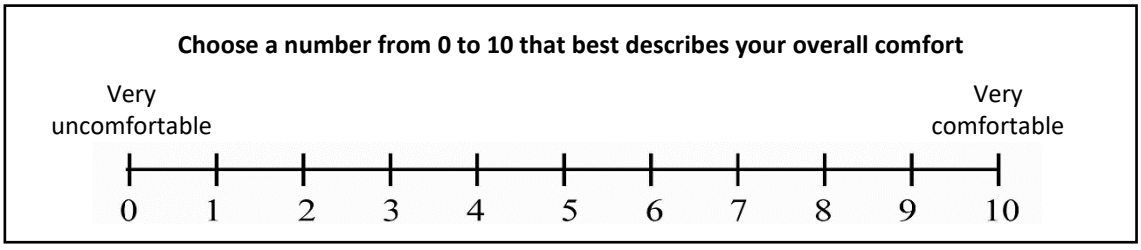
- **Difficulty of maintaining hygiene**



- **Pain of removal**



- **Overall comfort**



ANNEX 4.4: DERRIFORD APPEARANCE SCALE (DAS59)

DERRIFORD APPEARANCE SCALE (DAS59)				
Never – 0: Does not apply to me at all **A little – 1:** Applies to me to some degree or some of the time **Often – 2:** Applies to me a considerable degree or a good part of the time **Always – 3:** Apples to me very much or most of the time				
Item	**Score**			
	Never 0	**A little 1**	**Often 2**	**Always 3**
1. self-consciousness of the scar				
2. avoiding children in the street				
3. difficulty making friends				
4. avoiding undressing in front of partner				
5. avoiding school/college/work				
6. avoiding pubs/restaurants				
7. avoiding parties/discos				
8. taking a special interest in others' scars				
9. avoiding communal changing rooms				
10. avoiding photography				
11. avoid getting the hair wet				
12. being hurt by others' comments				
13. avoiding department stores				
14. avoid leaving the house				
15. raising subject of the scar before others do				
16. closing into a shell				
17. being irritable at home				
18. being misjudged				
19. avoiding school/college/work				
20. feeling an embarrassment to friends				
21. feeling a freak				
22. worrying about sanity				
23. adverse effect on sex life				
24. adverse effect on marriage				
27. feel unattractive				
28. feel unlovable				
29. feel isolated				
30. feel embarrassed				

31. feel inferior				
32. feel rejected				
33. feel useless				
34. distress when others stare				
35. distress when others make remarks				
36. distress when others ask about the scar				
37. distress when going to the beach				
38. distress when seen in a particular view				
39. distress when going to school/college/work				
40. distress when on public transport				
41. distress when seeing the scar in a mirror/window				
42. distress when meeting strangers				
43. distress from being unable to wear favorite clothes				
44. distress from being unable to change hairstyle				
45. distress from being unable to go swimming				
46. distress from being unable to play games				
47. distress when being unable to go to social events				
48. distress from being unable to answer the front door				
49. distress from being unable to look in the mirror				
50. distress when being unable to go to pubs/restaurants				
51. distress from being unable to go out in sunny weather				
52. how confident do you feel?				
53. how irritable do you feel?				
54. how secure do you feel?				
55. how cheerful do you feel?				
56. how normal do you feel?				
57. how masculine/feminine do you feel?				
58. how hurt do you feel?				
59. how hostile do you feel?				

Explanation

This scale contains 59 self-report items intended to assess the turmoil of everyday life, lowered self-esteem, problems with personal relations, and psychological distress associated with a perceived problem of appearance. A higher score is associated with a greater degree of image-related distress and dysfunction and therefore indicates worse QOL.

- Mild: 0 - 40
- Moderate: 41 - 85
- Severe: 86 - 130
- Extreme: 131 - 177