Original Article

Effect of Annular Defects on Intradiscal Pressures in the Lumbar Spine: An in Vitro Biomechanical Study of Diskectomy and Annular Repair

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Abstract

Background Integrity of intervertebral disks may influence, and be influenced by, the maintenance of hydrostatic pressures inside the nucleus pulposus. Disk degeneration causes decreased pressures, leading to overload and injury of the annulus fibrosus, increasing the risk of disk herniation. Diskectomies to treat disk herniation can cause further loss of hydrostatic pressures resulting in worsening degeneration. This study investigated the impact of opening the annulus on intradiscal pressure and whether implantation of an annular closure device (ACD) can restore physiologic pressures.

Methods The pressure responses under unconstrained moments in concert with axial compressive loads of nine human cadaver lumbar disks were biomechanically tested at baseline, immediately following posterior annulotomy, and immediately following implantation of the ACD.

Results The analysis of variance indicated a significant difference in the pressure response ($p = 0.0001$) among the three rounds of testing. Specifically, the post hoc Bonferroni test revealed that the pressure response after diskectomy was significantly different when compared with baseline ($p < 0.001$) and after ACD implantation ($p = 0.001$). However, baseline and ACD pressure responses were insignificantly different ($p = 1.000$).

Conclusion Our findings suggest that restoration of annular integrity during diskectomy with implantation of the tested ACD may restore pressures closer to preoperative levels. Whether or not restoring pressures to preoperative levels has any clinical benefit or effect on the rate of degeneration is an area for further clinical research.

Keywords
- annulus closure device
- biomechanics
- disk degeneration
- intradiscal pressure
- lumbar diskectomy

Introduction

The health of the intervertebral disk (IVD) depends on many factors, with hydrostatic pressure inside the nucleus one of the most crucial. Intradiscal pressure has been cited as an important parameter for evaluating IVD function and estimating internal stresses.[1] Normal physiologic pressures help regulate many key cellular processes such as anabolic gene and matrix-turnover enzyme regulation.[1–6] Healthy disks contain a highly hydrated nucleus that serves as a hydraulic cushion to distribute stress evenly between vertebrae and the surrounding annulus.[5] Reduced intradiscal pressures, in contrast, have been shown to cause peaks of compressive stress in the annulus fibrosus.[1,5,7–10] These high-stress gradients within the annulus, especially in the posterolateral region, cause an overload phenomenon manifested by a separation of the inner and outer lamellae of the annulus, with the inner lamellae migrating inward toward the nucleus and the outer

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lamellae buckling outward.[5] This annular fissuring can ultimately lead to further loss of pressure, injury, and progressive disk degeneration.[7,10,11]

Lumbar disk herniation, along with diskectomy as a treatment option, has been shown to accelerate the degenerative process in the lumbar spine.[12,13] Although such degeneration has multiple causes, it has been shown that pressures at the index level and at adjacent levels are drastically altered after diskectomy,[14,15] and animal studies have shown that annular defects commonly used in surgical diskectomy result in significantly reduced intradiscal pressure compared with intact disks even after 6 weeks of healing, implying an inability of the body's healing response to close the annular defect effectively.[16] These alterations of pressure distribution may affect the progression of degeneration after diskectomy.

Annular closure devices (ACDs) were developed to reduce reherniation risk in patients requiring diskectomy and have been evaluated in preliminary clinical studies. Early data suggest that such devices may reduce reherniation risk[17] and offer other benefits such as less facet degeneration.[18] Due to the integral role that the annulus plays in maintaining pressure and in the degeneration process, restoring the integrity of the annulus after diskectomy may be a mechanism for these observed clinical benefits. In this study we sought to investigate our hypotheses that (1) annulotomy (as part of a diskectomy) reduces intradiscal pressure under moderate to extreme loading, and (2) prosthetic annular closure can restore such pressure to the normal or intact state under similar loading.

Materials and Methods

Information on the Samples

All specimens came from tissue banks. The specimens used in the study came from two sources: Southeast Tissue Alliance, now renamed Regenerative Biologics Inc. (http://www.donorcare.org/), and Science Care (http://www.sciencecare.com/). Both tissue banks are based in the United States.

Fresh-frozen human lumbar cadaver functional spinal units were used for testing. Specimens were stored at − 20°C until the day before use, then thawed overnight (< 24 hours) at room temperature. Prior to biomechanical testing, all paravertebral muscles were removed, taking care not to damage any bony or ligamentous structures. The disks above and below the target level were then cut and the soft tissue removed down to the exposed cartilaginous end plates, leaving a functional spinal unit (FSU) consisting of two complete vertebrae and the intervening disk, along with all elements and ligamentous structures.

Computed tomography (CT) scans were available for each specimen, allowing for grading of degeneration adapted from Wilke et al.[19]

Roughly two thirds of each vertebral body was fixed in quick-hardening plastic to allow for insertion into a custom biomechanical test apparatus. This apparatus applied unconstrained moments in concert with axial compressive loads. The inferior pot of the FSU was held fixed in the test frame. A test fixture, consisting of pulley wheels, was attached to the superior pot. The pulley wheels were connected via cables to four air pistons (Airpel Model 32D-100, Airpot Corp., Norwalk, Connecticut, United States), two on each side, one anterior and one posterior. During testing, each piston was contracted simultaneously to apply compressive forces to the FSU in a sinusoidal manner. LabVIEW software (National Instruments Corporation, Austin, Texas, United States) was used to apply voltage to the air-piston controller in a sinusoidal manner, and a load cell recorded the passive load underneath the specimen. The position of the pulley wheels relative to the center of the FSU was offset by 10 mm to generate an applied moment (►**Fig. 1**). Because no active feedback capability was part of the test frame, the magnitude of the applied moment was calculated using this offset.

Testing consisted of application of moderate to extreme loads and moments simulating worst case herniation conditions, specifically application of 2.7 kN of axial load simultaneous with 24 Nm of flexion and lateral bending away from the possible herniation site (i.e., about an axis that is perpendicular to a plane that passes roughly through the annular defect and the center of the disk). To characterize behavior under moderate to extreme loading, these values represent small safety factors above the loading calculated from in vivo measurements under moderate labor of 2.1 kN axial load[20] and 20 Nm applied moment.[21] This was the only load orientation tested. The choice of load orientation and magnitudes of applied load and moment were chosen to challenge the ACD appropriately. Pressure inside the disk was monitored throughout testing with a custom pressure transducer consisting of an 18G needle and a miniature pressure transducer (Precision Measurement Company Model 060S, Ann Arbor, Michigan, United States) with a measurement range of up to 6.9 MPa. The transducer was introduced from the anterior of the disk, and care was taken to place the transducer in the middle of the disk in both the anteroposterior and lateral views (►**Fig. 2**). A motion tracking system (Polhemus, Colchester, Vermont, United States) was used to capture angular displacements of the FSU, with one 6 degrees of freedom sensor placed on each of the two plastic fixtures in which each vertebral body was held (►**Fig. 3**).

Five cycles of load were applied at 0.15 Hz, with both the axial compressive load and the bending moment ramped

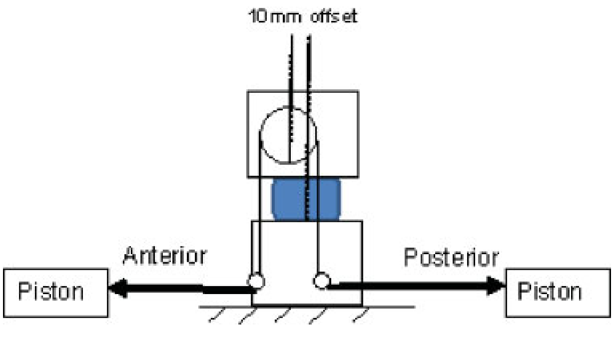

Fig. 1 Schematic of air-piston configuration to apply an axial load and flexion moment. The central pulley wheel is offset anteriorly from the center of the functional spine unit.

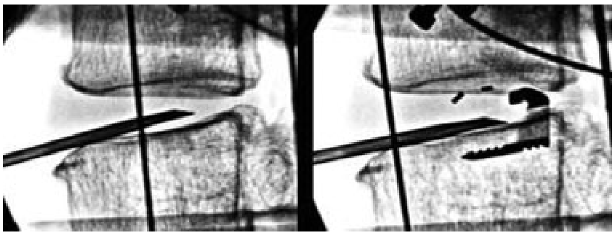

Fig. 2 A pressure transducer was placed intradiscally to monitor pressure as shown in the fluorograph taken during intact testing (left side) and after annular closure device implantation (right side).

sinusoidally in each cycle from zero (rest) to the maximum level and back to zero. To achieve greater repeatability, the first three cycles were considered preconditioning cycles.[22] The maximum pressure, change in pressure, and range of motion (ROM) was taken from the remaining two cycles. For each direction (i.e., flexion-extension, lateral bending, and torsion), ROM was defined as the difference in the maximum and minimum angular positions during the last two cycles of loading.

The same load application was performed for five cycles in each of three specimen states: First, with the specimen intact and second following performance of a posterior limited diskectomy (i.e., annulotomy intended to simulate a massive annular defect that might be found at surgery, without removal of the nucleus from within the disk space). In this step, a custom box-punch tool was used to create a rectangular 6 × 10 mm wide posterolateral box annulotomy, the largest defect size permitted by the instructions for use for the size of implant utilized in this study. Third, following repair of the annulotomy with an ACD, the annulotomy site was inspected visually before and after the testing in steps 2 and 3 to check for extrusion of nucleus, and any such extrusion was noted. Any extruded nuclear material was measured volumetrically through dry compression into a gradated syringe and then discarded. A total of nine FSUs were harvested from six fresh-frozen human cadaveric lumbar spines. ►**Table 1** shows the specimen characteristics.

Annular Closure Device

The ACD (Barricaid; Intrinsic Therapeutics, Inc.; Woburn, Massachusetts, United States; 10 mm size) that was used for closing the annular defect consists of a flexible nonabsorbable polymer (polyethylene terephthalate [also called polyester, PET, or Dacron]) mesh intended to occlude the annular defect, held in place by a titanium bone anchor inserted into either of the adjacent vertebral bodies (►**Fig. 2**). Implantation is done after annulotomy under fluoroscopic guidance.

Statistical Analysis

An analysis of variance (ANOVA) with repeated measures was performed to compare pressure and ROM after simulated diskectomy and after ACD implantation versus the baseline values of the intact disks. Based on the ANOVA results, a Bonferroni multiple comparison test was performed post hoc to identify which of the specific rounds of testing that were different in pressure and/or ROM. To investigate whether specimen characteristics were significantly correlated with pressure or ROM, the following statistical tests were used: regression analysis (age), unpaired *t* tests (gender), and Kruskal-Wallis tests (level and degeneration grade). To investigate whether specimen characteristics were significantly correlated with nuclear extrusion during the diskectomy

Fig. 3 Functional spinal units were plotted for testing in a custom load frame.

Table 1 Specimen characteristics, results of degeneration grading, raw range of motion values, and pressure testing

Specimen information					Baseline					Defect						Barricaid					
Spine	Level	Age, y	Gender	Degeneration grade	FE ROM, degrees	LB ROM, degrees	Tor ROM, degrees	Pressure, MPa	ΔPressure, MPa	FE ROM, degrees	LB ROM, degrees	Tor ROM, degrees)	Pressure, (MPa	ΔPressure, MPa	Extrusion? (if yes, cc)	FE ROM, degrees	LB ROM, degrees	Tor ROM, degrees	Pressure, MPa	ΔPressure, MPa	Extrusion? (if yes, cc)
1061	L2–L3	52	F	1	2.4	5.6	0.6	2.02	1.86	3.9	7.3	0.9	1.23	1.23	Yes, 0.2cc	3.9	7.7	1.3	1.75	1.67	No
1061	L4–L5	52	F	1	5.2	6.0	0.2	1.37	1.29	6.7	7.9	0.2	1.09	1.09	No	7.0	8.0	0.4	1.77	1.70	No
1042	L4–L5	56	M	1	11.7	8.0	0.5	1.26	1.21	12.3	8.9	0.5	0.78	0.72	No	11.4	9.2	0.7	1.52	1.32	No
794	L3–L4	52	M	1	2.4	8.7	0.7	1.78	1.70	1.6	6.2	1.1	1.47	1.37	Yes, 0.4 cc	2.1	6.6	0.9	1.77	1.53	No
1031	L3–L4	73	F	1	7.0	9.8	0.6	1.45	1.45	2.9	5.8	0.3	1.01	1.01	Yes, 0.6 cc	6.7	9.4	0.6	1.42	1.42	No
1400	L5–S1	54	F	1	8.6	8.3	1.0	2.23	1.80	3.7	3.6	0.7	0.76	0.76	Yes, 0.3 cc	4.8	5.7	0.6	1.50	1.02	No
1400	L3–L4	54	F	1	0.6	2.3	0.7	1.64	1.17	0.5	2.5	0.3	0.54	0.54	No	0.4	2.2	0.3	1.52	1.52	No
1406	L5–S1	53	F	1	10.4	5.6	0.5	1.53	0.98	6.2	4.9	0.3	1.39	0.93	No	5.1	4.8	0.5	1.91	1.51	No
1406	L3–L4	53	F	1	5.6	5.8	0.4	1.31	1.12	5.2	4.7	0.4	0.81	0.68	Yes, 0.3 cc	4.3	5.0	0.4	1.25	1.15	No

Abbreviations: F, female; FE, flexion-extension; LB, lateral bending; M, male; ROM, range of motion.

round of testing, the following statistical tests were used: Fisher exact test (gender, level, and degeneration grade) and unpaired *t* test (age). All analyses were performed using Intercooled Stata v.6.0 (Stata Corp., College Station, Texas, United States).

Results

Specimen Characteristics

All specimens were "grade 1," indicating mild degeneration, according to Wilke et al[19] with insignificant degrees of disk height loss, osteophyte formation, and sclerosis. Grading was performed by a single grader (R.B.) using CT scans instead of radiographs.

Post-diskectomy loading resulted in nuclear extrusions in five of nine specimens. The average volume of extruded material was 0.36 cc (range: 0.2–0.6 cc; 1 cc = 1 mL). After implantation of the ACD, loading resulted in no further extrusions.

Pressure

►**Table 1** shows the pressure measurements for each specimen in each state. Average intact intradiscal pressure was 1.62 MPa (range: 1.26–2.23; standard deviation [SD]: 0.33). After diskectomy, pressure dropped in all specimens with average pressure decreased significantly to 1.01 MPa (range: 0.54–1.47; SD: 0.31) under identical loading conditions. After implantation of the ACD, average intradiscal pressure increased in all specimens compared with the post-annulotomy state (range of increase: 17–60% of intact pressure), and was restored on average to 1.60 MPa (range: 1.25–1.91; SD: 0.21). ►**Fig. 4** shows a representative curve of intradiscal pressure in each state. ►**Fig. 5** is a box plot of intradiscal pressure in each state. Normalizing by intact values, the average intradiscal pressure after diskectomy and after ACD implantation was 63.7% (range: 33–91%) and 101.3% (range: 67–129%), respectively.

The ANOVA indicated a significant difference in the pressure response ($p = 0.0001$) among the three rounds of testing. Specifically, the post hoc Bonferroni test revealed that the pressure response after diskectomy was significantly different when compared with baseline ($p < 0.001$) and after ACD

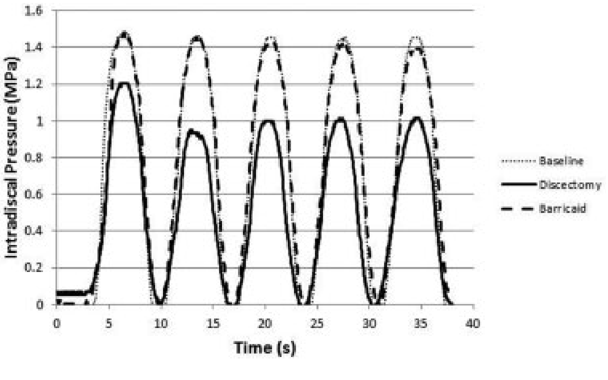

Fig. 4 Intradiscal pressure, representative curve (sample 1031 L3–L4).

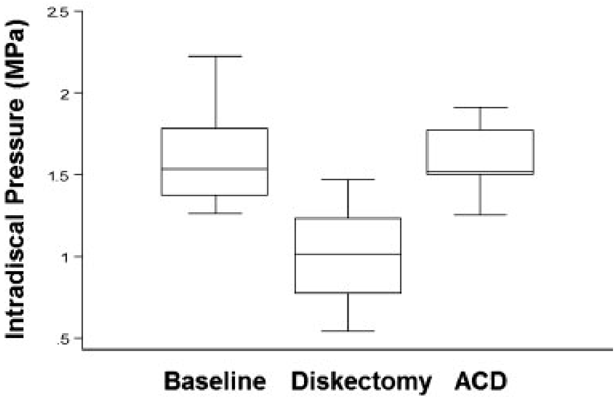

Fig. 5 Box plot of intradiscal pressure in each state.

implantation ($p = 0.001$). However, baseline and ACD pressure responses were insignificantly different ($p = 1.000$).

Range of Motion

Average normalized ROM in all directions (flexion-extension, lateral bending, and torsion) are shown in ►**Fig. 6**. No ROM differences in flexion-extension ($p = 0.2521$), lateral bending ($p = 0.2978$), or torsion ($p = 0.6386$) could be detected.

Specimen characteristics (age, gender, level, and degeneration grade) were not significantly correlated with any of the pressure or ROM data ($p > 0.14$). The specimen characteristics were also not correlated with occurrence of extrusion after diskectomy ($p > 0.49$). Peak pressure and peak ROM occurred simultaneous with peak load and moment application.

Discussion

Normal physiologic pressures promote optimal load sharing between the annulus, nucleus, and posterior column. Studies have indicated that diskectomies and annular defects can result in reduced intradiscal pressures that could adversely affect IVD health. In this biomechanical study, measurement of intradiscal pressure in nine cadaveric specimens intact, following annulotomy, and following prosthetic closure of the annular defect suggests that annulotomy reduces intradiscal pressure under moderate to extreme loading and that prosthetic annular closure can reverse this pressure loss. These results suggest that annular closure may be beneficial to IVD health by reversing to some degree the intradiscal pressure loss that can be harmful to segmental biomechanics.

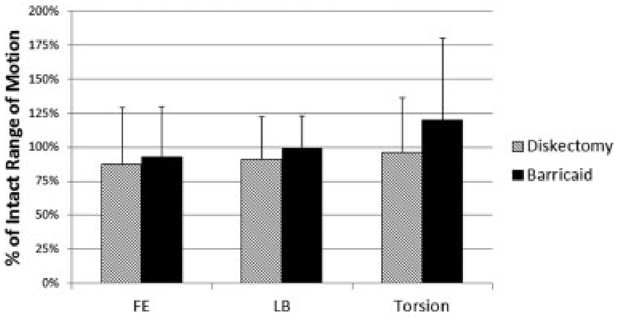

Fig. 6 Normalized ranges of motion in flexion-extension (FE), lateral bending (LB), and torsion.

Disk herniation and the diskectomy used to treat disk herniation can cause further degenerative changes in the lumbar motion segment, even in the long term.[12] McGirt et al[20] showed greater volumes of disk removal during diskectomy to be associated with more progressive disk height loss by 6 months after surgery. Barth et al[13] showed more aggressive diskectomies to be associated with greater loss of disk height and vertebral end-plate degeneration than less aggressive microscopic sequestrectomies. Use of an ACD may allow surgeons to safely retain more native nucleus, avoiding both disk height loss and recurrent herniation.

Mariconda et al[12] showed radiographic degenerative changes to be more frequent and severe in those patients receiving diskectomy 25 years prior than in patients treated conservatively. The pathophysiologic mechanism underlying these progressive degenerative changes after diskectomy is likely multifactorial, but further decrease of intradiscal pressure may be an integral cause.[8,15,16,21–23] For example, pressures within degenerative disks may drop to near zero after diskectomies in which little nuclear material is removed, in contrast to healthy disks that retain a substantial fraction of preoperative pressure after identical diskectomies.[22] In our study, nucleus pressure was lost after diskectomy even when a herniation did not occur, implying that the loss of integrity in the annulus leads directly to pressure loss, perhaps by allowing the nucleus to bulge into the annular defect under loading. The results of our laboratory investigation indicate that closing the annular defect at the time of diskectomy may restore, or come close to restoring, normal intradiscal pressure. Such restoration of a more normal pressure response may interrupt the degenerative cycle.

Steffen et al showed that reductions in nucleus hydrostatic pressures caused increased stresses in the annulus, resulting in decomposition of the lamellar structure and a fibrous substitution of the matrix of the annulus, followed by focal tears that spread radially outward.[11] Similarly, Adams et al[9] showed that disk degeneration reduced nucleus pressures by 30% while simultaneously increasing compressive stress peaks within the posterior annulus by 160%.[9] That study also showed that the decreased hydrostatic pressures of degenerative disks cause the outermost lamellae of the annulus to be forced outward and the inner lamellae forced inward toward the nucleus. This fissuring phenomenon ultimately weakened the annulus making the disk more prone to herniation.[8,11] Therefore strengthening, or prosthetic replacement, of the surgically weakened annulus could help restore the natural pressure balance in the disk and more appropriately transfer load to the annulus, slowing further degeneration.

Our findings suggest that implantation of the tested ACD may reverse to some degree the loss in pressure caused by diskectomy. Disks treated with the ACD retained an average 101.3% of preoperative pressure, after the diskectomy itself had reduced pressure to 63.7% of the preoperative level.

Moreover, it appears that ROM is not compromised by implantation of the ACD. Finally, five of nine specimens had extrusions of nuclear material after simulated diskectomy, prior to ACD implantation, and no extrusions were observed after ACD implantation. ACDs have been developed to prevent reherniations mechanically, particularly in the segment of the diskectomy population with massive annular defects who exhibit a reherniation rate as high as 27%.[24] Whether or not restoring intradiscal pressures to preoperative levels can provide any additional clinical benefit or effect on the rate of disk degeneration is an area for further clinical research.

Limitations of the Study

Although the results from our investigation suggest that implantation with an ACD during lumbar diskectomy may effectively restore pressures to preoperative levels, some shortcomings require mentioning. First, this study was conducted on cadavers, not live patients. Cadaver models cannot account for pressure changes that occur during muscle contraction[21] or physiologic functions like sitting, lying down, and standing.[25] It is unclear whether these differences would have any significant effect on pressure measurements.

A second limitation in this study is that disk degeneration was assessed by CT, not magnetic resonance imaging (MRI) or X-ray. MRI is potentially more sensitive and specific for diagnosing disk degeneration than CT, and it has been the imaging tool used to classify disk degeneration in many of the cited studies.[26,27]

Third, the annular defect size tested (6 × 10 mm) may not be typical of most defects in surgical reality, which may be smaller, but it is in the range of annular incisions in similar cadaveric testing models described elsewhere,[28,29] and larger defects have been associated with a higher risk of recurrent herniation and thus are more likely to be treated with an ACD.[23,27]

Fourth, to limit the length of the testing to avoid specimen degradation, we applied only a few cycles of loads and pressures representing moderate to extreme activities of daily living (sitting with maximum flexion, and lifting or holding loads up to 20 kg).[30] Our assumption is that the ACD will withstand "normal" pressures if it will not fail in extreme situations. Nevertheless to simulate the scope of daily activities a cyclic loading test would be desirable, as was reported by Wilke et al without pressure measurement.[31]

Fifth, the applied moment used in the testing could only be estimated due to a lack of active feedback in the test system. The use of self-matched specimens for each round of testing still permitted meaningful comparisons of pressure and ROM; however, the use of a more sophisticated test system would certainly be more robust. Another shortcoming was the small sample size used. Moreover, all of these disks had minimal degeneration at baseline (grade 1) making it difficult to apply these results to disks with more progressive degeneration. Another limitation was that the annular defect was not observed directly during loading, only after testing was stopped, and thus no conclusion can be drawn as to whether the nucleus may have been bulging into the annular defect during loading to explain any loss in pressure.

A final limitation is that we did not remove additional nuclear material from the disk, making it difficult to extrapolate results to patients undergoing more aggressive diskectomy. Similarly, the decision not to reinsert extruded nucleus into the disk prior to ACD implantation challenged the ability of the ACD to restore pressure, but it reduces the impact of the observation of no herniations following ACD implantation.

Conclusion

Our findings suggest that restoration of annular integrity during diskectomy with implantation of the tested ACD may restore pressures closer to preoperative levels. Whether or not restoring pressures to preoperative levels has any clinical benefit or effect on the rate of degeneration is an area for further clinical research.

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