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ORIGINAL ARTICLE

Comparison between femtosecond laser capsulotomy and manual continuous curvilinear digital image guided capsulorrhexis

Comparação entre capsulotomia assistida por laser de femtossegundo e capsulorrexe curvilínea contínua guiada por imagem digital

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ABSTRACT

Purpose: To measure and compare size and shape parameters of femtosecond laser capsulotomy with manually continuous curvilinear digital guided capsulorhexis (CCC) and their refractive outcomes. **Methods:** Laser capsulotomies in 40 eyes of 40 patients were performed using LenSx femtosecond laser device (Alcon, Forthworth, US) and its results were compared with the CCC digital guided carried out in 40 eyes of 40 patients using the Callisto Eye digital image system (Zeiss, Germany). Capsulorhexis circularity, shape and capsule overlap were measured using Adobe Photoshop (Adobe Systems Inc.) and postoperative refraction outcomes were evaluated in both groups. **Results:** Highly accurate and predictable capsulotomy diameter, size and shape were achieved with femtosecond laser capsulotomy compared with capsulorhexis and showed statistical difference between groups. Spherical equivalent comparison between groups showed no statistical difference. **Conclusion:** Femtosecond laser anterior capsulotomy with programed circularity had the intended diameter with average standard deviation values, indicating higher reproducible outcomes. Capsulorhexis performed by an experienced surgeon with auxiliary image guide and appropriate settings provides similar results our results suggest that different techniques are equally effective.

Keywords: Capsulorhexis/methods; Laser therapy; Phacoemulsification; Ocular refraction; Vision

RESUMO

Objetivo: Medir e comparar o tamanho e forma de capsulotomias realizadas com laser de femtossegundo com os de capsulorrexes curvilíneas contínuas (CCC) realizadas com auxilio guiado por imagem digital e avaliar o resultado refracional. **Métodos:** Durante cirurgia de catarata, 40 olhos de 40 pacientes tiveram a capsulotomia realizada com auxílio do laser de femtossegundo e seus resultados foram comparados com os de 40 olhos de 40 outros pacientes que tiveram a capsulorrexe guiada por sistema de imagem digital. Os parâmetros de circularidade, forma e *overlap* foram medidos usando o Adobe Photoshop (Adobe Systems Inc.) e os resultados refracionais pós-operatórios foram avaliados em ambos os grupos. **Resultados:** Os diâmetros, tamanho e forma de alta precisão e previsibilidade foram atingidos com laser de femtossegundo e houve diferença estatística entre os grupos. Quando comparado o equivalente esférico entre os grupos, não houve diferença estatística. **Conclusão:** As capsulotomias realizadas pelo laser de femtossegundo possuem circularidade programada, diâmetro pretendido e valores de desvio padrão médios, indicando resultados reprodutíveis mais elevados. No entanto, CCC realizada por um cirurgião experiente com auxílio guiado de imagem digital, com configurações apropriadas, fornece resultados semelhantes e sugere que diferentes técnicas são igualmente eficazes.

Descritores: Capsulorrexe/métodos; Terapia a laser; Facoemulsificação; Refração ocular; Visão

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Introduction

Cataract surgery is the most common surgical procedure in the world[1,2]. With the advent of phacoemulsification, it has become safer and more reproducible.In the United States alone, three million cataract procedures are carried out every year[2-4]. The procedure is increasingly indicated to younger patients who are still active and productive,and who are thus more demanding.Therefore, the procedure is often combined with refractive surgery[1], thus requiring greater precision and more predictable results. As the procedure becomes more popular, it is also required to become safer and more reproducible.

Capsulotomy or capsulorhexis may be the most important step for the success of the procedure. Since it was first described by Gimbel in 1985, continuous curvilinear capsulorhexis has become the technique of choice for anterior capsulotomy[5].With the advent of new crescent-shapedlens designs, the procedure is now performed mainly for refractive reasons[6]. A well-centred, regular-sized continuous capsulorhexis compatible with the intraocular lens (IOL) to be implanted is critical to ensure that the following stages are completed safely and effectively, the lens is correctly positioned, and rotational stability is achieved, thus meeting the procedures' objectives[7]. The reproducibility of the procedure provides an acceptable level of predictability and better refractive results.

However, successful capsulorhexis also depends on factors other than the surgeon's skill level, such as changes to the pupillary margin, a shallow anterior chamber, pupil constriction, zonular weakness, poor corneal visibility, and fibrosis, among others[8]. Facilitating methods can be used.

Various surgical techniques and technological solutions have been developed to assist surgeons. Surgical instruments have been created to mark the cornea or the anterior capsule in order to make the capsulorhexis as centred and regular as possible. Techniques involving diathermy, plasma blades, and neodymium:YAG laserfor anterior capsulotomy have been described in the literature[9-11]. Nevertheless, success depends in great part on the surgeon's skill level and favourable anatomical conditions[7].

Surgeons can now utilise elegant, efficient and accurate technological solutions to perform the capsulorhexis.These include computerised optical biometry systems which can superimpose images on the surgical field through the microscope. When using this tool, the surgeon must follow the outline superimposed by the device in order to achieve more accurate results. However, even though such systems can be very helpful, sufficient surgical skill is still necessary in order to ensure that the outline is accurately followed.

Femtosecond laser-assisted cataract surgery is currently the state of the art in cataract surgery. Initially intended to treat presbyopia[12], femtosecond laser is a tool which not only provides precision, but above all reproducibility[8], as it automatises the surgical steps which previously depended solely on the surgeon's skill level[13].

However, the high cost of this kind of equipment and its inputs can make them unaffordable[14] for the majority of surgeons; moreover, questions are still raised about its cost-effectiveness compared to other alternatives.

In this study, we compare the reproducibility, size, and uniformity of continuous curvilinear digital-image-guided capsulorhexis versus femtosecond laser capsulotomy.

Methods

This study was carried out in agreement with the ethical standards formedical and surgical research and was approved by the Research Ethics Committee (CAPPesq) of the Brasília Eye Hospital and the Hospital of the Armed Forces (HFA), Brasília/DF.

Patients were selected at the cataract outpatient clinic of the Brasília Eye Hospital and underwent cataract surgery between October 2013 and January 2014.

The study used a randomised, controlled, prospective, comparative design and included80 eyes of 80 patients submitted to phakectomy with implantation of an IOL to treat cataract. Patients were divided into groups according to the type of capsulotomy. The study was conducted in accordance with the principles of the Declaration of Helsinki.

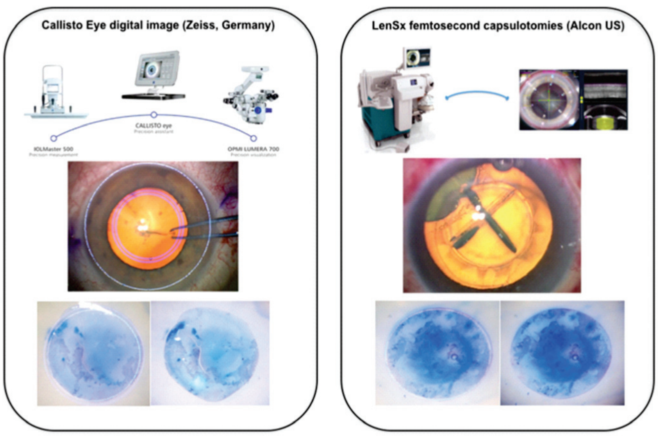
All procedures were carried out by the same experienced surgeon (W.T.H) using topical anaesthesia and under sedation. The conventional surgical procedure involved2.4-mm-long three-plane self-sealing clear corneal incisions in the steepest corneal meridian. The anterior capsule was stained with trypan blue vital dye and the anterior chamber was filled with viscoelastic. Manual continuous curvilinear capsulorhexis (CCC) was performed using an Ultrata capsulorhexis forceps, following the outline of the digital image projected onto the eyepiece of a OPMI Lumera 700 (Carl Zeiss Meditec Inc, Germany) surgical microscope by the Callisto Eye (Carl Zeiss Meditec Inc, Germany) computerised cataract surgery support system. The Callisto Eye System is completely integrated with the surgical microscope, which means that after the cornea is marked at 0 and 180 degrees the computer can identify the markings and project a digital image onto the microscope's eyepiece allowing the surgeon to perform all steps requiring exact positioning and millimetric precision, including incisions, capsulotomy, placement of the IOL, and intraoperative keratoscopy.

After configuring the system, the capsulorhexis size (4.9mm) was predetermined and the device superimposed a guidance image over the surgical field, automatically adjusting the image for the parallax effect caused by the corneal curvature. After the capsulorhexis, the anterior capsulewas recovered for subsequent analysis of diameter, curvature, and uniformity. The remaining surgical steps were then performed as usual: hydrodissection; hydrodelineation; dispersive-cohesive viscoelastic using the soft-shell technique; phacoemulsification using anInfiniti (Alcon) device;and lens cortex aspiration with implantation of the IOL into the capsular bag.

For femtosecond laser-assisted procedures, the Lensx (Alcon, Forthworth, US) system was used. The system uses a contact lens interface (softfit) for vacuum coupling and utilises real-time Optical Coherence Tomography (OCT) to precisely guide the surgical steps[2]. The procedure involved 2.4-mm incisions in the steepest corneal meridian; pre-planned capsulotomy with a 4.9-mm diameter; and identical energy, spotting, and layer separation parameters for all procedures. After successfulcoupling, the capsulotomy was centralised and the lens fragmentation patterns were determined based on the real-time OCT of the anterior segment provided by the surgical equipment. Once the parameters and image were confirmed, the laser was applied to the patient.

After the femtosecond laser stage, all patients underwent the subsequent steps in the same way: the anterior chamber was

Study Design



penetrated; the anterior capsule was stained with Trypan blue vital dye; the anterior chamber was filled with viscoelastic; the outcome of the capsulotomy was checked; and the anterior capsule was recovered for further analysis. The following steps were performed in the same way as in the conventional procedure, with hydrodissection, hydrodelineation, phacoemulsification, and implantation of the IOL.

The parameters used for comparison were: patient age; LOCS III classification system for cataract staging[15,16]; Pentacam Nucleus Staging (PNS); postoperative spherical equivalent; predicted spherical equivalent; circularity of capsulorhexis; and overlap area. All measurements were done using Adobe Photoshop CS5 (Adobe Systems, Inc., San Jose, CA) software, except for spherical equivalent and PNS.

The formula used to measure circularity was based on: radius of the circle tangential to the internal capsulotomy border (radius of the internal circle); radius of the circle tangential to the external capsulorhexis border (radius of the external circle); internal radius divided by the external radius.The closer the result is to 1, the more circular the capsulorhexis.

The overlap was calculated by subtracting the area of the external capsulorhexis circle, measured as described above, from the optical area of theIOL, multiplied by the fraction of real overlap covering the IOL.This area was divided into quadrants, each corresponding to 25% of the overlap, producing a factor multiplied by 0.25 for each quadrant. The ideal overlap area is when the external circle measures 4.9mm and the optical area of the IOLmeasures 6.0mm.

SPSS software was used for statistical analysis.

Results

In the femtosecond laser-assisted capsulotomy (LACS) group there were no suction breaks or intraoperative complications, but there were 5 (12.5%) cases of pupil constriction, 3 (7.5%) cases of micro-adhesions of the capsulotomy (capsular tags) under 5º, and 1 (2.5%) case of lack of treatment (under 10º).

Mean patient age was 65.2 years ± 8.8 in the digitally-guided CCC groupand 66.8 8.7 years in the LACS group, p=0.365. The LOCS III classification was 2.2 0.7 in the LACS group, compared to 2.1 0.8 in the CCC group, p=0.160. PNS was 1.9 0.9 in the LACS group and 1.9 0.8 in the CCC group, p=0.912 (Table 1).

In the LACS group, the mean predicted spherical equivalent was -0.30D ±0.39 and the mean postoperative spherical equivalent was -0.16 D ± 0.38, whereas in the CCC group the mean predicted spherical equivalent was 0.33 D ± 0.33 and the mean postoperative spherical equivalent was -0.03D±0.28 (Chart 1). There was no statistically-significant difference between the two groups (p=0.327).

The difference between predicted and actual postoperative spherical equivalent was +0.13±0.09D (-0.02 to +0.29) in the LACS group and +0.30 ± 0.29D (-0.20 to +1.07) in the CCC group. There was no statistically-significant difference between groups (p=0.327 - NS).

As regards the circularity, the mean values were 0.98±0.02 for LACS groupand 0.96±0.01 for the CCC group, p<0.01 (Chart 2).

As regards the capsulotomy area, the mean values were 18.5mm^2±0.605 for the LACS group and 18.0mm^2±0.478 for the CCC group, p<0.01 (Chart 3).

Discussion

Every cataract surgeon wishes to perform a perfect capsulorhexis. Good centralisation, correct sizing, sufficient overlap of at least 0.5mm around the IOL and, above all, integrity

Table 1

Mean and standard deviation for age and lens density in the groups submitted to femtosecond laser-assisted capsulotomy and continuous curvilinear digital-image-guided capsulorhexis

	Femto Mean ± SD	Manual Mean ± SD	p-value
Age	66.8 ± 8.7	65.2 ± 8.8	0.365 - NS
LOCS III*	2.2 ± 0.7	2.1 ± 0.8	0.160 - NS
PNS PENTACAM**	1.9 ± 0.9	1.9 ± 0.8	0.912 - NS

(*) LOCS (Lens Opacities Classification System)
(**) Lens densitometry; PNS,patient nuclear score.

Chart 1A

Correlation between actual and predicted postoperative spherical equivalent after femtosecond laser-assisted capsulotomy

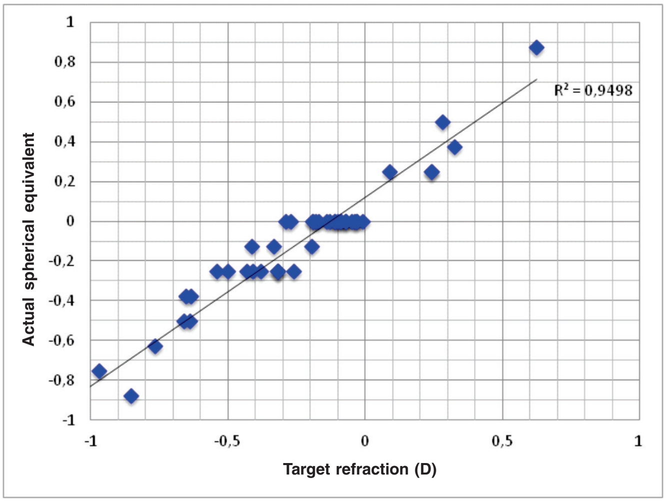


Chart 1B

Correlation between actual and predicted postoperative spherical equivalent after continuous curvilinear digital-image-guided capsulorhexis

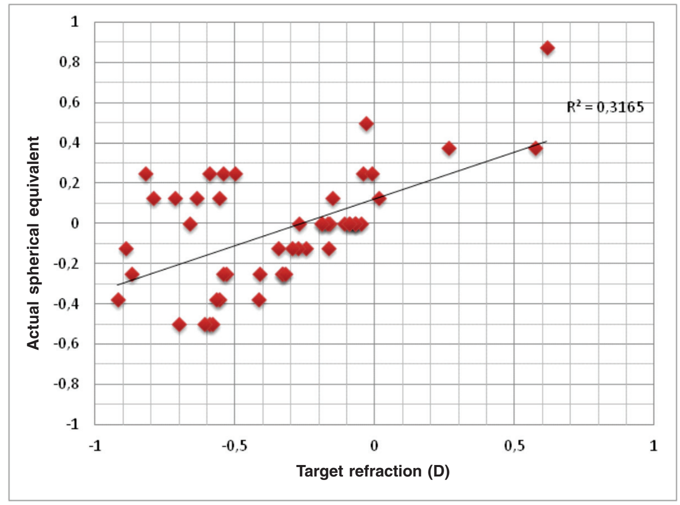
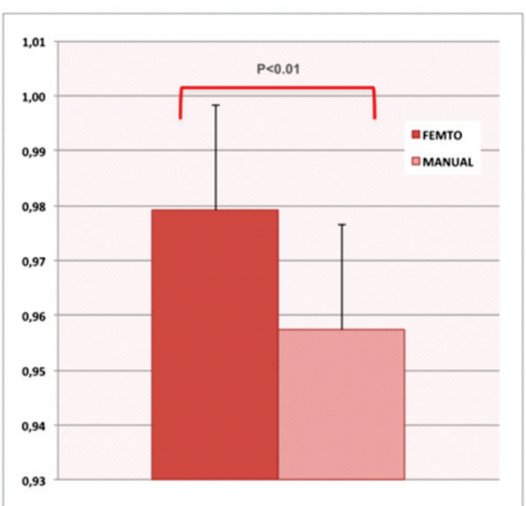


Chart 2

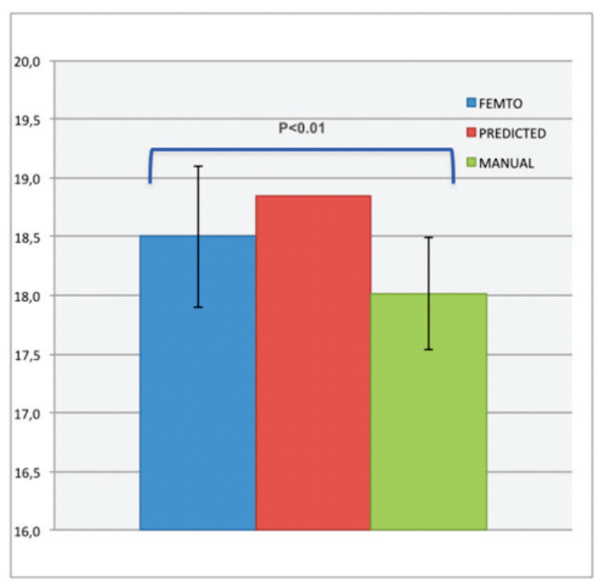
Comparison of circularity between femtosecond laser-assisted capsulotomy and continuous curvilinear digital-image-guided capsulorhexis



The circularity (ε= Ømin/ Ømax) following the femtosecond laser-assisted and manual capsulorhexis procedure.

Chart 3

Comparison of capsulotomy area (shape) between femtosecond laser-assisted capsulotomy and continuous curvilinear digital-image-guided capsulorhexis



are extremely important factors for the intraocular implant to function correctly.Decentralisation of a multifocal lens can cause much dissatisfaction and possibly even IOL explantation. In the absence of appropriate overlap the lens can be pushed into the anterior chamber, producing residual ametropia or even rotation of a toric lens. It should be noted that the architecture of the capsulotomy influences the position of the lens, which is the main source of error when calculating the dioptric power of the IOL. Cell growth and posterior capsule opacification are also correlated with the capsulotomy architecture. Very small or irregular capsulotomies are also associated with capsule contraction syndrome.

This study aimed to assess whether manual capsulorhexis guided by a digital image is sufficiently regular and uniform, when carried out by an experienced surgeon, to produce results similar to those produced by a femtosecond laser in LACS.

Any continuous curvilinear capsulorhexis system which does not immobilise the eye globe will probably representa complicating factor for the procedure[7]. Thus, even if the surgeon is guided by the digital image other complications could still happen.

However, when compared to less advanced technological tools described in other comparative studies[7], the digital image guidance system represents an excellent tool to facilitate continuous curvilinear capsulorhexis. It also allows the surgeon to check whether there are any imperfections and correct them.

Femtosecond laser capsulotomy, on the other hand, is free of several basic complicating factors found in manual CCC, even when digital image guidance is used, because the eyeball is immobilised by the patient interface and the procedure is facilitated by real-time OCT. However, consideration should be given to the cost of the equipment and whether it is really necessary for less demanding procedures[14]. There is also a learning curve to be overcome, and as the number of procedures increases, all steps, including the capsulotomy, become swifterand more reproducible[18]. Furthermore, there are complicating factors specific to LACS, such as patient movement, loss of suction, intraoperative pupil constriction[2], pupillary block, lack of treatment, or incomplete capsulotomy[18-20]. Something which seems safer can become a complicating factor, as irregularities in incomplete capsulotomy can lead to possible discontinuities in the anterior capsule. The major advantage of manual CCC is its continuity. While Bali et al.found in 2012 that the rate of this type of event was 4% in laser procedures, Marques et al.found in 2006a rate of 0.79% for manual CCC during routine phacoemulsification[21] carried out by an experienced surgeon. In 2014 Abell et al. carried out a study comparing these rates and found 1.87% in the group using femtosecond laser and 0.12% in the manual CCC group; however, it should be noted thatin the laser-assisted group the capsulotomy was always complete[22]. Specific techniques during LACS can reduce the frequency of complicationsduring the learning period, as described by Arbisser et al. in their "dimple-down" technique, where the anterior chamber is filledwith viscoelastic and the centre of the capsule is pressed down with the cannula, allowing the surgeon to identify an incomplete capsulotomy or lack of treatment[23]. Mastropasqua et al. did an electron microscopic analysis and found that manual CCC and LACS capsulotomies performed at low energy levels have smoother, more uniform borders. They also found a direct correlation between increased energy levels and border irregularities, as well as an inverse correlation with border thickness, which could increase the likelihood of discontinuities in the anterior capsule[24]. In 2013 Ostovic et al. made the same findings, as did Abell et al. [22].

In our study, there were no statistically-significant differences between groups in terms of age or cataract severity, thus enabling comparisons and a correlation with cataract density, similar to other studies[16].

There was no statistically-significant difference between groupswith regard to spherical equivalent, although the LACS group showed less variable results.

These results demonstrate that a capsulorhexis performed by an experienced surgeon with correct parameters and appropriate settings using digital-image guidance can produce results similar to femtosecond laser.

Statistically-significant differences were found between groups for circularity and capsulotomy area, with the LACS group showing more precision. Tackman et al. found no statistically-significant differencesin these parameters[7], but they also state that on many occasions the anterior capsule was removed in pieces in the manual CCC group. These patients were therefore excluded from the study, which meant that only the best cases were included, thus creating a bias. Reddy et al. showed statistically-significant differences between the manual procedure and femtosecond laser, with more precise size, shape and positioning of the capsulotomy[26]in the laser group. In their study, however, four different surgeons performed the procedures at random, thus creating a bias, and the study used a different laser platform.

Taking into account the degree of precision provided by a femtosecond laser, these results indicate that both a high surgical skill level and alternative technological assistance or even precision tools are necessary in order to achieve the same results as laser-assisted procedures. A study by Friedman et al. in 2011 reports that, when compared to the manual technique with no assistance, the laser-assisted method provides a capsulotomy which is 12 times more precise insize and 3 times more accurate inshape, as well as twice as resistant[8]. These results are similar to Auffarth et al.,who compared capsular resistance after manual CCC and femtosecond laser capsulotomy on pig eyes[27]. One of the reasons for the lower resistance in the manual method could be linked to the imperfect circular shape, which creates zones of higher and lower stress. Kranitz et al.compared the same parameters and found statistically-significant differences in favour of laser-assisted capsulotomy[28].

Intumescent cataract shows increased internal capsule pressure, increased lens thickness and a shallow anterior chamber, as well as a frail capsule and low red reflex. It is also prone to sudden discontinuous capsulorhexis which may extend to the periphery due to the high intra-capsular pressure and also a leakage of liquefied cortical material. The effectiveness of LACS to perform capsulorhexis in these cases is debatable. Our study did not analyse cases of red, intumescent, or subluxated cataract. Further investigation is required to measure the frequency of complications in special cases[29-31].

Cataract patients tend to show high levels of anxiety during the pre- and postoperative periods, as well as during the procedure. The emotional state of the patient is influenced by various economic, psychological and sociocultural factors, such as individual beliefs and perceptions, as well as fear, lack of confidence, and insecurity.Both the lack of information about the surgical procedure and expectations about the results may explain the anxiety and fear. Studies should be carried out to assess the emotional state of patients faced with new technologies which increase the cost and time of surgery, provide improved reproducibility and precision in the architecture of the capsulotomy and corneal incisions and, above all, significantly reduce the ultrasound energy used during phacoemulsification to remove the cataract[32,33].

In conclusion, femtosecond laser-assisted cataract surgery produces a capsulorhexis of better shape and circularity than the manual digital-image-guided procedure. Both methods managed to successfully predict the postoperative refraction.

Further studies are required to confirm the real impact of the greater precision provided by the femtosecond laser-assisted procedure and to determine whether its benefitswarrant its increased cost. However, the demand for better results pushes surgeons to look to perfect their surgical skills, which in turn increases the effectiveness of the procedure.

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