Quantifying Innovation in Surgery

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Introduction

Innovation in healthcare technology generally, and more specifically within surgery, can be defined as a dynamic and continuous process involving the introduction of a new technology or technique that initiates a change in clinical practice.[1,2] Innovation has been unrelenting in surgery since the introduction of aseptic technique and anaesthesia in the late 19th century, and has been spasmodic in line with the advent of novel and enabling technologies, most recently the advent of minimally invasive surgery (MIS).[3]

The study of innovation is a relatively mature academic field in social science and industry. It stems from seminal work undertaken by Ryan and Gross in the 1940s that related to the adoption of agricultural products,[4] although has become universal in its theoretical application.[2,5–7] Although there has been increasing interest in innovation theory and its application within healthcare,[3,8–12] a robust method or framework for quantitative analysis is missing. Progress across all healthcare disciplines has been limited by this lack of an appropriate and easily accessible metrics for innovation.[2,13]

The genesis of technological innovation is often identified as an original patent. A patent can be defined as "the right to exclude others from making, using, offering for sale, or selling an invention",[14] and represents a relevant, reliable, and readily accessible potential tool for measurement of technology development.[2] A more recognised alternative to patent data is the bibliometric analysis of peer-reviewed publications.[15] These metrics have both been proposed as measures of healthcare research output.[16]

Surgery has seen a recent paradigm shift in practice due to the development of MIS, which has been facilitated by technological innovations. As a result, innovation in surgical technology represents an excellent exemplar technology sphere with which to address the objectives of this study: the first was to assess the applicability of patents and publications as metrics of healthcare technology and innovation, the second, to evaluate the historical relationship between patents and publications, and finally, to develop a methodology that can be used to determine the rate of innovation growth in any given healthcare technology cluster.

Methods

Patent and publication data collation

Patent data were collated using the proprietary software *PatentInspiration* (AULIVE, Ypres, Belgium) which searches the "DOCDB" patent database using bibliographic data from over 90 countries.[17] Granted patents (titles, abstracts, and descriptions) were searched from 1980 to 2010 using the following Boolean search strategy: ("surgeon" OR "surgical" OR "surgery"). The search results were limited to single members of patent families to prevent duplication of data. Using the same strategy, a PubMed (National Library of Medicine, Maryland, USA) search was performed to extract publication data for the same period.

Normalisation of data

Over the course of time, both overall patent and publication counts have been rising exponentially (Figure 1). Both patent and publication counts were normalised using total patent and publication counts from 2010 (the year reporting the greatest number of patent and publications) using the equation below.

$$II_i^{normalised} = \frac{II_i^{original}}{c_i}$$

$$c_i = \frac{t_i}{t_{2010}}$$

Here, t_i is the total number of patents granted by the U.S. patenting office, or publications indexed on PubMed and c_i is the innovation constant for a given year, i, and II_i denotes the innovation index (defined as the number of patents or publications within a specific domain). This approach to scaling data has been previously utilised for analysis of patent data [18,19] but has not yet been applied to publication data, though the same principles apply.

Patent Codes

All patents are identified by a series of codes; these allow patents pertaining to similar technologies to be grouped together. The code structure is pyramidal with the most descriptive codes lying at the base of the hierarchy (see Figure 2). These descriptive codes were used when performing the analysis of patent performance, as outlined below.

Establishing the top performing and emerging technology clusters

Following compilation of the dataset, the top 30 performing patent codes (those patent codes under which the greatest number of patents had been applied for) were extracted. Codes were subsequently grouped into clusters of related surgical technologies (see Figure 2) by two authors (AHH & HJM) with any disagreement arbitrated by a third author (EKM).

In order to identify the patents granted within these technology clusters, but not captured within the top 30 patent codes, a Boolean search, specific to each cluster, was undertaken of the patent database (see Table 1 for specific search strategies). The same strategies were then used to search PubMed in order to acquire a measure of publication activity. Searches were limited to the well-defined areas of technological innovation; these were determined by two authors (AHH & HJM), with any disagreement, again, arbitrated by a third author (EKM). This process was undertaken to acquire a measure of technology and innovation year-on-year.

The above methodology was then repeated while limiting the search period to 2000 to 2010. Reframing the data to a more recent time period generated a contemporary list of the top 30 patent codes. The comparison of the two datasets allowed areas of recent technology expansion to be explored.

Statistical Analysis

Patent and publication data were plotted against one another to determine the nature of their relationship. If their relationship was monotonic, Pearson's (r) or Spearman's rank (r_s) correlation coefficient was utilised, depending on whether the association was linear or non-linear, respectively. Statistical analysis was undertaken using *GraphPad Prism* (GraphPad Software Inc, CA, USA).

Results

Data on patents and publications

The initial search of patent data retrieved a total of 52,046 patents. The largest proportion of patents was accounted for by the USA, representing 28% of the data pool (Figure 3). The initial search of the PubMed database retrieved a total of 1,801,075 publications. The original and normalised patent and publication data are illustrated in Figure 1, with surgical patenting activity exhibiting an overall upward trajectory over time in contrast to publication activity which appeared to peak in 1997, followed by a subsequent decline toward a baseline level.

Top performing technology clusters

The top performing technology clusters over the last 30 years are summarised in Table 2. The largest cluster was minimally invasive surgery (MIS), accounting for 40.1% of patents granted during the period studied. The four other technology clusters selected for in-depth analysis were image-guided surgery, robot-assisted surgery, surgical staplers, and ophthalmic surgery (Table 2).

When the same analysis was performed on patents from 2000 to 2010, there was re-arrangement in ordering of the top-performing technology clusters. Image guidance represented the most dominant group accounting for 27.4% of patents. Robot-assisted surgery, which did not feature in the initial 30-year analysis, also emerged as an important technology cluster (Table 2).

Relationship between patents and publications

As can be seen in Figure 4, the rapid growth in both robot-assisted surgery and image guidance appears to be closely related, with patent and publication rate very strongly correlated (r_s = 0.98 and 0.94 respectively, $p < 0.001$). As an established technology cluster, MIS had a unique patent and publication signature amongst those selected for analysis. The period from 1990 to 1994 saw a rapid rise in MIS patent and publication counts. This initial rise was followed by a sustained period of slower growth in publications and patents. Similarly high correlation was seen between patent and publication counts within MIS ($r_s = 0.95$, $p < 0.001$). Surgical staplers and ophthalmic surgery were the oldest of the technologies evaluated [20,21] and demonstrated a relatively constant rate of both patent and publication counts over the 30-year period examined, with poor correlation of these metrics ($r_s = 0.30$, $p = 0.10$ and 0.46 $p=0.009$).

Further post-hoc analysis of surgical stapler and ophthalmic surgery data was undertaken to investigate the observed flat and poorly correlated growth pattern. The analysis period was extended to span from 1950 to 2010 such that longer-term trends could be determined (Figure 3). This revealed sigmoid shaped growth curves followed by prolonged plateau phases for both technology clusters. Correlation of the stapler and ophthalmic surgery datasets over this period of time improved to 0.65 ($p < 0.001$) and 0.84 ($p < 0.001$) respectively.

Discussion

In this study a quantitative analysis of healthcare technology and innovation has been performed using a novel framework combining international patent and publication data. Using surgery as an exemplar, we have identified major technology clusters of influence and their respective patterns over time. Minimally invasive surgery was found to be the most significant innovation to have occurred over the past 30 years, with notable peaks in overall publication and patent counts corresponding closely with its progress of adoption into clinical practice. Looking forward, recent trends in these metrics suggest that image guidance and robotics will play an increasingly important role in the near future. The distinctly steep upward trajectories for publication and patent counts of these emerging technology clusters highlights potential future value in using these metrics as forecasting tools for clinical impact potential.

Rogers' *Diffusion of Innovations* theory describes the adoption curve of a technology as 'S-shaped'.[5] Attitudes and responses of potential adopters towards any given innovation vary along different portions of the curve, and this influences their status and timing of adoption.[5] This curve does not apply exclusively to the adopters. As evidenced by the data presented in this study, the theory can also be applied to specific innovation clusters themselves (Figure 4).[6]

Between 1980 and 2010 three phases of publication and patent activity were seen amongst the technology clusters selected for in-depth analysis; 1) a correlated exponential rise (i.e. image guidance, robotics and pre-1994 MIS), 2) a plateau (i.e. MIS post-1994), and finally a poorly correlated plateau in both patents and publications (i.e. surgical staplers and ophthalmic surgery post-1980). These phases correspond to the different periods of innovation highlighted in Figure 4. The first phase is one of *incubation* in which there is take off in growth corresponding to early patenting and publication activity.[22] The patents and publications filed in this stage are likely to be 'high value' due to their seminal nature and as such are likely to be highly cited. This incubation phase is followed by a phase of *exponential growth* [22] corresponding to maximal innovation reflected by a high innovation output by both surgeons (reflected in publication counts) and institutions and industry (reflected in patent counts). In the final phase of the curve, patent and publication numbers plateau, representing the point of *diffusion saturation*, at this point patent and publication counts are sustained by technological refinement [7,22] but the period of maximal innovation has passed.

Within the cluster of surgical staplers and ophthalmic surgery, the poorly correlated and comparatively flat trends in patent and publication counts were inconsistent with the other clusters examined and the expected sigmoid shaped growth curves. This plateau-like pattern may relate to the maturity of the technologies.[20,21] Similar poorly correlated flat growth trends have been documented outside of the medical literature as being indicative of a mature technology in which industry leaders incrementally refine patents to maintain market share.[7] The extended post-hoc analysis confirmed these plateaus to be the tail-end of a prolonged classical S-shaped innovation curve.[5]

Another curious trend is the decrease in number of patents granted from 2008 to 2010 across all datasets examined. There are two possible explanations for this. First, that innovation in surgery is currently in a state of *lapsed activity,* perhaps as a consequence of the recent global economic crisis. The second, and possibly more likely explanation, is that this downturn in patenting is a result of the *delay* between a patent being applied for and it being granted.[6]

Historically, research examining healthcare innovation has almost exclusively focused on the *qualitative* analysis of isolated case examples.[3,9,11,23] Within the wider healthcare context, much of the literature is orientated towards the generalisable process of adoption rather than innovations or technology clusters themselves.[8,12,24,25] The status of scientific study in healthcare innovation is therefore restricted in scope to assess performance of medical or surgical technologies objectively, or forecast future growth and potential for clinical impact. This study has addressed this restriction providing a *quantitative* framework, based on patent and publication data, with which to assess the impact of past, and potential impact of emerging areas of healthcare innovation.

The use of patent library data as a tool to measure healthcare innovation is under-utilised and under-investigated. Trajtenberg described a method for equating patent citations and counts with innovation value, and reported that these metrics were indicative of patent *value* within the then novel and expanding technology field of computed-tomography (CT) imaging.[2,26] This work demonstrated that patent counts, weighted by citations, were symptomatic of the value of innovation within the technology cluster of CT scanners. In addition to establishing relationships between patent citations and innovation, it was also postulated that simple patent counts were a good measure of the amount of research and development occurring within a given field.

Outside the healthcare literature, a number of other studies have also described a quantitative approach to analysis of innovation.[6,7,27] Bengisu *et al* examined the use of patent and publication data to forecast emerging technologies across a wide range of disciplines and demonstrated similar findings to this study.[7] Their findings being that technologies demonstrating a high correlation between patents and publications were most likely to become key technologies for industry in the future, while technologies that had relatively flat growth and low correlation had reached maturation, with developers minimizing risk by reducing investment in the product.[7]

In addition to being metrics of innovation, both patents and publications may themselves act as adjuncts to innovation. Both exist on publically available databases that are accessed as a matter of routine by ‘innovators’ as a repository of knowledge acting to inspire the development of novel ideas and technologies. As such, a rise in patents and publications may positively re-enforce the diffusion of innovation within a particular technology cluster. Although of interest, this feedback loop does not alter the efficacy of patent and publication counts as innovation metrics since the end product, innovation growth, is left unaffected.

Although this study offers a novel quantitative approach to assessment of healthcare innovation, it is not without limitations. Patents may ignore the output of independent inventors who do not have the financial resources to patent. A similar problem relates to an artificial publication lag, with developers potentially employing a strategy of deliberate academic publication delay until a patent has been granted. There are two further factors that may limit the predictive capacity of the model: firstly, the methodology prevents recognition of a valuable innovation in its nascence; and secondly, there is unavoidable time lag between an original patent application and patent granting.

Conclusions

Publicly available patent and publication data can be used to both identify and, to some extent, forecast technological innovation in healthcare.[2,7] Within this paper, these metrics have been utilised to empirically map 30 years of surgical history. In addition to establishing the influential technology clusters of the past, our results offer insight into the future landscape for surgical technology, with the fields of surgical image guidance and robotics undergoing exponential growth. The novel methodology proposed in this paper for intra- and inter-technology cluster assessment also holds potential value and can potentially be used to assist in the decision making process when determining future research agendas and allocating funding.

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Figure Legends

Figure 1. **Top row:** Rise in patent and publication counts year-on-year (1950-2010). The left hand axis relates to the *innovation index* for patents or publications, while the left right relates to those pertaining to surgery. R^2 values of exponential curves demonstrated better goodness of fit than those for linear relationships. **Bottom row:** Original counts and the corrected *innovation index* for patents and publications year-on-year related to surgery (1980-2010)

Figure 2. Patenting offices by percentage of total patents filed relating to surgery, data from the United States patenting office was used for the normalisation of data

WIPO = World intellectual property organisation, EPO = European patent office

Figure 3. Year-on-year *innovation index* for patent and publications within exemplar technology clusters. Where two y-axes are displayed the left pertains to *innovation index* for publications and the right for patents

Figure 4. Innovation Curve. 1) Period of technological incubation 2) Period of widespread innovation and technological adoption 3) Period of technological refinement

Supplementary Figure 1. Hierarchy of top 30 performing patent codes retrieved by the search "Surgery OR Surgical OR Surgeon" between 1980 to 2010 and 2000 to 2010. On the left hand side of the figure the patent codes and their cluster allocation in elucidated. ✶Denotes clusters chosen for in depth analysis