

# Epiduroscopy and radiofrequency technique: the Raffaelli–Righetti technique

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*Objectives:* Periduroscopy has been re-evaluated only recently for the diagnosis, and especially the treatment, of complex rachidian pain, such as that due to the failed back surgery syndrome (FBSS). The classic periduroscopy procedure has major limitations in that it can only use liquids as a method to visualize the dura space, and cannot overcome fibrotic (partial or complete) obstructions of the channel. In order to overcome these limitations, we added two modifications to the classic procedure – the Raffaelli–Righetti technique.

*Patients and methods:* A Fogarty balloon was used to clean the channel. This tool has allowed reduction by 50% of the volume of fluid used in the periduroscopy. The second innovation involves the use of the resaflex for the lysis of channel obstructions (fat and/or fibrotic tissues), which allows reaching the site of pain origin and improving the efficiency of the periduroscopy by 30%. The resaflex uses an electric wave to lyse tender tissues (lysing and coagulating at the same time or only coagulating), keeping the temperature at 63°C.

*Results:* Very few complications were observed in patients treated with this method. Moreover, it was possible to study normal and pathological morphologies of the dura with direct imaging.

*Discussion:* Only in a few cases was an anatomical-pathological image identified that modified the diagnosis. For this reason, epiduroscopy is not so important as a diagnostic tool, but offers greater therapeutic benefit than traditional epiduroscopy; it is also more easily performed and repeatable.

**Keywords:** periduroscopy, Raffaelli–Righetti technique, resablator, FBSS treatment

## Introduction

Periduroscopy was first developed in 1931 by Burman<sup>1</sup> and employed clinically in 1937 by Pool,<sup>2</sup> who published his experience with 400 patients in 1942.<sup>3</sup> The technique was not refined until the 1980s. In 1989, Bloomberg and Olsson<sup>4</sup> used it for anatomical studies and described a dorsomedian septum in the epidural space *in vivo*. Clinical application began in 1989, when cortisone was administered to 10 patients using a caudal endoscopic approach.<sup>5</sup>

Because of the lack of dedicated equipment and the appropriate technology, only studies performed on

small number of patients were available for many years; as a result, the technique did not spread into clinical practice. In this period, Racz *et al.*<sup>6</sup> developed a technique of non-endoscopic epidurolysis for the treatment of post-surgical fibrosis.

The endoscopic procedure was re-evaluated in 1990s by several groups, and was used for the diagnosis and treatment of complex rachid pain, with an improved technique and efficiency. Saberski and Kitahata<sup>5</sup> advocated the use of the caudal approach to the epidural space in the US. This method allowed for reduction in the chance of accidental subarachnoid entry and neurological complication. Successively,

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they reported the use of a flexible and manoeuvrable instrument that could locate exactly the pain triggers in patients with chronic back pain.

The Italian experience with this technique evolved independently from 1996,<sup>7</sup> using at first bronchoscopes and then dedicated instruments adapted by Raffaelli. He used two different approaches – a caudal approach and an interlaminar head-caudal lumbar approach. The latter approach was used to reduce intraspinal pressure and to permit the diffusion of the saline solution from the caudal space. In 1998, Raffaelli's group showed the efficiency and limits of traditional epiduroscopy.<sup>8</sup> This technique has been proved to be effective in 65% of cases; however, the benefit did not last for a long time (< 12 months). This limitation was thought to be due to the impossibility of removing fibrosis, when it either occluded the channel or was too adhesive to dura.

Has the potential of this technology been realized? We established a new method in 1999, in order to improve the epiduroscopy technique by introducing the use of a Fogarty balloon.<sup>7,9</sup> Successively, we designed a new instrument in 2001, which allowed the lysis of fibrosis without damaging dura and ganglion root. We published the first report in 2005, describing the results of the application of this new method (Raffaelli–Righetti technique)<sup>10</sup> and thereafter used it on a large number of patients. The technique was established to remove any pathology inside the channel, using a radio-frequency device named the 'R–ResAblator' and the Raffaelli–Righetti technique.<sup>11</sup>

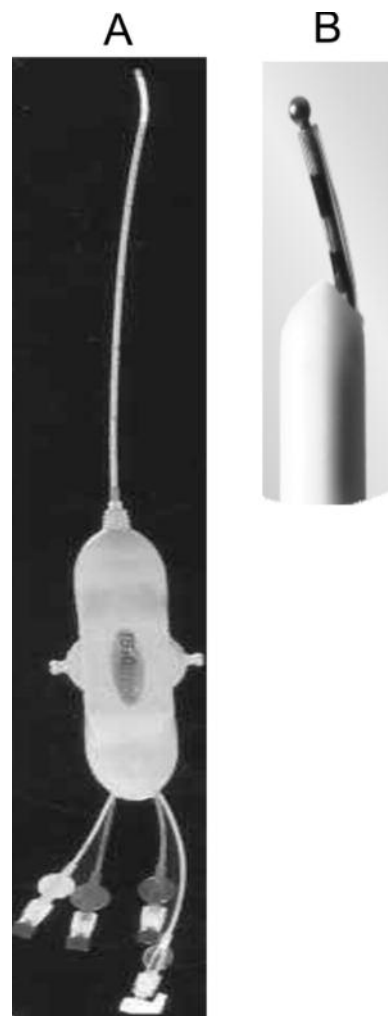
The characteristics required for a useful spinal endoscope are high-quality optical fibres, manoeuvrability, pressure control and more adaptive catheter guidance. For this reason, we have designed a catheter (Fig. 1A) to allow the simultaneous introduction of four instruments – a resaflex, a Fogarty balloon, an optical fibre and a catheter for the injection of the saline solution. In this review, we describe our experience with the Raffaelli–Righetti technique and the resaflex from 2001 to 2007.

## Patients and methods

### Patient selection

A total of 592 patients were submitted to epiduroscopy from 2001 to 2007; the resaflex was used for 128 of these from 2004 to 2007.

The main selection criteria were related to the assessment of pain, psychological status, imaging data and history. The inclusion criteria were the following: (i) pain with a demonstrable organic cause and



**Figure 1** Instrument used for the Raffaelli–Righetti technique. The figure shows (A) the video-guided catheter used during the periduroscopy and (B) the resaflex: spherical steel tip of 0.80 mm diameter, working depth of 1 mm beyond the tip, indicator of depth, shank with plastic insulation of 495 mm, cable flexible silicone extra, connector of push-pull

objective signs of disease; (ii) pain resistant to all medical, including physical, therapies; (iii) magnetic resonance imaging (MRI), computed tomography (CT) and neurophysiological investigation; (iv) positive psychological assessment; and (v)  $\geq 50\%$  pain relief after the analgesic injection according to the 'Raffaelli Trial Model'. This pain trial method was based on the assessment of pain type with spine trials and weekly responsiveness tests by injection in the subarachnoid space of morphine, anaesthetic or placebo.<sup>12</sup>

The exclusion criteria were: (i) no signs of surgical and/or medical emergency; (ii) non-stabilized central and/or peripheral nervous system conditions; (iii)

previous brain surgery for vasculopathy; (iv) primary and secondary epilepsy; (v) brain vasculopathy (aneurysm, angioma); (vi) ocular and retinal disease; (vii) glaucoma (under investigation and/or progressive); (ix) non-drug-related bleeding disorders (coagulopathy); (x) pregnancy; (xi) placebo trials with a positive response; (xii) pain relief > 50%; (xiii) evidence of severe psychiatric disturbance; (xiv) inability to give informed consent; (xv) chronic headache (except menstrual migraine); and (xvi) cervical stenosis with myelopathy.

#### Patient preparation

The spontaneously ventilating patient was placed in prone position, arms stretched forward resting on the armrests, and forearms slightly flexed downwards (90°). A local sacrococcygeal anaesthesia was performed by infiltration of 2% lidocaine or 6–10 ml mepivacaine, intravenous opioid analgesics (2 ml fentanyl) and hypnotics at subhypnotic doses (5 mg of midazolam, or 100 mg/20 min of propofol) to reduce conscious pain perception and, thus, psychological reactivity. The surgical instrumentation included resablator and resaflex.

Clinical monitoring was adopted; this was the reason why the procedure could only be performed under local anaesthesia with bland sedation to preserve patient alertness. The total amount of liquid injected should not exceed 350 ml (on average 220 ml). Sometimes, the injection of only 0.5 ml of saline solution was extremely painful and might (unless due to a psychological reaction) indicate a severe inflammatory hyperaemia. We think that this was due to the ‘allodynia’ for persistent pain such as the regional complex pain syndrome type 1 (RCPS) and/or tight fibrosis with distension-induced dural tenting (or ‘functional instability’).

#### Periduroscopy: Raffaelli–Righetti technique

The procedure can be divided into two phases – phase I and phase II.

#### Visualization of the lumbosacral canal

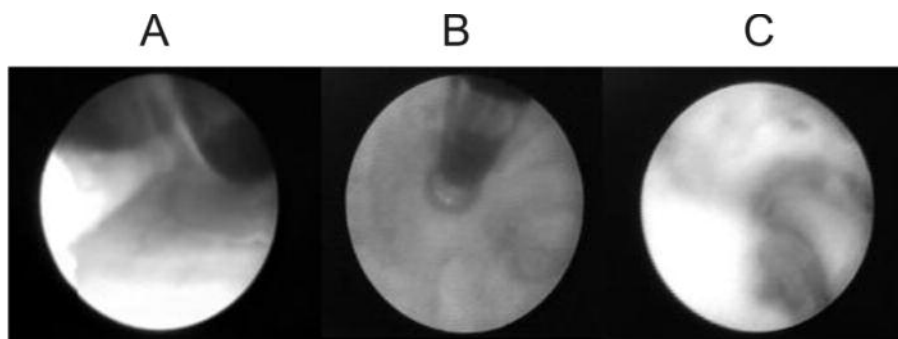
Access to the epidural space was attained by distension using boli of 2–3 ml saline solution flushed with a 20-ml syringe by one of the surgeons under direct vision. The purpose of using several small boli was to assess any resistance to the fluid (e.g. barriers or abnormal pressure) and distension-induced pain (localized pain; nugal pain). Intervals of 30 s should be observed every 3 or 4 boli to allow foraminal outflow. Injection velocity should be slow. Saline solution was injected in these intervals to improve vision.

#### Phase I

The aim of phase I (exploration) was to visualize the pannus and pathological areas by isolating the fibrotic structures and/or pathological adhesions to avoid blind advancement and exploration.

In this first phase, an initial mechanical dissection of the connective structures was performed. The procedure started with a slow advancement of the catheter, using a Fogarty 3-F balloon (Fig. 2A) to remove fat and little adhesive bridle, in order to reach the pathological area. The Fogarty balloon was introduced into the second channel of the video-guide, reached the structures surrounding the channel and/or the dural pannus (fat, mild fibrosis, adhering tissue), then it was expanded by injecting 0.5 ml of saline solution and finally was dragged back with a slight rotation. This manoeuvre was performed 2–3 times, injecting 3-ml saline after each distension. The purpose of this procedure was to isolate pathological structures that were enclosed with fat and peripheral reactive tissue, and to assess the resistance to canal distension.

This mechanical dissection also enabled the visualization of the pathological area, the isolation of the different components from the surrounding structures, and the identification of the fibrotic septa and/or hyperaemic areas and the zones where the dura adhered to the peripheral connective tissue. It was



**Figure 2** The Raffaelli–Righetti technique. (A) The Fogarty balloon inside the fibrosis and the images of the dura (B) before (here the tip of the resaflex is present) and (C) after the ablation

important to check the fibrotic tissue for septa containing networks of newly formed vessels. Hidden in the transverse membranes of the net of reactive and connective tissue, there might be blood vessels in the scar tissue septa that could cause a haemorrhage if damaged.

#### *Phase II*

In the second phase of the periduroscopy procedure, the resection with the resaflex probe was performed. After the isolation of the individual fibrous septa or the connective tissue adhering to the dura, the site with the least resistance was identified by traction with the tip of the Fogarty catheter, and then the tip of the resaflex probe was inserted at its base (Fig. 1B). The Fogarty catheter was withdrawn and the probe inserted into the space left empty by the balloon. The probe was oriented towards the base of the septum by rotating its tip. After positioning the tip near the site to be resected, a charge of 25 W was applied to the first lesion twice, consecutively, for a few seconds. The ablation tip was then pulled back a few millimetres and repositioned to treat the next lesions (in 3–5 steps of a few seconds). The charge was increased of 5 W per step, until a complete or partial vaporization (it was sufficient to remove the traction of the pathological tissue on the dural pouch) of the connective tissue and the detachment of the pathological septum or segment from the base was attained (Fig. 2B,C).

The site was then rinsed and the Fogarty catheter inserted in order to isolate, progressively, the fibrotic area. It was important to avoid damaging the dural base and to operate only where the dura–adhesion contact point was clearly visible. The sources of microbleeding were then selectively coagulated using the probe coagulation function. The instrumentation was finally removed after injecting antibiotic, saline solution and corticosteroids. The length of the whole procedure was usually 35 min.

#### *Clinical parameters to be monitored*

Nuchal or frontal pain was one of the parameters that were monitored during the procedure of periduroscopy. The injection of saline solution was suspended in situations of nuchal or frontal pain onset, and was resumed after a few minutes using 2 ml of saline solution. The procedure should be abandoned if pain is recurrent.

Axial chest pain and/or constriction (feeling of a tight band around the chest) were other important parameters monitored during the periduroscopy. The fluid volume was reduced in case of axial chest pain onset, and each following bolus was monitored.

#### *Data collected*

The data collected after the periduroscopy concerned the clinical benefit, using pain relief (Numeric Rating Scale, NRS) and disability scales (Oswestry Disability Index, ODI), monitoring the analgesic consumption, and short- and long-term clinical complications. The NRS is based on a 0–10 scale; where 0 represents no pain and 10 the worst possible pain.<sup>13</sup> ODI is designed to assess multiple aspects of disability with respect to pain, and is divided into 10 items: pain, personal care, lifting, walking, sitting, standing, sleeping, sex life, social life, travelling. Each item can be scored on a 0–5 scale, where 5 is the greatest level of disability.<sup>14</sup> All the scores are summed and the total score is doubled and expressed as a percentage, which corresponds to the final ODI level of disability.

Other data collected were the morphological-pathological characteristics of the dura, from the images with the camera connected to the endoscope, once the epiduroscope reached the site that was considered as the source of the pain.

#### *Ethics*

The study was approved by the Hospital Ethics Committee and conducted according to the Helsinki declaration principles on human clinical studies. All the patients gave written consent, after a thorough explanation of the procedure and the study.

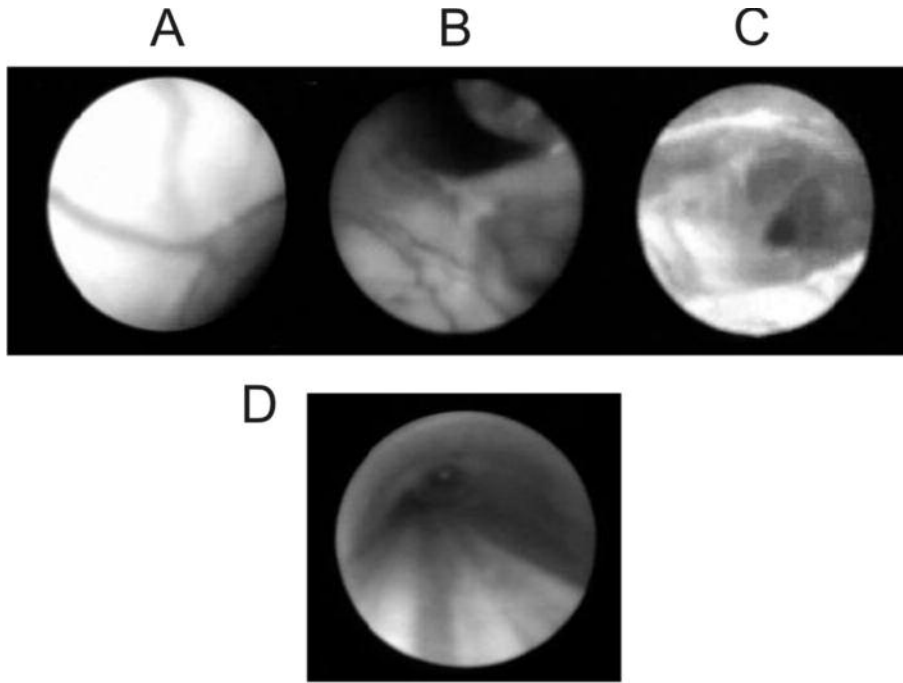
## **Results**

#### *Indications for dissection with the Raffaelli–Righetti technique*

This new technique for resecting epidural adhesions has considerable therapeutic advantages. It should be adopted in all conditions of ‘functional instability’,<sup>10,11</sup> where fibrotic-connective bands in the epidural space exert traction on dural pannus, perineural structures and nerve roots.

The second phase of the technique has allowed exploration of its advantages and limits, and definition of its characteristics to facilitate the operation.

The Raffaelli–Righetti technique uses the resaflex, which performs ablation of the fibrosis with a magnetic resonance technique, emitting energy quanta of 4 MHz, with a transmission of energy equal to the molecular bonds of biological tissues,<sup>10</sup> allowing the ablation to be performed at low temperature (< 50°C). The resaflex, for this reason, allows for improvement and optimization of the positive results obtained with standard myeloscopy, especially concerning the reduction of long-term, painful reiterations. Compared



**Figure 3** Normal and pathological morphology of the dura and subdural space. The images of (A) normal, (B) fibrotic adhesion (functional instability) to dura and (C) mild fibrosis were taken during the periduroscopy. (D) Image of the subdural space

with traditional procedures, in addition to therapeutic advantages in terms of pain relief, this technique also offers ease of performance and the possibility of repetition.

#### *Anatomical, morphological, and pathological appearance of the epidural space*

The dural pannus was visualized at the base of the endoscope, and the canal appeared dark. The area, which was close to the scar tissue and/or the inflamed/hyperaemic tissue surrounding the root, was flushed without losing sight of the dura (the reference point).

Two different classes of fibrosis could be found: mild fibrosis with transverse translucent strands (Fig. 3C), and fibrotic adhesions (functional instability; Fig. 3B), which are a network of connective septa resulting in partial or total reduction of channel calibre.

Only in a few cases did we identify an anatomical-pathological image that modified the diagnosis. For this reason, we think that epiduroscopy is not so important as a diagnostic approach, and should be used only when there is therapeutic indication or the epidural space in a unknown lumbar pain is to be evaluated.

#### *Subdural space*

The morphology of the subdural space is shown in Figure 3D. The photograph was taken by putting the

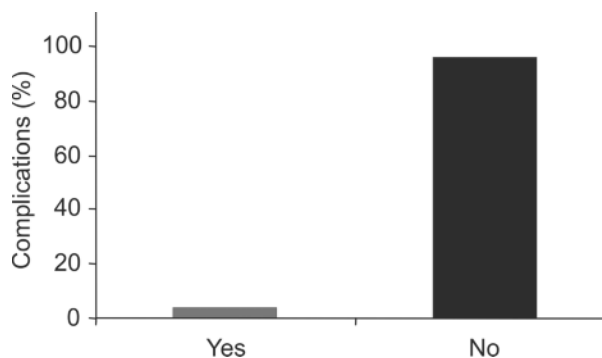
endoscopic instrument inside the subdural space without any complication. It was possible to explore all the compartments looking the arachnoid and nerve root composition underneath it and putting inside 40–50 ml of saline and opening the Fogarty balloon without any complication except for mild paresthesia for 30–60 min.

#### *Efficacy and complications of periduroscopy*

The resaflex allowed a reduction of 68% of disability (ODI), and 56% of patients reported a reduction of > 50% in pain intensity (NRS), as assessed 12 months after the periduroscopy. The reduction of pain and disability confirmed the efficacy and reproducibility of the Raffaelli–Righetti technique.

Concerning complications, in the initial phase of our experience, from 1996 to 1998,<sup>8</sup> when large fluid volumes were used (1200–1600 ml), there was a case of bradycardia, one case of dysaesthesia and mild asthenia with lower-limb seizures, and one patient had mild tonic-clonic seizures. In each case, the condition was quickly resolved. Only in one case was the procedure interrupted because of temporary lower-limb dysaesthesia, in order to avoid more severe complications.

No central or peripheral neurological complication occurred after 1999, when we began using smaller fluid volumes (< 350 ml) and the Fogarty balloon.<sup>9–11</sup> For this reason, we recommend that a total amount of



**Figure 4 Complications of the Raffaelli–Righetti technique. The complications recorded using the Raffaelli–Righetti technique were very few (4% of the patients treated)**

250–300 ml of fluid injection per operation should not be exceeded.

The complications associated with periduroscopy were generally few after 1998 (Fig. 4). Cases of accidental subdural and subarachnoid injection were rare and sometimes that was done because the fibrosis incorporated the dura. In this case, it was impossible to remove the fibrosis.

Infective complications, such as meningitis were uncommon, and responded to antibiotic therapy.

Dural puncture was another, rare complication of epidural endoscopy. Macular haemorrhage or bleeding in the internal layers of the eye could be experienced, when excessive volumes of saline solution flush caused a sudden and significant increase in intracranial pressure, risking also eye haemorrhage. At the moment, we do not know how this complication can be avoided, because we do not know its cause, *i.e.* if it is due to the injected volume or to the dura traction.

## Discussion

These results validate the endoscopic procedure. However, despite the improvement in surgical practice, there is still a high percentage (10–40%) of pain re-appearance after a spine surgical operation.<sup>15</sup> Patients, who have persistent back or leg pain after a surgical intervention, suffer from the so-called failed back surgery syndrome (FBSS). FBSS is due to a combination of severe nociceptive and neuropathic pains, causing psychosocial and behavioural difficulties.<sup>16</sup>

Between 5–50% of surgical operations on the lumbar spine result in chronic pain.<sup>17,18</sup> This is an extremely serious problem requiring resolution. Spinal endoscopy may be a solution for those patients that cannot find pain relief in any of the available

treatments. Although FBSS patients have been treated with different surgical techniques with controversial effectiveness,<sup>19–21</sup> spinal chord stimulation (SCS) seems to be effective.<sup>22</sup>

In 1998, we reported the effectiveness and limitations of periduroscopy,<sup>7,8</sup> which was effective in 75% of FBSS cases; however, in 25% of cases,<sup>7–9</sup> it needed to be repeated after 1 year. For this reason, we have tested a new instrument – the resaflex.

Thanks to this technique, we have shown that the epidural morphology in FBSS patients is more complex and heterogeneous than what had appeared from traditional investigation. Pathological morphology of the dura can be divided on the basis of the presence of inflammatory situations and vessel alterations (resulting in axial lumbar pain) or scarring and adhesion bands with no flogosis element. The fibrotic component can itself be divided into four categories, according to the pattern of adhesion fimbria in the epidural channel: median connective sedimentation, diffused ‘honeycomb’, blind transversal fimbria with total or partial stenosis, parallel to the side walls.<sup>10</sup>

The Raffaelli–Righetti technique has also allowed resolution of the limitation of classical epiduroscopy, which has to be suspended when a stenosis of the channel is present. With the resaflex, the fibrotic block can be lysed and the operation can be finished.

## Conclusions

Periduroscopy with the Raffaelli–Righetti technique is an important therapeutic tool for FBSS patients. It can, indeed, be very useful for research purposes, such as the development of block needles, for the identification of target therapy for FBSS, and for the study of the nerve root, which is poorly served by blood vessels and relies on cerebral spinal fluid for nutrient supply.<sup>23</sup> The therapeutic use of this technique includes drainage of cysts, abscesses and haematomata, and stereotactic placement of neurolytic substances.

However the technique needs some improvements, such as the use high-definition optical instruments to obtain 3-D pictures and of more innovative instrumentation for biopsies, access to the sub-arachnoid space and for monitoring the pressures.

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