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Communication

Mapping the Shifting Landscape of Urological Innovation

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Abstract: Introduction: Surgical innovation in urology has significantly transformed clinical practice, balancing the need for dissemination of novel techniques with rigorous safety and efficacy standards. Surgical innovation is influenced by regulatory standards, cost-effectiveness, and evolving publication requirements. This study examines publication trends in pioneering urological procedures and their implications on surgical innovation. **Methods**: This study analyzed 68 pioneering urological publications, examining the relationship between case numbers and publication trends over time. Data were collected through comprehensive database searches and analyzed using linear regression to identify correlations between publication case numbers and innovation dissemination. **Results**: A significant increase in the number of cases per publication was observed over time (R^2 = 0.798, OR = 6.29, 95% CI: 2.57–10.02, p = 0.007). Early transformative techniques were frequently published as single-case reports or small series, whereas incremental innovations required larger case volumes, potentially delaying publication from resource-limited settings. **Conclusions**: This study highlights the need for a merit-based approach to evaluating surgical innovations, balancing rigorous safety standards with timely dissemination. Frameworks like IDEAL offer structured pathways for evaluating surgical innovations, ensuring robust evidence generation while maintaining flexibility for diverse practice settings. This study advocates for a reassessment of publication criteria to foster a balance between innovation, safety, and inclusivity, ultimately promoting the efficient and equitable advancement of surgical techniques.

Keywords: innovation; surgical techniques; pioneering urology; surgical technology; publishing requirements

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1. Introduction

Innovation is key to the advancement of medicine and subsequent improvement in patient care [1]. This is particularly true in surgery, where pioneering techniques have transformed operative management from historically highly risky, peri-morbid, and disfiguring procedures to contemporary low-risk and minimally invasive approaches [2]. There is a delicate balance between enabling innovation and minimizing patient harm [3]. However, the pathway to surgical innovation is often fraught with numerous barriers, including the need to demonstrate not only clinical effectiveness but also cost-effectiveness and safety.

Regulatory requirements from agencies such as the Food and Drug Administration (FDA), European Medicines Agency (EMA), and National Institute for Health and Care Excellence (NICE) further complicate this landscape, each imposing distinct standards and hurdles that must be navigated before new techniques can be widely adopted [4].

A critical factor contributing to the propensity of journals to accept publications on novel surgical techniques is the number of cases included in the study. Higher case numbers often provide stronger evidence for the efficacy and safety of a procedure, making it more likely to gain acceptance from both peer-reviewed journals and regulatory bodies [5,6]. This emphasis on case numbers reflects a broader shift towards evidence-based practice, where substantial case series are needed to justify the adoption of new procedures, especially those that may involve higher costs or increased surgical risks.

2. Objectives

Our research aims to explore how publication trends, specifically regarding case numbers, have evolved over time within the urological domain. By examining pioneering urological publications, we aim to understand whether there has been a shift in the number of cases required for a technique to be considered innovative and worthy of publication. This analysis focuses on providing valuable insights into the changing landscape of surgical innovation and the factors influencing the dissemination of novel techniques in urology. Our findings seek to contribute to a more nuanced understanding of how surgical innovation can be fostered while ensuring patient safety and efficacy remain paramount.

3. Methods

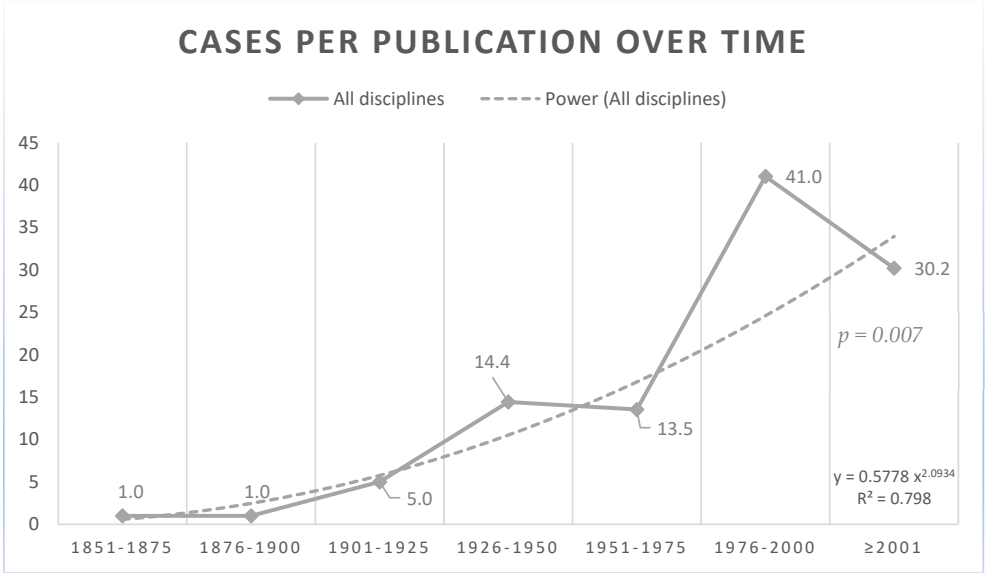
To explore this, a list of key urological operations was generated by a consultant urologist (D.A.), collated and cross referenced to urology operative texts (S.S. and D.H.). These novel techniques in urology were then assessed using a structured multi-reviewer analysis of pioneering urological publications. Criteria for inclusion were the first publication by chronological order describing a novel urological procedure on human subjects. This included initial multi search engine using Scopus, Ovid Medline, and PubMed. English language search was performed, and all published languages were included via reference chasing. Literature search and reference tracing were independently performed by multiple reviewers (S.S., B.D., and T.N.) with centralized adjudication and review (D.H.). Data extracted included paper title and type, year and journal of publication, number of cases with which technique was published, and technical procedural description. Data were analyzed to assess trends in case volume per publication over time with linear regression, and results were presented as odds ratio (OR) [95% confidence interval (CI)]. p-values < 0.05 were considered statistically significant. Statistical analysis was performed with StataBE v18.0 (StataCorp LLC, College Station, TX, USA) [7].

4. Results and Discussion

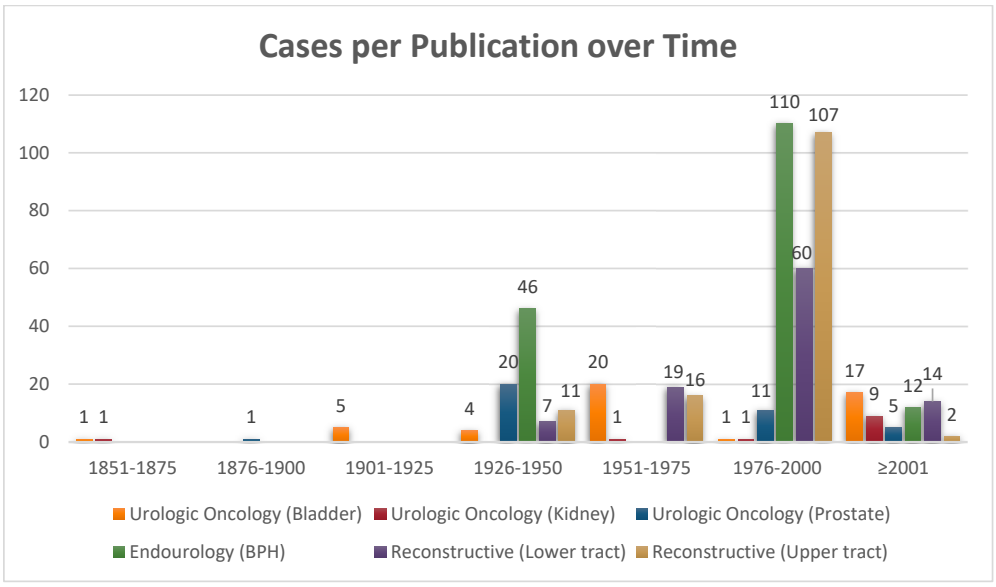
A total of 68 publications describing pioneering techniques in urology were identified (Appendix A). These included 16 isolated case reports and 52 case series. Among the case series, 22 involved small cohorts with 2 to 10 cases, while 30 featured larger cohorts with more than 10 cases. Initial analysis was performed by grouping publications in chronological ordinal groups, and ordinal logistical regression was performed. Pioneering urological techniques were then split into six discrete domains including uro-oncology (bladder), uro-oncology (prostate), uro-oncology (kidney), reconstructive urology (upper tract), reconstructive urology (lower tract), and endourology.

Prior to 1901, techniques in urology were published as solitary case reports (mean cases per publication [CPP] = 1) (Figure 1a). Publications from 1901 onwards demonstrated

a gradual increase in cases per publication (R^2 = 0.798, OR = 6.29 [95% CI: 2.57 to 10.02], p = 0.007) (Figure 1a). This can be largely attributed to the transformative nature of historical procedures allowing for the surgical technique itself to be a focus of the publication. Procedures such as open radical nephrectomy and open radical prostatectomy were considered transformative as they changed surgical management drastically. These procedures were widely adopted at the time, as their benefits were evident. In contrast, modifications to existing, widely adopted procedures often showed only incremental benefits. As such larger case series are often required to demonstrate the additional benefits derived from novel procedures and justify increased costs or surgical risks. A clear example was seen comparing the introduction of transvesical prostatectomy (1887, 1 case) to the Transurethral Resection of the Prostate (TURP) (1926, 46 cases) and to the Holmium Laser Enucleation of the Prostate (HoLEP) (1995, 110 cases) (Appendix A).



(**a**)



(**b**)

Figure 1. Historical analysis of pioneering techniques in urology. (**a**) Cases per publication total over all sub-specialties over time. Linear regression, R2 = 0.798, OR = 6.29 [95% CI: 2.57 to 10.02], p = 0.007. (**b**) Cases per publication per discipline (separate bar) over time.

When split into distinct domains, the findings were more heterogenous (Figure 1b). Whilst the general trend was an increase in CPP with time, recent surgical innovations paired with technological innovations have not followed this. This is well demonstrated by endourological publications where CPP peaked at 110 for the period 1976–2000 and subsequently decreased to 12 CPP from 2001 onwards. This was due to the low number of cases published in the initial case series of recent endourological procedures paired with technological innovation for the treatment of benign prostatic hypertrophy (BPH) such as Urolift and the Greenlight Photovaporization of Prostate and Rezum (Appendix A). A similar pattern was seen in reconstructive urological procedures, with the highest CPP seen in the period 1951–2000.

Our results reveal that many transformative surgical techniques were initially reported as isolated case studies or small series, underscoring the primacy of innovation over publication volume. This observation highlights the need for flexible publication standards that emphasize methodological rigor and robust peer review rather than adherence to arbitrary thresholds such as minimum case numbers. While larger case series offer strong evidence for the safety and efficacy of novel techniques, they are not without limitations. The extended time required to accrue substantial cohorts, particularly in centers with lower procedural volumes, can delay the dissemination and clinical adoption of potentially groundbreaking innovations. Additionally, the financial and logistical burdens associated with conducting large-scale studies may disproportionately affect resource-limited settings, thereby restricting the diversity and inclusivity of contributions to the surgical literature.

The Idea, Development, Exploration, Assessment, Long-term (IDEAL) framework, introduced in 2009, provides a structured approach to the optimal generation of evidence for surgical innovation. It outlines five stages: Idea, Development, Exploration, Assessment, and Long-term, guiding the progression of a novel procedure from its initial description through evaluation and exploration to its long-term study [8]. The IDEAL framework adds significant value by improving the quality of evidence for new surgical interventions. It specifies the appropriate study designs and reporting requirements at each stage, ensuring robust evaluation and collective learning. Additionally, it helps to determine when to advance to higher levels of evidence, such as randomized clinical trials. By encouraging standardization and transparency, the framework promotes safe, efficient, and evidence-based surgical innovation [4,8]. The integration of frameworks such as IDEAL can significantly enhance the systematic evaluation of novel techniques. However, maintaining flexibility within the publication process remains crucial. Journals should evaluate each submission on its individual merits, employing rigorous peer review to address potential limitations inherent in smaller studies. This approach fosters an environment where innovation can progress without compromising patient safety or the scientific rigor essential to maintaining the integrity of the evidence base.

This study's limitations include reliance on major databases and by selecting English-language-only publications. To mitigate this selection bias, the authors performed independent literature searches with multiple reviewers to reduce oversight and ensure consistency through centralized adjudication. A broad search strategy, using various databases (PubMed, Ovid, and Scopus) and diverse keywords, was employed to capture a wider range of pioneering techniques. Additionally, reference chasing and the inclusion of non-English publications aimed to minimize language bias. The inclusion criteria, developed with a senior urologist and cross-referenced with standard texts, ensured a comprehensive and rigorous search process, further addressing potential biases in study selection.

5. Conclusions

Safe and efficacious surgical innovation is essential for advancing the technical and technological aspects of surgery. Historical trends demonstrate that many transformative techniques were initially published with small case numbers, emphasizing the importance of early dissemination and peer review in fostering innovation. While the IDEAL framework offers a structured pathway for evaluating new techniques, its application must remain adaptable to accommodate diverse practice environments, including smaller or resource-limited centers. Imposing rigid publication requirements for large case series risks delaying the dissemination of promising innovations, thereby limiting timely peer feedback and potential patient benefits. A merit-based, balanced approach to publication criteria that prioritizes methodological rigor, adequate follow-up duration, and the potential impact of innovation will better serve the surgical community. Journals should continually reassess their criteria to promote timely and safe innovation without compromising patient outcomes or stifling creativity.

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Appendix A. Collated Data PDF

SN	Surgical Procedure	No. of Cases	Year	Reference
Surgical Procedures with a Single Case Report				
1	Open simple nephrectomy for benign disease	1	1869	Simon [9]
2	Open partial nephrectomy for benign disease	1	1870	Simon [9]
3	Open partial nephrectomy for renal tumour	1	1887	Herczel et al. [10]
4	Transvesical prostatectomy	1	1887	Belfield [11]
5	Boari flap reimplantation of the ureter	1	1947	Ockerblad [12]
6	Anderson-Hynes dismembered pyeloplasty	1	1949	Anderson et al. [13]
7	Open radical nephrectomy	1	1952	Foley et al. [14]
8	Reconstruction of the perineal urethra with a free full-thickness skin graft of the prepuce	1	1953	Presman et al. [15]
9	Lich-Gregoir extravesical ureteral reimplantation	1	1964	Lich et al. [16]
10	A penile flap procedure for the relief of meatal stricture	1	1963	Cohney [17]
11	Transperitoneal laparoscopic nephrectomy	1	1991	Clayman et al. [18]
12	Laparoscopic simple cystectomy	1	1992	Parra et al. [19]

SN	Surgical Procedure	No. of Cases	Year	Reference
13	Laparoscopic partial nephrectomy for benign disease	1	1993	Winfield et al. [20]
14	Retroperitoneal laparoscopic simple nephrectomy using a balloon dissector	1	1993	Gaur et al. [21]
15	Laparoscopic dismembered pyeloplasty	1	1993	Kavoussi [22]
16	Retroperitoneal laparoscopic partial nephrectomy	1	1994	Gill [23]
Surgical procedures with 2–10 cases				
1	Rectal urinary diversion for exstrophy bladder	8	1905	Remedi [24]
2	Ileal conduit urinary diversion	2	1911	Zaayer [25]
3	One-stage operation for hypospadias	7	1941	Humby et al. [26]
4	Open radical cystectomy	6	1949	Marshall et al. [27]
5	One stage urethroplasty with full-thickness skin graft	6	1963	Devine et al. [28]
6	Orandi one-stage urethroplasty using penile skin flap	10	1968	Orandi [29]
7	Ileocaecal continent urinary diversion	7	1974	Ashken [30]
8	Meatal reconstruction	7	1976	Brannen [31]
9	Quarty one-stage penile/preputial flap urethroplasty	10	1983	Quartey [32]
10	Aesthetic repair of meatal stricture	5	1984	De Sy [33]
11	Reconstruction of the fossa navicularis	5	1987	Jordan et al. [34]
12	Buccal mucosal graft for urethral reconstruction	6	1992	Bürger et al. [35]
13	Laparoscopic dismembered pyeloplasty	5	1993	Schuessler [36]
14	Penile circular fasciocutaneous flap urethroplasty (McAninch)	10	1993	McAninch [37]
15	Laparoscopic radical prostatectomy	9	1997	Schuessler [38]
16	Robotic-assisted laparoscopic radical prostatectomy	5	2001	Pasticier [39]
17	Percutaneous endopyeloplasty	9	2002	Gill [40]
18	Photoselective vaporization of the prostate (PVP)	10	2003	Hai [41]
19	Robotic radical nephrectomy	5	2005	Klingler [42]
20	Rezūm: transurethral convective water vapor treatment for BPH	7	2015	Dixon [43]
21	Modified orandi urethroplasty	10	2015	Goel [44]
22	Transurethral ventral buccal mucosa graft inlay urethroplasty for distal penile stricture	3	2016	Nikolavsky [45]
Surgical procedures with >10 cases				
1	TURP	46	1926	Stern [46]
2	Foley Y-V pyeloplasty	20	1937	Foley [47]
3	Millin's prostatectomy	20	1945	Millin [48]
4	Vertical flap pyeloplasty	12	1953	Scardino et al. [49]
5	Culp-DeWeed pyeloplasty	27	1954	Culp et al. [50]
6	Politano-Leadbetter reimplantation	14	1958	Politano et al. [51]
7	Ileal neobladder	32	1958	Camey [52]

SN	Surgical Procedure	No. of Cases	Year	Reference
8	Burch colposuspension	53	1961	Burch [53]
9	Lich-Gregoir extravesical technique	27	1964	Gregoir et al. [54]
10	Omental pedicle graft in the repair and reconstruction of the urinary tract	43	1967	Turner-Warwick et al. [55]
11	Two-stage urethroplasty using scrotal flap	17	1968	Blandy et al. [56]
12	Free full-thickness skin graft urethroplasty	60	1976	Devine et al. [57]
13	Cohen's cross-trigonal ureteral reimplantation	315	1977	Cohen [58]
14	Open radical prostatectomy	12	1983	Walsh et al. [59]
15	One-stage urethroplasty with oral graft	20	1993	El-Kasaby et al. [60]
16	Snodgrass tubularized, incised plate urethroplasty for hypospadias	16	1994	Snodgrass [61]
17	Holmium Laser Enucleation of the Prostate (HoLEP)	110	1995	Gilling et al. [62]
18	Two-stage repair of hypospadias	600	1995	Bracka [63]
19	Ventral onlay graft urethroplasty	13	1996	Morey et al. [64]
20	Dorsal onlay graft urethroplasty (Barbagli)	25	1996	Barbagli et al. [65]
21	Mesh graft urethroplasty	20	1997	Carr et al. [66]
22	Endoscopic skin-graft urethroplasty	53	1998	Naudé [67]
23	Dorsal inlay free graft urethroplasty (Asopa)	12	2001	Asopa et al. [68]
24	Robotic radical cystectomy	17	2003	Menon et al. [69]
25	Robotic partial nephrectomy	13	2004	Gettman et al. [70]
26	Robotic-assisted laparoscopic dismembered pyeloplasty	50	2005	Patel [71]
27	One side dorsal onlay buccal mucosa graft urethroplasty (Kulkarni)	24	2009	Kulkarni et al. [72]
28	UroLift	19	2011	Woo et al. [73]
29	Combined dorsal BMG and onlay penile skin flap urethroplasty for obliterative distal urethral strictures	12	2011	Gelman et al. [74]
30	Non-transecting anastomotic bulbar urethroplasty	22	2011	Andrich et al. [75]

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