ORIGINAL ARTICLE

Finding of a clinical trial on symptoms and patients satisfaction under surgery with tissue expander with external port

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Background: Tissue expanders are devices which are used to create enough skin to form suitable flap in restoration of great skin deficiencies which are not modified initially. The current study aimed at investigating the patients' satisfaction and the complications such as rupture, hematoma, wound infection, seroma, leakage, chronic pain, and expander expose of internal (implanted under the skin) and external (implanted outside) ports. **Materials and Methods:** In a prospective quasiexperimental study conducted at Alzahra and Imam Musa al-Kadhim educational referral hospitals in Isfahan, two matched groups of patients each one contained 38 patients undergone, external and internal ports, were followed-up weekly until the removal of expander and the injection was done weekly through port. The frequency of complications and patients' satisfaction between two groups were compared. **Results:** The of age for patients in internal and external groups were 25.5 ± 8.7 and 24.7 ± 9, respectively ($P = 0.71$). There was significant difference between average of operation time of internal and external group (97.3 vs. 79.6; $P < 0.001$). The rate of complications such as infection, hematoma, skin necrosis, and expander expose between two groups was comparable, while significant difference was found between groups in terms of pain intensity in injection [4.92(1.2) vs. 1.53(0.69), $P < 0.001$]. There was no significant difference between groups in terms of symptom incidence and tissue expander insertion place as well as patients' satisfaction. **Conclusion:** Although internal port has favorite appearance; however, some complications such as skin infection due to frequent injection, pain rate are higher than external port lead to its more acceptability by the patients.

Key words: Complication, external port, internal port, patient's satisfaction, tissue expander

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INTRODUCTION

Tissue expanders are devices which are used to create enough skin to form suitable flap in restoration of great skin deficiencies which are not modified initially. Tissue expanders are placed under the skin in a chamber form and gradually filled by liquid so that skin above it is subjected to tension and is expanded.[1] To inject liquid, some ports are used which are available in two types: Internal port placed beneath the skin and external port placed outside it, regarding the fact that to restore the soft tissue deficiencies in head and neck, the best case is to use the soft tissue of the same area, using tissue expanders in these patients who have suffered from deficiencies due to burning, radiation, or previous excisions results in improvement of tissue performance and better beauty.

The complications which may appear with use of tissue expander are capsule contracture, rupture, hematoma, wound infection, seroma leakage, chronic pain (pain for more than 2 months), and expander expose.[2]

In the studies undertaken so far, the general complications of using these expanders have been 10%, without any expose. According to these studies, there was seen no symptom of necrosis or hairless during the scalp restoration.[3] Based on anatomical area and expander volume, the final result can be different, but there is no significant relationship between success and age, sex, the number of expanders used, and their shape. Also, in the studies carried out so far, the patients` satisfaction with method of restoration with tissue expanders was acceptable. [4,5] Up to now, there has not been carried out ant study about the satisfaction and probable complication of using these two ports. While using internal port, we need to create another excision other than the main space to place skin expander. The port is place beneath the skin permanently and in several sessions, the liquid is injected into it.

Although the place of port is not specified in this method and it does not create any problem apparently, frequent skin injections cause the skin infection to become more probable. While we do not see any problem like those

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related to internal port in using external port, the patient may feel unhappy due to its unsuitable appearance and exposure. Therefore, it is controversial for surgeon to make decision which port should be applied. Therefore, the current study was conducted to investigate the patients' satisfaction and the complications such as rupture, hematoma, wound infection, seroma, leakage, chronic pain, and expander expose of internal (implanted under the skin) and external (implanted outside) ports.

MATERIAL AND METHODS

Study design and participants

This was a prospective quasiexperimental study which was started from the beginning of 2008 to the end of 2009 in Al-Zahra and Imam Mousa Kazem educational and referral hospitals in Isfahan. The study participants were the patients having been operated by tissue expander. The sample size (38 patients in each group) was calculated based on confidence level of 95% and power 80% for detecting the at least 30% difference of patients satisfaction between two studied groups. The main inclusion criterion was soft tissue damage in the patients so that they need tissue expander for restoration the study protocol was approved by the bioethics committee of Isfahan University of Medical Sciences and a written informed consent was obtained from all study participants.

Procedure and assessment of variables

The patients were randomly divided into two groups and synchronization was carried out based on location and type of skin trauma. In the first group, the tissue expanders with internal port and in the second group, the expanders with external port were used. In the first group, after the patient was anesthetized and the area was sterilized, the skin flap was removed and the expander was placed beneath it. Simultaneously, the internal port was inserted next to it under the skin. In the second group, the internal part was inserted on the skin after the tissue expander was placed. All the patients were followed-up weekly until the removal of expander and the injection was done weekly through port.

Demographic variables such age and sex of participants along with the main study variable, that is, patients' satisfaction (as a dichotomous variable with response categories yes or no) and the complications such as rupture, hematoma, wound infection, seroma, leakage, chronic pain, and expander expose of internal (implanted under the skin) and external (implanted outside) ports have been evaluated at end of follow-up period.

Statistical analysis

Quantitative variables were expressed as mean ± standard deviation and qualitative variable as frequency (percent). Between groups comparisons were done using t-test or Mann-Whitney U test as appropriate for quantitative variables and chi-square or Fisher's exact test for qualitative variables. All statistical analyses were conducted using SPSS statistical software version 16 (SPSS Inc.)

RESULTS

The mean age of 76 patients [38 under internal port (25.1 ± 8.8 years) and 38 with external port (24.7 ± 9)] was statistically different between two groups. No statistically significant gender difference was observed between groups. The location of expander in both group was comparable in which 8 subjects of both groups was in the face, 11 subjects in neck, 9 subjects from internal group, and 10 subjects from external group in scalp. In seven subjects of internal group and in five of external group, the location of expander was trunk and in three subjects of internal group and four subjects of external group it was extremities (resulted from Fisher's exact test). The round expander was used for 36 persons in internal group and for 26 in external group, while for 5 in external group and 4 in internal group it was rectangular (13.1% vs. 10.8%, $P > 0.1$). For 6 in internal group and 7 in external group, it was crescent (15.8% vs. 18.4%, $P > 0.1$).

Table 1 shows the results of comparisons of main studied variables between two statistically significant difference was found between groups based on operation time ($P < 0.001$). The rate of complications such as infection, hematoma, skin necrosis, pain, and expander expose between two groups were comparable, while significant difference were found between groups in terms of pain intensity in injection ($P < 0.001$). There was no significant difference in terms of symptom incidence and tissue expander insertion place as well as patients' satisfaction between two studied groups.

Table 1: The results of comparison of main variables between two studied groups

	Internal group (%) (*N* = 38)	External group (%) (*N* = 38)	*P**
volume average of expander	28.6	28.6 ()	1
Operation time (minute)	97.3	79.6 ()	*P*<0.001
Underwent symptoms	12 (31.6)	16 (42.1)	0.34
Infection	3 (7.9)	3 (7.9)	1
Pain	4 (10.5)	7 (18.4)	0.32
Hematoma	2 (5.3)	2 (5.3)	1
skin necrosis	2 (5.3)	2 (5.3)	1
expander expose	1 (2.6)	2 (5.3)	0.56
pain intensity in injection	4.92 (1.2)	1.53 (0.69)	*P*<0.001
Patient satisfaction			
completely	10 (26.3)	13 (34.2)	0.81
Satisfied	16 (42.1)	17 (44.7)	
Neutral	9 (23.7)	7 (18.4)	
Dissatisfied	2 (5.3)	1 (2.6)	

DISCUSSION

On the basis of present study, there is no significant difference in using tissue expander with external port compared with internal port in terms of symptom rate and patient's` satisfaction. In addition, the pain feeling in injection for external port is less than that for internal port. Regarding the synchronization of all variables in two groups, we tried to minimize the confounding factors.

In our study, there is not seen any significant relationship between two groups in terms of symptom incidence and expander location. In Bozkurt study, it was shown that anatomic area and expander volume influence the symptom incidence significantly.[6]

Regarding the significant reduction of the average of operation time in the group with external port (79.6 ± 15.5) compared with internal port (97.3 ± 18), other factors become less under the influence of operation time such as symptoms due to expander, infection, and anesthesia symptoms in group of external port.

The results showed that 31.6% of internal expander group and 42.1% of external expander group experienced complication but without a significant difference. This comparative trend has not been studied so far. In a study by Nazerani and Motamedi,[5] the overall complication rate of tissue expander was 10%.

In terms of complication brought about in this study, the infection rate, hematoma, and skin necrosis were 7.9%, 5.3%, and 5.3% in both groups, while pain was 10.5% and 18.4% in internal group and external group, respectively. Expander expose was 26% in internal and 5.3% in external groups. Compared with other studies,[7,8] this study conferred greater complication incidence, which can be due to observation of sterility conditions during operation, of health criteria by patient and life environment or personal features along with sterilization of injection solution, although effort to minimize the above factors has been done through personal training and provision of care protocols of these expanders.[6]

As with satisfaction, 70.2% of patients in internal port group and 78.9% in external port were completely satisfied. In a study by Kalaaji and Burehim and Spector *et al*.,[9,10] the satisfaction rate of the patients was greater than 80%.

What is important is decision making to insert these two ports by surgeon, internal port has a more favorite appearance but it brings about some complications such as skin infection due to frequent injection on the skin, pain rate in injection, while in external port, these symptoms and pain in injection are much lower and the patient should accept it. In addition, it is not necessary for patient to refer to surgeon for injection which is a benefit. Therefore, it is up to patient to choose the best option.

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AUTHOR'S CONTRIBUTIONS

All authors participated in designing and conducting the study and finally read and approved the manuscript.

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