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Intracapsular hemorrhage rates in non-fixated nylon sheet orbital implants for orbital fracture management☆,☆☆,☆☆☆

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ABSTRACT

Purpose: To examine the incidence of intracapsular hemorrhage in orbital fracture repair with non-fixated nylon sheet implants.

Methods: A retrospective chart review of 227 patients presenting from January 2013 to December 2016 for orbital fracture repair with nylon sheet implants.

Results: Of the 331 orbital fractures repaired over 4 years, a total of 227 met inclusion criteria. The average implant thickness was 0.38 mm and no implants were fixated. Four total implants (1.8%) were removed due to complications; one each secondary to exploration for ongoing postoperative diplopia, immediate post-operative orbital hemorrhage, a cystic mass anterior to the implant, and pain. There were no cases of intracapsular hemorrhage nor infection for any of the 227 patients over 4 years.

Conclusions: To the authors knowledge, this represents the largest case series to date to assess the rate of intracapsular hemorrhage in non-fixated nylon sheet orbital implants. In the 227 cases reviewed over a 4-year period, there were no cases of intracapsular hemorrhage. This suggests a much lower complication rate than previously reported.

Précis: A case series of 227 patients who underwent orbital fracture repair with non-fixated nylon sheet implants.

1. Introduction

A variety of orbital implant materials and techniques are available for repair of orbital floor and medial wall fractures. Nylon sheet implants are a common non-porous implant used in repair and can be placed with or without fixation. These implants have little or no tissue integration but become surrounded by a fibrous capsule which may serve as a location for potential complications [1]. Prior reports have suggested up to a 9.8% risk of spontaneous hemorrhage into the fibrous capsule surrounding nylon sheet implants [1]. In the authors' experience, there is a much smaller risk of intracapsular hemorrhage in appropriately sized and positioned non-porous orbital implants used in fracture repair. Therefore, a retrospective review of orbital fractures repaired with nylon sheet implants over a 4-year period was performed to assess the rate of spontaneous intracapsular hemorrhage and compare this to prior reports.

2. Materials and methods

The study was approved by the Indiana University School of Medicine (IUSM) Institutional Review board, compliant with the declaration of Helsinki, and HIPAA compliant. A retrospective chart

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review was conducted of patients with orbital fractures presenting to two oculoplastic surgeons (WRN and HBL), from January 2013 to December of 2016. Patients were identified with CPT codes 21390 and 21407 (orbital floor fracture repair, non-floor blowout fracture repair, respectively) and subsequently de-identified. Medical records reviewed included the initial oculoplastic consultation, operative reports, follow-up outpatient records and follow-up computed tomography (CT) results. Inclusion criteria included all patients that underwent primary repair of an orbital floor or medial wall fracture. Exclusion criteria included repair with a non-nylon orbital implant, secondary repair of orbital fracture and lack of postoperative follow up.

A second search was performed for code 67560 (orbital implant removal or revision) to assess whether any patients with nylon sheet implants returned for implant removal during the study period and for what reason.

The chart of each patient was reviewed to obtain data including age, gender, laterality, type of fracture, time elapsed from injury to surgery, thickness size of each implant, development of complications leading to removal of orbital implant, time from initial surgery to removal of implant, length of follow-up and residual symptoms at time of final follow-up. Patients lost to follow-up had no post-operative follow-up visits with the surgeons (WRN, HBL) in their respective institutions.

All orbital floor fractures were approached using a lateral canthotomy and inferior cantholysis, followed by a transconjunctival incision. All medial wall fractures were repaired using a transcutaneous medial canthal tendon incision as described by Timoney [2]. Combined medial wall and floor fractures were repaired with a single nylon sheet in a “wraparound” technique as described by Nunery [3]. No implants were secured with rigid fixation or adhesives.

3. Results

A total of 331 orbits that underwent fracture repair were identified for this study. Thirty-one patient encounters were excluded due to lack of follow up. Forty-seven patients had insertion of porous polypropylene, and were subsequently excluded. Twenty-six patients had bilateral involvement and one orbit was randomly chosen for exclusion. Of the remaining 227 patients, the average age at time of surgery was 38.6 ± 19.7 years (range 3–90 years), with 150 males (66.1% of patients) and 77 females (33.9% of patients). There were 100 right orbits and 127 left orbits. Eighty-nine patients had isolated fractures (83 floor, 6 medial wall), and the remaining 138 included complex fractures. The median time from initial injury to surgery was 13 days (range 0–4024 days). Average implant thickness was 0.38 mm (range 0.20–0.60 mm) with 218 (96%) being either 0.35 or 0.4 mm implants. No implant placed was fixated at the time of surgery. Average follow up time was 287.0 days (range 7 days–4.7 years). Four patients (1.8%) were found to undergo subsequent removal of the nylon implant due to complications of the implant or incompletely reduced orbital tissue. One patient underwent repeat orbit exploration with removal of the nylon sheet secondary to ongoing postoperative diplopia. Additional orbital tissue was identified posteriorly and reduced prior to placement of a new nylon sheet implant. One patient had immediate post-operative orbital hemorrhage noted in the recovery area and therefore the implant was immediately removed. One patient presented 17 months after fracture repair with concern of a cystic mass anterior to the implant which was identified pathologically as scar tissue. The implant was removed at the time of excisional biopsy although it was not in direct communication with the scar tissue. The final patient had pain on the inferior orbital rim over a titanium plate placed for repair of an inferior orbital rim fracture and the nylon sheet implant was removed simultaneously per patient request. No cases of intracapsular hemorrhage, infection, or skin-conjunctival fistula were found.

Statistical analysis of the patients with implants removed versus the patients without implant removal did not reveal significant differences between patient demographics, type of fracture, time from injury to surgery, or thickness of the nylon sheet implant.

An additional search for patients undergoing orbital implant removal or revision (CPT 67560) during the study period revealed two additional patients who had their primary repairs performed prior to the study period. One of these implants was removed for anterior migration and the other was revised for persistence of diplopia after surgery. There were no cases of intracapsular hemorrhage.

4. Discussion

A large and expanding selection of orbital implants for fracture repair has led to a lack of consensus on the ideal implant. Prior studies on non-porous orbital implants have demonstrated conflicting conclusions regarding rates and indication for subsequent implant removal [1,4]. Multiple case reports have reported hemorrhagic complications into the capsule of non-porous implants [5–10]. In 2003, Custer published a case series with a significant number of nylon sheet implants necessitating removal secondary to an intracapsular hemorrhage [1]. In that series, 4 out of 41 (9.75%) patients developed intracapsular hemorrhage over 13 years. An additional implant was removed secondary to abscess formation, for a total of 12.2% incidence of implant removal. Four out of five of the orbital implants removed were 0.8 mm thick and the fifth was 0.4 mm thick. Four out of five implants were secured with stainless steel fixation. Custer concluded that the aforementioned complications appeared to be directly related to the implant capsule itself, rather than the implant material. The authors postulated that the fine vessels and chronic inflammation found on pathology, surround the implant and may lead to symptomatic hemorrhage. Additional risk factors identified included larger implant surface area size, history of prior orbital surgery, increased time lapse from initial injury to subsequent repair [1].

In 2008, Park presented a case series and retrospective review of nylon sheet implants, in which all implants were fixated with titanium screws. Over nine years, 181 orbital fractures were repaired with nylon sheet implant placement, with three cases of implant removal: two were removed secondary to late abscess formation and one secondary to acute orbital hemorrhage. Orbital implant thickness of the removed implants were 0.5 mm, 0.6 mm and 0.8 mm and each had been fixated with a titanium screw. They did not have any cases of late intracapsular hemorrhage. The authors postulated that the decreased risk of intracapsular hemorrhage in their series relative to the report by Custer was due to their method of fixation with titanium screws [4].

The data presented in the current study suggests that fixation of nylon sheet orbital implants is not necessary to prevent intracapsular hemorrhage. Of the 227 patients undergoing orbital fracture repair with nylon sheet implants over a four-year period, none (0%) developed intracapsular hemorrhage. Furthermore, a search for patients undergoing orbital implant removal during this four-year period did not reveal any patients requiring removal of an implant secondary to intracapsular hemorrhage. Of the 227 patients in the current study, only two patients had implants with thickness greater than 0.4 mm. Each of these was a 0.6 mm thick nylon sheet. It is possible that thicker implants increase the risk of intracapsular hemorrhage as four out of five of the implants removed for intracapsular hemorrhage in Custer's study were 0.8 mm in thickness [1]. Our theory is that thicker implants are more rigid and may not follow the contour of the orbit as anatomically as a thinner 0.35–0.4 mm nylon sheet. Due to the rigidity, the implant may tent off the orbital wall and create bridging vessels that can be violated with minimal trauma. A thinner implant contours along the remaining orbital wall and reduces the risk of implant or capsular related trauma.

Our study has several limitations including its retrospective nature. Furthermore, the follow-up interval of the 227 patients was relatively short which may have prevented identification of late complications. However, the providers in this study cover all six major hospitals in their city and function as the primary orbital referral network for the state. Patient charts were assessed for any late complications, including

complications that may have been managed by other services, and none were identified. Additionally, a review performed on all patients undergoing orbital implant removal during the four-year interval further addressed this issue and did not identify any patients undergoing implant removal for intracapsular hemorrhage. While it is certainly possible that a patient presented elsewhere with late complications, we feel that this is less likely given our broad coverage of the region. Additional studies of long-term follow-up are ongoing.

5. Conclusions

In conclusion, our study demonstrates the safety of orbital fracture repair with non-fixated nylon sheet implants. The rate of implant removal for any reason is low (1.8%). While prior studies have suggested an increased risk of intracapsular hemorrhage with non-fixated nylon orbital implants, we find that the rate of intracapsular hemorrhage is minimal when implants of 0.4 mm thickness or less are placed without fixation. In a time of expanding options for orbital repair material, non-fixated nylon sheet implants remain a safe and effective implant for repair of orbital fractures.

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