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Complications of hydroxyapatite pegging: Comparison between polycarbonate and titanium peg system

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PURPOSE. *Polycarbonate peg has been customarily used for pegging of hydroxyapatite for years. For better movement, tissue tolerance, and to decrease the complications of pegging, titanium peg system has been used. This study compares the two systems.*
METHODS. *Complications associated with pegging (polycarbonate: Bio-Eye® or titanium: Dr-Perry new P-K®) were retrospectively reviewed from the charts of 153 patients admitted to the Labbafinejad Medical Center, Tehran, Iran, for over 5 years from 1997 to 2003.*
RESULTS. *A total of 153 cases were studied. Ninety-six (62.3%) were male and 57 (37.7%) were female, and the mean age was 27.7 years (6–59 years). In 88 cases pegs were polycarbonate and sleeve system and in 65 cases pegs were titanium. Forty-one (46%) of cases with polycarbonate and 18 (27%) of cases with titanium had at least one or more complications (p=0.018).The most common complications were granulation tissue, discharge, overgrowth of conjunctiva, and peg falling out in 25%, 23%, 13%, and 8% in polycarbonate peg and 15%, 5%, 1.5%, and 0% in titanium peg group. The prevalence of the last three complications was statistically lower in titanium peg compared with polycarbonate. Twenty-five cases (35%) with polycarbonate peg and 5 cases (7.5%) with titanium peg had two or more complications (p=0.03). Peg removal was done in 11 cases of polycarbonate but only two cases of titanium peg in order to treat the complication.*
CONCLUSIONS. *Both pegging systems had some complications, although these were less severe and prevalent in titanium peg. More studies on complications due to titanium pegs are recommended. (Eur J Ophthalmol 2007; 17: 408-12)*

KEY WORDS. *Hydroxyapatite, Pegging, Polycarbonate peg, Titanium peg, Complication*

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INTRODUCTION

Hydroxyapatite (HA) orbital implants are commonly used during enucleation, evisceration, and secondary orbital implant surgeries (1, 2). Its extensive pore system permits fibrovascular ingrowths; by attaching the extraocular muscles and coupling the prosthesis with the orbital implant using a peg, a wide range of prosthesis movement can be obtained (3, 4). The increased range of motion allows for a more lifelike quality in the prosthetic eye. Pegging is done once complete vascularization takes place. This generally

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occurs within 6 months in most individuals (4, 5).
Reported complications associated with peg placement include discharge, granulation tissue, peg falling out, overgrowth of conjunctiva, and exposure around peg (Tab. I) (6-9).
The original peg was a standard peg (sleeveless) made of polycarbonate. To improve motility, decrease spontaneous peg extrusion and other complications, and perhaps offer better prosthesis support, a "peg and sleeve" system was advocated (6).
The search for the ideal peg is ongoing, and new peg designs are continually being developed in an attempt to improve motility, improve host tolerance, and decrease complications. Recently, titanium peg system has become available from distributors of the Bio-Eye® and the FCI synthetic HA. Titanium has been used in facial reconstruction, as dental implants, as well as in many other areas for years. It is believed to be more biocompatible and better tolerated by human tissue than other materials (4). The FCI system involves a titanium sleeve with a HA coating so that when it is inserted into HA sphere, complete material compatibility (bioactive) takes place (10). Dr. Perry's new P-K™ titanium motility/support peg system involves a titanium sleeve system and peg without an HA coating. Once in position, the titanium sleeve sits directly against the HA with Drapery's new P-K titanium peg system. In this system power drilling is not required.
Complications associated with titanium peg have not been evaluated and no comparison was made with problems due to polycarbonate peg system. The cost of titanium peg is higher than polycarbonate. This report focuses on those complications occurring as a result of pegging of HA and compares complications of polycarbonate peg system and titanium peg system together.

MATERIALS AND METHODS

We retrospectively reviewed 153 patients who received an HA orbital implant (Bio-Eye) after enucleation or as a secondary implant by the oculoplastic team in Labbafinejad Medical Center, Tehran, Iran, from 1997 to 2003. All patients who had undergone the pegging procedure were included. The following variables were recorded: age, sex, type of surgery, time of pegging after implantation of HA, type of pegging system, duration of follow-up, and any complications following pegging. Technetium-99 bone scan was performed to document adequate implant vascularization prior to pegging. Peg placement was performed in the operating room under general anesthesia or retro implant local anesthesia. With the polycarbonate peg and sleeve system, the position of drilling on the HA implant (pilot hole) was located immediately preoperatively by watching the movement of the implant. A 3.8-mm hole was power-drilled and the sleeve was screwed in, a flat top peg was then placed into the sleeve. With Dr. Perry's new P-K titanium peg, a 20-gauge needle was used to make an initial hole into the HA. The initial hole was sequentially enlarged using no. 18, 16, and 14 needles. The hole was irrigated with gentamicin (40 mg/cc) and the threaded titanium sleeve was screwed into the hole. A flat headed peg was then placed into the sleeve.
In both peg systems, the patient was placed on oral and topical antibiotics and was seen by an ocularist 1 month later for placement of a round head peg and fitting of the prosthesis. Patients were followed up for at least 4 months and all complications were recorded. The authors managed these complications by 1) conservative: topical antibiotics and observation, 2) minor surgeries: resection of granulation tissue combined with cauterization of the base of lesion and in recurrent cases, application of mitomycin-c and resection of conjunctival overgrowth, 3) major surgery: removal of the peg in severe and persistent discharge, extrusion, and loosening of the sleeve and persistent and recurrent granulation tissue. Data were tabulated, summarized, compared, and analyzed accordingly using SPSS software.

TABLE I - COMPLICATIONS OF PEGGING OF HYDROXYAPATITE REPORTED IN THE LITERATURE

Discharge
Granulation tissue
Overgrowth of conjunctiva
Peg falling out
Exposure around peg
Poor trans movement of peg
Sleeve on angle
Sleeve sitting above
Nonspecific conjunctival inflammation
Postoperative pain
Popping peg
Broken peg

RESULTS

A total of 170 patients underwent peg placement from 1997 to 2003; after excluding 17 cases with inadequate follow-up, a total of 153 cases were studied. There were 96 males (62.7%) and 57 (37.3%) females. Age ranged from 6 to 59 years, with a mean of 27.7 years. In 88 cases peg was polycarbonate and in 65 cases it was titanium. Primary implantation was done in 130 cases (85%) and secondary implantation in 23 cases (15%). The size of implant was 20 mm in 134 cases (87.6%) and 18 mm in 19 cases (12.4%). The time interval of pegging after implantation ranged from 6 to 15 months with a mean of 10 months.

Forty-one (46%) of the patients with polycarbonate peg system and 18 patients (27%) with titanium peg system had at least one or more complications (p=0.019). Most complications in polycarbonate included granulation tissue 22 (25%), discharge 21 (23.9%), overgrowth of conjunctiva around the peg in 12 (13.6%), and peg falling out in 8 (9.1%); corresponding figures for these complications in titanium pegs were 10 (15.4%), 6 (9.2%), 1 (1.5%), and 0%, respectively (Tab. II).

The three later complications occurred significantly less in titanium pegs ($p \leq 0.05$). Two or more complications occurred in 25 (28.4%) and 5 (7.7%) patients with polycarbonate and titanium pegs, respectively. Twenty cases (48.8%) with complicated polycarbonate pegs (41 cases) and 11 patients (61.1%) with complicated titanium pegs (18 cases) were conservatively managed. Minor operations had to be done in 10 cases (24.4%) with polycarbonate pegs for treatment of complications, but only in 5 cases (27.8%) in the titanium group. Peg removal was performed on 11 patients (26.8%) with polycarbonate but on 2 patients (11.1%) with titanium peg (p=0.003).

DISCUSSION

Using peg for transmission of movement of the orbital implant to prosthesis not only had cosmetic results but also helped to maintain natural appearance of prosthetic eye and normal position of palpebral fissure and lower lid. However, complications of pegging were occurred and reported in the literature, especially for plastic type of peg (6-9).

This report is the second largest (for the largest review, see [8]) review of complications related to pegging HA to date and the first report of complications of titanium (Dr. Perry's new P-K). According to our study, both pegging systems had some complications, which are less severe and prevalent in titanium peg (p=0.019). Half of the complications are mild and there is no need for surgical intervention. Surgical intervention for treatment of complications (especially removal of sleeve) in titanium peg system was done less than in polycarbonate. The most common complication in both systems was granulation tissue and then discharges (57% of all complications). Granulation tissue was not different between the two systems. Prevalence of discharge, peg falling out, and overgrowth of conjunctiva were significantly lower in titanium than polycarbonate.

In Lee et al (8), on 256 patients, 191 cases received the original standard peg and 74 received sleeved peg system. The most common complications were peg falling out (27.2% in original pegs and 10.8% in sleeved

TABLE II - THE PREVALENCE OF COMPLICATIONS IN POLYCARBONATE AND TITANIUM PEGGING SYSTEM

Complication	Polycarbonate peg	Titanium peg	Total
Granulation tissue	22/88 (25)	10/65 (15.4)	32/153 (20)
Discharge	21/88 (23.9)	6/65 (9.2)	27/153 (17)
Conjunctival overgrowth	12/88 (13.6)	1/65 (1.5)	13/153 (8.5)
Peg falling out	8/88 (9)	0	8/153 (5)
Sleeve on angle	4 (4.5)	2 (3.1)	6/153 (3.9)
Poor transfer movement	4 (4.5)	1 (1.5)	5 (3.3)
Nonspecific conjunctival inflammation	3 (3.4)	2 (3.1)	5 (3.3)
Exposure around peg	4 (4.5)	0	4 (2.6)
Broken peg	2 (3.1)	0	2 (1.3)
Postoperative pain	1 (1.1)	0	1 (0.65)

Values are n (%)

pegs), granulation tissue in 4.2%, and HA exposure around peg in 3% of the patients.

In another study by Jordan et al on 135 cases (6), they employed peg original (53%), peg/sleeve (41%), and HA coated titanium sleeve (4.2%), respectively. The most frequent complications were discharges (37%), pyogenic granuloma (30.6%), and peg falling out (29%).The prevalence of these complications is more than those in our study.

In the study of Lin et al on 100 cases (7), 17 patients received the original peg and 83 patients received peg and sleeve. The most common complications were discharge (45.8%), peg falling out (20.8%), and granulation tissue (16.7%). With an overview of all studies the prevalence of peg falling out decreased in peg/sleeve system.

Although the frequency of peg falling out is decreasing with improvement in peg system (peg/sleeve), the most important consequence of major complications of pegging systems is removal of sleeve of peg, and this is more frequent in polycarbonate peg compared with titanium peg.

The causes of removal of sleeve of peg in polycarbonate were major discharge (2 cases), extrusion and loosening of sleeve (5 cases), and recurrent granulation tissue (4 cases). However, in titanium peg system, it was only recurrent granulation tissue (2 cases). These findings show that titanium peg is more secure than polycarbonate. It also causes less complications and therefore less extrusion of the sleeve. In all cases of sleeve removal, after healing of the hole and elimination of inflammation of the socket, re-drilling was done and titanium sleeve was inserted. Granulation tissue happened in one of these cases again. The sleeve was removed and received prosthesis without peg and was comfortable except for limited movement of prosthesis.

Because the HA is brittle, the less secure attachment of the peg may cause movement of the sleeve or peg in implant, which in turn induces conjunctival irritation and granuloma. Granulation tissue is a pink to red vascular lesion induced on the surface of ulcerated epithelium. In most cases, this is related to microtrauma and exposure of the HA around the sleeve and foreign body reaction. Exposure of tenon capsule is another cause. In order to improve the attachment of sleeve of peg in HA and decrease the movement of the sleeve or peg in implant, Jordan et al (10) introduced HA coated titanium sleeve. However, the most frequent complication was still granulation tissue. The other complications were discharge (9.2%), peg falling out (9.2%), and conjunctival overgrowth (1.8%). In this study in spite of more security of sleeve into HA, granulation tissue is the most common complication, so the theory of movement of sleeve in HA is not the only cause of granulation tissue and other factors should be evaluated.

We treated the granulation tissue by simple resection with cauterization, applying of mitomycin-c to the base of the granulation tissue after its removal in recurrent cases, and in severe and very recurrent cases, peg was removed.

Discharge was the next most common complication and occurred in 21 (23%) and 6 (9%) patients with polycarbonate and titanium peg, respectively. According to the definition of Jordan et al (6), patients who had discharge from the onset of their pegging or those who had increased discharge after pegging were considered to have discharge in this study. Major or minor discharges could be managed without any medical intervention or by using topical antibiotics. In the cases of treatment failure or severe discharge the sleeve of peg was removed. Employing titanium peg, however, reduces the chances of discharge. It seems that the reduction of discharge is due to increased biocompatibility of titanium sleeve and its increased security compared with polycarbonate. These features of titanium reduce conjunctival irritation and as a result cause less discharge.

None of the studies in the literature had similar conditions and settings as ours, so an exact comparison of the prevalence of the complications was impossible. Granulation tissue formation was the most common complication observed in ours as well as Jordan et al's (10) studies. Therefore, more research on the mechanism and prevention of this complication is recommended.

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