RESULTS

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Table (3): Patients data regarding groups, age, sex, history, saddling localization, complications and bone and Bioglass® density.

Case No.	Groups.	Age (YS.).	Sex.	History.	Saddling Localization.	Complications.	Bone density.	Bioglass® density one week post-operatively.	Bioglass® density six months post-operatively.
1.	Group A	19	♂	S.M.R	Bony and cartilaginous.	Incomplete correction.	1487	1003	1452
2.		22	♂	S.M.R	Bony and cartilaginous.	Incomplete correction.	1448	1053	1432
3.		32	♀	S.M.R	Bony and cartilaginous.	Irregularity	1494	1072	1464
4.		35	♂	External Trauma.	Bony only.	Incomplete correction.	1415	1028	1403
5.		36	♀	S.M.R	Bony and cartilaginous.	Incomplete correction.	1450	1014	1420
6.		40	♀	S.M.R	Bony and cartilaginous.	Irregularity	1487	1051	1453
7.	Group B	20	♂	External Trauma.	Bony only.	-	1493	1010	1472
8.		21	♂	S.M.R	Bony and cartilaginous.	-	1498	1016	1483
9.		22	♂	External Trauma.	Bony only.	-	1476	1054	1461

10.	23	♀	S.M.R	Bony and cartilaginous.	-	1425	1025	1404
11.	23	♂	External Trauma.	Bony and cartilaginous.	-	1544	1037	1493
12.	23	♀	External Trauma.	Bony only.	-	1532	1056	1489
13.	25	♂	S.M.R	Bony and cartilaginous.	-	1448	1032	1421
14.	26	♂	External Trauma.	Bony and cartilaginous.	-	1512	1076	1407
15.	32	♂	External Trauma.	Bony only.	-	1442	1042	1431
16.	33	♀	S.M.R	Bony and cartilaginous.	-	1550	1029	1495
17.	36	♂	External Trauma.	Bony and cartilaginous.	-	1481	1026	1457
18.	36	♂	External Trauma.	Bony only.	-	1545	1020	1419
19.	36	♀	External Trauma.	Bony and cartilaginous.	-	1518	1002	1446
20.	42	♂	External Trauma.	Bony only.	-	1467	1081	1450

♂ = Male.

♀ = Female.

S.M.R = Submucous resection of nasal septum.

Augmentation of the nasal dorsum was performed in 20 patients by Bioglass® particles and cases were divided into 2 groups according to operative procedures. Group (A) included 6 cases (No. 1 to 6 in table 3) with augmentation of the nasal dorsum by Bioglass® particles through inter-cartilaginous approach. While Group (B) included 14 cases (No. 7 to 20 in table 3) with augmentation of the nasal dorsum by Bioglass® particles through external incision (Table4).

Table (4): Distribution of studied groups as regards to approach and number.

Groups.	**A.**	**B.**
Approach.	inter-cartilaginous	External.
Number.	6	14
%.	30	70

Age range in this study was from 19 to 42 with a mean of 29.1 years. In group (A) age ranged from 19 to 40 (mean = 30.66 years), while in group (B) ranged from 20 to 42 (mean = 28.43 years) (Table 5).

Table (5): Comparison between the studied groups as regards age (in years).

Groups.	A.	B.	Total.
Range (Ys.).	19 – 40	22 – 42	19 – 42
Mean.	30.66	28.43	29.1

The study included 13 male patients and 7 females patients. Group (A) included 3 males and 3 females, while group (B) included 10 males and 4 females (Table 6).

Table (6): Distribution of studied groups as regards to sex.

Groups	A.		B.		Total	
	No.	%	No.	%	No.	%
Male	3	50	10	71.43	13	65
Female	3	50	4	28.57	7	35
Total	6	100	14	100	20	100

Regarding to history (etiology) of saddle nose deformity there were 9 cases with S.M.R and 11 cases with external trauma. In group(A) 5 cases due to S.M.R and one case due to external trauma. While in group (B) 4 cases due to S.M.R and 10 cases due to external trauma (Table 7).

Table (7): Distribution of studied groups as regards to etiology.

Etiology.	Group (A).		Group (B).		Total	
	No.	%	No.	%	No.	%
S.M.R.	5	83.33	4	28.57	9	45
External trauma.	1	16.67	10	71.43	11	55
Total	6	100	14	100	20	100

According to saddle nose localization there were 7 cases with saddling of the bony nasal dorsum only, while there were 13 cases with saddling of the both bony and cartilaginous nasal dorsum. In group(A) there was 1 case with bony saddling only, while there were 5 cases with bony and cartilaginous saddling. In group (B) there were 6 cases with bony saddling only, while there were 8 cases with bony and cartilaginous saddling. (Table 8) .

Table (8): Distribution of studied groups as regards to Saddle nose localization.

Saddle nose localization.	Group (A).		Group (B).		Total	
	No.	%	No.	%	No.	%
Bony nasal dorsum only.	1	16.67	6	42.86	7	35
Bony and cartilaginous saddling.	5	83.33	8	57.14	13	65
Total	6	100	14	100	20	100

Complications encountered in this study, incomplete correction and irregularity. These complications were occurred in group (A) only. Incomplete correction was occurred in 4 cases, while irregularity was occurred in 2 cases of group (A). There were no extrusion, infection or absorption to Bioglass® particles encountered in this study to any case in both groups (A & B).

The mean density of normal surrounding nasal bones was 1485.6 H.F.U, while the mean density of Bioglass® one week post operatively was 1036.4 H.F.U. Six months postoperatively the density of Bioglass® became 1447.6 H.F.U. Bone formation was occurred in all cases as the density of Bioglass® became near to bone density ***(Figures 28, 29 & 30)***.

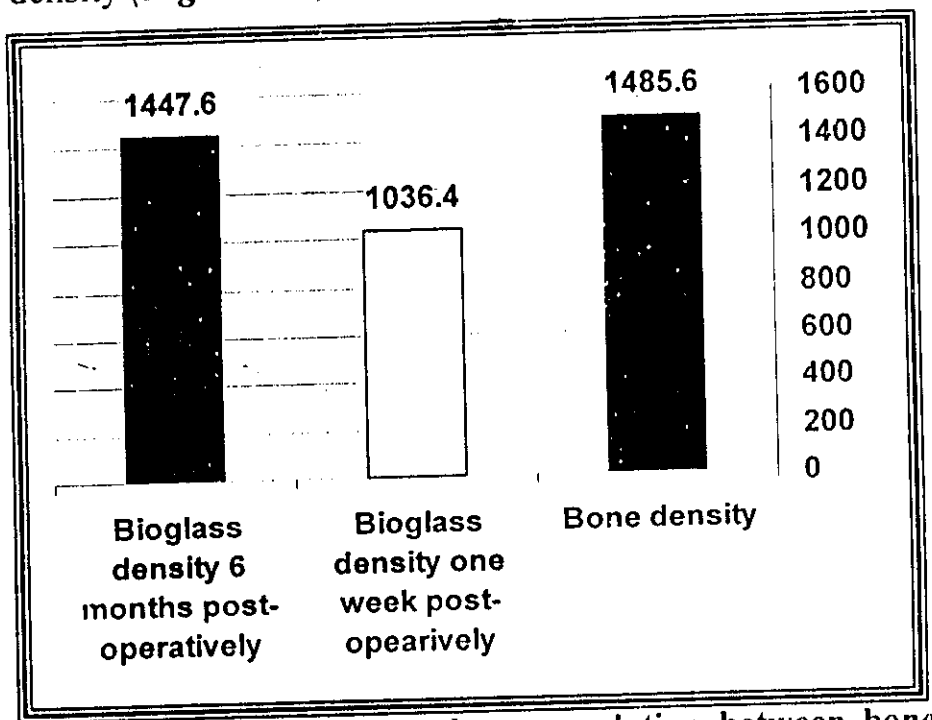

Figure (28): Histogram show correlation between bone and bioglass density one week and 6 months postoperatively.

Figure (29) : C-T (sagittal section) of male patient aged 42 years with correction of saddle nose deformity by bioglass particles one week post-operatively. There is big deference between the density of bioglass particles and adjacent bone.

Figure (30): the Same patients 6 months post-operatively. The density of bioglass particles became near to adjacent bone.

Figures (31 - 45) showed photos of some cases in this study before operation and 6 moths post-operatively.

Figure (31) :- Pre-operative photo.

Figure (32):- A photo of the same case in figure (31) 6 months post-operatively with irregularity.

Figure (33) :- Pre-operative photo.

Figure (34):- A photo of the same case in figure (33) 6 months post-operatively with incomplete correction.

Figure (35) :- Pre-operative photo.

Figure (36):- A photo of the same case in figure (35) 6 months post-operatively with complete correction.

Figures (37 &38):- Pre-operative photos.

Figure (39):- A photo of the same case in figures (37 & 38) 6 months post-operatively with complete correction.

Figures (40 &41):- Pre-operative photos.

Figure (42):- A photo of the same case in figures (40 & 41) 6 months post-operatively with complete correction.

Figures (43 &44):- Pre-operative photos.

Figure (45):- A photo of the same case in figures (43 & 44) 6 months post-operatively with complete correction.

DISCUSSION

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A saddle-nose deformity can be congenital or acquired. Various degrees of nasal dorsal depression can be noticed as a part of individual, familial, syndromic, and racial characteristics. Most saddle-nose deformities are acquired. A common theme in all acquired saddle-nose deformities is a structural compromise of the nasoseptal cartilage leading to decreased dorsal nasal structural support. The most common causes of saddle-nose deformities are traumatic and iatrogenic ***(Beekhuis, 1975)***.

A number of materials, both biological and alloplastic, have been used for nasal augmentation. Each of them has its merits and demerits.

Biological materials including fascia, cartilage and bone, are resistant to infection but have the disadvantages of resorption, curvature, difficulty in fashioning and donor site morbidity ***(Damien & Parson,1991).***

The disadvantages of biological grafts, gave attention to the use of synthetic materials. The later should have a high degree of

biocompatibility, shouldn't be extruded or resorbed, easily measured, contoured and should provide predictable and consistent sound transmission ***(El-Seifi and Fouad 1998)***. To these basic criteriae, ***Bingham and Hawthorne (1992b)*** added that the synthetic material should be available, inexpensive, not carcinogenic, with no risk of transmission of any form of infection and with successful animal studies before clinical application.

Different synthetic materials have been used in correction of the saddle-nose deformity such as precious metals (Titanium, gold, silver, metal alloys), inert bio implants (coral, ivory) and synthetic compounds (silicone, polytetrafluorethylenes, polyamide mesh). These materials didn't fulfill optimal criteria and showed many disadvantages e.g. considerable F.B. reaction, infection, absorption and lysis ***(Sclafani et al., 1997, Roma et al., 1998 and Niechajev, 1999)***.

Hydroxyl-apatite is the material most widely utilized as it has the best results among all synthetic materials regarding to its bioactivity and composition which resemble bone tissue ***(De Groot***

1988; Le Geros, 1988; Ricci, 1992; Kurashina et al., 1997 and Jackson and Yavzer 2000).

A comparative study of particulate Bioglass® to hydroxylapatite as a bone graft substitute in animal models, concluded that the Bioglass® was superior to hydroxylapatite because the later showed encapsulation by fibrous connective tissue, while Bioglass® showed true integration of the new bone without any encapsulation. In this study hydroxylapatite disappeared faster than Bioglass® , so that the empty spaces were not completely filled with new bone formation. Moreover, the speed of bone growth around the Bioglass® was much faster and bone formation was much denser and more mature than with hydroxylapatite *(Oonishi et al., 1997).*

Bioglass® is a bioactive and biocompatible material, which helps in new bone formation without encapsulation. These advantages open the way for clinical studies by many researchers.

Schepers et al., (1993); Shapoff, (1997) and Stanley et al., (1997) used Bioglass® in dental osseous lesion. They found that the

Bioglass® was effective in the treatment of oral bone defects without any complications.

Kinnunen et al., (2000) used Bioglass® in reconstruction of orbital floor fractures. He concluded that, bioactive glass implants are well tolerated and seem to be a promising repair material for orbital floor fracture. It provides favorable healing as it is bioactive, biocompatible and causes new bone formation.

Peltola et al., (2000) used Bioglass® in frontal sinus obliteration. He concluded that, the material has been well tolerated and Bioglass® is a good material for frontal sinus obliteration.

Up to our knowledge, Bioglass® is tried in this study for the first time instead of hydroxylapatite which is the widely used synthetic material in such surgeries.

The aim of this study is to evaluate the biocompatibility of Bioglass®, its ability of new bone formation and its performance in correction of saddle nose deformity.

Bioglass® can be used in particulate form or porous block (disk) form, alone or in combination with blood or autogenous bone

chips or debris ***(Schepers et al., 1993; Shapoff et al., 1997; Stanely et al., 1997)***.

In the present study we used bioglass particles for correction of saddle nose deformity. We preferred particulate form as it easy in application, can be contoured by fingers, giving ideal correction to the saddling deformity. The particles adhere to each other forming one mass. This makes displacement less possible and can not be extruded.

Before starting of this research we discussed the approaches for correction of saddle nose deformity by bioglass particles. Some prefer the endonasal approach through unilateral inter-cartilaginous incision as it is cosmetic and others prefer external approach because by endonasal approach we cannot press the particles firmly by fingers and if this occur the particles will escape from the incision and the amount of particles for correction of saddling cannot actually estimated due to edema after dissection.

This research was started by cosmetic endonasal approach in some cases and after complications of irregularity and incomplete correction, we continued the research through the external approach.

So, this study included 2 groups:-

Group (A): - six cases with augmentation of the nasal dorsum by bioglass particles through unilateral inter-cartilaginous incision.

Group (B):- fourteen cases with augmentation of the nasal dorsum by bioglass particles through an external incision.

Incomplete correction was occurred in 4 cases out of 6 cases of group (A), while the remainder 2 cases were showed irregularity. This was occurred due to inability for pressing of the particles by fingers because if this occurred the particles will escape from the inter-cartilaginous incision. So the actual amount and equal dispersion of the particles cannot actually estimated.

The previous complications were not detected in group (B) because the wound was closed by finger and the particles were compressed firmly by other hand, for this reason, the actual amount and equal dispersion of the particles can be estimated inspite of external edema.

There was no extrusion, infection or absorption to bioglass particles detected in any case in both groups. ***Stoor et al., (1998) and Ballantone et al (2000)*** referred to the antibacterial effect of bioactive glass which seems to be true since there is no infection to any case in our study through the 6 months of the follow up.

Our study demonstrated that correction of saddling nose deformity with bioglass showed significant bone healing with its density near to the normal surrounding nasal bones within 6 months. This result in agreement with ***Wilson et al., (1981)*** who reported that within 3-6 months the martial resorbs and regenerates bone depending on the site of implantation and the size of the bony defect.

In general, our results are comparable to previous results of Bioglass® application in different sites of human body ***(Schepers et al., 1993; Shapoff, 1997; Stanley et al., 1997; Kinnuen et al., 2000; Peltola et al., 2000)***. The material results in new bone formation in all cases.

Our study showed that the Bioglass® material is a bioactive, biocompatible, provides favorable healing, resist infection, easily prepared and placed, and provides new bone formation. All these

findings demonstrate that Bioglass® is a highly suitable synthetic material for augmentation of saddle nose deformity.