

Comparision of efficiency of chitosan vs collagen membrane for soft tissue wounds in Faciomaxillary region – a prospective clinical study

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Abstract

Introduction: The two main criteria that promote an esthetic clinical outcome after trauma and consequently affect the affected person's quality of life are wound healing and recuperation.

Collagen and chitosan are the two commonly accepted substances that meet the criteria for an optimal dressing substance and are also nontoxic to the biologic environment out of the historically accessible and recent therapies.

Collagen is a biomaterial that is used to stop bleeding and shorten the time it takes for wounds to heal. Chitosan accelerates tissue regeneration and induces haemostasis.

In this study, we want to assess the performance of these two dressings and figure out which one would best fit the criteria for the optimum dressing. A total of 30 patients were enrolled in the study then the patients were divided into two groups and were treated with chitosan sheet in one group and the other half patients were treated with Collagen sheet.

Conclusion: According to the study's findings, chitosan had better colour matching and better healing outcomes than the collagen group at the healing site. In comparison to chitosan, scar & contracture of the wounds were much more frequently associated with collagen; however, under moist conditions, there was no discernible difference in initial healing.

Keywords: Collagen, Chitosan, Material

Introduction

The two main criteria that promote an esthetic clinical outcome after trauma and consequently affect the affected person's quality of life are wound healing and recuperation. Effective scar tissue management, which is necessary for the healing process is crucial. For wounds with secondary healing intentions, the focus should be on reducing such scar tissue and producing results that are nearly natural. One such step is selecting a dressing material that best mimics the extracellular matrix of the skin in a biological way. Collagen and chitosan are the two commonly accepted substances that meet the criteria for an optimal dressing substance and are also nontoxic to the biologic environment out of the historically accessible and recent therapies.

Collagen is a biomaterial that is used to stop bleeding and shorten the time it takes for wounds to heal. The

collagen layer is still present in the tissue and is gradually consumed by inflammatory cellular activity. Fibrous tissues are then replaced by fibroblast, and granulation tissue grows at a normal rate to establish a normal wound bed. Chitosan is a basic polysaccharide constituted of free amino groups that is insoluble in water and composed of 2-amino-2-deoxy-D-glucopyranose and 2-acetamide-2-deoxy-D-glucopyranose units that are -(1-4)-linked. It has qualities like biodegradability, nontoxicity, an antibacterial effect, and is biocompatible with a pH of 6. Chitosan accelerates tissue regeneration and induces haemostasis. Due to the fact that it is broken down by human enzymes such as lysozyme, this substance is much more biocompatible than that of any synthetic material. Chitosan's cationic nature and extra antibacterial property aid in the care of wounds and may cause analgesia by having a relaxing, cold, and enjoyable impact, in this study, we want to assess the performance of these two dressings and figure out which one would best fit the criteria for the optimum dressing.

A total of 30 patients were enrolled in the study then the patients were divided into two groups and were treated with chitosan sheet in one group and the other half patients were treated with Collagen sheet.

To determine the choice of dressing material, sequentially numbered, opaque, sealed envelopes were used as the allocation concealment scheme. Each envelope contained the names of either one of the materials (chitosan/collagen) and was handed to the operator

Inclusion Criteria

1. Patients with facial soft tissue injuries/abrasion
2. Patients in the age group of 18-65yrs.

Exclusion Criteria

1. Medically Compromised Patients, i.e., patients with bleeding disorders, immune compromised patients
2. Mentally impaired patients
3. Patients with Extensively Deep wounds / Full-Thickness Wounds/ Infected Wounds.

Following the manufacturer's directions, the operator used the dressing material that was provided to him. Following the initial administration of the dressing, patients in the both groups were given oral NSAIDS (in the combination of Aceclofenac + Paracetamol) for 3 days.

Collagen sheet and collagen membrane, both of which are generated from cows, were employed in the study and come in two sizes: 5 x 5 cm & 8 x 8 cm. In this investigation, a collagen membrane made from bovine collagen that is commercially available under the name Collagen was employed. Chitosan sheet, which is commercially available and also is 100 percentages Chitosan (maxicel) generated from crustacean shells, was utilised in the study. It was available in two sizes, 5 x 5 cm and 8 x 8 cm. Both materials were provided in sterile preservation media that had been Gamma sterilized and were available in various sizes.

Betadine solution and regular saline were used to clean the wound. The membrane was immersed in sterile normal saline while adhering the dressing to the wound under stringent aseptic standards. A gauze bandage was applied over the membranes to keep it in place after the membrane had been attached to the wound. Every two days, as recommended by the manufacturer, the dressing was evaluated and changed.

An example proforma showing the visual analogue scale was given to each patient. Other factors, like scar pigmentation and scar healing, were judged and evaluated by a single operator. Once in the first week,

twice in the second, once in the third, once in the month, and once in the second week.

Vancouver Scar Scale

	Feature	Score
Vascularity	Normal	0
	Pink	1
	Red	2
	Purple	3
Pigmentation	Normal	0
	Hypo-pigmentation	1
	Hyperpigmentation	2
Pliability (Elasticity)	Normal	0
	Supple (flexible with Minimal resistance)	1
	Yielding (giving way to pressure)	2
	Firm (inflexible, not easily moved, resistant to manual pressure)	3
	Banding (rope-like tissue that blanches with extension of scar)	4
	Contracture (permanent shortening of scar, producing deformity or distortion)	5
	Flat	0
	<2mm	1
Height	2-5 mm	2
	>5 mm	3

Visual Analogue Scale: 0 (no pain) to 10(maximum pain)

Results

Statistical Analysis

Null Hypothesis: There is no significant association between different parameters and the groups.

Alternate Hypothesis: There is a significant association between different parameters and the groups.

Level of Significance: $\alpha=0.05$

Statistical test used: chi-square (χ^2) test

Decision Criterion: We compare the P-Value with the level of significance. If $P < 0.05$, we reject the null hypothesis and accept the alternate hypothesis. If $P \geq 0.05$, we accept the null hypothesis.

Scar score	Categories	Chitosan		Collagen		χ^2	P-Value
		n	%	n	%		
Vascularity	Normal	15	100%	14	93%	1.034	0.309
	Pink	0	0%	1	7%		
Pigmentation	Normal	10	67%	7	47%	1.222	0.269
	Hypo Pigmentation	5	33%	8	53%		
Pliability	Normal	9	60%	10	67%	0.144	0.705
	Supple	6	40%	5	33%		
Height	Flat	3	20%	5	33%	0.682	0.409
	<2 mm	12	80%	10	67%		

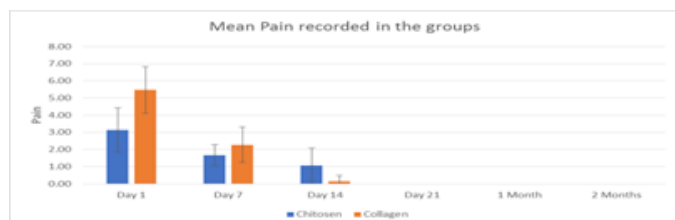
Age and Gender Distribution

Thirty patients in total—15 in each group were chosen. Gender and age distribution were statistically negligible in both groups. In comparison to women, more men have been recorded (12 males and 3 females in Group A, 11 males and 6 females in Group B). In both groups, the ages ranged from 18 to a high of 45.

Regions affected

Each group's impacted area or locations underwent an evaluation. No appreciable statistical difference existed between the two groups in the distribution of wounds. The most frequently afflicted regions in both groups were discovered to be the malar, nasal, and temporal regions. Most of the abrasion was mostly superficial however the lips surrounding lesions had significantly deeper flaws.

Pain



On Day 1, more mean pain was noted in the collagen group than in the chitosan group, and the difference between

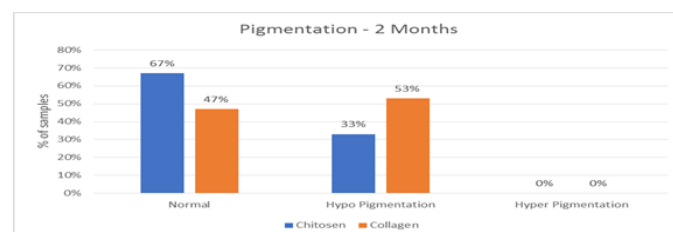
the two groups were confirmed to be statistically significant ($P < 0.001$). On day 2, when the patient was still taking analgesics, the collagen group had higher mean pain than the chitosan group, although the difference between the two groups wasn't really statistically significant ($P > 0.05$).

Although both groups' pain levels had decreased by the conclusion of the week.

Injured Judgment

Draaijers et al Vancouver's scale evaluates the scar in four areas: vascularity, pigmentation, pliability, and height (table). The range of scoring is 0 to 13. The worst result is shown by a maximum score, while normal skin is indicated by a zero score.

Pigmentation



On day 7, there was a statistically significant correlation between the groups and pigmentation ($P < 0.05$). In the first several weeks, the majority of samples in the collagen group exhibited hypopigmentation, whereas the majority of samples in the chitosan group had hyperpigmentation. However, in the 2-month follow ups, the collagen group showed a higher proportion of recovery with hypopigmentation (53%) than the control group. Only 47% of individuals showed signs of regaining their usual pigmentation. The discrepancy of regular pigment and hypo/hyperpigmentation between both the two groups, which was 67% with normal group and 33% with hypopigmentation in the chitosan group, was statistically significant in favour of chitosan.

Vascularity

On day 1, there was a statistically significant correlation between the groups and vascularity ($P < 0.05$). Compared to the chitosan group, a greater proportion of samples in the collagen group displayed "Red" vascularity. At the other time periods, there was no statistically significant correlation between the groups and vascularity ($P > 0.05$).

Pliability

In most cases, there were no scars left behind. However, in the majority of cases when scar formation was apparent, the type of contracture / scar were supple (Chitosan = 40%, Collagen = 33%). Some instances in both groups had firm scars and a consistency similar to rope. Compared to chitosan, collagen displayed more contracture and scarring.

Height

About 80% of patients who underwent both dressings returned to their normal height and shape.

Discussion

The goal of the index study was to clarify the advantages of collagen and chitosan as superior adhesive dressing materials in terms of numerous clinical functions. Although each of these materials is well known in its own right, our study aims to compare their effectiveness in terms of patient's condition and observer metrics. Both collagen and chitosan have biological characteristics that make them more than merely adhesive materials and provide them special angiogenic and anti-microbial qualities. Collagen membrane is known to stabilise the coagulum and improve the initial epithelial proliferation from the surrounding tissues. According to research by Thoma et al., K [3,4,] good epithelialization was obtained in 19 cases (63.3%), medium in seven cases (23.3%), and bad in four cases (13.3%). Better colour matching to the surrounding normal tissues led to faster re-epithelialization.

Chitosan, on the other hand, improves the activities of fibroblasts, macrophages, and polymorphonuclear neutrophils. Chitosan encourages granulation and order as a result. In the USA, chitosan has recently received regulatory permission for usage in dressings and other hemostatic products. By keeping a sterile wound exudate below a dry scab like a semipermeable biological covering, it optimises the circumstances for healing and guards against dryness and wound contamination. Avoiding infections and promoting rapid reepithelialization are the two most crucial ways to minimise excessive scarring. Collagen achieves both objectives and prevents scar contracture. According to Sanjay Rastogi et al., the degree of contracture was acceptable in six cases (20%), medium in 16 patients (53.3%), and poor in 8 cases (26.6%), which was comparable to our study's findings of 67% regular contracture & 33% supple types. In our study, in addition to assessing scars integrity, we also measured pain perception in both groups using matching analgesics. On the first day of application, pain was significantly reduced in the collagen group and gradually decreased in the chitosan group. However, over the course of a week, both groups experienced total pain alleviation. We believe that reducing the need for analgesics and opioids while still managing pain are equally vital. Collagen and chitosan both demonstrated importance in this context. In contrast to our trial, where collagen was challenging to work with, chitosan demonstrated to be a simple dressing material to place, maintain, and remove without any pain. We assessed and contrasted the pace of wound healing (as determined by scar judgement) between collagen and chitosan and found that chitosan had a somewhat faster rate of healing than collagen. To encourage orderly tissue regeneration, Biagini et al. applied delicate pad of freeze dried

Ncarboxybutyl chitosan to a donor locations. The results showed that the dermal level of the donor sites performed better in terms of architectural order, greater vascularization, as well as the lack of inflammatory cells than the epidermal level did in terms of malpighian layer proliferation. They came to the conclusion that chitosan promotes the development of cutaneous tissue that is consistently organised and lessens unexpected healing. [3,11] By encouraging the deposition and structuring of newly produced fibres & granulation tissue in the wound bed, collagen is a natural material that fosters a favourable environment for wound healing [4]. In our study, the healing of the wounds with the two materials was compared based on the assessment of the scars. Based on our observations, chitosan was superior to collagen in terms of pigmentation, whereas in the other parameters examined, the vascularity, pliability, and height of the scars in the majority of the wounds displayed grades of hypo-pigmentation while treated with collagen. Both materials left various degrees of scarring on the wounds they treated. Collagen was used more frequently than chitosan to treat scar contracture. Histologically, the skin covered by chitosan dressing in the study by Stone et al. demonstrated distinct differences from skin covered by the traditional dressing at the freshly healed time point. In the papillary dermis, chitosan biopsies revealed a looser connective tissue stroma with improved vascular and neuronal regeneration. Additionally, chitosan treated areas showed an earlier restoration to normal skin tone, according to digital colour separation examination of donor site scars [3, 5]. Azad et al. carried out a comparable clinical trial to look into the construction of a chitosan membrane on a dressing for wound healing. After 0.010 to 0.015 inches of skin were removed from a skin transplant donor site, a fresh wound occurred, and

chitosan membranes were used to treat it. Chitosan membrane was used to cover half of the wound, and control Bactigras was used to cover the other half. Clinical studies showed that the chitosan membrane mesh supported effective adhesion, hemostasis, wound healing, and re-epithelialization [3, 6]. Chitosan is more expensive than collagen. When compared to a more recent material like chitosan, collagen is a proven substance. It is simpler to find collagen. The acceptance of chitosan as a dressing material is still the subject of numerous studies.



Figure 1: Application of chitosan over abrasion: (a)pre-application;(b) post application;(c)2months post-op application



Figure 2- application of collagen over superficial abrasion ;(a) pre-application;(b) post-application;(c)2-months post application.

Conclusion

According to the study's findings, chitosan had better colour matching and better healing outcomes than the collagen group at the healing site. In comparison to chitosan, scar & contracture of the wounds were much more frequently associated with collagen; however under moist conditions, there was no discernible

difference in initial healing. Thus, it can be said that chitosan satisfies all criteria for an ideal treatment material for cosmetic abrasions. To assess the effectiveness and long term outcomes with relation to many other features of such a biological dressing material, larger double-blinded RCTs are needed.

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