Review article

Twenty-first century radical hysterectomy – Journey from descriptive to practical anatomy

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ARTICLE INFO

Keywords:
Radical hysterectomy
Nerve-sparing
Descriptive anatomy
Practical anatomy
Lateral parametrium
Terminologia Anatomica

ABSTRACT

The resulting characteristics of 20th century radical hysterectomy demonstrated that, in the quest for a radical cure, its surgical procedure became extended. The consequences of this were increased difficulty in the procedure with risk of massive hemorrhage and vesical and anorectal dysfunction. Moreover, the cardinal and transverse cervical ligaments, which were individually recognized during the 19th century, became regarded as synonymous during the middle of the 20th century. Because of this, traditional surgical procedures such as Wertheim and Latzko’s were not precisely followed, further delaying the advent of a new idea(s) for radical hysterectomy. The desired goal for 21st radical hysterectomy should be an anatomy and operative procedure that clarify and rectify these aforementioned negative surgical outcomes. In 1998, International Federation of Associations of Anatomists (IFAA) introduced clinical terminology in Terminologia Anatomica. With the IFAA’s decision in mind, the author focused, out of the many theories and surgical procedures for cancer of the uterine cervix, on three noteworthy proposals. From these proposals, the possibility for a new idea(s) on theories and surgical procedures was explored through the fusion of anatomy and clinical practice. The idea for a new procedure(s) required a morphological distinction between description in textbooks and intraoperative findings, that is: a) a traditional anatomy that was based on gross/systemic anatomy; and b) an anatomy in which part of an artifact resulting from applying an artificial maneuver to a living body could be regarded as surgical anatomy. The author has tentatively called the former descriptive anatomy and the latter practical anatomy. The development of this practical anatomy led to the idea for and practical application of a less-extirpating and nerve-sparing operation, which improved patient’s outcome. Radical hysterectomy of the 21st century should be conducted following this new anatomy that is concentrated around practical anatomy and independent from descriptive anatomy.

1. Introduction

Historically, surgery for cervical cancer has evolved from new procedures coming into existence based on new anatomic theories. However, since the publication on Mackenrodt’s transverse cervical ligament (1895) regarding clinical anatomy and Latzko & Schiffmann’s method (1919) or Meigs’ the so-called Wertheim operation (1945, 1950) regarding surgical procedure for cervical cancer, there was no remarkable development apparent until the 1990’s (Yabuki et al., 1991, 1996). Thus, creation of any new theory was delayed. However, intraoperative hemorrhage was controlled barely with progress in surgical technique, which was one of the objectives of 20th century surgery. But no further theoretical and technical progress was made in the preservation of bladder and rectal function (Yabuki et al., 1991, 1996, 2000, 2005). One of the reasons for this delay was that gynecologists did not possess, except for gross/systemic anatomy (descriptive anatomy), a means of expressing artifacts emanating from intraoperative maneuvers. Consequently, discrepancy arose between theory and practice, leading to obstacle of thought (Yabuki et al., 1991). Another reason was a contradiction in the cardinal and transverse cervical ligaments being regarded as synonymous. This contradiction made the distinction between Wertheim and Latzko procedures vague, leading to a delay in theoretical and surgical response regarding hemorrhage and bladder paralysis (Yabuki et al., 1991, 1996, 2000, 2005; Yabuki, 1997, 2007).

In 1998, International Federation of Associations of Anatomists (IFAA) introduced clinical terminology into the text of Terminologia Anatomica (1998). Although many interpretations exist on this action, it led the author to believe that IFAA had recognized the necessity for clinical terminology to be included in anatomic terms.

In this article, a review was conducted on surgical procedures based on traditional descriptive anatomy and practical anatomy, the latter an...
anatomy in which part of an artifact results from applying an artificial maneuver to a living body. Ultimately, from the information gathered, a proposal was put forward to solve this contradiction that emanated from the two anatomies as well as to carry out a 21st century radical hysterectomy that was consistent in both anatomy and surgical procedure.

2. Definition

The following two anatomies, descriptive and practical, are clearly distinctive.

2.1. Descriptive anatomy is defined as one in which a living body is clearly seen as it is depicted.

2.2. Practical anatomy is defined as a field to express a surgically created artifact (Yabuki et al., 2011, Yabuki, 2016).

3. Terminology

3.1. Position and direction for practical anatomy

The terms describing position and direction for practical anatomy were determined from a dorsal position (Yabuki, 2016). From a surgical viewpoint, direction is divided into medio-lateral, cranio-caudal and dorso-ventral directions.

3.2. Cardinal ligament, transverse cervical ligament and paracervix

For the cardinal and transverse cervical ligaments (CL and TCL), the author has adopted the assertion made by Savage (1870, 1880) and Mackenrodt (1895) as the paracervix being anatomically distinguishable from CL and TCL.

3.3. Abbreviations used in this article are presented as follows

CL: cardinal ligament, IFFA: International Federation of Associations of Anatomists, IHP: inferior hypogastric plexus, L&S: Latzko and Schiffsman, TP: lateral parametrium, LUL: lateral umbilical ligament, NSRH: nerve-sparing radical hysterectomy, P&A: Peham-Amreich, PSN: pelvic splanchnic nerve, Q&M: Quereu and Morrow, RH: radical hysterectomy, TA: Terminologia Anatomica, TCL: transverse cervical ligament, TMMR: total mesometrial resection, VUL: vesicouterine ligament.

3.4. Change of terminology

The superficial and deep layers of the vesicouterine ligament, which were the author's original coined terms in previous articles, appear to be misleading and have led to misunderstandings, so the terms bladder pillar and anterior mesoureter have been used in this article, the former of which is equivalent to the superficial layer of the vesicouterine ligament and the latter the deep layer of the vesicouterine ligament (Yabuki et al., 1996). This resulted in using the term posterior mesoureter instead of the mesoureter.

3.5. CL (of Mackenrodt)

In the mid-twentieth century, the term cardinal ligament (of Mackenrodt) began to appear in articles written by Uhlenhuth et al. (1948) and Reifenstuhl (1982) and Clemente (1985). To conform to this, CL and TCL were made synonymous by TA.

CL was Savage’s concept (1870, 1880) translated from the German term by Kocks (1880), which indicated a bundle on the medial aspect to the ureter. In 1895 Mackenrodt described TCL as ‘Fiber bundles extend from the pelvic fascia and attach to the posterior wall of the cervix’ (Speert 1996). Thus, these two ligaments cannot be regarded as synonymous.
4. Traditional lateral parametrium

Conventional pelvic ligaments are regarded as standard morphology as depicted by Peham and Amreich (1930, 1934) and Netter (2006). They are horizontally multilayered consisting of three plates: the lateral paracystium, lateral parametrium, and lateral paraproctium (Yabuki et al., 1991; Yabuki, 2019). For this reason, the principle of RH has been inherited from the procedure in which a space is created by dissecting the areolar tissue on the ventral and dorsal aspects of the lateral parametrium followed by its sagittal resection along the pelvic sidewall. However, this technique and its associated anatomy can only be applied to the resection of CL. Therefore, if applied to resection of TCL, massive hemorrhage and bladder/rectum dysfunction will ensue (Yabuki et al., 1991, 1996, 2011; Yabuki, 2016). The lateral parametrium depicted by Peham-Amreich and Netter is an image based on descriptive anatomy, which is a concept that is applied to Wertheim surgery (Fig. 1A). The space created by Latzko surgery is demonstrably different from that created by Wertheim surgery, so that a more clinically oriented description is required (Fig. 1B).

4.1. CL resected by Clark’s and Wertheim’s methods

Clark (1895) and Wertheim (1911, 1912) developed the ventral aspect of CL by separating the bladder followed by severance of the bladder pillar. They then resected the sacrouterine ligament and created a space behind CL, resecting CL at the medial aspect of the ureter (Figs. 1A and 2A). Thus, the term CL was passed down as a ligament that attaches parallel to the lateral aspect of the uterus (Fig. 2A).

4.2. TCL resected by L&S’ method

L&S excavated the paravesical and pararectal spaces on the lateral aspect of the ureter and separated the septum. They stated that this septum was the Mackenrodt ligament (Mackenrodt, 1895) (Fig. 1A and B). As seen in Fig. 1B and 2B, the Mackenrodt ligament extends in a dorsal direction (never a caudal direction) and reaches the sacrosinous ligament. Finally, a hole was pierced in this ligament followed by its separation (black arrow in Fig. 1B). However, in P&A’s textbook, TCL was initially depicted perpendicularly to the uterus. But, at the time of its resection, it was depicted longitudinally at its origin. In other words, it was clamped horizontally to the uterine axis en masse followed by its resection (P&A, 1934). Thereby, TCL was judged to be the ligament that horizontally connects the lateral aspect of the uterus/vagina and pelvic sidewall, reaching the vicinity of the urogenital hiatus. The contradiction shown in these two diagrams has never been questioned even till the present time.

4.3. Contradiction with resection method for the lateral parametrium

In his article published in 1912, Wertheim stated as follows: Mackenrodt criticises us claiming that by the application of these clamps (Wertheim’s clamps) more parametrium is left on the pelvic floor. We cannot agree to this as happily, these clamps can be very closely applied on the pelvic floor. This indicates that CL of Wertheim does not reach the pelvic sidewall but continues to the pelvic floor. This traditional controversy continues to the present day from a viewpoint in which the lateral rectal ligament or lateral ligament of rectum is included within CL or TCL. As a result, the pararectal space is excavated to the sacral aspect, which causes damage to the middle rectal vessels and sacral venous plexus, leading to hemorrhage (Yabuki, 1991, Posover et al., 2000).

Furthermore, the ligament theory for CL continues to exist through modification of the Wertheim operation by Meigs and Höckel and the statement by Q&M the part of the cardinal ligament that is medial to the ureter is mainly fibrous, whereas the part that is lateral to the ureter is non-fibrous (Meigs, 1945; Piver et al., 1974; Höckel et al., 1998; Q&M, 2008). However, since the 1930’s, there have been negative opinions on LP being a ligament (Bastian and Lassau, 1982; Berglas and Rubin, 1953; Koster, 1933; Fritsch, 1992; Range and Woodburne, 1968; Ricci et al., 1947). Besides, one must not ignore the fact that LP is the main route for the lymphochannel of the uterine cervix. Concurrently, the rate of carcinoma extension is few in the avascular areolar connective tissue surrounding LP. Moreover, the view of CL and TCL as being synonymous has led to a state of confusion of whether hysterectomy should be radical or semi-radical.

5. Classification of surgical anatomy

In traditional RH, gynecologists did not possess a means to describe artifacts that were created by surgical maneuvers other than describing them through the means of descriptive anatomy. To make one’s procedure consistent under this condition, discrepancy between theory (anatomy) and clinical practice (surgey) ensued, an example being L&S’ surgical procedure (Latzko method). Further, resolution of this anatomic contradiction in CL and TCL that have been made synonymous.

Fig. 2. Two forms of the lateral parametrium. A denotes a P&A and Netter’s schematic illustration of the descriptive form of post-deformation of LP. The ventral aspect of LP; which horizontally connects the lateral aspect of the uterus and pelvic sidewall, is exposed by an incision to the anterior leaf of the broad ligament and mobilization of the bladder. This was followed by creation of the pararectal space by excision of areolar connective tissue along the dorsal aspect of LP. B is a modified version of a schematic illustration in an article by Yabuki, et al., 1996; 62: 370-8 showing a practical form of post-deformation of LP. Spontaneous and perpendicular excavation of the pararectal space takes place on the lateral aspect to the ureter. Perpendicular excavation of the paravesical space is also carried out, though it is not depicted. The relationship between the uterus and LP is perpendicular. a; uterus, b; bladder, c; rectum, d; uterine cervix, e; vagina, f; ureter, g; ureteral artery, h; deep uretene vein, i; ascending branch of the uterine vessels, j; descending branch of the uterine vessels, k; vesico-
has become a necessity. To resect an organ without damage to another, surgeons implicitly understand that an approach is required through knowledge of practical anatomy, which is specific to surgery, rather than one acquired in laboratory dissection.

In this article, a distinction in surgical anatomy has been made between the descriptive form of pre-deformation and practical form of post-deformation (Fig. 2A and B), the former being defined as preoperative morphology that closely resembled descriptive anatomy, and mainly applies to CL or in Wertheim surgery (Fig. 2A). The latter indicated initial surgical morphology following application of a surgical maneuver, specifically corresponding to the stage in which the para¬rectal and paravesical spaces were excavated followed by separation of TCL. This mainly applied to TCL or Latzko method and its modification (Fig. 2B).

5.1. Surgical theory based on descriptive form of pre-deformation.

5.1.1. Ontogenetic anatomy and total mesometrial resection advocated by Höckel et al.

A unique anatomic idea with excellent results has been reported (Höckel et al. 1998, 2003, 2005). These reports have consistently ignored any description of the lateral rectal ligament since publication of an article by them in 1998. The reason for this is inferred from the fact that the relationship between the lateral parametrium and lateral paraproctum is based on descriptive anatomy in which they are always separated horizontally, hence no description of the vaginal vein (deep uterine vein) in their reports. This is the reason why TMMR is defined as separated horizontally, hence no description of the vaginal vein (deep uterine vein) in their reports. This is the reason why TMMR is defined as

\[ \text{TCL} \]

This mainly applied to TCL or Latzko method and its modification (Fig. 2B).

5.2. Surgical theory based on practical form of post-deformation.

5.2.1. The vesicouterine ligament of Okabayashi

VUL has been devided into the anterior and posterior leaves (Fig. 4A and D) (Okabayashi, 1921, 1952). The paravesical space was excavated to separate the posterior leaf of VUL (Fig. 4D). Resection of the posterior leaf separated the bladder and TCL, exposing the paracolpium. Yabuki, et al. divided Okabayashi’s anterior leaf of VUL into the bladder pillar consisting of fascia and the roof of the ureteric tunnel (roughly corresponding to CL; dotted red triangle in Fig. 4C) that is equivalent to the neurovascular bundle (Fig. 4A, B, and C). In addition, morphology and function of Okabayashi’s posterior leaf of VUL (Fig. 4D) were elucidated, naming the extensive area the anterior mesoureter (Figs. 4E and 5A) (Yabuki et al., 1996, 2000, 2005). Then, to carry out simultaneous resection of the roof of the ureteric tunnel and excitation of Okabayashi’s paravesical space, the fourth space was created (Fig. 4A, B, E, and 5A). Furthermore, the conception of the fourth space led to an idea of new semi-radical hysterectomy (double-headed white arrow in Fig. 4E).

5.2.2. Yabuki’s lateral parametrium

Fig. 3A and B show intraoperative findings and Fig. 3C and D anatomy of a fresh cadaver. The main points on the practical form of post-deformation concerning TCL of Yabuki and his associates’ (Yabuki et al., 1991, 1996, 2000, 2005, Yabuki, 2019) are as follows: 1) The bundle (Fig. 3A, C and D), which appears when the paravesical and pararectal spaces are excavated at the lateral aspect to the ureter, is a continuum consisting of the vesicoth ygastic fascia, TCL and lateral rectal ligament (Fig. 2B). Yabuki et al. named this continuum the supporting system, for the relationship became perpendicular with the pelvic organs (Yabuki et al., 1991, 1996, 2000, 2005, Yabuki, 2019); 2) Fig. 3A shows intraoperative finding during development of the paravesical and pararectal spaces with vessels of the supporting system exposed. These vessels contain not only those of the uterus, but also the visceral branches of the internal iliac vessels of the bladder and rectum (Fig. 3D); 3) Seen in 3B are vessels shown in 3A, which have been individually separated and severed at their respective origin. The dorsal limit of the supporting system is the lateral stump of the sacropsinuous ligament; and 4) Fig. 3D shows a cranial view of the supporting system following development of the pararectal space.

A summary of findings on practical anatomy of LP is as follows: (1) The visceral branches of the internal iliac vessels form a plate on a perpendicular plane and lie parallel in a ventral to dorsal direction; (2)
PSN and hypogastric nerve are linked to each other, forming IHP, and represented on a sagittal plane; (3) As a result of the development of the pararectal space, the supporting system and aggregation of nerves are centered at their origins and separated into a V-shape; and (4) The perpendicular supporting system, which is dissected during surgery, is different from horizontal LP in its direction and morphology depicted by P&A and Netter (Fig. 2).

5.2.3. Yabuki’s paracervix and anatomy of the paracolpium
The uterine cervix is anatomically divided into the supravaginal and vaginal parts (TA, 1998), and Yabuki has described each of their lateral supports as follows: 1) The lateral support fuses with the supravaginal part roughly corresponding to the area of TCL (Fig. 4A and C). A part of TCL and CL can be seen overlapped on the medial aspect to the ureter as shown by a dotted red triangle (Fig. 4C). Furthermore, the dorsal aspect of TCL joins the lateral rectal ligament, and the LUL/vesicohypogastric fascia bifurcates from its ventral aspect (Fig. 4C). 2) The lateral support to the vaginal part consists of the following tissues from a medial to lateral aspect: bladder pillar, CL or the roof of the ureteral tunnel, ureter/anterior mesoureter, LUL/vesicohypogastric fascia, and

Fig. 3. The supporting system. A shows the vessels of the supporting system following development of the paravesical and pararectal spaces with the uterine artery excised. B shows a severed end of the supporting system on the pelvic wall. The vesico-hypogastric fascia, TCL and lateral rectal ligament constitute one lamina (Figs. A and C). Shown in C is the supporting system that is viewed from the pubic aspect following excavation of the paravesical space. Shown in D is also the supporting system viewed from a sacral aspect following excavation of the pararectal space. A and B show modified versions of original figures from an article by Yabuki, et al. (1991) and C and D from an article by Yabuki, et al. (2005). a; uterus, b; bladder, f; ureter, g; uterine artery, h; deep uterine vein, n; Latzko’s pararectal space (upper portion), o; common iliac vessels, p; internal iliac vessels, q; paravesical space, w; paracolpium, x; tendinous arc of the pelvic fascia, y; supporting system, aa; middle vesical vessels, bb; middle rectal vessels, cc; PSN, dd; hypogastric nerve, ee; IHP, ff; lateral stump of the tendinous arc of the pelvic fascia and sacrospinous ligament complex, uu; pelvic side wall.

Fig. 4. Anatomy of the lateral uterine ligament. Shown in A is a mock RH using a fresh cadaver. The vesicouterine, fourth, retroperitoneal and pararectal spaces are observed. The paravesical space is to be excavated within the dotted oval black circle. B is a schematic illustration of A. The paravesical space is developed, and the exposed anterior mesoureter is depicted. C denotes the structural component of the paracervix. The dotted red triangle denotes CL. D denotes the separated posterior leaf of VUL of Okabayashi. The superior vesical vein is seen to be transparent (Yabuki et al., 1996). E shows separation of the superior vesical vein and vesical nerve branch following excavation of the fourth space (Yabuki, 2019). a; uterus, b; bladder, f; ureter, g; uterine artery, h; deep uterine vein, k; vesicohypogastric fascia, l; TCL, m; lateral ligament of the rectum, n; Latzko’s pararectal space (upper portion), p; internal iliac vessels, q; paravesical space, r; CL, w; paracolpium, z; LUL, gg; vesicouterine space, hh; retroperitoneal space, ii; fourth space, jj; bladder pillar (superficial layer of VUL), kk; anterior mesoureter, ll; posterior mesoureter, mm; superior fascia of the pelvic diaphragm, nn; superior vesical vein, oo; vesical nerve branch, yy; Okabayashi’s pararectal space.
retroperitoneal tissue (Fig. 4A and C). Between these ligaments exists areolar connective tissue, and spaces are surgically created from a medial to lateral part: vesicouterine, fourth, paravesical and retroperitoneal spaces (Figs. 4A and 5A). Only the bladder pillar and CL are true related tissues of the uterus. Considering these facts, the paracervix was identified as a complex consisting of the bladder pillar, TCL, CL, ureter/anterior mesoureter and LUL/vesicohypogastric fascia (Fig. 4B and C) (Yabuki, 2019). Furthermore, this complex possessed a three-dimensional structure where horizontal and perpendicular planes were intricately combined (Fig. 4B and C) (Yabuki et al., 1991, 1996, 2000, 2005).

There is a popular saying ‘the greater the amount of the vaginal excision, the worse the bladder paralysis.’ As the truth of this popular saying cannot be ascertained, there remain many unresolved issues concerning anatomy and dissection of the vagina and paracolpium. Mackenrodt (1895) stated the following regarding the paracolpium: ‘Short fibrous bundles arise from the fascia of the levator ani as a sort of inferior continuation of the transverse cervical ligament and attach to the side of the connective tissue sheath surrounding the vagina,...’ (Speer, 1996, in English). This fascia can be interpreted as the deep investing fascia or superior fascia of the pelvic diaphragm. This denser connective tissue fiber is to the parietal endopelvic fascia. The area surrounded by a dotted green line (Fig. 5C) shows the pelvic organs severed at the superior most of the vagina (Yabuki, 2019). The area surrounded by a dotted green line indicates the paracolpium (Fig. 5B) and dotted double red arrow indicates the area where the fourth space is created (Fig. 5C). In principle, the length of vaginal resection is irrelevant to the bladder function.

6. Twenty-first century RH.

An issue of RH during the 20th century was confusion of descriptive and practical anatomies which emanated from CL and TCL being regarded as synonymous. This issue was solved by examination of Wertheim and Latzko methods from the viewpoint of practical anatomy, resulting in less-extirpating RH, followed by NSRH (Yabuki et al., 1991, 1996, 2000). Specifically, as shown in Fig. 5A, TCL has been skeletonized by excavation of the paravesical, fourth, Latzko’s pararectal and Okabayashi’s paravesical spaces transversally, separating the continuum consisting of the anterior and posterior mesostructures longitudinally (Fig. 5A). The utilization of this structure in 1991 led to the development of a less-extirpating RH, in which only TCL was selectively resected from the complex (supporting system) consisting of the vesicohypogastric fascia, TCL and rectal lateral ligament. Further, the anterior mesoureter was divided into the vascular and neural parts with only the former being resected. This procedure resulted in a marked decrease in bladder complication, establishing NSRH (Yabuki et al., 1996, 2000). Twentieth century RH, which is based on practical anatomy with its description centered around less-extirpating RH and NSRH, is summarized as follows. In addition, this procedure can be applied not only to abdominal open RH but also to laparoscopic or robot-assisted RH (Hoshiba, et al., 2000, Kanao, et al., 2018).

1. Abdominal incision.
2. Division of the round ligament of the uterus.
3. Excavation of the retroperitoneal space.
4. Pelvic lymphadenectomy.
5. Excavation of the lateral or Latzko’s pararectal space: The vascular
sheath of the internal iliac vessels and posterior fascia of TCL are separated from their respective tissues. The ureter remains attached to the reverse side of the posterior leaf of the broad ligament together with the separated vascular sheath. However, the sacral plexus/piriformis fascia/PSN are not exposed (Fig. 4A and 4C) (Yabuki, et al., 1996).

6. Excavation of the medial or Okabayashi’s pararectal space and separation of the anterior portion of the ureter and posterior mesoureter: Okabayashi’s pararectal space is developed between the posterior leaf of the broad ligament and its subserous fascia (Yabuki, et al., 1996).

7. Mobilization of the bladder

8. Excavation of the paravesical space: the vesicohypogastric fascia is pierced between the ureterine artery and superior vesical artery (P& A, 1934). The space is then developed by separating the ureterine artery and bladder.

9. Excavation of the fourth space: This space is excavated by the dissection of the CL or the roof of the ureteric tunnel and a retrograde incision, i.e. cephalically cutting, of the residual ureteric roof (Fig. 4A and B) (Yabuki, et al., 1996, 2000).

10. Separation of the anterior mesoureter: The ureter/neurovascular bundle is separated between the paravesical and fourth spaces.

11. Denudation of CL/TCL by the excision of the fascia of LP.

12. Separation and severance of the ureterine artery and superficial vein.

13. Separation and ligature of the deep ureterine vein (Fig. 4E).

14. Incision of the peritoneum of pouch of Douglas and excision of the sacrouterine fold: Resection of the rectouterine ligament at the ventral aspect of IHP (Fig. 4D) (Yabuki et al., 1996).

15. Resection of the infundibulopelvic ligament.

16. Separation of the anterior and middle portions of the ureter from the anterior mesoureter.

17. Separation of the superior vesical vein from the vesical nerve together with the separated vascular sheath. However, the sacral plexus/piriformis fascia/PSN are not exposed (Fig. 4A and 4C) (Yabuki, et al., 1996).

7. Conclusion

The greatest issues concerning surgery for cervical cancer during the 20th century were prevention of massive intraoperative hemorrhage and functional preservation of bladder and rectum. These problems were solved by: a) development of a new anatomy, i.e. practical anatomy, that is precisely perceived and described as morphologic changes produced by surgical manipulation of a living body; and b) creation of a new surgical procedure, i.e. less extirpating and nerve-sparing RH based on this practical anatomy.

Author Contribution section

The author conducted the cadaver dissections, surgical procedures and writing the manuscript.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgments

The author is deeply appreciative of Gen Murakami, a former Professor of Anatomy, Sapporo Medical College, Hokkaido, Japan, for his guidance and cooperation in cadaver dissection. The author thanks Dr. Shimpachiro Ogiwara, former Professor at the University of Kanazawa, and Mrs. Sandra M. Ogiwara, CSP (UK), BScPT (C), for English editing of the report. This study was self-funded and not supported by any other grants.

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