Abstract: Tissue expansion was developed for a specific indication; however, within a very short time, the concept of tissue expansion found wide applicability. The indications for tissue expansion were burns, trauma, and sequel of previous surgery resulting massive contraction/contracture/scaring or disfigurement of the local tissue. Expander actually helps in growing the local tissue as per requirement so that the disfigurement can be corrected easily with the same type of tissue. Tissue expansion is a good and safe technique. Tissue expanders have been of great value in maxillofacial, plastic and reconstructive surgery. It is usually imported from foreign countries at cost of around Rs 20,000 - 40,000/=. Cost is a major area of concern and we wish to reduce the cost. Our aim and approach is to lowering the cost of the tissue expander (within the range of 3000/- to 5000/-) by using indigenous technology for manufacturing the same.

Keywords: Tissue expander, silicone rubber, hemocompatibility, mechanical strength, animal study.

1. INTRODUCTION

Tissue expansion is a reconstructive surgical technique which allows the body to “grow” extra skin where there has been tissue loss due to trauma or disease. The most common application is in post-mastectomy breast reconstruction, but tissue expansion can be used in almost any part of the body following most types of injury (Hallock GG, 1995). It is also quite advantageous for reconstruction of the scalp, because the “new” skin created contains matching hair follicles (as opposed to using skin grafts or flaps from other parts of the body, which may leave bald spots on the scalp (Azzolini A, Riberti C, Cavalca D, 1992). There was no increased complication for the other age and anatomic site groups, previous expansion, concomitant expansion and type of expander used.

2. MATERIALS AND METHODS

Raw material used in the study to fabricate the tissue expander were, Silicone rubber & liquid silicone rubber (Schmidt SC, etal, 1991). A mechanical press (44 Kg/cm²) with adequate heating arrangement for the moulds was used. The moulds were specifically designed and fabricated for our requirements. Medical grade silicone (Dow Corning) in dough form was cured with RTV-liquid for an hour in room temperature. Then the mould was preheated and smeared with a separating media using soap soln. Then the cured dough was placed in the die and heated to 250-300 °C for 15-mins. and pressed at a pressure of 44 Kg/cm². Then the pressure was removed and the die was allowed to cool for 30 mins. or so. Then the product, (Figure 4) was removed from the die and inspected for its suitability or any defect.
3. STERILIZATION
Sterilization was done by moist heat using autoclave at a temperature of 126°C for 20 minutes.

4. TESTING OF THE PRODUCT
4.1 Biocompatibility Test
The biocompatibility study of a material is essential before implantation. The following tests were performed

(i) Systemic toxicity test

No systemic reaction was noticed after intramuscular implantation of the material in a healthy rabbit following ethical guidelines. After 3 weeks, the blood test report (RBC, WBC, Platelet count, Hb%) was found to be satisfactory, when compared to the normal group.

(ii) Intracutaneous irritation test

The silicone expander was implanted subcutaneously in a rabbit and observed for 4 months. No irritation and toxic reaction were found in the rabbit after every week of close observation.

(iii) In vitro haemolysis test

The silicone sheet samples were found to be highly haemocompatible, using ASTM protocol.

4.2 Mechanical Test
Tensile strength: The silicone sheet was tested under tension using Multi test 10 i (Mecmesin) testing machine kept in the Project Room, KPCMC&H, Jadavpur. The load deformation record is shown in Figure 5.

The ultimate strength in tension was found to be 5.15 MPa at a % elongation of 380.

Tensile strength after 3 week implantation of the tissue expander:

Breaking load: 38.26 N.

Strength of the material: 4.81 N/mm² at a % elongation of 362.

5. ANIMAL EXPERIMENT
5.1 Preparation of Animal
All experiments on laboratory animals were performed as per the guideline of the Animal Ethics Committee of KPC Medical College & Hospital, Jadavpur. Sexually matured animals were indentified from the animal house of the College.

12 Healthy rabbits of 3 to 4 months old (weight between 900-1200 gm) were used as the host in this study. Each rabbit was immunized with Injection Tetanus Toxoid 0.1 ml IM.

5.2 Surgical Procedure
General anesthesia was given intramuscularly to the rabbit using diazepam (0.5 ml I.M.) and 2% lignocaine hydrochloride was used to obtain a dry surgical field.

In incisions were made in the back side just behind the neck. After the anesthetic procedure the surgical field was cleaned with raw betadine and the area was cleaned of hair with non toxic hair removing cream. A small incision (10 mm) was given and the skin was raised with the help of a dissecting scissor and a pocket was made according to the size of the tissue expander.

The tissue expander was inserted into the pocket which was already created under the skin. Just beneath the surface...
of the skin a tiny tube was left with a self-sealing valve through which a small amount of normal saline was injected to start the expansion process.

Then the wound was properly closed using 4/0 black braided silk suture thread. After implantation rabbits were placed in their own cage in the A/C room and post surgical care was taken. Antibiotic ointment (soromycin) was used for 7 days to control infection and faster healing. No anesthetic complication was observed during or after the surgery. Uneventful recovery was observed throughout animal experimentation. (Figure 7)

After the incision was healed, the rabbit was taken to the O.T. periodically to inflate the expander with additional normal saline injections to enlarge the expander, further stretching the skin. This procedure and the resultant stretching of the skin may cause minor discomfort for some rabbit.

6. RESULT
After 6 weeks of inflation significant amount of skin was developed, then we removed the expander and made a skin defect adjacent to the expanded skin and repositioned the new skin in the defect area and sutured. After proper healing the defect disappeared.

7. DISCUSSION AND CONCLUSION
The material and the product developed were found to be adequately strong and flexible (> 300% at break point) for the purpose it was developed. We also found its high level of haemocompatibility after analysis of its hemolytic property and biocompatibility after animal experimentation using 6-rabbits. This material is easy to handle and sterilizable using autoclave.

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REFERENCES