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ORIGINAL ARTICLE

Results, experience and technical points learnt with use of the SKy Bone Expander kyphoplasty system for osteoporotic vertebral compression fractures: a prospective study of 40 patients with a minimum of 12 months of follow-up

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Abstract To describe our centre's results, experience and technical points learnt with the SKy Bone Expander System for osteoporotic vertebral compression fractures (VCFs). Forty consecutive patients with painful single level T12 or L1 osteoporotic VCF who had failed conservative management for more than 3 months had 40 single level SKy Bone Expander kyphoplasties performed. Using local anaesthesia with patients in a prone, hyper-lordotic position, a unilateral, percutaneous, intra-pedicular approach was employed. Once correctly positioned, the SKy Bone Expander was expanded, creating a void. It was subsequently contracted, removed and bone cement injected. Pre-kyphoplasty and 12-month post-kyphoplasty radiological and functional outcomes were recorded. Statistical analysis was by Wilcoxon Signed Ranks Test. Median percentage increase in anterior, middle and posterior vertebral body heights at 12-month post-operative was 51.25% [inter-quartile range (IQR) 17.21–93.22], 52.29% (IQR 26.50–126.17) and 9.84% (IQR 4.94–19.26) respectively, while median percentage decrease in kyphotic angle was 30.77% (IQR 17.06–46.61). There was no significant vertebral body correction loss at 12-month post-operative. Visual analogue score, North American Spine Society and Short Form-36 scores for physical functioning and bodily pain scores improved by medians of 5.0 (IQR 3.0–8.0), 1.45 (IQR 0.68–2.90), 20.5 (IQR 0.0–40.8) and 10.0 (IQR 0.0–20.0) respectively. All *P*-values were <0.001. There were eight adjacent/remote level VCFs, three cases of cement extravasation and one case of the SKy Bone Expander being unable to be contracted and withdrawn from the vertebral body. It was left in situ. This is the first reported incidence of such a complication. The SKy Bone Expander System appears to be a viable alternative to balloon tamp kyphoplasty. Important technical considerations include proper device positioning within the vertebral body before expansion, single use of devices, familiarity with salvage procedure and injection of bone cement under close image intensifier guidance to prevent cement extravasation.

Keywords Kyphoplasty · SKy Bone Expander · Vertebral compression fracture · Osteoporosis

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Introduction

The patient with a painful osteoporotic vertebral compression fracture (VCF) is a common clinical presentation. Most patients with osteoporotic VCFs respond to conservative management with analgesia and rehabilitative physiotherapy. Some patients, however, remain unresponsive to conservative therapy. These patients have persistently painful osteoporotic VCFs which limit functional activities [5], impair quality of life [4] and increase healthcare costs [3].

Vertebroplasty and subsequently kyphoplasty have since been developed to provide patients with faster pain relief and expedite their return to function [8]. Vertebroplasty

involves the injection of poly-methyl-methacrylate (PMMA) bone cement into the vertebral body, usually via a percutaneous technique. Kyphoplasty is a development over vertebroplasty in that a void is first created within the vertebral body by mechanical means with either a balloon or other expandable device. PMMA bone cement is then injected into this void as per vertebroplasty. Kyphoplasty has the proposed advantages over vertebroplasty of being able to correct for sagittal alignment of the spine, as well as decrease the risk of cement extravasation [18].

A number of kyphoplasty systems are now commercially available. The balloon tamp kyphoplasty system, as characterized by the KyphX system (Kyphon Inc., Sunnyvale, CA, USA), is popular and has reports of good results [7]. Another available system is the SKy Bone Expander System (Disc-O-Tech Medical Technologies Ltd, Herzeliya, Israel). This kyphoplasty system is based on an expandable polymer device. Proposed advantages of the Sky Bone Expander System over the balloon tamp kyphoplasty include no likelihood of balloon rupture, as well as better directional control during device expansion.

The aim of this paper is to describe our centre's results and experience with the Sky Bone Expander System for osteoporotic VCFs, as well as to discuss any technical points learnt with the use of the SKy Bone Expander System.

Materials and methods

This clinical study was performed at a tertiary referral centre with a spinal surgery division serving a catchment population of more than 5 million persons and receiving more than 1,000 new cases of osteoporotic VCFs a year. From May 2004 to October 2005, 40 consecutive patients with single level osteoporotic AO Classification A1.2 and A1.3 VCFs at either T12 or L1 who have failed at least 3 months of conservative therapy with analgesia and rehabilitative physiotherapy were recruited into this prospective clinical trial. We defined failure of conservative therapy arbitrarily as a visual analogue score (VAS) for back pain of more than 5 with continued analgesia requirements at 3 months post-VCF. Exclusion criteria included patients with a history of malignancy or neurological deficit post-VCF. Patients who were unable to tolerate or assume a prone position for the kyphoplasty procedure were also excluded (for example patients with severe or poorly controlled chronic obstructive lung disease and congestive heart failure). The VCFs were confirmed radiologically with the aid of plain X-rays, as well as by magnetic resonance imaging. The vertebral levels T12 and L1 were chosen as they are the two most frequently involved vertebral levels for osteoporotic VCFs. In addition, the biomechanics acting at T12 and L1 (the thoracolumbar spine) are similar and provide for a more equitable comparison as opposed to including VCFs from all vertebral levels. As per the manufacturer's recommendations, only type A1.2 and A1.3 VCFs were included in this study. The study protocol was approved by our hospital's Ethics Committee. Informed consent was obtained from each patient and medical confidentiality was assured by the non-disclosure of any of the patients' identities or personal particulars.

Each patient was assessed pre-operatively for fitness for surgery by a senior anesthetist. All surgeries were performed by the four senior authors, each of whom had performed at least ten SKy Bone Expander System prior to commencement of this clinical trial to familiarize themselves with the SKy Bone Expander kyphoplasty system's surgical instrumentation and technique.

Antibiotics prophylaxis (1 g of intravenous Cefazolin) was administered half an hour before commencement of surgery. This was administered provided there were no contra-indications. Should the patient be allergic to Cefazolin, 1 g of intravenous Vancomycin was administered instead. This antibiotics prophylaxis was continued for 24-h post-operative.

The manufacturer's recommended surgical technique was followed. All surgeries were performed under local anaesthesia with lignocaine and marcaine infiltration, as well as light sedation with propofol administered by an anaesthetist. The patients were placed in a prone, hyperlordotic position with pillows placed under their chest and pelvis to facilitate postural correction/reduction of their VCF. A cannula was inserted into the collapsed vertebral body via a percutaneous, unilateral, intra-pedicular approach under image intensifier guidance. Once the cannula was correctly positioned, the Sky Bone Expander System was introduced into the vertebral body in its contracted device configuration. The SKy Bone Expander System was then gradually expanded to its pre-determined height of 14 mm and length of 17 mm, creating a void of 2.6 cm^3. The size of the SKy Bone Expander System used in this clinical trial was standardized to the 14 mm height version. With the optimal vertebral height and void achieved, the SKy Bone Expander System was then contracted and removed. Mendec Spine Bone Cement (Tecres S.p.A., Verona, Italy) was subsequently injected into the created void and allowed to set. Please refer to Fig. 1.

Post-operative pain relief consisted of oral analgesia with 1 g of Paracetamol 6 hourly, 75 mg of Voltaren SR 12 hourly and 20 mg of Omeprazole 12 hourly. Should the patient be allergic to these medications, 50 mg of Tramadol 8 hourly was served instead. Each patient underwent a standardized post-operative physiotherapy program. This

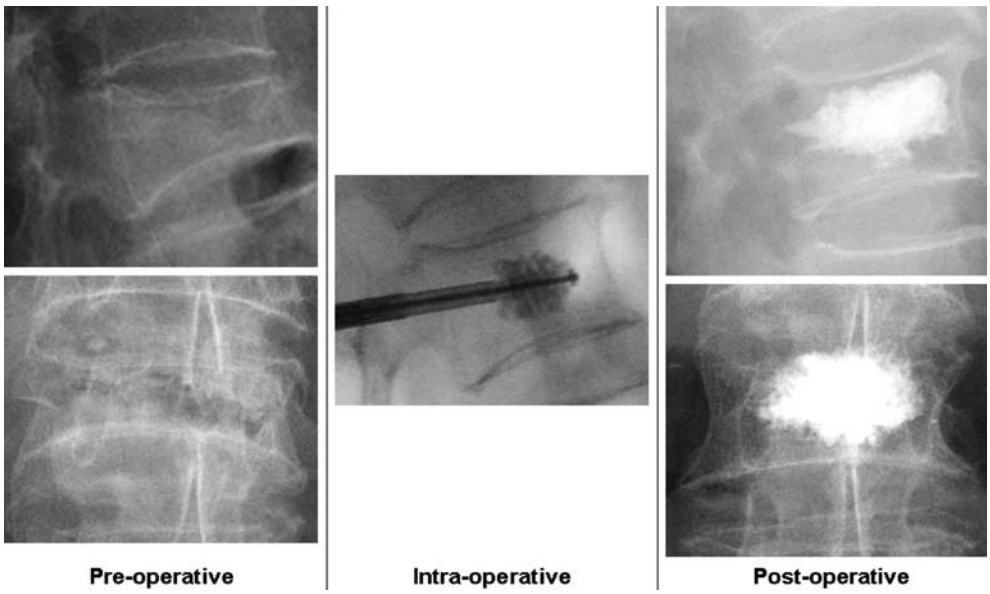

Fig. 1 Images of a L1 kyphoplasty using the SKy Bone Expander System

involved back strengthening exercises and ambulatory physiotherapy as soon as possible.

Standardized series of standing antero-posterior and lateral plain X-rays of the spine were performed pre-operatively, on the first post-operative day and at 12 months post-operatively. All radiographs were performed at the same radiology centre. Radiological data was collected separately and independently by two research assistants. The following radiological data was collected [21]:

1. Anterior vertebral body height on lateral X-ray view
2. Middle vertebral body height on lateral X-ray view
3. Posterior vertebral body height on lateral X-ray view
4. Kyphotic angle (with respect to the superior end-plate of vertebra above and inferior end-plate of the vertebra below) on lateral X-ray view
5. Ipsilateral (with respect to the cannulated pedicle) vertebral body height on antero-posterior X-ray view
6. Contralateral (with respect to the cannulated pedicle) vertebral body height on antero-posterior X-ray view

Pre-operative and 12-month post-operative functional score data were also collected. These included:

1. Visual Analogue Score (VAS)
2. North American Spine Society (NASS)
3. Short Form-36 Item for Bodily Pain (SF-36 BP)
4. Short Form-36 Item for Physical Functioning (SF-36 PF)

In addition, all patients had their 12-month post-operative lateral X-rays screened for new adjacent and remote level osteoporotic VCF (defined as loss of anterior vertebral body height of >25%) [1]. Any post-operative complications or adverse effects, especially device related, were documented.

A statistician independent of the surgical and research team analyzed the data using SPSS Version 13.0 for Windows (SPSS Inc, Chicago, IL, USA). Wilcoxon Signed Ranks Test was performed as appropriate.

Results

All 40 patients approached consented to participate in this clinical study. The average patient age was 72 years with an age range of 52–91 years. Mean patient height and weight were 152.72 cm (SD 11.55 cm) and 58.20 kg (SD 10.80 kg), respectively. The sex ratio was 10 males:30 females. Mean length of follow-up was 19.4 months (SD 5.3 months). There was no loss to follow-up.

There were an equal number of T12 and L1 VCFs in this study. Using the AO classification for vertebral fractures, there were 15 type A1.2 and 5 type A1.3 T12 VCFs. Among the L1 VCFs, 12 were type A1.2 and 8 were type A1.3.

The median percentage increase in anterior, middle and posterior vertebral body heights on lateral X-ray view at 12-month post-kyphoplasty compared to pre-kyphoplasty was 51.25% [inter-quartile range (IQR) 17.21–93.22], 52.29% (IQR 26.50–126.17) and 9.84% (IQR 4.94–19.26), respectively. When comparison was made between 12-month post-kyphoplasty and estimated pre-fracture vertebral body height instead, the median percentage increase in anterior, middle and posterior vertebral body heights was 23.16% (IQR 11.93–36.52), 28.73% (IQR 16.31–45.74) and 8.85% (IQR 4.94–16.37), respectively.

The estimated pre-fracture vertebral body height was calculated by taking the average height of the vertebral bodies immediately cephalad and caudad to the fractured vertebra level. Please refer to Table 1.

The median percentage increase in ipsilateral and contralateral vertebral body height on antero-posterior X-ray view (with respect to the cannulated pedicle) at 12-month post-kyphoplasty compared to pre-kyphoplasty was 42.03% (IQR 15.98–69.98) and 37.60% (IQR 12.79–61.53), respectively. There was a statistically insignificant difference of 4.43% between the median percentage height increases of the ipsilateral and contralateral sides ($P = 0.171$). Please refer to Table 2.

The median percentage decrease in kyphotic angle at 12-month post-kyphoplasty compared to pre-kyphoplasty was 30.77% (IQR 17.06–46.61). Please refer to Table 3.

A comparison was made between 12-month post-kyphoplasty and first day post-kyphoplasty radiological measurements. There was no significant radiological evidence of loss of vertebral body correction at 12-month post-operative. All radiological measurement P values were <0.0005. Please refer to Tables 1, 2 and 3.

Visual analogue score, NASS and SF-36 scores for physical functioning and bodily pain scores improved by medians of 5.0 (IQR 3.0–8.0), 1.45 (IQR 0.68–2.90), 20.5 (IQR 0.0–40.8) and 10.0 (IQR 0.0–20.0), respectively. All functional score measurement P-values were <0.001. Please refer to Table 4.

Six patients developed eight adjacent and remote level VCFs. Five patients had a single adjacent level VCF. Among these five patients, the single adjacent level VCF was immediately caudad in four and cephalad in one of them, respectively. The last/sixth patient had one adjacent and two remote level VCFs (the adjacent level VCF was caudad, while the remote level VCFs were both cephalad to the previously fractured vertebral level). Of the six patients with adjacent and remote level VCFs, three of them were asymptomatic. These were all caudad, single, adjacent level VCFs. In the remaining three symptomatic patients, one of them (a caudad, single, adjacent level VCF) elected to undergo a second kyphoplasty procedure, while the other two chose conservative management with analgesia and rehabilitative physiotherapy. None of these patients had any associated cement extravasation into the adjacent intervertebral disc spaces.

Cement extravasation occurred in three patients. Cement extravasated into and was limited to the superior intervertebral disc space in two of the patients. In the third patient, cement had extravasated into the anterior vertebral veins. There was, however, no cement or pulmonary embolism.

Implant failure was experienced with one patient. In this particular case, the SKy Bone Expander System could not be contracted and withdrawn from the vertebral body. Its expanded distal polymer end had to be disengaged and was left in situ surrounded by bone cement within the vertebral body. Fortunately the patient did not experience any adverse effects.

There were no cases of post-operative infection or cement embolism. No other adverse events, complications or morbidities were documented.

Discussion

Literature has been published supporting the efficacy of kyphoplasty, frequently over that of vertebroplasty, in providing immediate pain relief, partial restoration of the collapsed vertebral body's height and correction of the sagittal spinal deformity, as well as reduction in the risk of cement extravasation [12, 19, 21]. However, the majority of the

Table 1 Anterior, middle and posterior vertebral body heights on lateral X-ray

Median vertebral body height on lateral X-ray	Pre-kyphoplasty (mm)	First post-kyphoplasty day (mm)	12-month post-kyphoplasty (mm)	Percentage increase over pre-kyphoplasty vertebral body height (%)	Percentage increase over estimated pre-fracture vertebral body height (%)
Anterior	13.5	21.1	20.8	51.25	23.16
IQR	9.8–18.7	16.8–24.2	16.5–23.5	17.21–93.22	11.93–36.52
Min/max	7.8/20.2	12.2/30.2	12.1/29.9	14.66/230.21	8.29/66.94
Middle	11.6	18.2	18.1	52.29	28.73
IQR	7.7–14.4	15.5–21.3	15.4–20.8	26.50–126.17	16.31–45.74
Min/max	6.9/20.1	12.0/28.9	12.0/28.7	22.90/300.91	11.62/68.86
Posterior	25.6	28.2	28.1	9.84	8.85
IQR	22.4–28.6	26.2–31.1	26.1–31.1	4.94–19.26	4.94–16.37
Min/max	20.2/33.9	24.1/36.5	24.1/36.5	2.52/53.88	1.42/23.44

IQR inter-quartile range, *Min/max* minimum/maximum values

All vertebral body height increases were statistically significant ($P < 0.001$)

Table 2 Ipsilateral and contralateral vertebral body heights with respect to the cannulated pedicle on antero-posterior X-ray

Median vertebral body height on antero-posterior X-ray with respect to the cannulated pedicle	Pre-kyphoplasty (mm)	First post-kyphoplasty day (mm)	12-month post-kyphoplasty (mm)	Percentage increase (%)
Ipsilateral	13.5	20.1	19.9	42.03
IQR	9.8–18.8	16.9–23.1	16.8–23.0	15.98–69.89
Min/max	9.0/21.2	16.1/25.9	16.1/25.7	12.32/79.64
Contralateral	13.4	18.8	18.7	37.61
IQR	10.1–18.4	15.3–22.8	15.3–22.7	12.75–64.88
Min/max	8.9/21.4	14.9/24.7	14.8/24.3	10.54/70.25

IQR inter-quartile range, *Min/max* minimum/maximum values

No statistical difference between the ipsilateral and contralateral vertebral body heights on antero-posterior X-ray ($P = 0.171$)

Table 3 Kyphotic angle on lateral X-ray

Median kyphotic angle on lateral X-ray	Pre-kyphoplasty (°)	First post-kyphoplasty day (°)	12-month post-kyphoplasty (°)	Percentage decrease (%)
	18.4	10.9	11.0	30.77
IQR	12.6–23.6	7.1–17.4	7.1–17.5	17.06–46.61
Min/max	9.8/36.4	1.6/19.4	1.6/19.8	8.69/85.43

IQR inter-quartile range, *Min/max* minimum/maximum values

Wedge angle decrease was statistically significant ($P < 0.001$)

Table 4 Visual Analogue Score (VAS), North American Spine Society (NASS), Short Form-36 Bodily Pain (SF-36 BP) and Short Form-36 Physical Functioning (SF-36 PF) scores

Functional scores	Pre-kyphoplasty	12-month post-kyphoplasty	Functional score improvements
Visual Analogue Score (VAS)	8.0	1.0	5.0
IQR	5.0–9.8	0.0–4.0	3.0 – 7.9
North American Spine Society (NASS)	4.55	2.15	1.45
IQR	3.33–5.08	1.70–3.65	0.68 – 2.90
Short Form-36 Bodily Pain (SF-36 BP)	22.0	50.5	20.5
IQR	12.0–38.8	31.0–74.0	0.0–40.8
Short Form-36 Physical Functioning (SF-36 PF)	5.5	27.5	10.0
IQR	0.0–35.0	10.0–68.7	0.0–20.0

IQR inter-quartile range

All functional score improvements were statistically significant ($P < 0.01$)

published literature on kyphoplasty has been with respect to balloon tamp kyphoplasty. A PubMed search only revealed two papers describing the use of the SKy Bone Expander System, and both of these papers originated from the same institution [11, 22]. The aim of this paper is to help address this deficiency in published data on the outcomes, experience and safety profile of using the SKy Bone Expander System.

In our study, the SKy Bone Expander System gives relatively good radiological and functional results. At 12-month post-kyphoplasty, all radiological measurements of vertebral body height were increased, especially that of the anterior and middle vertebral body height which had median percentage height increases of 51.25 and 52.29%, respectively. Sagittal spinal deformity was partially corrected with median kyphotic angle improvement of 30.77%. There was no significant radiological evidence of loss of vertebral body correction when the 12-month post-kyphoplasty X-rays were compared with the first day post-kyphoplasty X-rays. All pain and functional scores also showed better results post-kyphoplasty. These results were all statistically significant and comparable with published balloon tamp kyphoplasty results [14, 16].

Although data has been published describing no difference in results (vertebral body strength, stiffness and height) between uni-pedicular and bi-pedicular kyphoplasties [20], concerns and controversy still abound as to which surgical approach is optimal. All things being equal, a uni-pedicular kyphoplasty would be more advantageous as operating time, risk and cost would be reduced. We measured the ipsilateral and contralateral vertebral body heights (with respect to the cannulated pedicle) in the antero-posterior plain X-ray view in order to determine if a unilateral, intra-pedicular kyphoplasty approach as employed in this study gives satisfactory results. Our results revealed a statistically insignificant difference of 4.42% between the median percentage height increases of the ipsilateral and contralateral sides ($P = 0.171$). To achieve a symmetrical increase in vertebral body height, we draw attention to the technical importance of using a medial cannula trajectory to ensure a precise device position in the mid-line or middle third of the vertebral body [10, 23]. This is the optimal position for device expansion. For accuracy, this final implant position must be confirmed on both antero-posterior as well as lateral views.

Studies have documented a higher rate of adjacent and remote level VCFs post-kyphoplasty, compared to the natural history data for untreated VCFs [6]. The incidence of adjacent and remote VCFs 1 year post-kyphoplasty in our study was 20% (8/40). This result is similar to that of reported rates in the literature [9, 17]. A total of 75% (6/8) of these new VCFs were adjacent level and 83.3% (5/6) of them were in turn caudad to the previously fractured vertebral body. This may according to micro-structural finite element analysis be due to the substantially altered bone stress distributions in both treated and adjacent vertebral segments, especially at the superior vertebral body endplates [13]. Lin et al. [15] observed in their series that 58% of the vertebral bodies adjacent to an inter-vertebral disc with cement leakage fractured during the follow-up period, compared to 12% of vertebral bodied adjacent to inter-vertebral disc without cement leakage. They concluded that cement leakage into the inter-vertebral disc increases the risks of a new fracture at adjacent vertebral bodies. This observation was, however, not duplicated in our study.

Kyphoplasty has the proposed advantage over vertebroplasty of reducing the risk of cement extravasation [21]. Our 7.5% incidence of cement extravasation is comparable to the reported incidence of 9% for kyphoplasties in a systemic review of 69 clinical studies by Hulme et al. [12] and 7% by Bouza et al. who had reviewed 26 clinical studies on kyphoplasty [2]. A technical point of note specific to the SKy Bone Expander System is that unlike the balloon tamp kyphoplasty system which allows the surgeon to read off the volume of the balloon (and hence the void created) as the balloon is expanded, the SKy Bone Expander System has no such readable graduated measurements. This makes it difficult to estimate the amount of bone cement to be injected into the vertebral body after the device is removed, especially when the SKy Bone Expander System was not fully expanded to its pre-determined fully expanded volume of 2.6 mm^3 (for the 14 mm height version). As such we recommend that the surgeon be guided by continuous or at least sequential image intensifier during the bone cement injection phase of the procedure.

We had one episode of implant failure with the SKy Bone Expander System. To our knowledge, this is the first reported incidence of the SKy Bone Expander System being unable to be contracted and withdrawn from the vertebral body. Three technical points were learnt from this experience. The first technical point is that the SKy Bone Expander System has to be accurately positioned in the midline or middle third of the vertebral body before it is expanded. Specifically, it is very important that the expandable portion of the Sky Bone Expander System be centrally and completely within the vertebral body before expansion, least there be pedicle or cortical wall fracture with possible attendant SKy Bone Expander System damage. The manufacturer's recommendations of at least 5 mm from the posterior wall and 3 mm from the anterior wall should be closely adhered to. The second technical point is that if the SKy Bone Expander System has already been expanded and re-positioning of the device is required, then the device needs to be fully contracted, removed and a completely new SKy Bone Expander System used. Re-use of the SKy Bone Expander System is not recommended. The third technical point is that surgeons using the SKy Bone Expander System need to be familiar with the salvage mechanism and procedure. A specially designed salvage driver is available which is attached to a bolt on the proximal end of the SKy Bone Expander System, next to the T-shaped handle. This bolt is then rotated anti-clockwise for ten full turns, manually contracting the SKy Bone Expander and allowing it to be gently withdrawn from the vertebral body.

Conclusions

In conclusion, the SKy Bone Expander System appears to be a viable alternative to the more widely used balloon tamp kyphoplasty system, as long as a number of technical considerations are followed. These include accurate and proper positioning of the device within the vertebral body before device expansion, single use of devices if re-positioning is necessary, familiarity with the salvage procedure and injection of bone cement under close image intensifier guidance to prevent cement extravasation.

The above study complies with the current laws of the country in which it was performed, inclusive of ethics

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