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Abstract

Introduction: The standard treatment for complex wound care is autografting. The advent of dermal substitutes has provided a novel tool for the preparation of the bed to be grafted. However, most types of dermal matrices require the application of a skin graft a second time. Currently, other strategies have been developed to improve the vascularization process, such as negative pressure wound therapy (NPWT), which has been reported to reduce the time required for vascular growth and dermal matrix integration and thus achieve a shorter waiting period for autologous graft application. The present study aims to evaluate the effectiveness and safety of dermal matrix management associated with NPWT in the treatment of complex wounds. Methods: Seven patients with a diagnosis of complex wounds were enrolled in this study between July 1, 2015, and June 31, 2016. After debridement and having an adequate wound bed, patients who met the criteria for the application of combined therapy were treated with dermal substitutes and a negative pressure system. The percentage of graft integration into the wound bed, complications, length of hospital stay, and duration of therapy were analyzed. Results: The mean age was $42.5 \pm 16 (39 - 54)$ years old; three women and four

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men were included in the study. The approximate size of skin loss was $120.7 \pm 75 \text{ cm}^2 (25 - 250 \text{ cm}^2)$. The combined therapy of dermal matrix plus NPWT was instituted in all cases for a period of 14 days. There were no complications, with 100% graft integration in 6 of 7 cases. Patients were discharged after a mean hospital stay of 5.4 days. **Conclusions:** This study demonstrates that the utilization of combined dermal matrix plus NPWT therapy can be performed safely and effectively in patients with complex wounds with low complication rates and a short hospital stay.

Keywords

Negative Pressure Wound Therapy, Complex Wound, Dermal Matrix, Wound Therapy

1. Introduction

Various types of acute and chronic diseases can lead to skin defects. In wounds, the standard treatment is autografting, which often results in complications such as scar formation and the generation of new wounds in the donor sites. Although complex wounds have been described or mentioned in the literature, no specific criteria have been developed to classify them. The characteristics of complex wounds have been described, and one or more of the following conditions must be present for a wound to be classified as a "complex" type:

1) Extensive loss of integument (an important criteria and to be considered as the most important) in addition to whether it is an acute or chronic wound.

2) Chronic infected wound.

3) Compromised viability of superficial tissues (necrosis), or signs of impaired blood circulation, either venous or arterial; leading to extensive tissue loss.

4) Association with systemic pathologies that impede wound healing and fail to heal with simple care.

The treatment of complex wounds aims to rapidly treat the loss of the skin surface in order to reduce comorbidities and avoid complications caused by second intention healing, especially in patients with sequelae of burns [1] [2].

The introduction of dermal substitutes has provided a novel method for repairing various serious skin defects. These substitutes act as dermal regenerative templates, which facilitate dermal reconstruction and regeneration. Burns could be included in this group of complex wounds, but they are traditionally separated from this group because burns have been considered a special condition to be treated in specialized burn centers. However, they are, by definition, complex wounds [2].

The benefits and action of dermal matrices, such as Integra®, have been well documented, especially in patients with deep burns [3]-[9]. Integra®, manufactured by Integra LifeSciences in Plainsboro, New Jersey, is a dermal regeneration template that differs from other dermal substitutes in that it comprises two lay-

ers. The first layer with a "dermal" function is a synthetic material with a porous layer of cross-linked type I bovine collagen and chondroitin-6-sulfate. This layer is then covered by a second layer with an "epidermal" function, which is a semi-permeable silicone sheet. After implantation, once the dermal layer has vascularized, it is replaced with a thin autograft.

The phases of normal wound healing have been reproduced in dermal substitutes and have been best described in Integra[®]. Histological examination has demonstrated that Integra[®] integration involves the following phases: 1) imbibition, 2) fibroblast migration, 3) neovascularization, and 4) remodeling and maturation [10].

Negative pressure therapy is useful for both the first and second histological stages, in addition to stimulating the formation of granulation tissue, mitosis, and angiogenesis. It also prevents the formation of hematomas and maintains an environment without excessive humidity. Since the most common complications reported in the failure of dermal substitutes are bad beds, hematomas, and seromas, these points are of great help for dermal substitutes [11].

In recent years, the use of negative pressure systems has been used to improve the integration of skin grafts. It can be used not only to prepare the wound bed but also directly on skin grafts or dermal substitutes to improve integration [12]. A significant increase in granulation tissue has been observed in wounds treated with negative pressure systems [13], as well as an improvement in wound perfusion demonstrated by Doppler ultrasound [14]. This suggests that negative pressure systems can stimulate perfusion and angiogenesis.

In the present study, the efficacy of the treatment of complex wounds will be analyzed with the use of Integra[®] dermal matrix, which will be removed before the definitive autograft is performed, together with the use of negative pressure systems. Although this dermal substitute already exists on the market in commercial form, no studies have been carried out to analyze the possible synergic effect of the negative pressure system.

2. Methods

This is a cohort study that was conducted at the South Central High Specialty Hospital PEMEX during the period from July 1, 2015 to June 31, 2016. Patients who met the criteria for dermal substitute were included, and the use of a negative pressure system was added for analysis.

Patients with non-infected complex wounds with the following characteristics were included:

1) Third-degree burns.

2) Wounds with deep dermal involvement, or exposing deep tissues.

3) Wounds with a history of chronicity (3 months or more) due to vascular or infectious complications.

4) Wounds in patients with comorbidities that limit the alternative treatment of local or distal free flaps.

Through non-probabilistic convenience sampling, a total of 10 patients who met the inclusion criteria were identified. However, one of them was eliminated because they did not have a complete registry and two others were excluded due to lack of follow-up. Finally, 7 patients participated in the study. As a dermal substitute, we used Integra®, and the negative pressure system was placed to evaluate them at 14 days after we proposed definitive graft placement, and we determined the success rate of placing such an autologous epidermal graft early. The decision to place such a graft was made by observing the patient's bed and classifying it as adequate. The latter was determined by observing granulation tissue in the wound bed, as well as its coloration and the absence of necrotic or infected tissues. After the observation and placement of the graft had been carried out, the outcomes obtained were analyzed. Afterward, the success rate and viability of the graft placed were evaluated individually. This was analyzed as a percentage of integration of the graft to the prepared bed, as well as the description of the complications presented and unexpected results in each case performed.

The participation of patients in this study entails one type of risk in accordance with the ethical standards of the Declaration of Helsinki and article 17 of the Regulations of the General Law of Health on Health Research.

The Pemex ethic and bioethics commit endorsed the protocol. The data will be kept in a database and it will stay password-protected. Using the data gathered, this study will be conducted, and it is planned to save this data for other studies, so that it won't be lost and can be finished with new research subjects. Given that it is a descriptive study using information from the electronic clinical record, informed permission is not necessary.

As for the statistical analysis, a descriptive analysis was performed for the nominal variables and an inferential analysis for the numerical variables, Shapiro Will normality tests were applied and then the relevant statistical test was selected. The jamovi program version 2.3.18 was used to perform the analysis. The writing of the article was based on the STROBE guidelines for objective reports. A search for articles was carried out in PubMed, Cochrane Library, Google Scholar and a synthesis of current knowledge.

3. Results

Seven patients were admitted to the study, all of whom met at least one of the inclusion criteria for complex wounds and were suitable for this treatment. The characteristics of the wounds varied greatly, with very little tissue involvement manifested by tendon, muscle, or bone exposure in all of them. The approximate size of skin loss ranged from 25 cm² to 250 cm², presenting a mean with a standard deviation of 120.7 ± 75 cm². Within these 7 patients were four males and three females, ranging in age from 9 years to 57 years old, with a mean of 42.5 ± 16 years and a median of 50 years. Three male patients were active workers in the company, and another one was retired. He is presented as the only patient

with chronic degenerative disease in the study, with hypertension. The three female patients, two adults and one minor, aged 9 years, had no associated comorbidities. Their diagnoses included trauma to the left foot following a car accident in the 9-year-old patient; fasciitis in the right hand and forearm in the dorsal region following an injury in a 50-year-old patient; and another 54-year-old patient with septic arthritis in the left knee, which was managed with healing following debridement, for which she was admitted to the study.

As for the male patients, all within the company's staff, three active and one retired, there was a diagnosis of burns in two patients; one of electrical type in a 57-year-old patient, with involvement in both hands, being a candidate for our study a wound in the left wrist, with exposure of flexor tendons; and another 38-year-old patient with direct fire burn, with deep involvement in the back of the right hand, which merited the treatment of our study.

Two additional male patients were identified with complex wound injuries in the lower limbs. One patient, aged 51 years, was found to have involvement in the middle third of the right leg, in the posterior region, due to a complicated exposed fracture. Additionally, another patient aged 39 years was found to have involvement in the distal third of the right leg due to a history of exposed fracture injury (**Table 1**).

Once the patients were admitted to the study, they were offered treatment with this synergy of acellular dermal matrix plus negative pressure in order to improve the preparation time for an adequate bed for the reception of a definitive autologous graft. Informed consents were signed by the patients, their parents (in the case of minors), and witnesses. After completing the above, the Integra[®] plate was placed in a sterile condition in the operating room. This was performed on a debrided surgical bed without any evidence of infection. In none

Patient	Age (years)	Gender	Diagnosis	Anatomical site	Wound evolution
1	54	F	Septic arthritis	Left knee	2 years
2	50	F	Fascitis	Right hand and forearm	1 week
3	57	М	Electrical burn	Left wrist	1 month
4	9	F	Friction wound	Left foot dorsum	3 months
5	38	М	Burn by direct fire	Right hand dorsum	1 year
6	51	М	Exposed fracture Middle third of right leg		1 year
7	39	М	Exposed fracture	Distal third of right leg	5 months

Table 1. Distribution of study patients. F = female, M = male.

of the cases presented, the surgical bed had granulation tissue, and in all of them there was tendon or fascia exposure, and in one of them there was bone exposure of less than 1 cm^2 .

The dermal substitute plate was placed over the wound edge by no more than 2 mm and was fixed with sutures. The Integra* plates were randomly cut between 5 and 7 mm in order to optimize the distribution of the negative pressure and enhance adhesion of the acellular dermis plate to the wound bed. Subsequently, a sterile microporous sponge was placed for the subsequent placement of the negative pressure system; VAC* was the brand used for this purpose. The hermeticism was assessed using self-adhesive patches, and intermittent negative pressure was applied at a pressure of 100 mmHg continuously for a duration of 14 days. The patient was discharged in five cases the day after placement with a portable negative pressure device, with evaluation of the good functioning of the system every week. In two of the cases, due to associated comorbidities, the patient remained hospitalized for those 14 days.

Afterward, once the proposed time for bed preparation was completed, the negative pressure system was removed, also in the surgery room, and the quality of the surgical bed was evaluated at that moment, after removing the outermost layer of silastic from the dermal substitute plate, for the subsequent placement of the definitive autologous graft. In the 7 patients selected, an adequate graft recipient bed was obtained, characterized by granulation tissue and a bright red coloration of the bed, which speaks of good vascularity of the bed. In addition to the clinical parameters of a suitable recipient bed, the absence of infection, hematoma, or a high number of fibrin creations was also assessed. The surgical bed was qualified as adequate in the 7 selected cases, giving a bed preparation success rate of 100%.

In the operating room, at that moment, after discovering the wound bed and observing in each of the 7 patients the good conditions of the same, a thin partial thickness graft (0.006 - 0.008 inches) was taken with a pneumatic dermatome, the donor site being the anterolateral side of the thigh. Afterward, the partial-thickness graft was placed in the wound bed site and fixed to the wound edges. The negative pressure system was placed again with a microporous sponge, with an intermittent pressure of 100 mmHg.

The last graft was removed 5 days after the placement of the graft and the negative pressure system. The removal of the last graft was performed in the outpatient clinic, resulting in graft success with 100% graft integration in 6 of the 7 patients. In a female patient who presented with a diagnosis of fasciitis of the dorsum of the right hand and forearm, a lysis of the graft was observed in the central region of the defect in the dorsum of the hand, measuring 2 cm in diameter, accompanied by the exposure of the extensor tendons. In this case, the graft was integrated into 90% of the wound (**Table 2**). This complication was treated by removing the lysed graft area and repositioning a dermal substitute plate. The patient underwent conventional treatment, involving occlusion of the

Patient	Wound size	Affected skin layers	SPN/DA placement time	Bedding quality after	Integration of graft	Complications
1	50 cm ²	All	14 days	Appropriate	100%	No
2	100 cm ²	All	14 days	Appropriate	90%	Lysis of 10% of the graft
3	25 cm ²	All	14 days	Appropriate	100%	No
4	120 cm ²	All	14 days	Appropriate	100%	No
5	100 cm ²	All	14 days	Appropriate	100%	No
6	250 cm ²	All	14 days	Appropriate	100%	No
7	200 cm ²	All	14 days	Appropriate	100%	No

 Table 2. NPWT/AD synergy treatment results.

NPWT/AD: Negative pressure wound therapy/Acelular dermis.

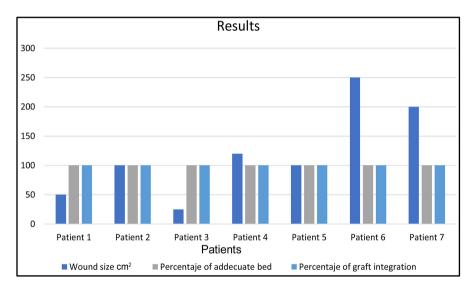


Figure 1. Summary of results found, showing a graphical comparison of wound size, percentage of adequate bed and percentage of graft integration.

same and weekly evaluation until 21 days after placement. Following this, a silastic plate was removed from the dermal substitute plate, resulting in the identification of a suitable bed with adequate coverage of the extensor tendons and good viability for the placement of an autologous graft. This bed was distinguished by granulation tissue and a favorable coloration, with no evidence of infection. After that, the graft was placed and covered with anti-adherent gauze (a negative pressure system was not used). It was reviewed 7 days later, and it was found that 100% graft integration was achieved without complications.

4. Discussion

The findings of this investigation, as described in **Figure 1**, show an encouraging synergy between these two systems, the acellular dermal substitute and the nega-

tive pressure system. The patients are a small, homogeneous population of 57% male and 43% female, with a mean age of 42.5 years and a wound size of 120.7 cm2. Regarding the medical history of comorbidities, the only case was a patient with a diagnosis of arterial hypertension, who, being an isolated case, could not be given an adequate analysis. In spite of this, it was a case in which no complications occurred.

The percentage of presentation of an adequate bed, with the clinical characteristics already described, was adequate in all cases, with a success rate of 100%. This was achieved by the synergy of dermal substitute plus a negative pressure system in intermittent mode for 14 days. Once this was done, the success of the definitive graft was not perfect due to a minor complication, which was 90% graft integration with lysis of the remaining 10% with no evidence of infection or hematoma.

The time of evolution of the initial diagnosis was very variable, ranging from 1 week (7 days) to 2 years (730 days), with a mean of 248.1 ± 240 days of evolution and a median of 150 days. In this case the complication found is in the minimum value of our range of time of evolution, of which, we did not find any clinical correlation that makes these events related, more than perhaps, the debridement prior to the placement of the treatment synergy to be studied was not adequate.

Regarding the analysis of the size of the skin defect, there is no statistical or clinical relationship with the complication presented, since the size of the wound with complication is approximately 100 cm², very close to the mean of 120.7 ± 75 cm².

The analysis of this complication should focus on the questioning of the true success of bed preparation at this level, as characteristic data at this level was the greatest tendon exposure of all the cases studied. As previously described, a negative pressure system has main virtues at the wound bed level, including stimulating angiogenesis, decreasing edema, and preventing infections.

Despite this premise, it should be noted that in the case of the largest skin loss presented in these cases, which was approximately 250 cm^2 , there was a bone exposure of 2 cm in diameter which was completely covered by the acellular dermal matrix, in addition to presenting adequate integration of the graft at that level.

Another factor to consider is the success of definitive graft integration. The mean percentage of graft integration was 98% with a standard derivation of 3.5 and a variation coefficient of 0.0355. The only adverse event was the lysis of 10% of the graft already described.

Something important in this study was the absence of serious complications. For the acellular dermal substitute plate, there are several issues described: lack of integration to the surgical site due to poor adhesion to the site, hematoma and infection. The reason this synergy was proposed is to avoid these complications. The lack of integration is, to a great extent, a complication presented by the poor adherence of the plate to the wound bed, this can happen due to a bad fixation of the plate, due to a shearing mechanism performed by the patient, or due to a bad occlusion to achieve a uniform pressure of the dermal substitute to the bed. With the negative pressure system, we achieve an adequate adhesion to the wound bed, this together with the perforations or cuts made to the silastic plate and to the acellular dermal substitute plate itself.

Another common complication leading to failure of dermal substitute placement is the presence of hematoma separating the adhesion of the plate to the wound bed. This was also absent in our study, with an apparent synergy of the negative pressure system to the acellular dermal plate, which through the suction exerted could have drained an eventual hematoma. And finally, no infection was present, this achieved by the mechanism of dragging and hermetic occlusion of the wound, which produces an inhospitable environment for any bacterial infection.

In addition to this, the negative pressure system maintains an adequate humidity environment, stimulates angiogenesis and, by means of dragging, keeps the wound bed free of fibroblast-inhibiting cytokines, which favors an acceleration of the healing process; all of the above, widely described in wounds at the molecular and histological level.

In general terms, a shortening of the process of closure of a complex wound was achieved which, using the same resources, the healing time could have been from 21 days for dermal substitute placement plus 7 days for graft integration, giving a total of 28 days; to a decrease of 14 days plus 5 days for graft integration, both accelerated by the aid of the negative pressure system, giving a total of 19 days.

5. Conclusions

Since this is a Pilot Study, it fulfills the objective of being an initial sampling for the advent of a larger-scale study, giving the guideline and showing the safety of the model used, and above all, giving favorable results for the motivation to conduct randomized, comparative trials with a larger universe of patients.

It should be noted that, although one patient achieved 90% integration, the rest achieved excellent results. This motivates us to reduce the placement times of the synergy mentioned in the study to 10 - 12 days. Due to the fact that the acellular dermal substitute plate utilized in our service is Integra[®], which utilizes synthetically created microtunnels that stimulate the advancement of blood vessels. Furthermore, it has been reported that the timeframe for accelerated angiogenesis by negative pressure ranges from 21 to 10 - 14 days. Therefore, we do not recommend removing the suction prior to the minimum duration of 10 days for grafting placement. This study provides a good result in terms of accelerating the process of integration of the dermal substitute plate to the bed, shortening the usual times, and above all, a decrease in the most common complications. The great limitation of the study for its statistical analysis was the size of the

sample, but, with these favorable results, we will be motivated to capture a larger number of patients and perform a statistical analysis of greater impact for the benefit of our patients, to shorten their convalescence time, and to offer them a procedure with a minimum risk of complications.

Informed Consent

As this is a non-experimental clinical trial, the informed consent of the institution South Central High Specialty Hospital Petróleos Mexicanoswas used in which the benefits, risks and possible complications with this treatment are addressed, the patient, in case of not wanting to be part of this treatment will be excluded from this study, as previously commented.

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This study was conducted with resources from the authors.

Conflicts of Interest

The authors declare that they have no conflict of interest.

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Umbilicoplasty: An Important Step in Abdominoplasty Surgery for Massive Weight Loss Cases

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Abstract

Aim: Excessive increase of weight followed by massive weight loss distorts the shape of the umbilicus as part of the affected skin of the abdomen. There is usually discrepancy between the elongated umbilicus at the time the patient was gaining excessive weight and the thinned abdominal wall after the massive weight loss. This study discusses a procedure that aims at restoring the shape of the umbilicus to its original shape as much as possible. Patients and Methods: In 4 years retrospective study from the 1st of March 2016 till the end of February 2020, the files of the patients who underwent abdominoplasty after massive weight loss with umbilicoplasty performed, as part of the procedure, were reviewed. In these patients the caudal part of the umbilicus at 6 o'clock site was excised in an oblique direction with slanting cut going to both 3 and 9 o'clock directions to shorten the elongated umbilicus keeping the cephalic part at 12 o'clock intact. This residual elongated cephalic part was utilized to make the shape of the hood of the umbilicus. A bolster suture was used at 12 o'clock to add a small depression above the hood. This technique gave the umbilicus the vertical "T" triangular shape with hooding. A questionnaire to assess patients' satisfaction regarding the shape, depth, location, size, scarring and overall result of the umbilicoplasty procedure was conducted. The questionnaire used a five-point Likert-type scale as follows: 1 (poor), 2 (fair), 3 (good), 4 (very good), and 5 (excellent). Results were collected and evaluated. Results: 197 patients underwent full abdominoplasty surgery during this 4 years study. Those who underwent umbilicoplasty during the abdominoplasty procedure were 34 patients. The results of the questionnaire could be obtained from 23 patients of them. Each patient gave a number from 1 - 5 for each aspect of the questionnaire of the umbilicus shape, depth, location, size, scarring and overall result. This resulted in total number of points of 115 for each aspect (23 patients \times 5 points). The patients' satisfaction with the shape of the umbilicus was 78.3% (90 out of the 115 points), 80.9% satisfaction rate with the depth (93 out of 115), 98.3% with the location (113 out of 115), 89.6% with the size (103 out of 115), 82.6% with the scar (95 out of 115) and 86.1% as an overall result (99 out of 115). **Conclusion:** Shortening of the elongated umbilicus at its caudal part with slanting incision directing to its cephalic part gives it the preferred vertical triangular "T" shape. Utilizing the length of the cephalic part in making the hood of the umbilicus and using a bolster suture to make a depression above the hood adds a shape near to the original natural one. The patients' satisfaction ranged from "very good" to "excellent" according to the five-point Likert-type scale.

Keywords

Umbilicoplasty, Hooding, Abdominoplasty, Massive Weight Loss

1. Introduction

The umbilicus is the only normal scar on the body and it is the most noticeable scar following abdominoplasty [1].

It is described as a depressed scar surrounded by a natural skin fold that measures 1.5 to 2 cm in diameter and lies anatomically within the midline at the level of the superior iliac crests [2] [3].

When the patient gains weight, the umbilicus as the rest of the abdominal wall becomes surrounded by excess fat. Its skin stretches forwards with the protrusion of the abdomen of the patient. The umbilical stalk becomes elongated with time as the deposition of the subcutaneous fat continues (Figure 1).

After bariatric surgery or with diet and exercises, the patient starts to lose weight with loss of fat around the umbilicus as part of the rest of the abdomen. The previously stretched umbilicus faces downwards by gravity with more loss of weight. The sagging down of the surrounding skin around the umbilicus gives it the "*Sad Face*" appearance (Figure 2).

This results in much discrepancy in length in these patients between the elongated umbilical stalk and the thinned skin of the abdominal wall around it (**Figure 3**). Trying to suture the umbilicus to the surrounding skin in its new location during abdominoplasty procedures as it is, without shortening it, will cause

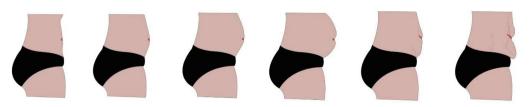


Figure 1. Changes which happen in the skin of the abdominal wall by increasing weight followed by excessive weight loss.



Figure 2. The "*Sad Face*" appearance of the umbilicus after excessive weight loss.



Figure 3. Length discrepancy between the elongated umbilical stalk and the thinned skin of the abdominal wall around it. Four different cases.

eversion and protrusion of the umbilicus with other misshape forms (Figure 4).

Our aim is to return the umbilicus close to its original ideal shape as much as possible.

The ideal shape of the umbilicus has been a matter of debate.

On their search for the ideal shape of the umbilicus, Craig, *et al.* did a panel photographic analysis of 147 female patients and found that the "T"—or vertically shaped umbilicus with superior hooding had the highest score in the aesthetic appearance [4]. Some of the studies called the "T" shape of the umbilicus as the triangular shape and reported high patients' satisfaction with it [5] [6]. We



Figure 4. Protrusion and eversion of the elongated umbilicus when sutured without shortening to the surrounding skin.

tried to give the umbilicus that shape as much as possible. This study discusses the procedure done to achieve that goal (**Figure 5**).

2. Patients and Methods

This is a 4 years retrospective study from the 1st of March 2016 till the end of February 2020. During this period, the files of the patients who had abdominoplasty surgery for massive weight loss, either post bariatric surgery or post diet and exercises, were reviewed. The patients who underwent umbilicoplasty as part of the abdominoplasty procedures in these patients were included in the study. Pre- and post-operative photographs were evaluated. A questionnaire for the patients who had at least 6 months passed after the surgery was conducted to assess their satisfaction with the results of the umbilicoplasty procedure.

The patients were asked, either during their OPD follow up or through the phone, to evaluate and rate their new umbilicus in terms of shape, depth, location, size, scarring and the overall result.

Patients' satisfaction with the results of the surgery were rated using a five-point Likert-type scale as follows: 1 (poor), 2 (fair), 3 (good), 4 (very good), and 5 (excellent).

Percentages of each of these items were calculated to assess the patients' satisfaction with the performed procedure (**Appendix 1**).

2.1. The Performed Procedure

All the procedures are done under the effect of general anaesthesia with the patient lying in the supine position. An incision is made from a midline point 7 cm cephalic to the vulvar commissure in females or the root of the penis in males and extends laterally in a concave line on each side as much as required for removal of the sagging skin. The wound is deepened using the monopolar diathermy till the fascia superficialis and the anterior rectus sheath preserving the overlying thin lymphatic tissue layer. The dissection is continued in a cephalic direction to the umbilicus. Skin hooks are used to elevate the umbilicus up from the table and a forceps is inserted inside it to measure its depths. Usually, the umbilicus in massive weight loss cases takes the shape of a "Volcano" when lifted up due to its elongation and the thinning of the surrounding skin (**Figure 6**). The umbilical stalk is preserved. Dissection is continued circumferentially



Figure 5. Cases of the "T" shaped umbilcus with superior hood and small depression above it.

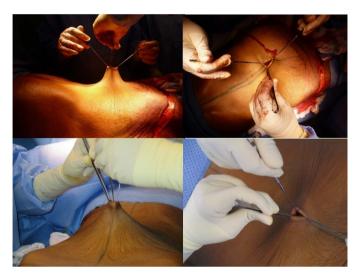


Figure 6. Two different cases showing the "Volcano" shape of the elongated umbilicus when pulled up from the surrounding thinned skin. Views from the side and top of the "Volcano".

around the umbilicus from the elevated abdominal flap. From this level, the dissection is continued in about 10 cm width in the midline region in the cephalic direction till the xiphisternum.

If there is muscular diastasis, repair of the recti muscles is done in 2 layers using non absorbable sutures. The lower part of the skin flap is excised. Haemostasis is ensured. The umbilicus is extruded through the advanced overlying skin. If the umbilicus is much elongated compared to the surrounding skin and has more lumen depth in relation to its deeper fibrous umbilical stalk part, umbilicoplasty is done. The caudal part of the umbilicus is excised at 6 o'clock site in an oblique direction with slanting cut going to both 3 and 9 o'clock directions. This decreases the length of the umbilicus at its caudal part while keeping the length of the umbilicus in its cephalic direction at 12 o'clock intact without excising part of it. The excised part takes the shape of a "moustache" (Figure 7). A bolster stitch is passed from the skin of the abdomen at the 12 o'clock position to the umbilicus and back to the skin of the abdomen. It is tied over two pieces of Vaseline gauze; one kept at 12 o'clock of the umbilicus and one opposite to it on the abdominal skin. When this bolster suture is tied, it pulls the cephalic part of the umbilicus at 12 o'clock position under the skin of the abdominal flap making the umbilical hood shape. The slight depression above the hood can be performed by removal of small part of the fat from this area of the abdominal flap (Figure 8). The umbilicus is sutured to the rest of the surrounding skin with half



Figure 7. Excision of the caudal part of the elongated umbilicus at 6 o'clock in a slanting direction till 12 o'clock. The excised part usually takes the shape of a "moustache".

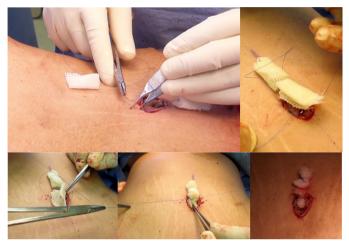


Figure 8. Bolster suture applied at 12 o'clock on the abdominal skin, passed at the cephalic part of the umbilicus and back again to the abdominal skin. The suture is tied on 2 pieces of Vaseline gauze; one kept at the cephalic part of the umbilicus and one opposite to it at the abdominal skin.

horizontal mattress non absorbable sutures. The Scarpa's fascia is repaired with 2/0 inverted absorbable sutures. The skin is sutured in two layers using 3/0 absorbable inverted interrupted dermal sutures and continuous subcuticular absorbable sutures. The wound is drained using two negative pressure drains; one kept at the epigastric region and the other one at the lower part of the wound. Dressing is applied with overlying compressive garment.

2.2. Postoperative Care

The patient is kept postoperatively in the bed in the modified Fowler's position. Mobilization is started on the first postoperative day. Subcutaneous low molecular weight heparin 40 mg is started 6 hours postoperatively and continued once daily for 7 days. Antithrombotic pneumatic compression stockings are started in the operation theatre and continued till the patient is discharged. The drains are kept on negative pressure and removed when the drainage is less than 20 ml of fluid in 24 hours for each drain. The patient is usually discharged by the fifth postoperative day. The bolster suture and the rest of the umbilical sutures are removed after 2 weeks. The patient continues to wear the abdominal pressure garment after the abdominoplasty surgery for a period of one month. If plication of the recti muscles is done during the abdominoplasty procedure, the duration of the pressure garment is extended to 3 months postoperatively (Figure 9 & Figure 10).

3. Results

During this 4 years study period 197 patients underwent full abdominoplasty surgery with dissection around the umbilicus.

Out of these 197 cases of full abdominoplasty surgery, 120 patients were cases of massive weight loss; 118 of them by undergoing previous bariatric surgery and the other 2 by diet and exercises.

Out of the 120 patients of massive weight loss, 34 patients had umbilicoplasty done during their abdominoplasty surgery; 32 of them had previous bariatric surgery while the other 2 patients had weight loss by diet and exercise.

The 34 patients who underwent umbilicoplasty during their abdominoplasty surgery were 15 females and 19 males. The mean age was 34.3 years (22 - 55 y).



Figure 9. Pre- and post-operative photos of a male patient.



Figure 10. Pre- and post-operative photos of a female patient.

As plication of the rectus abdominus muscles in two layers shortens the length of the umbilical stalk, so umbilicoplasty was performed in combination with plication of the recti muscles in only three patients. The other 31 patients had umbilicoplasty done without plication of the recti muscles during their abdominoplasty surgery.

One of the patients who underwent umbilicoplasty as part of his abdominoplasty operation developed postoperative haematoma next day of the surgery. Evacuation of the haematoma was done with resuturing of the umbilicus as it was in the previous surgery. No patients developed seroma, wound infection, necrosis of the umbilicus or other complications.

A questionnaire about the umbilicoplasty procedure was conducted for those who had at least 6 months passed after the surgery. 23 cases of the 34 patients were able to fill the questionnaire form. The other 11 patients could not be contacted with loss of their follow up. The mean follow up period was 715 days (181 - 1356 days).

Each patient had to give points from 1 - 5 according to his/her satisfaction with the results of the umbilicoplasty surgery using a five-point Likert-type scale as follows: 1 (poor), 2 (fair), 3 (good), 4 (very good), and 5 (excellent). For the 23 patients, this created 115 score points for each of the categories of shape, depth, location, size, scarring and overall result.

The patients gave 78.3% satisfaction rate about the shape of the umbilicus (90 out of the 115 points), 80.9% for the depth (93 out of 115), 98.3% for the location (113 out of 115), 89.6% for the size (103 out of 115), 82.6% for the scar (95 out of 115) and 86.1% as an overall result (99 out of 115) (**Table 1**).

Considering the gender, the males had 80% satisfaction rate about the shape of the umbilicus (52 out of the 65 points), 76.9% for the depth (50 out of 65), 96.9% for the location (63 out of 65), 93.8% for the size (61 out of 65), 76.9% for the scar (50 out of 65) and 83.1% as an overall result (54 out of 65).

On the other hand, the females had 76% satisfaction rate about the shape of the umbilicus (38 out of the 50 points), 86% for the depth (43 out of 50), 100% for the location (50 out of 50), 84% for the size (42 out of 50), 90% for the scar (45 out of 50) and 90% as an overall result (45 out of 50).

	Males 13		Females 10		Total 23	
	Points 65	Percentage	Points 50	Percentage	Points 115	Percentage
Shape	52	80%	38	76%	90	78.3%
Depth	50	76.9%	43	86%	93	80.9%
Location	63	96.9%	50	100%	113	98.3%
Size	61	93.8%	42	84%	103	89.6%
Scar	50	76.9%	45	90%	95	82.6%
Overall	54	83.1%	45	90%	99	86.1%

Table 1. The patients satisfaction rates; gender related and total.

4. Discussion

The umbilicus is essential to the aesthetic appearance of the abdomen. Although it has no function after birth most of the people are concerned about its shape.

The umbilicus is classified into three main types; vertical, round or transverse. There is a variety of umbilical shapes encountered in the literature, including crescent, round, triangular, and oval (vertical, transverse, or oblique). In the adult the depressed umbilicus is far more frequent than the elevated or button-shaped type. The button-shaped umbilicus is an infantile form. A large umbilicus of the horizontal type is usually associated with a wide linea alba and diastasis of the recti abdominis muscles. Obesity has a tendency to produce the funnel-shaped umbilicus [7].

Many studies discussed the most preferred shape of the umbilicus.

Craig, et al. tried to assess the aesthetic appeal of differing types of the female umbilicus. A total of 147 photographs were categorized by the authors and then scored by a panel of 21 (predominantly male) examiners. A T-shaped umbilicus was the most prevalent and also scored highest on aesthetic appeal. The presence of hooding was shown to increase the score, whereas a protruding, large, or distorted umbilicus scored lower [4]. Cavale and Butler tried to assess the result reached by Craig et al. by conducting a Web site survey depicting color photographs of five female umbilical shapes. They received 251 responses (84 male and 167 female participants). The hooded oval (T-shaped) umbilicus was overwhelmingly preferred by both male and female participants. The second most popular choice among male participants was the horizontal shape [8]. The oval horizontal shape of the umbilicus in male patients was also considered to be the ideal umbilical shape in males by examining 81 photographs of top male models by Graham and Livingston [9]. In our study we chose the vertical T-shaped triangular umbilicus and we found that the satisfaction with it in males was 80% and in females 76%.

To give the umbilicus the triangular "T" shape, many procedures were prescribed. While Yazar, *et al.* used the key and hole pattern flap [10], Aboueldahab used a superiorly based triangular flap from the abdominal skin which was sutured to the umbilicus after slitting it at 12 o'clock to accommodate the flap [11]. The same principal was prescribed by Ramirez O.M. who used either superiorly or inferiorly based flaps [12].

These procedures had good results but did not give the umbilicus the proper hood shape with the area of depression above the hood. Removal of the sutures of the "V" shaped triangular flap inside the depth of the umbilicus can be another issue in the postoperative period.

In our procedure, a "V" shaped triangle was excised from the caudal part of the umbilicus shortening it and keeping all the sutures at the superficial skin level with easy removal in the postoperative period and at the same time preserving the hood of the umbilicus at its cephalic part with the small depression above through the bolster suture. Bruekers, *et al.* shortened the umbilicus circumferentially leaving a stalk with a small (0.5 cm wide) epithelialized part of the umbilicus [13]. It resulted in decrease of the depth and size of the umbilicus. In our study the only part which was shortened was the caudal part of the umbilicus but the cephalic part was not excised and was utilized to make the hood of the umbilicus. This maintained the depth of the umbilicus and its size. The patients' satisfaction with the depth of the umbilicus was 80.9% and with the size of the umbilicus was 89.6%. Reducing the width of the umbilicus to 0.5 cm as performed by Bruekers, *et al.* can increase the hazard of its stenosis or even complete obstruction if the patient has liability for hypertrophic scar or keloid formation. In our study the patients' satisfaction with the scar was 82.6%.

On their study to determine the best exact location of the aesthetically pleasing umbilicus Abhyankar S.V., *et al.* evaluated 75 cosmopolitan female volunteers in the supine position. They found that the best location of the umbilicus is situated around the midline plane such that the ratio of the distance between the xiphisternum and the umbilicus and the distance between the pubic symphysis and the umbilicus is 1.6:1; also, the ratio of the distance between the umbilicus and anterior superior iliac spine and the inter–anterior superior iliac spine is approximately 0.6:1 [14]. In our study the patients' satisfaction with the location of the umbilicus was 98.3%.

5. Limitation of the Study

Further studies need to be conducted on a bigger number of patients to have a more appropriate assessment of their satisfaction with the results of their umbilicus in abdominoplasty surgery.

6. Conclusion

Our results show that shortening the elongated umbilicus at its caudal part in a slanting direction to the cephalic part and giving it a vertical "T" triangular shape reduces the discrepancy between the elongated umbilicus and its surrounding thinned abdominal wall skin. The residual elongated skin at the cephalic part of the umbilicus can be used to form the hood of the umbilicus. Keeping a bolster suture above the hood, after slight defattening of the abdominal flap, makes a small depression above the hood and gives it a shape near to its original normal shape. The patients' satisfaction with the result of this technique ranged from "very good" to "excellent" according to the five-point Likert-type scale.

Compliance with Ethical Standards

This study was approved by Abu Dhabi Region Ethics and research Committee, Zayed Military Hospital Abu Dhabi. Reference No. 2023.10.

Surgical consent was obtained from all the patients before surgery. Consents for photography and publication were also signed by all the patients.

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Competing Interests

The authors have no relevant financial or non-financial interests to disclose.

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Appendix

Name:Medical Records No.:Age:Sex:Please evaluate the rate of your satisfaction with the result of your umbilicus interms of shape, depth, location, size, scarring and the overall result by ticking inthe appropriate box of a number from 1 - 5 for each of these items as follows: 1(poor), 2 (fair), 3 (good), 4 (very good), and 5 (excellent).

Appendix 1. Questionnaire of Patient's satisfaction with the umbilicus result.

Item	1 (Poor)	2 (Fair)	3 (Good)	4 (Very Good)	5 (Excellent)
Shape					
Depth					
Location					
Size					
Scar					
Overall					



Managament Wound Healing: The Importance of a Wound Clinic in Hospital Centers

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Abstract

Background: In clinical practice, acute and chronic wounds continue to be a challenge. Unfortunately, wound care is often inadequate or inappropriate. The implementation of wound clinics involving an interdisciplinary team for wound care and treatment yields favorable clinical outcomes as well as a reduction in economic expenses due to a higher rate of healing, a decrease in hospital stays, and a reduction in the number of readmissions. The establishment of wound clinics enhances the utilization of diagnostic, preventive, and therapeutic resources, improving the quality of life of patients and facilitating their reintegration into their normal lives. The objective is solely to describe the importance of wound clinics in the medical profession. Methods: A retrospective literature search was conducted to include articles no more than 10 years old that reported measures or results of the study in order to perform a literature review and describe the importance of wound clinics in medical practice. Results: A total of 7 articles were obtained with the inclusion criteria, the most recent being from the year 2023 and the oldest from 2013. Conclusion: An important area for improvement in the healthcare industry is the management and treatment of complex wounds. The establishment of wound clinics offers comprehensive and specialized care for both acute and chronic complex wounds with the goal of enhancing secondary illness patients' prevention, treatment, and rehabilitation.

Keywords

Wound Clinic, Pressure Ulcer, Chronic Wound, Wound Healing, Quality of Life

1. Introduction

Complicated acute and chronic wounds are a challenge for health care personnel and are a major problem due to their high prevalence. The impact on quality of life encompasses both the patient and primary caregivers as a result of the socioeconomic implications arising from the underlying pathology [1]. According to estimates, 6.5 million people are affected by chronic wounds in the United States, with annual treatment costs of up to \$25 billion USD [2]. Chronic wounds affect approximately 2% of the population, with a variety of etiologies and a mortality rate comparable to some types of cancer [3].

Various therapies have been employed in wound healing, and certain therapies have endured for a long time, especially those whose origins can be traced back to ancient Egypt, Greece, and Rome.

J. Lister observed a correlation between the putrefaction of surgical wounds and high mortality; thus, he devised an antisepsis protocol whereby moist bandages soaked in carbolic acid were applied to wounds [4]. Studies carried out by Bull, *et al.* [5] and Schilling, *et al.* [6] demonstrated a favorable evolution of chronic wounds covered by a dressing formed by a semipermeable nylon window fixed to a polyvinyl adhesive frame. In 1962, George Winter published in the journal Nature the benefits of wound healing in a moist environment, which healed twice as fast as traditional therapy [7].

When specialized wound care clinics began to be implemented in some hospital units in the late 1990s, advances in wound care became relevant [8]. Wound clinics emerged as units responsible for the management, prevention, treatment, education, and rehabilitation of patients with complex wounds [9].

In the world, there has been an increase in the care and advanced management of complex wounds, as well as the importance of having specialists for the management of highly complex injuries [10]. In certain institutions, wound care is still performed empirically, and there are no dedicated physical spaces for wound care. This makes it challenging to provide comprehensive patient management due to the lack of a comprehensive assessment of all aspects and implications in the daily life of a wound [9].

In Mexico, a set of general guidelines has been developed for the implementation of wound clinic models of care within health units. The objective is to facilitate universal access to healthcare services that are specialized in the care of acute and chronic wounds, thereby enhancing the quality of life of patients, influencing the prevention of injury development in hospitalized patients, and reducing the economic impact of wound care in general [11]. Our country has sufficient technology for advanced wet therapy, and new products for wound care are being incorporated. However, few health personnel have the academic endorsement and support of professional practice for the care, treatment, and follow-up of patients with wounds [12].

The intervention of specialists in the management of complex wounds has a direct impact on the efficacy of treatment and healing [13]. It has been shown that the most frequent integration of the wound care team consists of: nurses: 29%, surgeons: 17%, physicians: 15%, rehabilitation: 14%, podiatrists: 9%, nutrition: 5%, administrative: 7% and family: 1% [14]. Chronic wounds whose healing process is impaired should be managed on a multidisciplinary basis [10].

The objective of this article is to comprehensively review the literature on the advantages of having specialized clinics in hospital centers for the management of complicated wounds that require interdisciplinary approaches.

2. Material and Methods

This is a descriptive and retrospective study in which a bibliographic review of indexed articles related to the analysis of the clinical and economic benefits obtained with a wound clinic in hospital centers by an interdisciplinary team in specialized units was performed.

The review of articles was performed in the period from January 2023 to July 2023, the databases consulted were: MEDLINE, PUBMED, Cochrane, Science-Direct, as well as primary sources from congresses associated with wound care. The key words for the search were: wound clinic, clinical wound benefits, pressure ulcer, chronic wound, wound healing, quality of life. Information necessary to identify the wound-related topic was collected.

The inclusion criteria for the selection of articles were articles less than 10 years old and articles that reported measures or results of the study, only papers written in English and Spanish were included. A total of 32 articles were found of which 25 were excluded because they did not meet the inclusion criteria. In the end, 7 articles were included that complied with similarities in demonstrating the benefits obtained in a wound clinic in hospital centers by an interdisciplinary team in specialized units.

The analysis of the data related to wounds was divided into 3 themes: as well as a decrease in economic costs by achieving a higher rate of healing, decrease in hospital stay, as well as the number of readmissions, and a decrease in the number of hospitalizations.

3. Results

A total of 32 articles were found, of which only 7 met the inclusion criteria established for the study. Of the 7 articles found, the majority correspond to the year 2013 (28%), the following articles are from the year 2016, 2018, 2019 and the most recent from the year 2023. The most frequently observed chronic wounds in wound clinics are diabetic foot ulcers, pressure ulcers, venous ulcers. A description of the results of the articles found has been added, the description of the literature can be found in the discussion section.

4. Discussion

Acute complicated, and chronic wounds are a serious public health problem worldwide. When wound healing does not proceed normally and anatomical and functional integrity is not achieved within approximately 4 weeks, wounds are considered chronic [15]. Several wound-associated factors are important contributors to wound non-healing: infection prolongs the inflammatory response, delays collagen synthesis, epithelialization, and tissue damage [2].

The chronic wounds most commonly seen in wound clinics are diabetic foot ulcers, pressure ulcers, venous leg ulcers, and non-healing surgical site infections. Diabetic foot ulcers are estimated to have an annual incidence of between 1% and 4%, with a lifetime risk of occurrence between 15% and 25%. The annual expenses incurred for amputation, rehabilitation, and long-term care for diabetic foot ulcers in the United States amount to approximately \$10.9 billion, and these figures are projected to continue rising as a greater number of new cases of diabetes are diagnosed [16]. Pressure ulcers affect between 1.3 and 3 million adults, are a common problem in nursing homes, and are estimated to cost between 1,687 million EUR and 1,769 GBP per year in Spain and the UK [17]. Venous leg ulcers affect up to 1% of the world's population, not to mention the recurrences that occur in up to 70% of the population [18]. Surgical site infections occur in up to 5% of procedures and are an increasingly frequent postoperative complication. About 0.5% of the total hospital budget in the United States is estimated to be spent on the management of these complications [19].

The economic benefits of having wound clinics in hospital centers for the prevention and treatment of chronic wounds are not well documented in published articles [20]. The primary expenses incurred in the clinics encompass the treatment itself and its associated complications, such as delayed healing, pain, infection, amputation, admission, hospital stay, and delayed discharge. Ramsay, *et al.* identified the necessity for the creation of models to enhance the precision and practicality of economic evaluations of wound treatment [21].

The different studies examining wound treatment costs vary in complexity, addressing costs, time spent by health care personnel, and cost-effectiveness studies. The cost reduction results are consistent with the existence of a specialized clinic. In terms of cost-effectiveness and health care benefits, the expense of wound care procedures is outweighed by the resources that are used differently [20].

There are reports suggesting that having a specialized wound clinic will reduce the number of hospital stays as well as the number of complications and treatment costs. The reduction in amputations has been demonstrated in numerous studies, with a rate ranging from 82% to 62%. Most of the cost reductions were obtained in nursing and waste disposal products [22].

The impact of chronic injuries on the quality of life is impacted by the disruption of personal and familial integrity resulting from hospitalizations, occupational inactivity, and financial expenses. Siersma, *et al.* assessed the quality of life of patients with chronic injuries in hospital centers using the EuroQol questionnaire (EQ-5D). Their findings revealed a score of 0.58 (SD 0.33), indicating a low quality of life. Therefore, it is recommended that treatment should be comprehensive, encompassing physiotherapy and pain management by specialized personnelx. It has been documented that the efficacy of treatment and healing is influenced by specialized wound clinic staff [23].

Chronic wounds cause significant morbidity and mortality, leading to significant medical costs. It is vital to ensure that nursing staff are prepared to care for patients with wounds and that they have access to continuing education programs and clinical practice guidelines with the latest evidence. This will ensure that the quality of interventions implemented to promote wound healing is maintained [2]. Preventive and therapeutic measures encompass disease-specific approaches [9].

It is essential to replace the use of traditional healing materials (alcohol, hydrogen peroxide, and conventional gauze) with modern moist interactive dressings, as well as complementary therapies that promote healing, such as negative pressure therapy. This would be a more cost-effective option for patients who do not achieve lesion closure but have the capacity to heal [15].

Several current techniques in wound bed preparation have proven to be effective in aiding the healing process. The process begins with a correct diagnosis of the wound's etiology and optimization of the patient's medical status, including blood flow to the wound site. Debridement is emphasized as the basis for most wound healing strategies. In order to determine the timing of advanced therapeutic intervention, it is important to monitor the progress and evolution of wound healing with weekly measurements. A reduction in the wound area of 10 to 15% per week is considered normal healing and does not require a change in the current wound healing strategy. On the other hand, in the event that the aforementioned reduction in wound area is not consistently achieved on a weekly basis, other healing alternatives should be considered [24].

Mexico does not have a national epidemiological registry, so federal entities approach it from a perspective of obtaining information that can be used to determine, the epidemiological panorama and costs of chronic wound care in health secretariat units [25].

Finally, wound care costs represent an important economic cost for medical units as well as for the health sector. Wound care programs can help reduce costs for patients with impaired healing. The program should include: 1) Continuous training of personnel in charge of wound prevention and treatment, to promote the necessary skills and ensure adequate follow-up and evolution of the wounds. 2) Acquisition of quality supplies that promote wound healing and is used at the right time according to the initial assessment and follow-up. 3) Record of information and empidemiology regarding the behavior of the wounds [26].

5. Authors' Position

In 2003, the wound clinic was founded at the North Central Hospital (NCH) PEMEX by MD. Cuahutémoc Márquez Espriella with the purpose of attending patients with complex wounds as well as making visits to the hospitalization services with the aim of reducing the average number of days of hospital stay and readmissions. As a part of the program, there is a home visit program for disabled patients, where highly trained nurses record the history of the wound's progression, capture a photographic record of the wound's healing, and promote self-care and discharge plans for the patient and primary caregiver. The wound clinic receives between 70 and 80 patients per week.

The patient registry is maintained by means of an electronic database, which is maintained by the nursing staff of the NCH PEMEX wound clinic. The service offers a wide variety of dressings for wet therapy, healing materials, and negative pressure systems that help the healing process. Currently, the wound clinic is under the supervision of MD. Alberto Ignacio Cahuana Quispe, who is committed to providing quality care to patients. He formed a highly qualified interdisciplinary team specializing in the management of chronic wounds.

Wound clinics have become an important tool for the evaluation and treatment of patients; clinical and economic results have shown a reduction in the number of amputations, shorter hospital stays, reduced readmissions, and an improved quality of life for patients.

6. Conclusion

The management and care of intricate wounds presents a significant opportunity for enhancement in the healthcare sector. The implementation of wound clinics provides comprehensive and specialized care for acute and chronic complex wounds, with the aim of improving prevention, treatment, and rehabilitation for people with secondary diseases that can become temporarily incapacitated. The preparation and commitment of the interdisciplinary team of the wound clinic makes a priority the need to implement specialized wound clinics in third level centers in order that people can return to their daily activities with an adequate quality of life, and consider it a medical-surgical subspecies, both for nurses and surgeons.

Conflicts of Interest

The authors of this article declare no conflicts of interest.

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Quick Review and Technical Approach for Regenerative Peripheral Nerve Interface Surgery

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Abstract

Regenerative peripheral nerve interface RPNI's surgery was originally designed for prosthetic control. RPNI's has demonstrated to be an effective tool to prevent neuroma formation by providing free muscle grafts as physiological targets for peripheral nerve ingrowth. Nerve transection injuries can result in painful neuromas that adversely affect patient recovery. This is especially significant following amputation surgeries, but they can also be used in surgeries in which the nerves can be visualized with a noticeable lesion. The first series of patients undergoing RPNI implantation for treatment of symptomatic postamputation neuromas was published in 2016. The series included a report of 46 patients undergoing RPNI. The clinical outcomes of RPNI have been optimistic with a reduction in neuroma pain up to 73% and phantom pain reduction of 53% along the uniformly high patient satisfaction. Since then, studies have been expanded, and knowledge regarding physiology has increased, providing us with new tools for a better understanding and giving these procedures more benefits and applications.

Keywords

Component, Formatting, Style, Styling, Insert

1. Introduction

Painful neuromas result from traumatic injuries to nerves and cause substantial

physical disability, psychological distress, and decreased quality of life. Pain can be a major issue after total or partial amputation, with reported incidences up to 8% for finger amputation and 85% for major limb amputation. Pain can originate in the amputated stump which is mostly described as residual limb pain (RLP) or as a result of phantom limb pain (PLP). Symptomatic neuromas result from a disorganized proliferation of transected peripheral nerves [1]. The origin of RLP lies in the peripheral nerve system and can be caused by skin problems, infections, poor prosthetics, and poor soft tissue coverage, but the principal cause of neuropathic pain due to a scar-tethered residual nerve stump or end neuroma at the site of transection. These neuromas cause neuropathic pain. PLP occurs in both peripheral and central nervous system. Psychological factors have an influence on this as well as on the severity, frequency, and impact of the pain. It is not understood why some neuromas remain asymptomatic and further investigation into the pathophysiology is needed [1] [2]. Components of the nociceptive response of painful neuromas have been identified, including central sensitization, accumulation of ion channels, and an inflammatory response that sensitizes the neurons, leading to hypersensitivity. Importantly, painful neuroma development after primary nerve repair is rare because the nerve has a target to innervate.

Nonsurgical management of symptomatic neuromas includes desensitization, anesthetic and or steroid injection, electrical nerve stimulation, and opioids. Conservative treatment for post-amputation pain shows a little effect [3]. Opposite, the prevention of a painful neuroma after amputation by means of nerve surgery in the same session has promising results [4] [5]. However, there is no clear consensus of which surgical technique provides the best surgical outcome in terms of pain prevention [5]. The Regenerative Peripheral Nerve Interface (RPNI) was developed to overcome these limitations. The RPNI consists of an autologous free muscle graft secured around the end of a transected nerve. The muscle graft provides regenerating axons with end organs to reinnervate, thereby preventing neuroma formation [6]. We have shown that this simple and safe surgical technique successfully treats and prevents neuroma formation in major limb amputations. In this paper, we describe RPNI surgery in the setting of major limb amputation and highlight the promising results of RPNIs in animal and clinical studies [7].

2. The Regenerative Peripheral Nerve Interface

RPNI is a surgical treatment approach for management and prevention of painful neuromas. RPNI is a simple surgical solution and constructed by implanting the distal end of a transected peripheral nerve into a free skeletal muscle graft.

The muscle graft initially de-vascularized at the time of the harvest undergoes a process of degeneration followed by regeneration. The muscle graft at the time of the implantation is supported by imbibition. After the regeneration process becomes revascularized just as any free tissue graft would be. The skeletal muscle becomes a perfect target for the denervated axons for regenerating spouting from the end of the peripheral nerve. As a result, substantially fewer regenerating axons will be part of the inflammatory process and undergo a problematic neuroma. After peripheral nerve transection injury, the nerve undergoes 3 biological processes Wallerian degeneration, axonal sprouting/regeneration, and muscle reinnervation if end organs are present.

In the context of amputation, the end organs are missing, and the end of the peripheral nerve continues to sprout and regenerate until they form a neuroma.

The RPNI surgery provides ample denervated muscle fiber to facilitate the reestablishment of neuromuscular junction. The muscle graft displays dispersion of acetylcholine receptors along the sarcolemma and expresses a variety of neurotrophic factors. An environment conducive to reinnervation [8].

A regenerating axon contacts a denervated muscle fiber and provides necessary trophic support to prevent atrophy. Electrophysiologic experiments confirmed that these new neuromuscular junctions were functional and capable of transducing nerve signals to muscle action potentials [9].

3. Description of Technique

Multiple descriptions of the surgical technique have been made. The free skeleton muscle graft that is used to create RPNI's is ideally harvested from the amputated limb but at times a separate incision will need to be made to harvest healthy free muscle graft from another site.

Following completion of the limb amputation, the specimen is passed off the field but kept sterile so that it can be used for free muscle graft harvest if appropriate.

It is important to avoid placing too large of graft as this can interfere with perfusion of the muscle from the wound bed and lead to greater necrosis.

3.1. Preparation of Peripheral Nerves

RPNI surgery can be performed any time peripheral nerves are transected and direct nerve repair cannot reapproximate these axons back to their native targets. In immediate RPNI surgery, major peripheral nerves are isolated, marked and sharply transected in the residual limb during the amputation. Traction neurectomy is not performed to purposefully avoid proximal retraction of the nerve end [10].

During a Below-knee amputation (BKA) surgery the tibial nerve is identified in the deep posterior compartment adjacent to the posterior tibial vessel. The nerve is transected and dissected free from surrounding soft tissues to allow creation of an RPNI around the end of the nerve.

For superficial and deep peroneal nerves, RPNI can be created within the BKA site.

To isolate SPN and DPN prior to segmentation and decrease the number of free muscle grafts placed distally in the residual limb after BKA, the common peroneal nerve (CPN) can be exposed through a proximal separate incision between the fibular head and the distal lateral thigh.

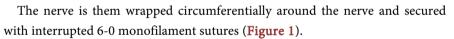
3.2. Skeleton Muscle Graft Harvest

In general, an approximately $3 \text{ cm} \times 2 \text{ cm} \times 0.5 \text{ cm}$ free skeleton muscle graft is used of as many nerves fascicles as needed depending on the nerve size. For example, the sciatic nerve may require up to 5 fascicles obtained through interneural dissection. Thus, for larger caliber nerves fascicular dissection is performed to enable multiple fascicular RPNI's rather than creating a single large RPNI. Grafts that are too thick will undergo central necrosis. Doing so, also improves the ratio of denervated muscle fibers to regenerating axons to maximize reinnervation. For each isolated nerve a small free muscle graft is harvested from healthy, autologous skeletal muscle. In the case of major limb amputation, these free muscle grafts can be harvested directly from the amputated limb unless this is not appropriate due to ischemia tumor or infection. If no healthy muscle can be obtained from the amputated limb, the muscle grafts can be obtained from a more proximal donor muscle (e.g., vastus lateralis) through a separate incision [10].

3.3. RPNI Surgery

After all nerves are isolated and free muscle graft are obtained, The RPNIs are created by implanting each distal nerve end into a corresponding muscle graft.

The transected peripheral nerve end is placed in the center of the muscle graft parallel to the muscle fibers. At the interface between transected axons and the muscle graft, 6-0 non absorbable monofilament sutures are placed. Only the epineural portion and a minuscule portion of muscle are incorporated into each stitch.



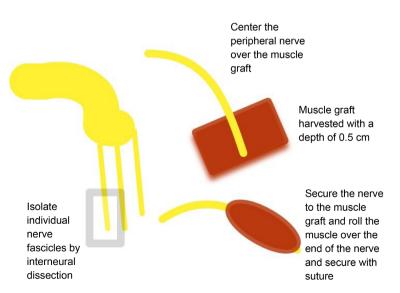


Figure 1. Diagram illustrating the steps of RNPI procedure.

Finally, a space is created for the placement of RPNI in an area remote from the surgical incision and away from the weight bearing surface.

3.4. RPNI Outcomes

The clinical outcomes of RPNI have been favorable with a reduction in neuroma pain up to 73% and phantom pain reduction of 53% along the uniformly high patient satisfaction. A decrease at painkillers intake and the improvement in chronic pain in everyday activities, and Most of the patients were satisfied with the RPNI surgery [11].

4. Conclusions

Patients whose limbs have been amputated are at high risk for neuropathic pain and phantom limb pain, which can generate a decrease in the quality of life. It can be prevented by performing RPNI at the same time as surgery.

Current clinical and experimental studies are promising and have shown a decrease in pain, patient satisfaction, and lower consumption of analgesics. Therefore, RPNI surgery should be considered in patients who are going to undergo amputation of a limb.

They should also be considered in any peripheral nerve injury such as inguinal hernia repair surgery, in case of ilioinguinal or iliohypogastric nerve injury.

RPNI surgery may be considered in any peripheral nerve injury for pain prevention, but further study is required.

Conflicts of Interest

The authors have no financial interest to declare in relation to the content of this article.

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