EXTERNAL NASAL APPROACH VERSUS INTERNAL ONE IN RECONSTRUCTION OF SADDLE NOSE DEFORMITY USING BIOACTIVE GLASS®.

Department of Otorhinolaryngology, Faculty of Medicine, Benha University, Egypt

ABSTRACT
This study was designed to evaluate the biocompatibility and performance of Biolglass® in reconstruction of saddle nose deformity and to compare the results of 2 different surgical approaches. Twenty patients with traumatic saddle nose deformity were included in this study. They were classified into 2 groups according to surgical approach: Group (A) 10 patients with saddle nose deformity were reconstructed using Biolglass® through internal nasal approach and Group (B) 10 patients with saddle nose deformity were reconstructed using Biolglass® through external nasal approach. A pre-operative photo to nose deformity and another photo 6 months post-operatively were taken for every patient in this study. Also CT scan one week and 6 months post-operatively was done for every case to compare the density of Biolglass® and adjacent bone measured by hounse field unit (H. F. U) to confirm bone formation. In Group (A) there were 6 cases with incomplete reconstruction and 4 cases with irregularity, while all cases in Group (B) were showed complete regular reconstruction. Bone formation was occurred in all cases as the density of Biolglass® became near to that of bone density.

Biolglass® is a highly suitable synthetic material for correction of saddle nose deformity. We recommended the use of this material through an external nasal approach. By this approach we can estimate the actual amount needed for correction and equal desperation of the particles will be achieved. However, there is minimal scar which less ugly than Saddle nose deformity.

INTRODUCTION
A saddle-nose deformity is most visibly characterized by a loss of nasal height. This deformity has also been a saddle-nose deformity A saddle-nose deformity This often accompanies a shortened nose and compromised nasal support structures (1).

A Saddle nose deformity can be congenital or acquired, but most saddle-nose deformities are acquired. The most common causes of saddle-nose deformities are traumatic and iatrogenic (2).

Biological grafts, autografts or allografts have been used in correction of saddle nose deformity such as cartilage and bone. Infection, vascular necrosis, atrophy, resorption and limited amount of material supply, are the main drawbacks of biological grafts (3).

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, in expensive, not carcinogenic with no risk of transmission of any form of infection and with successful animal studies before clinical application (4).

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, polytetrafluorethylene, polyamide mesh). These materials didn't fulfill optimal criteria and showed many disadvantages e.g. considerable F.B. reaction, infection, absorption and lysis (5, 6, and 7).

Bioglass® "45S5" is a bioactive glass ceramics which is composed of 45% silicone dioxide, 24.5% calcium dioxide, 24.5% sodium oxide and 6% phosphorous pentoxide (8).

Bioglass® is a osteoconductive resorbable, bioactive glass which has the most potent effect on bone cell function, The surface of the layer similar to mineral phase of bone. Bioglass® particles remodel in the presence of osteogenic precursor cells, providing a scaffold for new bone growth and holding dimensions until the host bone takes over (9).

Fortunately, the constituent chemical of Bioglass® (calcium, sodium, phosphate and silicate) are all found in the body and at the concentration derived from an implant didn't disturb the adjacent tissues. Many tests showed that Bioglass® was not carcinogenic nor toxic to any of the tissues or systems with which it was in contact (10).

Any material which allows close contact of living cells at its surface, which doesn't contain leachables which produce inflammation and which doesn't prevent growth and division of cells in culture, can be considered biocompatible, such materials are the Bioglass® (10).

The aim of this study is to evaluate the biocompatibility and performance of Bioglass® in reconstruction of saddle nose deformity and to compare the results of 2 different surgical approaches.

MATERIALS AND METHODS

This study was conducted upon 20 patients with traumatic saddle nose deformity, presented to outpatient clinic of Benha University Hospital. All patients were subjected to:-

I) Pre-operative assessment.
II) Operative procedures.
III) Follow up.

I) pre-operative assessment:-

Detailed history of the disease for selection of cases with traumatic history. Nasal examination to exclude pathological causes of saddle nose. Every patient was discussed about his problem and the nature of material used in reconstruction of saddle nose deformity. After patients consent, systemic examination, laboratory investigations, ECG and plain X-ray chest were done to assess fitness of the patients for operation. A pre-operative photo to nose deformity was captured. The telephone number and address of every patient was recorded in his file and all patients were informed that follow up is mandatory.

II) Operative procedures:

Cases were operated upon through the period from November 2003 to January 2005. We used Bioglass® in particulate form presented in vials containing 1 gm of sterilized Bioglass® (Figure 1). The operations were done under general anaesthesia. According to the operative procedures cases were classified into 2 groups:-

(1) Group (A):-

Ten cases with reconstruction of nasal dorsum through inter-cartilaginous incision in one side (endonasal approach).

(2) Group (B):-

Ten cases with reconstruction of nasal dorsum through external incision in one side of the nasal bone.

Surgical techniques:-

In Group A:-

Unilateral inter-cartilaginous incision after injection of vasoconstrictor solution was done through the nasal vestibule (Figures 2 & 3). Dissection by small scissor wide enough to expose the dorsal portion of the cartilaginous and bone dorsum leaving tissue on the lateral aspect of the nose intact. By this method, the dissection was sufficient to place the Bioglass® and prevent its escape laterally. The periosteum on the nasal bone is incised in the midline and at the lower border of the nasal bone and then dissected laterally by fine suction dissector (Figure 4). Bioglass® particles were evacuated from vial in the groove of a gouge (Figure 5) and were pushed to the nasal dorsum with find dissector till the
desirable external nasal shape is obtained (Figure 6). The wound was closed by continuous sutures to prevent escape of particles from the wound. A light nasal pack was used in the side of incision only, and then it was removed after 24 hours.

**In Group B:**

Small incision about 1 cm was done externally at the nasomaxillary suture after injection of vasoconstrictor solution (Figure 7 & 8). Dissection was done by scissor from incision till reach to the other side. Also the periosteum was dissected by sharp dissector to make Bioglass® particles in contact with bone and cartilage (Figure 9). Bioglass® particles were placed at the incised edges directly and were pushed by dissector till the desirable external nasal shape is obtained (Figure 10 & 11). Closing of the wound by finger and pressing of the particles firmly by other hand to be sure that there was no irregularity and the amount of Bioglass® particles were enough. If the particles not enough, we add more amount and press a gain till the reconstruction of saddling be enough (Figure 12). Wound closure was done by one stitch with 5/0 fine needle. Pieces of plaster were inserted externally covering the wound and the dorsum of nose (Figure 13). Plaster and stitch were removed 5 days post-operatively.

**III) Follow up:**

C.T scan was done one week and 6 months post-operatively to compare the density of Bioglass® and adjacent nasal bone by hounse field unit (H. F. U) to confirm bone formation. Every patient was evaluated by symmetrical nasal pyramid, recurrence of deformities and detection of any complication by regular visit every month for six months. Another photo was taken at the end of six month post-operatively to compare it with pre-operative photo.
Figure (1): The particulate form of Bioglass®.


Figure (2): Injection of vasoconstrictor solution.

Figure (3): Unilateral inter-cartilaginous incision.

Figure (4): Periosteum elevation by suction dissector.

Figure (5): Bioglass® particles evacuated in the groove of agouge.

Figure (6): Saddle nose deformity after correction.
Figure (7): Injection of vasoconstrictor solution.

Figure (8): External incision at nasomaxillary suture.

Figure (9): The Wound after dissection.

Figure (10): Bioglass® particles evacuated at the incised edges directly.

Figure (11): Bioglass® particles pushed by dissector.

Figure (12): Saddle nose deformity after correction.

Figure (13): pieces of plaster covering the wound and dorsum of the nose.
RESULTS
Reconstruction of the nasal dorsum was performed in 20 patients by Bioglass® particles (11 were males and 9 were females). Their ages ranged from 19 to 42 years with a mean of 29.1 years. Regarding to history of saddle nose deformity, there were 9 cases with submucous resection operation of nasal septum and 11 cases due to external trauma. 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.

Complications encountered in this study included, incomplete reconstruction and irregularity. These complications were occurred in Group (A) only. Incomplete reconstruction was occurred in 6 cases, while irregularity was occurred in 4 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 14, 15 & 16).

Figures (17: 29) showed photos of some cases in this study before operation and six months postoperatively.

![Histogram showing correlation between bone and bioglass density one week and 6 months postoperatively.](image)

Figure (14): Histogram show correlation between bone and bioglass density one week and 6 months postoperatively.
(1) Bone density = 1476 (H.F.U)
(2) Bioglass density = 1054 (H.F.U).

Figure (15): C-T (sagittal section) one week post-operatively. There is big deference between the density of bioglass particles and adjacent bone.

(1) Bone density = 1476 (H.F.U).
(2) Bioglass density = 1461 (H.F.U).

Figure (16): the Same patients 6 months post-operatively. The density of bioglass particles became near to adjacent bone.

Figure (17): - Pre-operative photo

Figure (18): - A photo of the same case in figure (17) 6 months post-operatively with incomplete correction

Figure (19): - Pre-operative photo.

Figure (20): - A photo of the same case in figure (19) 6 months post-operatively with irregularity.
Figures (21&22):- Pre-operative photos

Figure (23):- A photo of the same case in figures (21 & 22) 6 months post-operatively with complete correction.

Figures (24 &25):- Pre-operative photos
Figure (26):- A photo of the same case in figures (24 & 25) 6 months post-operatively with complete correction.

Figures (27&28):- Pre-operative photos.

Figure (29):- A photo of the same case in figures (27 & 28) 6 months post-operatively with complete correction.
DISCUSSION

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 (2).

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 (11).

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 (12). To these basic criteria, Bingham and Hawthorne (13) 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, polytetrafluorethylene, polyamide mesh). These materials didn't fulfill optimal criteria and showed many disadvantages e.g. considerable F.B. reaction, infection, absorption and lysis (2,6, and 7).

Hydroxylapatite 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 (14, 15, 16, 17, and 18).

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 (19).

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.

Scheipers et al., (20) Shapof et al., (8) and Stanley et al., (21) 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., (22) 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., (23) 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.

Bioglass® can be used in particulate form or porous block (disk) form, alone or in combination with blood or autogenous bone chips or debris (20, 6, and 21).

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

This research was started by cosmetic endonasal approach in 10 cases and after
complications of irregularity and incomplete reconstruction, we continued the research through an external approach in another 10 cases.

Incomplete reconstruction was occurred in 6 cases out of 10 cases of Group (A), while the remainder 4 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 were no extrusion, infection or absorption to bioglass® particles detected in any case in both groups. Stoor et al., (24) and Ballantone et al. (25) 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 reconstruction 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., (10) who reported that within 3-6 months the material 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., (20), Shapoff et al., (8), Stanley et al., (21), Kinnunen et al., (22); Peltola et al., (23). The material results in new bone formation in all cases ,where 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.

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 reconstruction of saddle nose deformity.

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