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LABORATORY STUDY

An investigation of intraocular lens damage and foreign bodies using an injectable hydrophilic acrylic lens implant

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Abstract

Aims **To determine the nature of intraocular lens (IOL) surface abnormalities seen after the injection of hydrophilic acrylic lenses (Rayner C-flex^{TM} 570C), through their accompanying pre-packaged disposable injectors. Hexagonal and round nozzle injectors from the same lens manufacturer were compared.**

Methods **A series of lenses were injected into a petri dish, using two different manufacturer-supplied disposable injectors. The injector nozzle, plunger, and IOL were subsequently examined by light and scanning electron microscopy (SEM) for defects.**

Results **When using the hexagonal nozzle, eight out of nine lenses had linear surface abnormalities along the posterior surface of the IOL in the direction of injection. These abnormalities appeared to be scratches on the surface of the IOL and there were no corresponding defects on the nozzle. A newly introduced injector, with an oval nozzle and a larger compressible plunger, eliminated the vast majority of these surface abnormalities.**

Conclusions **Manufacturer-supplied hexagonal nozzle injectors, but not oval nozzle injectors, produce linear scratches on the posterior surface of the IOL. These scratches did not disappear with time *in vivo*.**

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Introduction

With modern cataract surgery we are constantly trying to insert lenses through smaller incisions to speed recovery, minimise risks, and be astigmatically neutral. We have therefore moved away from the relatively simple insertion of rigid PMMA lenses with forceps to a much more complex affair, in which soft silicon or acrylic lenses are either folded or rolled and are then injected. As a consequence of this increased manipulation, intraocular lenses (IOLs) are more prone to damage. This is particularly true for hydrophilic acrylic lenses, in which up to 28% have been reported to be damaged after injection.[1] The cause of IOL damage is varied. Studies have shown that it can be caused by poor packaging,[2] handling with forceps,[3,4] inappropriate loading,[5] overriding injector plungers,[6] friction during transit through the injector nozzle,[1] the quality and shape of the injector tip,[7,8] split injector nozzles,[9] and varies depending on the type of viscoelastic used for injection.[1]

In this paper, we describe our experiences with the Rayner C-flex^{TM} 570C hydrophilic acrylic lens and disposable injector system. In 2005, Rayner packaged their IOL with a disposable injector that had a hexagon-shaped nozzle and a hard plunger. In 2006, however, Rayner packaged the same lens with a redesigned injector that had an oval-shaped nozzle and a soft-tipped plunger. In clinical practice, we had noted three recurring problems with the original hexagonal injector: haptic fractures, lens surface abnormalities, and intraocular foreign bodies. These problems seemed to virtually disappear when we began

using the new oval injector. To determine the origin and nature of these injector-related problems we injected a series of lenses through both injectors and looked at the lenses and injectors using light and scanning electron microscopy (SEM).

Materials and methods

The Rayner C-flex 570C is a single-piece lens with a closed loop, non-vaulted design. It is a hydrophilic acrylic copolymer of 2-hydroxy ethyl methacrylate and methyl methacrylate, with ethylene glycol dimethacrylate as a cross-linking agent. It has a water content of 26%. It is supplied in a 0.9% saline solution in a pouched blister pack.

Identical *in-vitro* experiments were conducted using the two injector designs. Nine IOLs were selected for each injector: three of high power (28-30D), three of low power (8-10D), and three of middle power (21-23D). The lenses were loaded into the injectors according to the manufacturer's instructions, although differing quantities of Healon (1% sodium hyaluronate, AMO) were used to see whether this could influence the outcome. The nozzle and loading chamber were lined with scarce, some, or copious amounts of Healon. A lens was then positioned in the chamber, manipulated into place by its haptics, and the chamber closed. The lens was immediately injected, according to the manufacturer's instructions, into a petri dish containing balanced salt solution. The injector nozzle and lens were then inspected under the operating microscope for defects (40 $\times$ magnification). Each lens with its corresponding injector was subsequently sent to the SEM department for analysis.

For scanning microscopy the plunger and nozzle of each injector were removed with a razor blade. The lens, nozzle, and plunger were then rinsed in several changes of distilled water to remove all traces of Healon and saline. They were subsequently air dried, mounted on aluminium stubs with double-sided sticky tabs (TAAB), coated with gold using an SC500 (EMScope) sputter coater before being examined, and photographed using a Philips 501 scanning electron microscope. After scanning the posterior surface of the lens, the lens was then flipped, and the anterior surface was gold coated and scanned in a similar manner.

Results

Controls

Examination of control uninjected IOLs and injectors revealed no visible defects. Figure 1 illustrates the differences between the original hexagonal injector with rigid plunger (Figure 1a–c), and the newer oval injector and soft compressible plunger (Figure 1d–f). Note that the rigid plunger (Figure 1b) is composed of two halves welded together. These halves were frequently poorly aligned, potentially leaving sharp edges.

IOL blister-pack solution

Before loading the lenses, the unopened blister pack containing the IOL was inspected with the operating microscope. This revealed that 17 out of 18 blister packs contained fine particulate matter floating in the solution. The largest particles were visible with the naked eye if examined closely. The blister pack supernatant was therefore collected, centrifuged, and examined by SEM. This revealed a combination of small irregular filaments and sheets of material (Figure 2).

Hexagonal injector

When injecting lenses through the original injector with the hexagon-shaped nozzle and the small hard plunger, eight of nine lenses had identifiable surface abnormalities visible at high magnification, with both the operating microscope and the SEM (Figure 3). All surface abnormalities were linear, on the posterior surface of the lens, and in the direction of injection. The appearance of defects did not correlate with either the IOL power or the quantity of Healon used. Four lenses had significant abnormalities (Figure 3a and b), two had minor surface abnormalities (Figure 3c), two had what appeared to be imprints or crease marks on the posterior surface (Figure 3g and h), and only one lens was completely unscathed. At high power these surface abnormalities appear to be of three types: fine irregular wavy filaments (Figure 3c), triangular surface abnormalities, with the apex nearer the leading haptic, and the base towards the trailing haptic (Figure 3d). These tended to curl as they lengthened and could break free to resemble foreign bodies (Figure 3d and e). Finally, large curls that had partially broken free from the IOL could be seen (Figure 3e and f). All three abnormalities can in fact happen on the same lens in a linear fashion (Figure 3a and b).

Only one injector nozzle had any visible defect after injection. It was a linear deep groove centrally on the inner surface, at the end of the tip, in the direction of injection (Figure 4). This defect precisely corresponds to where the welded edges of the plunger sit (Figure 1c).

Oval injector

When the newer injector with its oval-shaped nozzle and larger compressible soft-tipped plunger was used, only one of the nine lenses was thought to have a visible

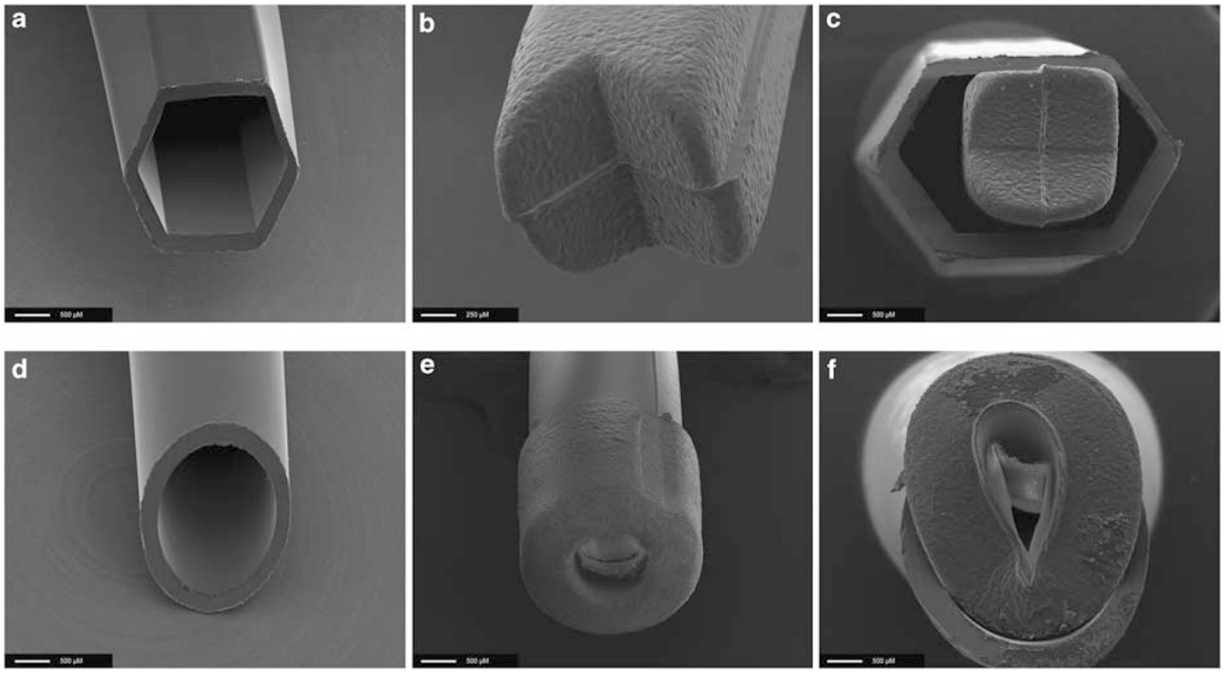

Figure 1 Scanning electron micrographs of the old hexagonal nozzle (a) and plunger (b) showing how much space there is between components (c). The new oval nozzle (d) and soft compressible plunger (e) are a tighter fit (f).

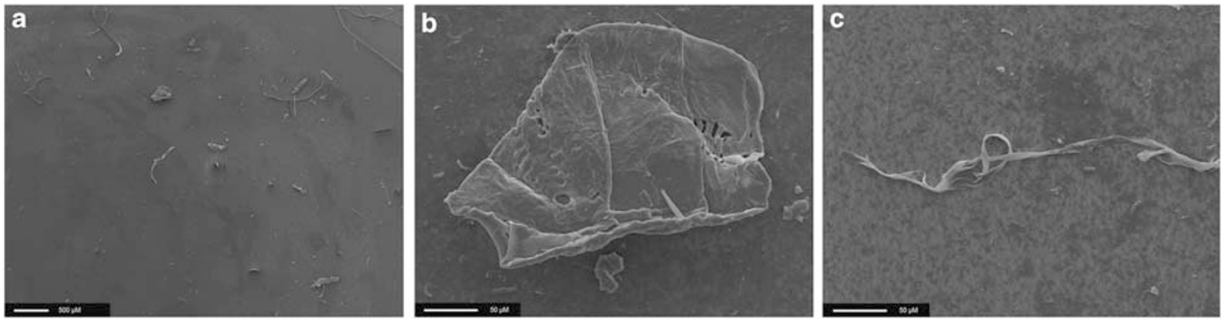

Figure 2 Scanning electron micrographs of debris found in fluid taken from blister packs at low (a) and high power (b, c) showing a mixture of irregular sheets (b) and fibrils (c).

surface abnormality under the operating microscope. Scanning electron microscopy, however, revealed the three lenses to have very minor surface abnormalities with the occasional wavy filaments similar to Figures 3c. All injector nozzles and plungers were free from defects or fractures both before and after injection, as judged using the operating microscope and SEM.

Discussion

Background

Intraocular lens design and technology are continually evolving and are driven by the competitive quest for the perfect lens implant. However, with each new lens material, design, and injection system comes a unique set of technical idiosyncrasies that need to be mastered to minimise patient risk through IOL damage. Given that we are now operating on younger patients with higher visual expectations and longer life expectancies, it is our professional responsibility to be vigilant when using new devices.

In our clinical practice, based across three hospitals, a 3-month prospective audit identified a number of recurring problems, the most common of which were IOL surface abnormalities, intraocular foreign bodies, and haptic fractures. In an attempt to determine the nature and origin of these problems we conducted this *in vitro* experiment.

Haptic fractures

Prior to this study we had discussed the problem of haptic fractures with the manufacturer and the most likely cause was thought to be a poor loading technique,

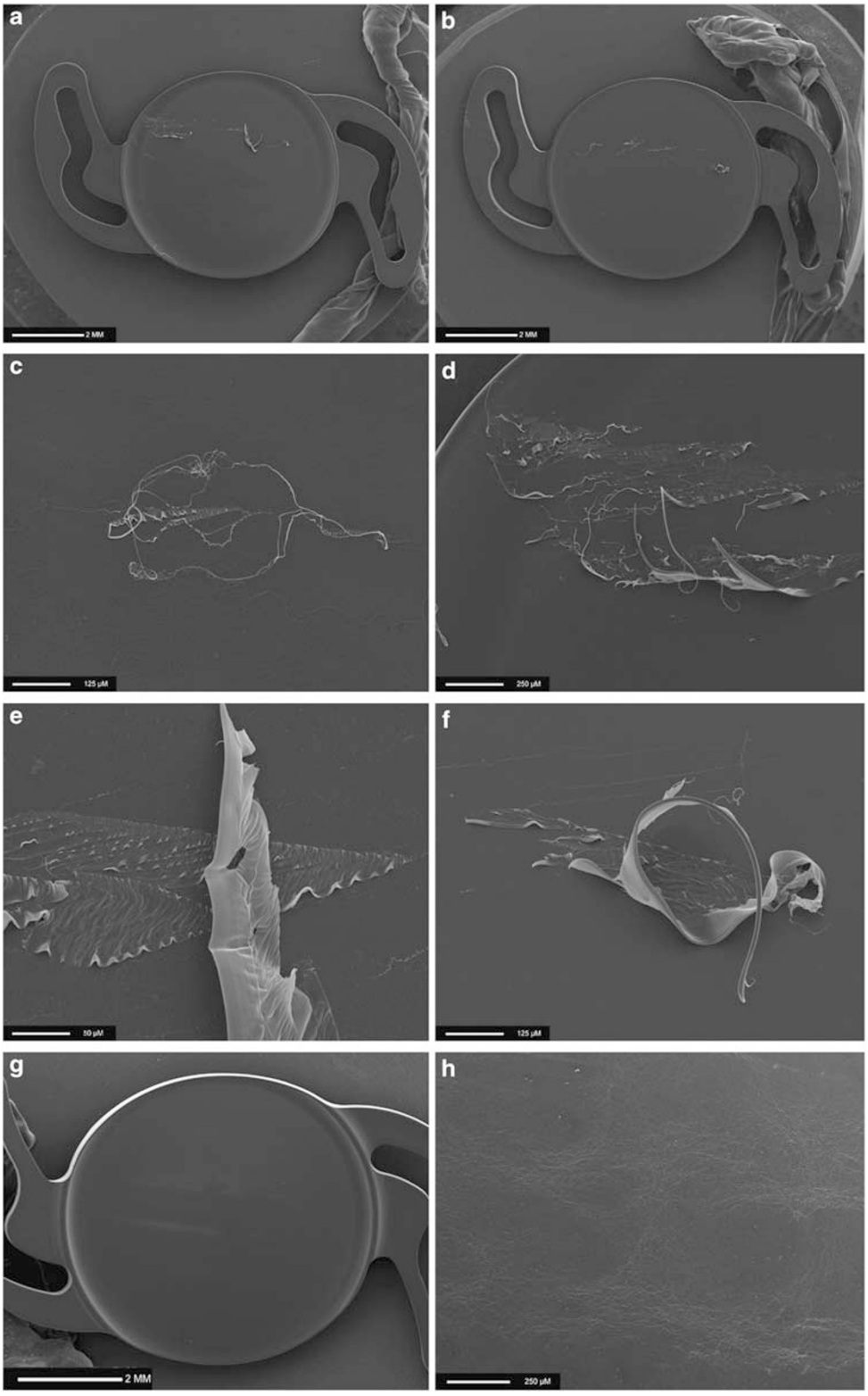

Figure 3 Scanning electron micrographs of IOLs showing linear posterior surface abnormalities at low power (a and b). At high power the surface of the lens can be seen to break up into fine wavy filaments (c), triangular-shaped rippled sheets (d), which break off to form foreign bodies (e), which may form curls (f). Some IOLs had linear surface impression (g), which at high power is actually a wrinkling of the surface (h).

causing entrapment of the haptics when closing the loading bay, and thereby fracturing the haptics on attempted injection. While there were no haptic fractures in the small number of IOLs that we used in this study, scanning electron micrographs of the injector reveal another possible cause of this problem. Owing to the relatively small size of the rigid plunger in relation to the nozzle, particularly at the wider proximal end of the tapered nozzle, it would be quite possible for the plunger to over-ride the haptic or lens during injection. Even at the narrowest point of the injector, at the tip of the nozzle (Figure 1c), one can see that there is ample room for the haptic to become trapped between the plunger and nozzle. Indeed, such a mechanism has been described in the literature previously.[6] In contrast, the new injector uses a larger soft compressible plunger that completely fills the loading bay and proximal nozzle. As the IOL is injected the plunger is compressed to conform to the shape of the nozzle tip (Figure 1f). Our clinical impression with this new injector is that the incidence of haptic fractures is reduced.

Surface abnormalities

Our clinical experience, confirmed by our audit, identified surface abnormalities and foreign bodies to be a recurring problem. The abnormalities were linear, on the posterior surface of the lens, and oriented in the direction of injection. Faschinger[10] described three types of surface abnormalities: surface impressions (lasting indentation/compression), surface onlays (something pressed onto the surface), and surface defects (scratch/crack). We wanted to determine exactly what these abnormalities were.

In this study, the hexagonal injector produced surface abnormalities on eight of the nine IOLs. High-power SEM strongly suggested that these abnormalities were surface defects or scratches rather than exfoliations. We identified three morphological types of abnormality: fine wavy filaments, triangular areas of rippled or corrugated lens surface, and large curled shavings, which resemble foreign bodies (Figure 3). We suggest that these three types most likely represent a spectrum going from mild superficial to deeper surface abrasions. Mild superficial abrasions tend to free tiny filaments of acrylic polymer from the surface of the lens, which subsequently lie randomly on the surface (Figure 3c). Deeper abrasions, on the other hand, tend to start at a leading point and cause a triangular downstream rippling of the lens surface, rather like an avalanche. The deepest scratches, however, cause thick shavings to be lifted from the surface, and these are thrown into curls by friction (Figure 3f). We compare this with the decorative curling of ribbon, that is, running a length of ribbon, on stretch, over the edge of scissors to create curls. Consistent with these defects being IOL material, light and scanning electron microscopy of all plungers and nozzles showed no evidence of damage from injection.

This study contrasts with earlier publications that link the lens abnormalities to nozzle fractures, stress lines, or nozzle exfoliations, which become IOL onlays.[1,6,11] In keeping with this, the IOL debris has been noted to move over time, or even disappear within 1 month of surgery.[10]

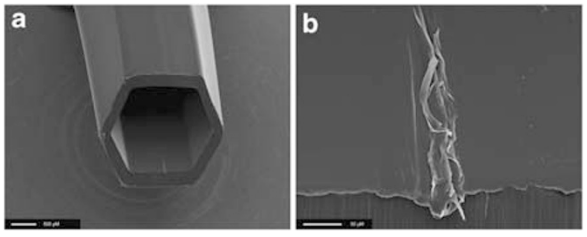

Figure 4 Scanning electron micrograph of a hexagonal nozzle (a) that has a deep gouge at the tip that can be seen clearly at high power (b).

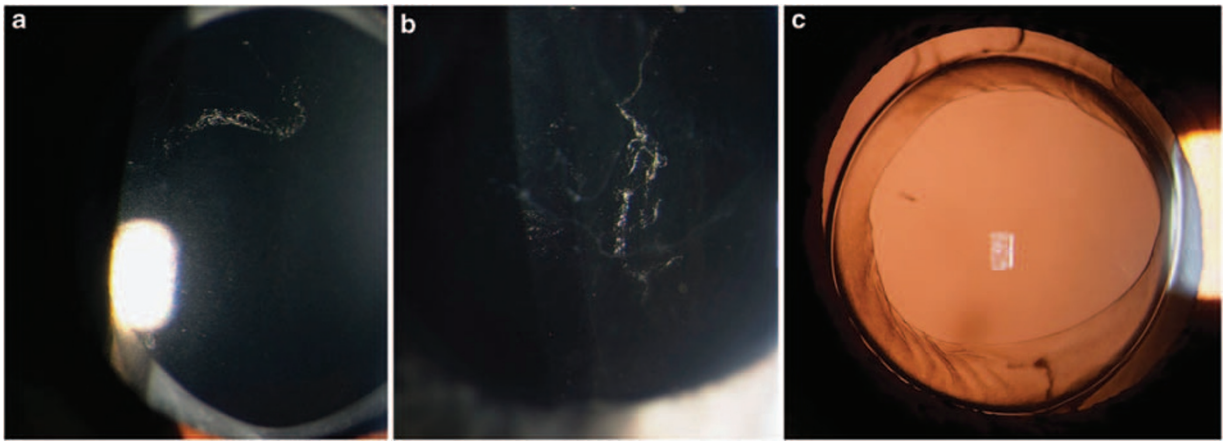

Figure 5 Anterior segment photographs of IOL surface abnormalities (a and b) and an IOL foreign body (c) 3 months after surgery.

To reinforce that our surface abnormalities were not onlays, we recalled five patients who were identified in our audit as having pronounced lens abnormalities visible at the time of surgery. In all cases, the surface abnormalities were still present 3 months postoperatively (Figure 5a–c). One patient had mildly prolonged postoperative uveitis, but no patient in this study expressed dissatisfaction with their IOL, or had lens exchange. It is well known that lens defects may cause dysphotopsia, be more proinflammatory, and are associated with greater bacterial adhesion[12,13] and should therefore not be taken lightly.

With the redesigned injector, surface abnormalities were very much reduced. With SEM only three of the nine lenses had occasional wavy filaments and mild impressions. We attribute this improved performance to the shape of the nozzle tip. One other study has described a similar phenomenon, whereby injections through a hexagonal tip caused the nozzle to fracture and linear posterior surface abnormalities to appear on the IOL optic, whereas injection through a round tip did not.[8] The relatively minor surface abnormalities that were seen on three IOLs (Figure 3g) may represent impressions that possibly would have disappeared with the fullness of time *in vivo* as described earlier.[10]

Foreign bodies

Before this study, intraocular foreign bodies were occasionally seen clinically after lens injection. This study suggests two possible sources of this material. Firstly, high-magnification operating microscope images of the unopened IOL blister packs clearly showed small foreign bodies floating freely within the saline solution. After discussion with the manufacturers about the origin of this material, one possible explanation was abnormal storage conditions causing crystals of saline to form. However, SEM shows that these foreign bodies were not crystalline in nature (Figure 2). Further, X-ray microanalysis of debris from the blister packs showed it to be composed of carbon, hydrogen, and oxygen. Their origin remains obscure.

An alternative explanation for the foreign bodies detected during our clinical practice was that the injection process might have liberated material from the IOL or injector. This study suggests that the origin is most likely from the lens surface, rather than the injector.

Summary

In summary, *in-vitro* studies have shown how using the Rayner C-flex 570C lens with the older hexagonal injector resulted in broken haptics, linear surface defects, and foreign bodies. This occurred without damage to the injector nozzle or plunger. The fractured haptics may in part be because of the plunger overriding the haptic, whereas the surface defects appear to represent scratches to the IOL caused by the hexagonal injector nozzle. These lens defects persisted over time, contrary to reports in earlier studies. Switching to the new oval injector with soft plunger prevented IOL damage. This study presents a strong case for the importance and power of clinical observation and audit in identifying problems, and taking effective investigative action to reduce risk and improve the clinical outcomes.

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