SMOOTH NYLON FOIL (SUPRAFOIL) IN MANAGEMENT OF ORBITAL FRACTURES

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ABSTRACT

Objective: The objective of this study is to to evaluate the efficacy, safety , advantages and disadvantages of a nylon foil (supraFOIL) implant in orbital fracture repair.
Study design: Prospective, noncomparative, interventional case series.
Patients and Methods: Thirty patients who underwent orbital reconstructions using 0.4-mm smooth nylon foil (supraFOIL) sheets for the repair of orbital fracture were included. A subciliary approach was the main approach used in the patients. The mean postoperative follow-up was 13.7 ± 4.7 months. Postoperatively, results and complications such as diplopia , enophthalmos, infraorbital nerve parasthesia and infection were followed-up on the first day, the first week, monthly for the first 3 months and then every 3 months thereafter.
Results: Twenty patients had symptomatic diplopia before surgery. The diplopia resolved in 16 patients. Only four patients had persistent post operative diplopia. Preoperative enophthalmos resolved in four of seven patients . Infraorbital nerve parasthesia resolved in six of nine patients.
Conclusion: .The low rate of reported postoperative diplopia, demonstrates acceptable results in using supraFoil patch for reconstruction of the orbital fracture in this study, it was found that the anatomical eyeball position and eyeball movement were normal after surgical treatment using the supraFoil implant .Furthermore, supraFoil is a cost-effective material as it costs significantly less than PDS foils or titanium mesh.
Key words: Suprafoil; Orbital fractures.

INTRODUCTION

Zygomatic and orbital fractures make up an estimated 15% and 10%, respectively, of all facial fractures.[1]

Orbital floor fractures often occur when a blunt force is applied to the orbit. Two mechanisms play a role. The first is hydraulic compression of the globe and orbital contents, leading to an explosion of the orbital soft tissue through the weakest part of the bony orbit – usually along the medial portion of the orbital floor and the inferior portion of the medial wall of the orbit.The second mechanism consists of buckling forces transmitted to the posterior orbital walls [2]

Reconstruction of orbital floor fractures seeks to restore the integrity of the orbital floor, provide support of orbital contents, prevent enophthalmos, extraocular muscle entrapment, diplopia, and vision loss. For this purpose, surgeons have the choice among autogenous grafts, implants, and numerous biomaterials.The ideal material for implantation would be non immunogenic, easily implantable, easily shaped, long-lasting, economical, and easily removable when needed. Various implants are available and can be divided in 2 categories: porous and nonporous implants. Porous implants such as porous polyethylene (Medpor) and porous polyethylene with embedded titanium (Medpor Titan) allow tissue ingrowth and integration of the implant. Nonporous implants such as nylon foil (SupraFOIL), silicone (Silastic), and polytetrafluoroethylene (Teflon) are relatively inert materials that provide structural support to the fractured orbital wall with little or no tissue incorporation. Alloplastic materials have largely supplanted autogenous bone as the graft of choice in the repair of orbital wallf ractures [3]

Smooth Nylon Foil (supraFOIL) is a nonabsorbable clear sheeting material manufactured from standard nylon suture [2]

There are few recent studies in the last few years recommending smooth nylon foil (supraFOIL) in treatment of orbital floor and medial wall fractures [2,3]

PATIENTS AND METHODS

From October 2009 to December 2011, 30 patients with orbital fractures either isolated or associated with other facial fractures were treated in the Ophthalmology Department and Otolaryngology,Head and Neck Department , Faculty of Medicine, Zagazig University Hospitals.

Orbital fracture with sever injury to the eye eg: rupture globe , absence of diplopia, insignificant enophthalmos , absence of entrapped tissues through the fracture line in CT with negative forced duction test, non-displaced or minimally displaced ZMC fractures and any patients with congenital anomaly of the bony orbit were excluded from this study.

Informed consent was obtained from all patients after they had been told about the treatment procedure. Patients were examined ophthalmologically and had radiographic examinations including axial and coronal computed tomograms (CT). A complete history of the cause of the injury was obtained and the injury and the damaged surrounding tissue were

examined. All patients were evaluated for visual changes, size of the pupils, ecchymosis, oedema, ptosis, diplopia, extra-ocular movements , enophthalmos, paraesthesia of the infra-orbital nerve, dystopia, muscular entrapment (using the forced duction test), displacement of the canthus (inferior angle of the eye), palpebral deformities, and zygomatic depression.

Twenty four patients had surgery within 2 weeks of the initial trauma, and the others underwent a delayed repair (> 2 weeks). Most of patients were operated on via a subciliary approach. Smooth nylon foil ((SupraFOIL, S. Jackson, Inc., Alexandria,VA, U.S.A.) sheets were used in orbital wall fractures for defects with periosteum disruption and were fixed by a single titanium screw. The implants were cut with surgical scissors and contoured to cover the edges of the orbital wall defect . An intraoperative forced duction test was performed to ensure the release of the incarcerated inferior rectus muscle.

Surgical procedure:

At the lateral canthus, 5cc of local anesthetic (2% lidocain with epinephrine 1;200,000) was infiltrated just under the skin of the lower lid, and down to the orbital rim.

The skin incision was made parallel to the free edge of the lower eyelid, 2 – 3mm away from the margin, it might be extended laterally approximately 1 – 1.5cm in one of the skin creases which form the lower limits of the crow's foot wrinkles. The skin was dissected, for few millimeters, from the superior part of the orbicularis muscle. Then the muscle was penetrated at a lower level producing a stepped incision. Preseptal dissection was done exposing the anterior aspect of the inferior orbital rim.The periosteum was incised 3 mm below the inferior orbital rim.Subperiosteal dissection was performed using a periosteal elevator and small gauze swabs to push away the tissues till exposure of orbital fracture. The orbital floor fracture was exposed, orbital soft tissues were elevated from the defect, and dissection was continued until the entire floor fracture perimeter was visualized both laterally and posteriorly.

After gently elevating all herniated orbital tissue from the fracture sites, and replacing it in the normal anatomic position within the orbit, a 0.4-mm–thick nylon foil (supraFoil) implant was cut in an ovoid pattern that adequately spanned the fracture site as a single unit. In most cases the implant was secured by using a single titanium screw .Titanium microplates and microscrews were used for fixation. At least 2 screws were applied on each side of the fracture. The wound was sutured in three layers, the periosteum, the muscle and the skin.

Statistical analysis:

Mcnemar test was used for the preoperative and postoperative (end of follow up) comparisons of parameters; $p < 0.01$ was considered highly statistically significant and $p < 0.05$ was considered statistically significant. All analyses were done with SPSS software (version 16, Professional Statistics Release, Chicago, IL, USA).

RESULTS

The age of the patients ranged from 5 to 58 years. The mean age was 26.3 years and the median age was 24 years. The highest incidence was in the second decade of life(36.7%.). The lowest incidence was in the first and the sixth decades of life (6.7%) The sex distribution was 25 males (83.3%) and 5 females (16.7%), the male-to-female ratio was 5:1.

The most frequent aetiology was motorcycle accidents , accounting for, 12 out of the 30 patients (40%) ,car accidents was the second most significant causal factor; this occurred in 7 patients (23.33%),interpersonal violence occurred in 6 patients (20%),fractures from falls or others (6.67%) and sports(3.3%) (Figure,15)

The most common fracture site was the orbital floor 100% of the patients, followed by the lateral wall in 33.3% ,followed by medial wall (10%) .

Associated fractures in this study ,nasal fractures (10%) and mandibular fractures (20%), accounted for the greatest proportion of fractures coexisting with the orbital fractures.

Double vision was the most common complaint of patients with orbital fractures in our study. Diplopia was found preoperatively in 20 patients (66.7%) and postoperatively only in 4 patients (Table 1).

High statistically significant difference was observed between preoperative diplopia and residual diplopia after surgery p=0.000

Parasthesia was present in 9 patients in the distribution of the infraorbital nerve (30%).No statistically significant difference was observed between preoperative parasethesia in the distribution of the infraorbital nerve and residual postoperative parasthesia p=0.11

Enophthalmos was apparent in 7 cases (23.33%).No statistically significant difference was observed between preoperative and residual post operative enophthalmos p=0.289

Table (1): Post-operative outcome of diplopia, infraorbital nerve hyposthesia and enophthalmos.

	Preopertiv	Postoperative	*significance*
Diplopia	20	4	*0.000 (Highly significant)*
Hyposthesia	9	3	*0.11 (Non Significant)*
enophthalmos	*7*	*3*	*0.289 (Non Significant)*

The surgeries of orbital fracture repair were performed after a mean interval of 13.53 days after the trauma event (4to 44 days; median of 9days).

The most utilized surgical access to the fractured sites was a subciliary approach in 19 cases (63.3%)of patients, this being a consequence of the great incidence of lesions of the inferior orbital rim and orbital floor. Transconjunctival approach was utilized in four (4) patients with orbital floor fracture .Transantral endoscopic approache was utilized in 4 patients with orbital floor blowout fractures. Combined tarnconjunctival and transcaruncular approaches were utilized in three (3) patients with combined medial wall and orbital floor fractures .

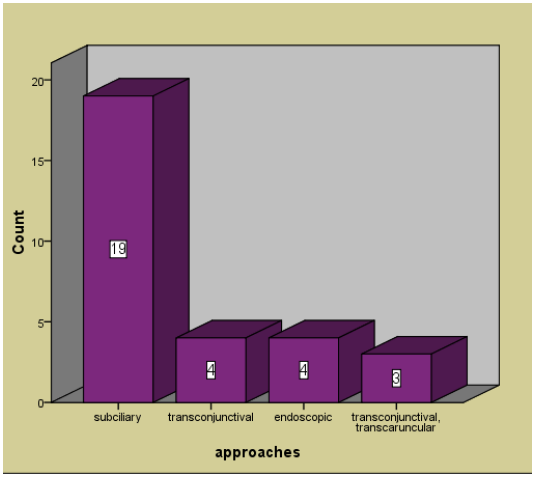
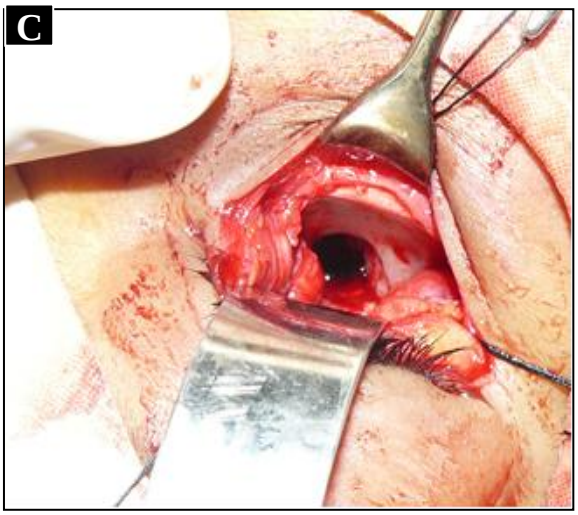
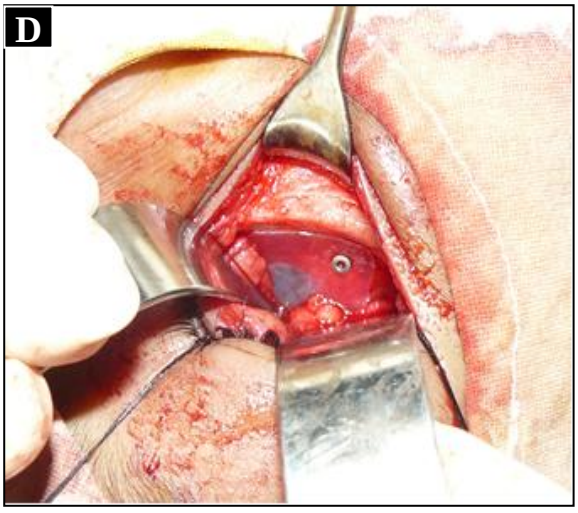
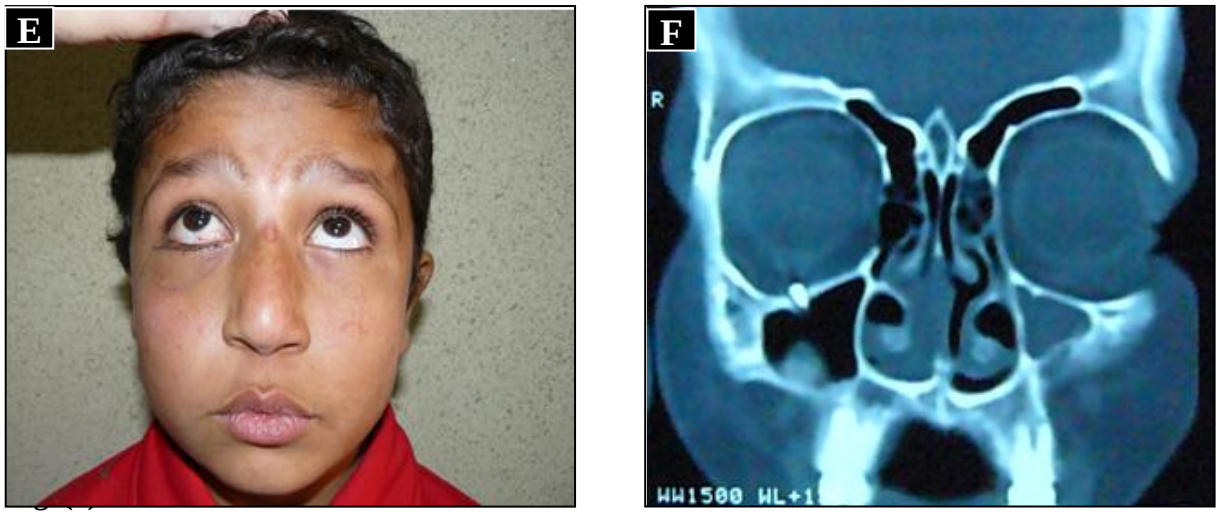


Figure (1): surgical approaches in treatment of orbital fractuers







A) preoperative frontal view of the patient with right orbital blowout fracture demonstrates limitation of upward gaze of right eye.
B) CT scan coronal section demonstrates left orbital fracture with intraorbital air entrapment
C) intraoperative view demonstrates orbital floor fracture .
D) intraoperative view of suprafoil sheet implant secured by titanium screw inserted over the edge of orbital floor defect
E) postoperative frontal view demonstrates free upward gaze of the right eye.
F) postoperative CT scan " coronal section" demonstrates suprafoil sheet secured by titanium screw .

DISCUSSION

This study showed a high incidence of orbital fractures in men (83.3% of the total), especially in the 11-20 years age group(36.7%).

In 2004 Delilbasi et al.[4], using records from 100 patients with midfacial fractures, reported that the highest incidence was in the 10- to 19- year age group. In contrast, Shankar et al.[6]; Ahmed et al. [7] and Adebayo et al.[8] found that the third decade of life was the most vulnerable age group.

In our study the male:female ratio was 5:1. Gassner et al.[9]; Brasilerio and Passeri .[10] and Ahmed et al.[7] reported that a male:female ratio varying from 2.1:1 to 4:1, even reaching higher disparities such as 11.1:1 respectively in previous reports.

In this study, road traffic accidents (RTA) constituted the commonest cause for orbital fractures, accounting for 62.07% of the total number,being 37.93% and 24.14% for motorcycles and car accidents respectively. The violence was the second common cause in orbital fractures in our study accounting for 20.69%.

Ahmed et al.[7]; Brasileiro and Passeri. .[10] reported that the traffic accidents were the most frequent cause of facial trauma in many countries.

Associated fractures in this study ,nasal fractures (10%) and mandibular fractures (20%), accounted for the greatest proportion of fractures coexisting with the orbital fractures. This could be explained on an anatomic basis, the mandible and the nasal bones being the most prominent facial bony projections.

Ferreira et al.[5] in a study on 297 patients with zygomatico-orbital fractures, found that mandibular fractures (25%) and nasal bone fractures (9.8%) were the most common associated fractures. Gomes et al. 11noted that the most common facial fractures associated with the zygomatico-orbital fractures were mandibular (7.6%), maxillary (5.4%), and nasal fractures (5.1%).

In the this study, the most common complaint by the patients at presentation was double vision , it was present in 66.7% of cases. Hyposthesia in the distribution of the infraorbital nerve; it was present in 30% of the cases. Other symptoms included , ecchymosis 40%, limited mouth opening in 20%, epistaxis in 13.3%, and epiphora in 6.67% of the total number.

According to study performed by Ploder et al. [13] in 2003 they concluded that double vision was the most common complaint (60%), followed by numbness of the cheek (53.3%). These data were similar to those reported by Steven et al.[12], as diplopia (66%) and infraorbital anaesthesia (54%) were the commonest symptoms .In contrast, Mwanza et al.[14]found that diplopia was present in 36.4% and hypoesthesia in the distribution of the infraorbital nerve in only 9.1% in a study on 11 patients with orbital floor fractures.

In this study, the average length of time between injury and surgery was 13.4 days, with a range of 4 days to 44 days. Twenty four patients (80%) had early surgical intervention (within 14 days after trauma).The time elapsed from trauma to

surgery, in the present study, was longer than that of most western series. In series performed by Kovacs and Ghahremani [15], Krause et al.[16], and Edward and Tan.[17] they noted that the mean delay between injury and surgery was 4, 3, and 7.1 days respectively. It was evident that some factors could influence these periods, such as delay in the presentation, delay in referral of other departments, financial problems, and the presence of associated injuries .

As shown in figure(1),the subciliary approach was the commonest approach for the exploration of the infraorbital rim and the orbital floor in this study (63.33%), followed by the transconjunctival approach (13.33%).

In a study performed by Calderoni et al. in 2010[18], the subciliary approach was the commonest approach for orbital floor exploration accounting for 89.9%.

In this study endoscopy was used only in treatment of 4 cases of orbital floor blowout fractures ; all of them suffering from preoperative diplopia in upward gaze .Diplopia improved in all patients postoperatively.Our results show that the transantral endoscopic approach does facilitate the repair of orbital floor fractures and yields results that seem comparable with those expected with a traditional open approach. The most obvious of these was release of periorbital tissue trapped in a hinged or small blowout defect.

Persons and Wong.[26]in 2002 performed a study on 5 patients to evaluate transantral endoscopic orbital floor repair using resorbable plate and reported that; no patients developed enophthalmos ,the three patients with preoperative diplopia had full resolution and the one patient with entrapment had restoration of upward gaze. Emara and Hassan.[27] in 2012 performed a study on 13 patients with orbital floor fractures to evaluate transantral endoscopic orbital floor repair using Medpore (1.5mm) grafts and reported that; all preoperatively entrapped muscles were successfully freed and diplopia improved postopertaively in 6 out of 8 patients.

In this study relevant diplopia was present in 20 patients preoperatively. Restoration of the binocular vision was acquired in 16 patients (80%), postoperatively. There was a definite relationship between the improvement in diplopia and a brief interval before surgery. The patients with persistent diplopia were operated after one month of trauma. The mean time between trauma and surgery was 34.5 days in patients with residual diplopia and 9.5 days in patients without diplopia.

In a study performed by Cope et al. [19] in 1999 , they concluded that the longer the time between injury and surgery the longer the time needed for resolution of diplopia.In a study performed by Burnstine.[20] in 2002, he noted that surgery within 2 weeks provided a very satisfactory outcome of diplopia because the entrapped soft tissue in the fracture, if not speedily repositioned within the orbit, it underwent atrophy within 2 to 3 weeks from the trauma, with consequent enophthalmos and/or diplopia. Koide et al.[21],in his study, declared that surgical release of entrapped orbital structures was indicated in the first 24 to 48 hours to prevent permanent muscle damage. In the absence of entrapment, they proposed a wait and see policy, keeping the patient under close observation for 10 to 14 days to allow for resolution of the oedema .Baumann et al.[22], in a study on 32 patients treated for orbital fractures, found that 25 patients had preoperative diplopia. The interval between trauma and surgery ranged between 1 day to 9 days (average, 3.6 days). Only 2 patients (8%) showed postoperative significant residual diplopia .

In this study, enophthalmos was encountered in 7 patients preoperatively. Enophthalmos was corrected in 4 patients (57.14%) .

In a study on 16 patients with orbital wall fractures which was performed by Hong et al.[28], of the 7 patients who had enophthalmos preoperatively, 2 patients (28.6%) remained enophthalmic postoperatively .

The incidence of persistent significant enophthalmos varied considerably from one report to the other. In the series of Iatrou et al. [23,] Talesh et al.[24], and Baumann et al.[22] they reported that incidence of persistent significant enophthalmos was 20%, 5%, and 22.6% respectively.

In current study there was one case of infection 3.3%.Morrison et al.[25] reported an infection rate of 6.8% with no reported mean follow-up period in a series of 311 patients with orbital fractures repaired with silicone implants.Park et al.[3] reported 2 cases of infection in 181 cases of orbital fracture treated with supraFoil implants and they suggested that largerimplants predispose to infections in the postoperative period .

Nine patients with orbital fractures, in this work, were presented with infraorbital nerve hypoesthesia. Improvement occurred first postoperatively in 6 patients (66.67%). Persistence of infraorbital anaesthesia (up to 2 years) was found in 3 patients (33.3%).In a study performed by Vriens et al.[29],they found that the incidence of postoperative persistent infraorbital sensory disturbances was 35.4%.Talesh et al.[24]in 2008 reported that there were no cases with persistent infra orbital hypoesthesia post operatively from 20 patients with preoperative infra orbital hypoesthesia

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دراسة رقائق النايلون الناعمة (سوبرافويل) في علاج كسور حجاج العين

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تمثل كسور الحجاج حوالي ١٠% من إجمالي كسور الوجه وتحدث غالبا بسبب قوة ماضية موجهة للعين وهناك تقنيتين لهذه الإصابة :الأولى : هى الضغط الهيدروليكي لكرة العين ومحتويات الحجاج مما يؤدى إلى كسرالعظم الرقيق من خلال أضعف نقطة في عظم الحجاج وهو ما يكون غالبا الجزء المتوسط من عظم قاع الحجاج والثانية : هي قوة إنبعاجية تنتقل إلى عظم الحجاج الخلفي.إن الهدف من إعادة تنظيم أو بناء كسور الحجاج من جديد هو إعادة سلامة عظم قاع الحجاج لتوفير الدعامة لمحتويات العين وبذلك تحول دون حدوث سقوط العين ، إحتبال عضلات العين ، الرؤية المزدوجة ، فقد البصر.ولكي تكون الرقعة مثالية لابد أن لا تكون معرفة مناعيا ، وسهلة الزرع والتشكيل وتدوم لفترة طويلة وتكون اقتصادية ويمكن إزالتها عند الحاجة .و قد تكون الرقعة من عظام الجسم . ونظرا للمضاعفات التي قد تحدث أثناء أخذ رقعة العظم فقد تم استبدال رقعة العظم الذاتية بمواد أخرى يتم تثبيتها فى حجاج العين قى معظم جراحات كسور الحجاج .وهناك العديد من المواد التى يمكن استخدامها في ويمكن تقسيمها إلى فئتين: مثقبة وغير مثقبة . تشمل المواد المثقبة :البولى إثيلين المثقب والمزود بالتيتانيم والتي تسمح بنمو الأنسجة وتكاملها من الجزء المزروع . و من المواد الغير مثقبة رقائق النايلون ، التيفلون ، السيليكون ، التيتانيوم .

أجري هذا العمل في قسم طب وجراحة العيون وقسم الأذن والأنف والحنجرة ،مستشفى جامعة الزقازيق ،مصر ،خلال الفترة من ٢٠٠٩ إلى ٢٠١١ وقد شملت هذه الرسالةُ ثلاثين حالة من حالات كسور الحجاج وقد خضعوا لاعادة البناء المداري مم باستخدام رقائق النايلون ناعمة (supraFOIL) لإصلاح الكسر المداري. وكان النهج subciliary النهج الرئيسي المستخدم في المرضى. كان متوسط المتابعة بعد العملية الجراحية ١٣,٧ ± ٤,٧ أشهر. بعد العمل الجراحي، وكانت النتائج والمضاعفات مثل شفع، خوص، تحت الحجاج الوخز الأعصاب والعدوى في اليوم الأول، والأسبوع الأول، الشهرية لأول ٣ أشهر وبعد ذلك كل ٣ شهور بعد ذلك.
كان عشرين مريضا أعراض يعانون ازدواج الرؤية قبل الجراحة. وقد تحسن هذا العدد الي أربعة مرضى فقط بعد الجراحة.كان سبعة مرضى يعانون من خوص قبل الجراحة وقد تحسن هذا العدد الي ثلاثة مرضى فقط بعد الجراحة . وخز العصب تحت الحجاج حل في ستة من تسعة مرضى.