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Clinical Efficacy of an Indigenously Developed Tissue Expander

B K Biswas^{*1}, S Pal², S Bag³

^{*1} KPC Medical College & Hospital, Jadavpur, Kolkata, India

² School of Bioscience & Engineering, Jadavpur University, Kolkata, India

³ JIS College of Engineering, Kalyani, West Bengal, India

sandipbag76@gmail.com

Abstract

Reconstruction of tissue defects in face with the similar kind of tissue is very challenging as the skin of the other parts of the body does not match properly. Recently tissue expansion using tissue expander is being used more frequently in reconstructive surgery for the treatment of a variety of problems in both children and adults. The concept of tissue expansion has opened a whole new frontier in reconstructive surgery. The tissue expansion technique is advantageous in facial reconstruction because it makes it possible to resurface wider defects with neighbouring skin that is similar in colour and texture. Conventional tissue expansion may result in epidermal hypertrophy, decreased dermal muscle and adipose thickness, bone resorption. To overcome such problem we have developed a tissue expander using medical grade silicone with a mixture of biocompatible materials which is highly flexible and cost effective. To determine the efficacy of new tissue expander requires animal experimentation followed by clinical trial. The result obtained from the clinical trial shows its biocompatibility as well as effectiveness.

Keywords: Reconstruction, tissue expander, tissue expansion, flexible, biocompatibility.

Introduction

Tissue expansion is a reconstructive surgical technique which allows the body to "grow" extra skin where there has been tissue loss due to various reasons such as Burn, trauma or disease^{1, 2, 3}. The most common application is in post-mastectomy breast reconstruction, but tissue expansion can be used in almost any part of the body following tissue loss due to any reason whatsoever^{4, 5, 6, 7}. It is also quite advantageous for reconstruction of the scalp, because the "new" skin created contains matching colour and hair follicles (as opposed to using skin grafts or flaps from other parts of the body, which may leave bald spots on the scalp or mismatch of the colour)^{8, 9, 10}.

Tissue Expander is an implantable medical device used in plastic and reconstructive surgery for the development of extra tissue (Skin / Composite flaps) which is required for reconstruction of tissue defects and deficiencies (burn contracture, congenital defects etc.)^{11, 12}. The device is placed subcutaneously / below the muscle and injected periodically with sterile isotonic saline until the required tissue is fully developed¹³. The device is removed normally once the expansion is up-to the desired level (6-8 weeks). Presently there is no such company which is producing silicone tissue expander in India. It has tremendous scope and can be used in various clinical situations

particularly Plastic and Reconstructive surgery of head, neck & face^{14, 15, 16, 17}. If commercially available can solve a lot of reconstructive problems as well can help in earning foreign revenues too.

The conventional tissue expander has some limitation such as less expansion ability, less flexible (because of thickness of the expander), formation of hard fibrous capsule over implantable expander (silicone though bio-compatible, but still produces some degrees of inflammatory reaction to the local tissues and over time it attracts bacteria over its surface which is also responsible for fibrosis) and high cost.

Therefore aim of this present work is to develop indigenous cost effective tissue expanders which is more flexible and bio-friendly and has the ability of expansion in many folds, normally required in maxillofacial, plastic and reconstructive surgery.

Fabrication of Tissue Expander

Silicone rubber and liquid silicone rubber along with some biocompatible materials like titanium hydroxide (TiO₂) were used as raw material in the study to fabricate the tissue expander. To fabricate such tissue expander special type of moulds with heating arrangement was used. The moulds were

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specifically designed and fabricated for our requirements. The dough form of medical grade silicone was mixed with the pre-decided formula in the mixing mill and then cured with RTV-liquid for an hour in room temperature. Then the mould was preheated and smeared with a separating media using soap solution. After that the cured dough was placed in the die and heated at 250-300°C for 15-minutes and pressed at a pressure of 44 Kg/cm². Then the pressure was removed and the die was allowed to cool for 30 minutes or so. After cooling the product was removed from the die and inspected for its suitability or any defect. Some special shapes of expanders developed in this study are shown here. After washing, ultrasonic cleaning, boiling, and drying, packing were done with clean air atmosphere. Gamma Ray sterilization was done for animal and human study. The properly packaged tissue expander was radiated with 13.5 Kgy (Killo Gray) of gamma ray for 3 hours 09 minutes and 15secs as specified by the quality controlled experts.



(a) (b) (c)

Fig-1: Different types of tissue expander

Patient Selection and Choice of Tissue Expander

The patient was a 24 year old young female had a birth mark (Blue Nevus) leaving an unaesthetic appearance on the left side of her face extending superiorly to the left lateral portion of the forehead above the eyebrow up to hairline who will require local tissue for the reconstruction purposes and where adequate tissue will not be available for the same.



(a)



(b)

Fig-2: Female patient had a birth mark (Blue Nevus) (a) Front view (b) Side view

Prior to expander placement, the integrity of the system was confirmed by inflating the expander with air and submersing it in a basin of sterile saline.



Fig-3: Pre-operative image of a spherical tissue expander

Surgical Procedure

Pre anesthetic check-up done 24-48 hours before the operation schedule and as per requirement pre-medications are given for the comfort & safety of the patient. Normally general anesthesia is recommended for the comfort of the patient but sometimes it can be done with local anesthesia where general anesthesia is risky or contraindicated.

Insertion

Normally pre-marked area is incised with a small incision (but sufficiently large enough to introduce the expander easily) to create the required pocket under the skin for inserting the expander. Once the selection of the Tissue Expander was made, at a proper depth a 3 cm incision was given 1 cm away from the tragus at the lower portion of the defect. A blunt subcutaneous pocket has been created to make room for the insertion of the desired tissue expander. The silicone-shelled tissue expander was inserted into the created pocket after proper homeostasis. Just beneath the surface of the skin a tiny tube was left with a self-sealing valve through which a small amount (5ml) of saline is injected to begin the expansion process. The wound was properly closed using 4/0 prolene suture material. All the procedures were performed under proper sterile operatory conditions.



Fig-4: Insertion of tissue expander



Fig-5: Closing of wound after insertion of tissue expander

Expansion

After two days of insertion, the expander was carefully inflated with isotonic sodium chloride solution (5 cc of normal saline) through an intravenous cannula at its end and the patient was instructed of self filling the expander according the given instructions. After 1 week the expansion was seen as followed



Fig-6: Filling of tissue expander with saline solution



Fig-7: Self sealing valve was placed after filling

Reconstruction:

After achieving the required expansion the second surgery is required to remove the expander and complete the reconstruction surgery with the excess skin. The Phase II Surgery was carried out under General Anesthesia. After removal of the Tissue Expander, discolored portion of the skin was incised according to the marking given. The new tissue created by the expansion process was repositioned over the excised raw surface area without creating tension to the suture line (passively fit surface). After the completion of the surgery, suturing was done to close of the incision.



Fig-8: Desired expansion



Fig-9: Post Operative photograph after Reconstruction



Fig-10: Final outcome after 30 days of reconstructive surgery

Microscopic Analysis of the Specimen obtained from the Pocket

Reactive Tissue was collected from Silicone tissue expander surface during phase II surgery and histological examination was performed to check its biocompatibility. Sections show the histology of epidermis covered tissue containing sebaceous and sweat glands. There is collection of lymphocyte, plasma cells, macrophages, eosinophils and multinucleated giant cells around the blood vessels and adnexal structures and granulation tissue formation.

Conclusion

Tissue expansion is a good technique as it provides good skin / tissue bulk for producing desired amount of tissue which gives matching tissue to the face & regional area along with normal perception. We have also seen that any amount of skin can be created by this method. The most advantage is that it is a very simple procedure & can be done even by inexperienced hand. Color & compatibility of the newly formed skin

are very good regarding to the local site. The desired amount of expansion required should be calculated precisely and judiciously. The lag phase for new tissue formation is important & for this sufficient time (minimum 14 day's) should be allowed to achieve normal texture & flexibility (non stretched).

It is more cost effective than the conventional tissue expander as the conventional tissue expander costs is Rs 18,000-Rs 40,000 where as the developed tissue expander costs are approx Rs 2500/ (which is very important for Indian economic scenario). Tissue reaction of the developed tissue expander is more body friendly because of the formation of the thin pliable fibrous capsule, causing less chance of fibrosis & scarring whereas in conventional tissue expander due to the formation of hard fibrous capsule, puckering of the tissue may occur.

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