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A PROSPECTIVE TRIAL ON REUSE OF TISSUE EXPANDERS

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SUMMARY : A report on a prospective trial on the reuse of tissue expander is presented, to determine the feasibility of reusing these implants, the risks involved and the incidence of complications. Four tissue expanders of different capacities were repeatedly used in 17 patients for different indications, after explaining the possible risks to all of them. Two patients encountered complications while reusing the expanders, but this did not compromise the final result. We feel that like refurbished cardiac pacemakers, the reuse of these expanders has no untoward effect on the patient as well as on the reconstructive procedure. A protocol for expander removal, resterilization and testing has been described.

INTRODUCTION

Tissue expansion has now become an important and indispensable surgical armament for most of the plastic and reconstructive surgeons. This procedure has gained popularity in most of the developed countries over a short period of time. However, this is not so in less developed countries, where the restrictive factor has been the high cost of the implant[1]. Expanders supplied by the developed countries, are being reused in quite a few plastic surgery centres in the third world countries[2]. Until now there has been no study on the reuse of these expanders.

The cardiac pacemakers with medical grade silicone coating are being reused the world over because of its high cost, without significant morbidity and mortality, though these are labeled for single use[3,4,5]. As was the case with cardiac pacemakers initially, there are lot of doubts in the minds of surgeons and patients alike, while reusing the expanders. To know the life of these implants with careful use and the problems, if any in reuse, a prospective trial has been carried out, the result of which is presented.

MATERIAL AND METHOD

Four tissue expanders which have been put into trial are 250-400cc capacity rectangular expanders with remote port manufactured by different agencies. Out of these one expander was used in 7 patients, one in 4 patients and rest two were used in 3 patients each for different indications.

Patients who needed tissue expansion but could not afford a new one and were willing to accept the already used expander were included in the trial. Before surgery, it was explained to these patients that the expander was recommended for single use, but that we were reusing it because of its high cost and they were explained the possible complications. A written consent was obtained before surgery.

High risk patients with history of malignancy, infectious diseases, jaundice, promiscuous or abnormal sexual behaviour, drug addicts or haemophiliacs were excluded from the study. None of the patients had received blood or blood product transfusions in the recent past. Only patients with negative serological tests for HIV type 1 & 2, and HBsAg were considered for the study.

The method of insertion and expansion was the same as described in the literature[6]. While removing the expander and the port, utmost care was observed not to puncture either of them. Before making the skin incision, the expander was deflated partially. Then the incision was made carefully through the skin and the capsule using a cutting cautery or a round tip blade. A finger was then insinuated between the capsule and the balloon to protect it while extending the incision and the expander was then removed. The port and the connecting tube were also removed through the same incision by following the course of the connecting tube.

After using it in a patient, the expander was rinsed thoroughly with plain warm water repeatedly. The expander was then checked for any leak by injecting approximately 100cc of saline and applying manual pressure over the expander.

Expanders were sterilized by autoclaving using the recommended standard gravity cycle viz. 121 degree C at 1 Kg/sq.cm for 30 minutes. Before using it for another patient the expander and the port were re-checked for any leak and surface swabs were collected for aerobic and anaerobic cultures. After insertion of the expander the cavity was drained for 2-3 days. Thereafter, the usual method of expansion was followed and reconstructive surgery was performed after requisite skin expansion.

RESULTS

The reconstruction was completed successfully in all the 17 patients. Complications were encountered in three patients, of which only two were with reuse. When the expander was used afresh in the first patient there was a collection of blood in the shell cavity which started oozing during the third postoperative week. The culture from the discharge was negative. One patient who failed to report for the removal of the expander as per schedule, had extrusion of the expander edge. Another patient had inflammation over the expander requiring antibiotic cover and delay in inflation of the expander.

The only change noticeable in the tissue expander after repeated use is its colour. The fresh greyish white implant becomes yellowish and a little less transparent than before. The swab cultures taken from the expander each time, showed no growth from any of them.

DISCUSSION

The tissue expanders are made of medical grade silicone elastomers composed of long chains of dimethyl-silicone. This chemical product is heat-stable, time-stable, not altered by the body, causes minimal tissue reaction and does not adhere to the tissues[7]. Hence the clinical characteristics of the expander should not change when put to reuse. As anticipated we did not find any physical change in the implant with reuse except for the colour change.

The main fear while reusing the expander is the anticipated complications, the chief of them being leakage. It may result from a technical error in the form of a puncture of the balloon, a faulty assembly of the connecting device or from the dome through the previous needle puncture sites. Despite using the same expander repeatedly, we have not encountered leakage from any part of the implant. Before removal of the expander, partial deflation of the balloon and careful opening of capsule has successfully avoided the puncture of the balloon.

The leak through the connecting device is due to a fault in the assembly of the connection and is reported even with new expanders[6]. Most expanders are now available as a single unit. Though the surgeon has the choice of shortening the length of the connecting tube, we did not do so in any of our cases, to avoid creating a point of leakage. Anger[2] in 1992 had sectioned the connecting tube to facilitate cleaning and sterilization, which may be one of the factors responsible for high incidence of leakage on reuse of the expanders in his series. The injection port is the most vulnerable site for leakage as it is punctured repeatedly for inflation, deflation and during sterilization. Though 21G or 22G needles have been recommended for puncturing the dome[8] we used only 23G or 24G needles. Despite being punctured as many as 97 times, the dome of the first expander showed no evidence of leak. It is surprising that significant leakage has been noticed in first reuse itself, despite using a 27G butterfly needle by Anger[2].

The extrusion of tissue expander due to the erosion of the overlying tissue has been described in upto 30% of the cases when used afresh[9]. However, in spite of repeatedly reusing the expander we have come across this complication only in one patient.

In one of the patients where the expander was used afresh, there was bleeding during the third week which we thought was due to postoperative haematoma in the shell cavity. This prompted us to drain the cavity as a routine in the immediate postoperative period, which helped us to avoid this complication in other patients.

The tissue expander was sterilized by autoclaving before each use. The surface cultures taken were all negative. Transmission of HIV and hepatitis was included by excluding all high risk patients. Infection is a relatively rare complication in tissue expansion. Manders et al in a series of 41 expansion encountered major infections in 3 patients requiring removal of the implant, though they had used fresh expanders[10]. However, in a series of 17 expansions where 14 were with reused expanders, infection was encountered only in one patient (Table 1).

TABLE 1

Complications with reuse of tissue expanders in 14 patients.

Complications	No. of Patients
Infection	1
Exposure	1

Overall complications with tissue expansion are high. Manders et al reported major and minor complications to the extent of 40%[10]. Antonyshyn et al encountered complications in 48% of patients[9]. Hence it seems the complication rate does not increase with reuse of the tissue expanders.

The high cost of these expanders for the needy patients of our country prompted us to initiate this prospective trial. Reuse of cardiac pacemakers was started with the same aim in mind and now, it is being done even in some developed countries[4]. With a maximum follow-up of 126 months in the published literature, none of the patients with refurbished permanent pacemaker in situ had any complication referable to immune reaction, mediated by antigenic proteins from another person[5]. However, it will be interesting to follow our cases for a long period.

With tissue expanders, being the only temporary implants available, unlike all the other silicone implants, it is all the more imperative to establish by controlled trial, whether repeated use is at all detrimental. Reuse will ease the financial burden on a lot of patients, institutions and the governments if further results are as good.

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