Foreword

The initial objective of this work was to reduce stress incontinence surgery from a major surgical procedure (requiring up to ten days in hospital) to a minor day-care operation. From the beginning it was clear that the two major impediments to achieving this goal were post operative pain and urinary retention. Addressing these problems became a long and winding road and culminated in the Integral Theory.

The IVS 'tension-free' tape operation was inspired by Dr Robert Zacharin's anatomical studies. Though Zacharin suggested that the ligaments and muscles around the urethra were important for urinary continence control, he did not say how. The observation that implanted foreign materials created scar tissue led to the hypothesis that a plastic tape inserted in the position of the pubourethral ligament, would leave behind sufficient scar tissue to reinforce that ligament, which would then anchor the muscles for urethral closure.

In September 1986, two prototype Intravaginal Sling operations were performed. A Mersilene tape was inserted with neither tension nor elevation, in the position of the pubourethral ligament. Restoration of continence was immediate and both patients were discharged on the day following surgery without requirement for catheterization. There was minimal pain, and immediate restoration of continence. After six weeks the tapes were removed. Both patients were still continent at last review 10 years later. The results appeared to confirm the importance of a midurethral anchoring point. Furthermore, as there was no elevation of the bladder neck, the results cast doubt on the validity of the prevailing 'pressure equalization theory' of Enhorning.

In 1987, with Professor John Papadimitriou and colleagues from Royal Perth Hospital, a series of experimental animal studies was performed to scientifically analyse the safety, efficacy and modus operandi of a tape implantation. Tape implantation was found to be safe and it worked by creating a linear deposition of collagen in the position of implantation.

The first of 30 operations were performed at Royal Perth Hospital, Western Australia, between 1988 and 1989. An adjustable intravaginal Mersilene sling was sited at midurethra. The sling was set in an elevated position but this caused urgency and obstructed flow post-operatively. As the sling was lowered, these symptoms disappeared, yet most of the patients remained cured of their stress incontinence.

On comparing the pre-operative and post-operative x-rays, no elevation of bladder base was evident. This appeared to invalidate the 'Pressure Equalization Theory' for maintenance of urinary continence. Furthermore, when the midurethral tape was anchored by grasping it with a haemostat, the distal urethra was seen to move forward, but the Foley balloon catheter moved backwards and downwards

around the midurethral point. From these observations the concept of two separate closure 'mechanisms' emerged. Over the space of a year, a theoretical framework that integrated these disparate findings with known anatomy was developed (the Integral Theory 1990). The key concepts were that the suspensory ligaments were essential for normal bladder function, and that bladder dysfunction occurred because of connective tissue damage within these same ligaments.

In 1990 a collaboration with Professor Ulf Ulmsten began. Further studies were performed, and the first formulation of the Integral Theory was published:

> *For different reasons, stress and urge derive mainly from laxity in the vagina or its supporting ligaments, a result of altered collagen/elastin.*

Separate urethral and bladder neck closure mechanisms were described. Abdominal ultrasound studies in 1990 demonstrated that the urethra was closed from behind by the hammock closure mechanism. Bladder instability in the non-neurological patient was defined as a premature activation of the micturition reflex.

In 1993 the second exposition of the Integral Theory presented radiological and urodynamic studies and brought a higher level of proof.

Five prototype suburethral sling operations for stress incontinence were analysed with reference to *modus operandi* and surgical methodology (1993 Integral Theory). A problem that remained was the relatively high rate of Mersilene tape erosion. This was largely solved in 1996 by Professor Ulmsten's Scandinavian group (Ulmsten et al. 1996) through use of a polypropylene mesh tape. The 'posterior fornix syndrome' was described (1993 Integral Theory). Reconstruction of the posterior ligaments improved symptoms of urge, nocturia, abnormal emptying and pelvic pain. These findings were seminal in the construction of the Pictorial Diagnostic Algorithm.

The ten years to 2003 has seen a consolidation and international acceptance of many parts of the Integral Theory, in particular, the treatment of stress incontinence with a midurethral sling. The Theory framework has expanded to include faecal incontinence, abnormal emptying, and some types of pelvic pain. New ultrasound and urodynamic techniques promise to improve diagnostic accuracy, especially when used with the 'simulated operations' technique described later in this book. Improvements in surgical methodology have been running on a parallel path with the expansion of the Integral Theory. These new methods were developed because traditional vaginal surgery methods of excision and approximation were unable to restore tissue strength sufficiently to restore structure, as described by the Integral Theory system. To overcome this deficiency, double layered techniques such as the 'bridge' repair, which recycles excess vaginal tissue (Petros 1998), and the Posterior IVS (Petros 2001) were developed. Tightening the suburethral hammock in addition to a midurethral sling has increased the cure rate for stress incontinence and intrinsic sphincter defect (Petros 1997). The posterior sling has been further improved and simplified.

In particular, the new tissue fixation system (TFS) appears to be a major advance on the existing 'tension-free tape' slings in that it is possible to repair *any* ligament or fascial defect in the pelvic floor. The TFS operations are more anatomical, far less invasive, and they are able to be performed *under direct vision*.

This book has been written in the hope that it will further clarify and disseminate the ideas of the Integral Theory and help provide the basis required for further advances in theory, diagnosis and surgical techniques to alleviate problems in the female pelvic floor.

Chapter 1 is an introduction and overview of the Integral Theory. It outlines the 'problem' being addressed, that is, the various symptoms of pelvic floor dysfunction, current knowledge and treatments. The overview explains normal function, and introduces the causes of dysfunction, diagnosis of damaged structures and the principles of minimally invasive surgical repair according to the Integral Theory.

Chapter 2 aims to familiarize the reader with the roles of ligaments and muscle forces and describes how they work synergistically to maintain form and function of the pelvic organs. It describes the anatomy of the pelvic floor, the interrelated roles of bone, muscles, ligaments and organs in the context of structure, form and biomechanics. It describes the static and dynamic anatomy of the pelvic floor and the seminal role played by connective tissue in function and dysfunction. It introduces the concept of the 'three zones' of the vagina, which is a central part of the Integral Theory diagnostic system, surgical anatomy and techniques.

Chapter 3 describes the Integral Theory system for diagnosis of connective tissue damage in the three zones of the vagina. Two diagnostic pathways are discussed in detail: the Clinical Diagnostic pathway, suitable for the general clinician, and the Structured Assessment pathway for use in specialist pelvic floor clinics. The components of these pathways and their role in the diagnostic process are described thoroughly. The concept of the 'simulated operation', used for verification of diagnosis, is introduced. This is an invaluable part of the Integral Theory system. It is used for preoperative direct testing of the zone of diagnosed anatomical damage.

Chapter 4 discusses the conceptual basis for minimally invasive pelvic floor surgery and introduces a new perspective on the surgical anatomy of the three zones of the vagina. It presents the minimally invasive surgical techniques developed for addressing anatomical defects in each of the zones, in particular the 'tension-free' tape anterior and posterior slings, and introduces the tissue fixation system.

Chapter 5 explains the pelvic floor rehabilitation exercises that were developed from the Integral Theory approach. Originally these exercises were designed as an alternative to surgery, but it has been found that they also assist the patient in maintaining the benefits they have attained from surgery.

Chapter 6 gives an anatomical basis for the 'mapping' of connective tissue dysfunction and the anatomical basis for urodynamics is explained. Many of the internal contradictions within conventional urodynamics are explained using the Chaos Theory framework, non-linear methodology and Boolean algebra. Boolean algebra is used to explain the concept of switching between the closed and open phases of the bladder. There are descriptions of the expanded use of transperineal ultrasound to the middle and posterior zones.

Chapter 7 discusses current and emerging issues related to further enhancement of the Integral Theory system, in particular, faecal incontinence. The potential of the new scientific concepts, methodologies and technologies in making the diagnostic

process more efficient is discussed. The Integral Theory Diagnostic System (ITDS), a computer based diagnostic system, incorporating the potential of a large data base developed across the internet is presented.

Chapter 8 is the conclusion. It briefly tracks the evolution of the Integral Theory from theory to working system and discusses the future importance of the internet for this new direction for pelvic floor science.

The questionnaire and other tools used in the diagnostic process are included and described in Appendix 1. References and further reading are included in Appendix 2.

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