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Treatment of discogenic back pain and sciatica in daily practice: report of 100 sequential cases of interventional spinal pain treatment with DISC-FX

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Introduction

Back pain due to internal disruption of the intervertebral disc may be common, with estimates between 26% and 42%.[1–3] In a series of consecutive cases referred specifically for further diagnostic assessment at two American specialist centres,[1] 39% were positive to provocation discography. Higher prevalence estimates of discogenic pain may therefore reflect a degree of selection in referral and may not reflect the prevalence of discogenic pain in more general practice. Discogenic pain may result from a variety of potentially overlapping pathologies affecting both the annulus and nucleus[4–11] and including increased stress in the posterior annulus.[12]

To date, attempts to treat discogenic pain by addressing the annulus with radiofrequency (RF) heat denervation by the intradiscal electrothermal annuloplasty (IDET)[13,14] or biacuplasty[13,15] techniques have yielded variable results. Percutaneous decompression of the nucleus by coblation nucleoplasty is now approved in the UK by the National Institute for Clinical and Healthcare Excellence (NICE) for the treatment of back pain and of sciatica due to contained disc protrusion. It has been evaluated as a stand-alone technology (single technology appraisal)[16] and as part of a comprehensive pathway of back pain management.[17] These approvals validate the concept of discogenic pain and the possibility of treatment at least by removal of small volumes of disc nucleus.[18] It may, however, be logical to target both annular and nuclear pain generators to obtain optimal results.

DISC-FX™ (Elliquence, NY) is a day case fluoroscopically controlled, three-step technique using a single 3 mm access cannula (see Figure 1). Step 1 allows disc nucleus decompression by mechanical nucleotomy employing fine pituitary graspers. Step 2 uses a specially designed steerable 'Trigger-Flex' RF catheter deploying a specialised waveform for RF ablation of the nucleus analogous to coblation but utilising higher frequency RF energy at 1.7 MHz (designated 'Turbo' mode). In the third step, the RF generator is adjusted to produce RF heating (designated 'Hemo' bipolar mode) and the Trigger-Flex catheter is then steered along the inner surface of the posterior annulus to denervate and modulate fissures.[19] It is also referred to as microtubular decompression and nucleotomy or mini-micro discectomy.[20]

This approach therefore aims to produce a definitive adjustment of pain-generating pathological disc tissue as a treatment principle for back pain. Favourable longer term outcomes have been reported with this technique, in up to 71 cases[20,21] in Europe and Asia.

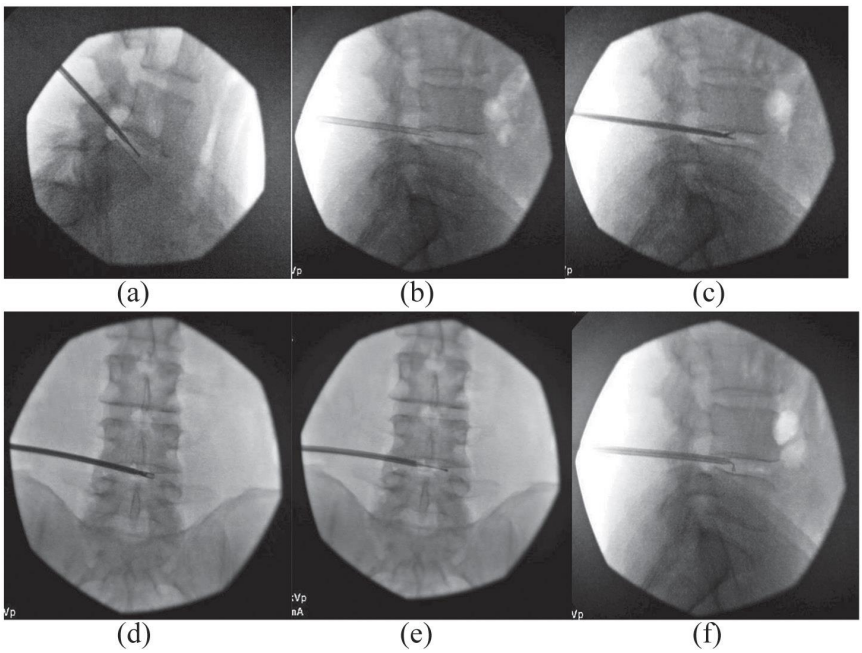
We report here the results of the diagnosis and treatment of discogenic pain by DISC-FX in 100 sequential, prospective cases of back pain and/or sciatica. Results reported here add to the available data on this treatment. These results may suggest that the treatment of spinal disc-related pain should be included in routine clinical interventional pathways.

Methods

Patient selection

Patients referred by general practitioner for spinal pain were seen by a single clinician (A.H.) at a small private clinic (Kings Hill Medical Centre, West Malling, Kent: KHMC) and then a

Figure 1. Steps in the DISC-FX treatment of L4/5. (a) Lateral view of introducer and guidewire in position across annulus into nucleus. (b) Lateral view of working channel in position to commence decompression (c) Lateral view of deployment of nucleotomy forceps. (d) PA view of nucleotomy forceps confirming central position in nucleus. (e) PA view of steerable 'Trigger-Flex' RF catheter deployed across central nucleus for ablation in 'Turbo' mode. (f) Lateral view of 'Trigger-Flex' catheter positioned across posterior annulus for heat denervation in 'Hemo' mode.



larger private hospital (KIMS Hospital, Maidstone, Kent). Approval for data collection was given by KHMC Medical Advisory Committee. Patients were both insured and self-funding; six National Health Service (NHS) cases were also included. Cases reported were treated between October 2011 and April 2017. The cases reported here are those who progressed to DISC-FX treatment under the progressive interventional pathway described below. Selection for DISC-FX treatment was informed but not restricted by recommended clinical and radiographic selection/exclusion criteria for DISC-FX, which include 50% retained disc height and moderate protrusion only. On this basis, the first 100 sequential cases in which DISC-FX was deployed are reported. These cases were drawn from a group of 114 patients. A further 14 patients who provided no or uninterpretable data were excluded. Data were collected in routine consultation and at the time of procedures. In consultation, patients completed pro forma result sheets prior to meeting with A.H. Data entry was independent of the clinician.

Treatment pathway

Treatment of peripheral pain generators

Potential discogenic pain generators were assessed clinically on the basis of history, examination, radiology and magnetic resonance imaging (MRI) scanning. Therefore, when necessary other possible pain generators were treated first, for example, peripheral multiple muscle trigger points and nerve root pain were treated by epidural or related injections, and medial branch pain and sacroiliac joint pain were treated by injection or RF denervation. Techniques were deployed according to Spine Intervention Society (SIS) technical standards,[13] and best evidence or clinical practice was followed.

Discography

Only where prior techniques failed to resolve the patient's pain syndrome and where history, physical signs and or imaging suggested that axial pain may have discal origin, as assessed by A.H., pain provocation discography to SIS standards was undertaken including manometric measurement using the

Arthrocare Disc Stimulation System in most cases. Discs were selected on the basis of clinical and radiographic suspicion and a control disc was included. The provenance of discography has been fully discussed previously.[22]

Disc selection

Discography positive discs were treated by DISC-FX, either at the time of discography or as a second step. Ideal criteria for DISC-FX include 50% retained disc height and no or moderate, contained disc protrusion.[19] However, in this series, strict disc morphological selection criteria were not applied and positive discs were treated if accessible and judged relevant. Up to four discs were treated in the same session. Occasional cases were encountered where multiple positive disc levels were diagnosed at discography but one of these was not accessible for DISC-FX, for example, being too narrow or the disc margin occluded by osteophytes. In this situation, DISC-FX was carried out at accessible levels and a palliative such as pulse RF at the non-accessible levels.[23,24]

Disc-FX

Standard DISC-FX technique was employed.[19] Briefly, the patient is placed prone, skin prepared and draped. Light continuous sedation and local anaesthetic is used for comfort and safety. Under continuous fluoroscopic imaging, a 16-g introducer needle is passed to and beyond the anterior face of the subjacent superior articular process into the target disc (Figure 1(a)). A skin-stab incision is made with a size 11 scalpel and sequentially, a guidewire, dilator and working channel and annulotomy catheter are deployed, the 3 mm diameter working channel left in position visualised across the depth of the annulus in anteroposterior (AP) view (roughly the diameter of the facet mass) and in the posterior third of the disc diameter in lateral projection (Figure 1(b)). The three-step procedure is then progressed with nucleotomy to remove approximately 1 cc of nucleus by pituitary forceps (Figure 1(c) and (d)) and then bipolar RF nucleus ablation by steerable 'Trigger-Flex' catheter using six passes in 'turbo' mode (Figure 1(e)). Finally, the Trigger-Flex is deployed across the posterior annulus in lateral than AP screening control (Figure 1(f)) and 'hemo bipolar' RF heating mode at up to 80°C deployed using three passes of 6 seconds in the upper, middle and lower portions of the annulus. This is intended to denervate the internal aspect of the annulus, to seal fissures and to contract the annulus. Up to 30% reduction in cadaveric annulus and concomitant 9% improvement in volume of epidural space have been noted (Elliquence, data on file). Intravenous antibiotics are given (cefuroxime 1.5 g or gentamicin 320 mg or ceftriaxone 2 g) and the disc irrigated during the procedure via an infusion port in the Trigger-Flex catheter with 20 mL bupivacaine 0.25% containing 10 mg/mL cefuroxime (or equivalent) and dexamethasone 10 mg per disc to reduce post-procedure pain. Patients were discharged on day of treatment and recovered at home on reduced activity for 1 to 4 weeks. First follow-up in clinic was at week 4.

Outcome measures

Measures taken were area of pain on a 100-square body mannequin grid, visual analogue scale (VAS) average back and right or left leg pain, worst pain at any site, Oswestry Disability Index (DI), post-treatment VAS, global improvement (GI) and Likert-type scale. Measures were collected as part of routine practice from first consultation, before each procedure, including the day of DISC-FX, during follow-up and at discharge. Forms were filled in by patients in the waiting room, or on the ward for procedures. Results were abstracted and entered onto an Excel database by research nurse (C.O.) and student assistant (M.H.). Statistical analysis was by AcaStat Software. Patients were assisted where needed but not formally supervised or placed under duress to fill these in and hence at times some parts would be omitted. N numbers for individual data sets reported here therefore vary.

Follow-up

As this is an as-observed clinical practice report, there was therefore no opportunity to schedule long-term follow-up solely for the purpose of data collection. Patients were reviewed at week 4 post-procedure and monthly till mutually agreed discharge either following treatment success or failure. Usually, short follow-up therefore represents rapid, clinically adequate improvement. In this context, average follow-up was 4 months and median 3 months. Twenty-six patients were discharged at 1 month, 36 by 2 months and 52 by 3 months while 25 took longer than 6 months to conclude and the longest was 13 months. Patients were invited to return if problems recurred, and those who had failed treatment were referred on as appropriate or returned to family practitioners.

Results

Complications

No procedure complications or cases of discitis occurred. One patient was admitted to hospital overnight for pain control. Ten patients were referred onwards for surgical consideration post treatment, including five who experienced a re-protrusion and one with protrusion at a new level. Four patients have re-presented late, after initial successful discharge, for further management within the 6-year span of this report.

Table 1. Initial and final VAS for average and worst back and leg pain, area of pain, Oswestry DI, percentage global improvement (GI) and Wilcoxon Z scores for 100 sequential cases treated by a pragmatic sequential interventional strategy including percutaneous disc decompression by DISC-FX.

Variable	Mean		Percentage improvement	Wilcoxon (z)	p < value
	Initial	Final			
Average back pain	58.2	29.3	49.6	6.485	<0.0001
Worst back pain	74.7	39.9	46.6	6.254	<0.0001
Average leg pain	36.9	13.8	62.7	5.454	<0.0001
Worst leg pain	41.2	20.0	51.5	4.119	<0.0001
Area	11.3	5.2	52.8	6.479	<0.0001
Oswestry (pre/post)	40.1	27.1	32.5	5.235	<0.0001
Average % global improvement			57.4		

Patients and demographics

One hundred patients, 53 women and 47 men of average age 43.7 and 44.8 years, respectively (range 17–78), were treated. There were no gender differences in respect to variables studied (data not shown). With regard to number of discs, there were 39, 52, 8 and 1 instances of 1-, 2-, 3- and 4-level treatments (total 171 discs). While there were trends, there was no statistical relationship between age, duration of symptoms, number of discs treated, and patient's %GI achieved (data not shown). In clinical categories, 38 cases were back pain, 40 back and leg, 5 sciatica, 10 described as complex and 7 non-assigned. Patient %GIs were numerically similar in each group at 58.9%, 55.9%, 60.8% and 63.5%, respectively. Mean total duration of pain was 58.5 months, continuous pain 22.4 months. The maximum duration of spinal problems was 45 years and 19 had spinal pain for over 10 years.

VAS back and leg pain, area of pain, Oswestry DI and %GI

Mean initial and final VAS scores for average daily back and/or leg pain, worst experienced back or leg pain, area of pain, Oswestry DI and perceived global improvement (%GI) are shown in Table 1. All reduced in a statistically significant fashion and with numerical results at and above the conventional 50% clinically important pain relief level, and the average %GI reported by all patients was 57.4%.

Likert-type scale and quartiles of response

Categorical responses on a 5-point Likert-type scale (N = 89) were as follows: Much worse 0 (0%), Worse 5 (5.6%), Same 22 (24.7%), Better 30 (33.7%) and Much Better 32 (36.0%). Accordingly, 69.7% of patients rated themselves Better or Much Better. The %GIs consistent with each response were 0.2%, 15.2%, 64.7% and 86.8%, respectively. Percent GI responses were then divided for illustrative purposes into four quartiles to examine the spread and degree of benefit and to determine the proportion of patients achieving over 50% improvement as follows (N = 97): 0%–24%, 23 (23.7%); 25%–49%, 8 (8.2%); 50%–74%, 24 (24.7%); and 75%–100%, 42 (43.3%). Accordingly, 66 (68%) patients crossed a notional 50% response hurdle and the average %GI achieved in each of these quartiles were 5.2%, 37.4%, 61.1% and 87.7% and for those over 50% was 77.7% (see Figure 2).

Exploration of interventional pathway

Patients were treated on a pragmatic pathway with interventions to reduce superficial pain generators prior to discography and DISC-FX. We therefore examined the relative contributions of the interventions delivered prior to DISC-FX. Thirty-seven patients had discography and DISC-FX only and no other procedure. Twenty-six had a procedure before DISC-FX, 16 after and 21 both pre and post. A total of 141 additional procedures were used throughout the study.

Among the patients who had procedures pre-DISC-FX, there exists the possibility that the prior interventions were responsible for the benefits seen. Forty-seven patients had procedures pre-DISC-FX (including those who also had procedures after) and 40 have available data, though some data sets are poorly completed (worst leg pain).

Changes seen from initial to pre-DISC-FX scores among those with prior procedures are 17.1%, –11.9%, 31.5%, –6.5%, –6.6% and 0.1% for area, average leg pain, worst leg pain, average back pain, worst back pain and Oswestry, respectively, whereas the same data in the step from pre-DISC-FX to final in the same group were 55.9%, 58.7%,

Figure 2. Percent global improvement (GI) divided into quartiles of response among 97 patients. Of these, 0–24%, 23 (23.7%); 25–49, 8 (8.2%); 50–74, 24 (24.7%); and 75–100, 42 (43.3%). Average % GI among 68% of patients achieving over 50% GI was 77.7% and for 43.5% of patients achieving over 75%, average GI was 87.7%.

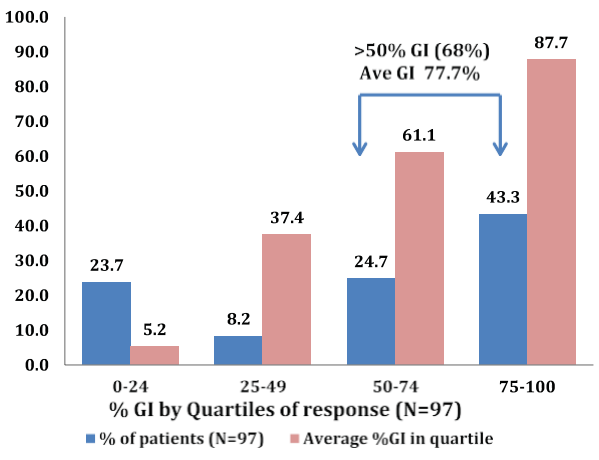
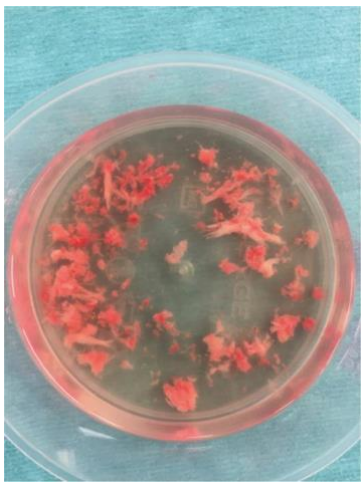


Figure 3. Inflamed, pathological disc nucleus removed during the nucleotomy step of DISC-FX treatment.



70.8%, 48.7%, 45.9%, 34.3% and 57.4% GI. Among those with procedures post-DISC-FX, the benefits from pre-DISC-FX treatment to final were almost exactly the same at 58.7%, 46.2%, 72.2%, 50.7%, 45.7%, 31.8% and 55.9% GI, respectively.

Discussion

Patients with contained disc protrusion which is thought to be causing back pain and/or sciatica do not have easily available surgical options[25] while fusion and disc replacement surgery is not recommended for back pain in current UK guidance.[17] UK national guidance, however, does recommend disc decompression by coblation for back pain and sciatica when considered as an individual technology,[16] and its use as an intervention in back pain and sciatica as part of a strategy in which RF denervation of facet joint in low back pain is the principle recommendation.[17] However, since dominant facet pain may represent a minority of cases, certainly in younger back pain sufferers,[1] there remains significant unmet clinical need where a discogenic source is thought to be the principal pain generator.

The DISC-FX technique is a 'mini-micro discectomy' which employs mechanical and RF nucleotomy and annulus modulation. The RF component is analogous to nucleoplasty decompression treatment which uses proprietary coblation RF technology. In DISC-FX, however, a higher frequency of 1.7 MHz[19] is used, which is also modifiable in two modes to create tissue lesions at low temperature (Turbo) and also heat-based RF modulation (Hemo) of the posterior annulus, thus addressing both the major domains of disc pathology. In many cases, volumes of pathological, presumably inflammatory nucleus material are removed (Figure 3). Whereas there are European clinical data showing successful outcomes over 2 to 4 years,[20,26] and Asian data,[21] there are no equivalent UK data. Moreover, there are no data illustrating the likely utility of discal treatment in everyday use where patients are not specifically selected as optimal responders. We therefore report open label, prospective results of a stepwise pragmatic strategy of interventional care including DISC-FX in 100 sequential patients with chronic or persisting back pain which had failed conservative care.

In the author's experience, patients with discogenic back pain of the sort reported here usually give a characteristic history of episodic pain and spasm, often with compensatory scoliosis frequently described as 'I put my back out'. In those who progress, such episodes become more severe, frequent, long-lasting and ultimately continuous with exacerbation spontaneously or by trivial provocation, and the patient has to 'walk on egg shells' to avoid these. Consistent with this history, in this series the average overall duration of pain history was 58.5 months and the duration of the continuous phase was 22.4 months. The longest history of pain seen here was

45 years and 19 patients had pain of over 10 years' duration emphasising that chronic pain of this type is not untreatable if the correct diagnosis is made.

While other authors emphasise that patients usually have a single pain generating pathology and combinations of facet and disc pain occurred in only 5%, in one series,[27] in the cases reported here A.H. was struck by the apparent complexity and variability of symptoms and signs and therefore potential multiple clinical diagnoses at presentation among patients who ultimately respond maximally to discal treatment. This may be explained by central sensitisation,[28] essentially, that in the presence of a significant competing pain generator the sensitivity of clinical testing, and hence false positive tests, may rise while specificity falls. Consistent with this concept, Bogduk[13] advise that 'it would seem pertinent and wise to clear patients of zygapophyseal joint pain and possibly sacroiliac joint pain before undertaking disc stimulation'. This principle has been extended in this study to include all potential pain generators where these seemed clinically indicated including central pain amplification, muscle trigger points and neural tension as well as apparent facet and SIJ pain.

However, since clinical signs, for example of facet pain, do not correlate with objective testing by Medial Branch Block,[29] it is not possible to know prospectively whether a physical sign on examination is true or false positive. We speculate this phenomenon may affect pain blocks and provocations also. We have therefore, in general, used the least invasive techniques for the preliminary steps to avoid unnecessary overtreatment, for example, facet or SIJ injection rather than medial or lateral branch RF.

We understand these procedures may offer temporary relief of pain but argue that is sufficient for this purpose. True pain generators can be treated definitively subsequently if symptoms persist. Where patients respond fully to these treatments, management stops but continues with disc management if pain persists. The intention in so doing is to remove peripheral pain sources and leave the disc as the most likely persisting pain generator, thus optimising sensitivity and specificity for the more invasive disc testing and subsequent treatment.

Under this strategy, 37 patients progressed to disc management directly, while the remainder had treatments before or after DISC-FX in addition. The numerical improvements in measured parameters achieved by pre-DISC-FX procedures were minimal, while almost the total benefit was seen in the step from DSIC-FX to final. Improvements seen were almost identical when comparing those who had prior with those having subsequent interventions, suggesting the interventions other than DISC_FX were not material. This may also imply that most of the apparent signs of alternate sources of pain were indeed false positive. This argument, however, is circular, since under the pathway, patients responding adequately to other treatments did not progress to discal therapy.

While we have not documented the details, all patients had failed prior conservative therapy and many had received extensive and sometimes prolonged prior treatment without resolution of the ongoing problem, and 19 patients reported spinal problems for over 10 years. However, despite such previous failure, by utilising available palliative injection and definitive RF techniques, and by recognising the central role of disc pain in those whose problems are not resolved by those techniques, it appears here that a good proportion of patients can be relieved of the majority of symptoms, with 19 patients reporting over 90% improvement. Responses to Disc-FX treatment are likely to be long-lasting, with reported 4 year results appearing stable.[20]

The results obtained here are not as emphatic as some, with those reported internationally with reductions from VAS 7.6–8.6 to 1.6–2.6 sustained over 1 to 3 years[30] This may reflect less exclusive case selection and the everyday treatment as opposed to clinical trial setting. With regard to complications, in this series, six patients experienced re-protrusion events (one at a non-treated level) and a further four have returned with further disc problems to date, treatments having commenced in 2011, similar to reports from structured follow-up.[20]

The radiographic diagnosis of lumbar disc pain is complex. MR scanning is necessary but not sufficient since the relation between pain and radiology appearances is poor,[31] though features such as a High Intensity Zone (HIZ) may be a reliable clue.[5,32] In this study, we estimate that 53% of patients would be wrongly assigned to treatment on the basis of MRI findings alone, and we therefore propose that systematic pain provocation discography to SIS standards should be considered as a preliminary to disc treatment. However, Hellinger[20] used discography only to establish annulus competency and the technique remains contentious; for example, the author has experienced two cases of discitis in over 20 years' clinical practice, none in this series. Thirty-nine 1-level, 52 2-level, 8 3-level and 1 4-level cases were recognised and treated (total 171 discs). Multiple-level disc treatment would be difficult to achieve by other means.

Limitations

This is an observational study with numerous limitations. These include the potentially restricted patient profile in UK private practice which may not be widely representative, single practitioner management, short follow-up, unblinded/clinician-led data collection, lack of control population and potential uncontrolled confounding variables. In this series, no long-term follow-up was carried out but patients were invited to return if problems recurred. The presumption of long-term benefit

therefore depends on the fact that few (four) patients did re-present in this time frame. We accept this is a significant limitation in drawing conclusions about the long-term efficacy of the procedure, though structured long-term follow-up shows benefits are stable over 4 years.[20] Should these results be confirmed in controlled studies as part of an appropriate pathway, the magnitude and stability of responses seen would be of considerable potential significance to a common group of back pain patients. Finally, cost-utility is not addressed here, nor are return to work data, but again such data may not be generalisable from a mainly insurance-based patient group. However, early surgical discectomy may be cost-effective at a threshold of €40,000 per QALY.[33] Since in the UK percutaneous decompression and injection treatments are substantially less expensive, it is possible it would prove cost-effective in routine use.

Conclusion

Percutaneous decompression and annulus modulation by DISC-FX is the major contributor to initial positive outcomes in an interventional pathway of management of chronic discogenic spinal pain in a sequential prospective analysis. Further, formal study appears warranted.

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Conflict of Interest

A.H. has received support for conference expenses in one instance from Elliquence, NY.

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