The Journal of Arthroplasty 31 (2016) 1366–1372

Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

Educational Update

Quantitative Analysis of Technological Innovation in Knee Arthroplasty

Using Patent and Publication Metrics to Identify Developments and Trends

David M. Dalton, MB, MCh, MRCS [a, *], Thomas P. Burke, MB, BCh, MRCS [b], Enda G. Kelly, MB, MCh, MRCS [a], Paul D. Curtin, MD, FRCS (Tr & Orth) [a]

[a] Department of Orthopaedic Surgery, Cappagh National Orthopaedic Hospital, Finglas, Dublin, Ireland
[b] Department of Surgery, Royal College of Surgeons in Ireland, Dublin, Ireland

ARTICLE INFO

Article history:
Received 3 September 2015
Received in revised form
5 December 2015
Accepted 14 December 2015
Available online 20 December 2015

Keywords:
innovation
arthroplasty
knee
technology
governance

ABSTRACT

Background: Surgery is in a constant continuum of innovation with refinement of technique and instrumentation. Arthroplasty surgery potentially represents an area with highly innovative process. This study highlights key area of innovation in knee arthroplasty over the past 35 years using patent and publication metrics. Growth rates and patterns are analyzed. Patents are correlated to publications as a measure of scientific support.

Methods: Electronic patent and publication databases were searched over the interval 1980-2014 for "knee arthroplasty" OR "knee replacement." The resulting patent codes were allocated into technology clusters. Citation analysis was performed to identify any important developments missed on initial analysis. The technology clusters identified were further analyzed, individual repeat searches performed, and growth curves plotted.

Results: The initial search revealed 3574 patents and 16,552 publications. The largest technology clusters identified were Unicompartmental, Patient-Specific Instrumentation (PSI), Navigation, and Robotic knee arthroplasties. The growth in patent activity correlated strongly with publication activity (Pearson correlation value 0.892, $P < .01$), but was growing at a faster rate suggesting a decline in vigilance. PSI, objectively the fastest growing technology in the last 5 years, is currently in a period of exponential growth that began a decade ago. Established technologies in the study have double s-shaped patent curves.

Conclusion: Identifying trends in emerging technologies is possible using patent metrics and is useful information for training and regulatory bodies. The decline in ratio of publications to patents and the uninterrupted growth of PSI are developments that may warrant further investigation.

Innovation is a cornerstone of surgical practice. Knee arthroplasty has evolved drastically through innovation. In 1861, knee arthroplasty entailed joint resection but progressed to interposition arthroplasty, linked devices, and eventually, the precursor of the modern knee implant; Townley's Total Condylar implant in 1972 [1]. Nonetheless, many of the fundamental principles remain controversial including balancing mechanisms, kinematic vs non-kinematic resection, and rotating vs static platforms. The last decade has seen the introduction of computer navigation knees, surgical robotics, and patient-specific instrumentation. With the rate of knee arthroplasties set to rise over the coming years, competition between implant manufacturers competing for a share of the market will only increase [2].

Innovation is defined as "an idea, practice, or object that is perceived as new by an individual or other unit of adoption" [3]. It can involve a change in instrument technology or surgical technique but often one necessitates a change in the other [4]. Innovation is equivalent to translational research; applying principals of basic science and results of basic scientific research to

No author associated with this paper has disclosed any potential or pertinent conflicts which may be perceived to have impending conflict with this work. For full disclosure statements refer to http://dx.doi.org/10.1016/j.arth.2015.12.031.

* Reprint requests: David M. Dalton, MB, MCh, MRCS, 9 Lansdowne Tce, Ennis Rd, Limerick, Ireland.

http://dx.doi.org/10.1016/j.arth.2015.12.031
0883-5403/

everyday patient care [4]. Successful surgical innovations require rigorous clinical studies for validation and to accurately identify unexpected failures [5]. Innovation in surgery is complex and faces a number of barriers, including international regulation, ethical considerations, medical practice patterns, and education [6,7].

Surgical innovation has been explored previously [4-6,8-10]. It is a cyclical process and has 3 main phases (1) era of ferment (abundant interest in research and many new ideas), (2) era of incremental growth (interest in one technology grows rapidly as it becomes the dominant design and focus of research), and (3) technological discontinuity (the dominant design reaches a technology ceiling and ceases to grow) [4,11-13]. An enabling and/or disruptive technology results in a change in current thinking and established practices, leading to a flood of new technologies and/or procedures (ie, an era of ferment) that have the potential to greatly improve outcomes, for example, arthroscopy. Incremental and/or sustaining technology builds on established practices, slightly improving results, making it more difficult for new ideas and firms to breakthrough [4].

A patent is defined as the "right to exclude others from making, using, offering for sale, or selling an invention"; therefore, it is both a reliable and an easily accessible method for identifying technological development. It has recently been proposed as a measure of health care research output [8,9].

This is the first study that assesses innovation to be carried out in the orthopedic field. The primary aim of the study was to objectively establish key areas of technological innovation in knee arthroplasty. We review patent and publication data over the last 35 years. We use these data to quantify, evaluate, and highlight trends in innovation within individual technology clusters using a previously published methodology [8,9]. Correlating patents to publications assesses the scientific support for innovations.

Methods

A Boolean search strategy specific to knee arthroplasty was used to establish patenting and publication activity from 1980 to 2014 (Table 1). A search was performed of the PatentInspiration database [14]. This database contains patent data from over 90 countries. The top 50 performing patent codes were identified based on the number of times the code appeared within the total patents generated by our search (each individual patent may contain a number of codes). Only one representative patent per family was included to avoid duplication. The patent codes were sorted into clusters of similar technologies by 2 authors (D.D. and T.B.). If there was disagreement as to what cluster a code should be assigned to a third author, E.K., had the casting vote. Only well-defined technology clusters were selected for in-depth analysis. Clusters such as instruments and codes referring to generic anatomic sites were excluded from further analysis. In addition, the top 50 cited patents were analyzed for any major development that may have been missed on the initial search. Any previously missed major development identified in this way was treated as a technology cluster. To accurately quantify these clusters, further individual Boolean searches of the PatentInspiration database was undertaken specific to each cluster. A search of the PubMed database was undertaken using the same search strategies to generate a measure of year-on-year publication activity.

A previously validated formula for correcting for the exponential growth in patents and publications is used:

$$II_i^{\text{normalized}} = II_i^{\text{original}} \Big/ c_i$$

$$c_i = t_i / t_{2014}$$

where II is the innovation index, "i" is the year in question, t is the total amount of patents granted by the US patent office, and c_i is the innovation constant; 2014 is used to normalize the data, as it is the most recent year and the year with the highest number of patents and publications. Four-year moving averages were used to allow better visualization and understanding of trends.

Table 1
Knee Arthroplasty, Unicompartmental, and Robotics Search Strategies Were Searched in Patent Title, Abstract, and Description.

Patent Group	Search Strategy
Knee arthroplasty	"knee arthroplasty" or "knee replacement"
Unicompartmental	"knee arthroplasty" or "knee replacement" AND unicondylar or uni or unicompartimental
Patient-specific implants	"knee arthroplasty" or "knee replacement" AND "custom" or "customised" or "patient-specific" or "personalized"
Navigation	"knee arthroplasty" or "knee replacement" AND "navigation"
Robotics	"knee arthroplasty" or "knee replacement" AND "robot" or "robotics" or "robotic"

Custom and navigation searches substituted claims for description to maintain specificity.

Results

The initial search generated 3574 patents and 16,552 publications. The top 50 performing patent codes of the initial search are summarized in Table 2.

The top performing clusters were instruments and components comprising over 31% of patents granted combined. A further 29.2% were codes that were nonspecific and excluded from further analysis. The chosen technology clusters for further investigation were Patient Specific Instrumentation Knee Arthroplasty (PSI), Navigation Knee Arthroplasty, and Unicompartmental Knee Arthroplasty. Citation analysis (most cited individual patents) highlighted robotic surgery in addition to the clusters identified previously as a potential influential innovation. Robotic Knee Arthroplasty was therefore included as a term for further analysis.

Normalized 4 year moving average patent and publication counts were plotted against time. Individual graphs were plotted for the 4 technology clusters identified to establish growth curves for each of the technologies.

Figure 1 graphs patent activity and publications in knee arthroplasty for the 4 technologies against time. Placing the innovation curves alongside each other allows comparison of the growth rates in an attempt to identify a current or future dominant design. Based on the patent curves, PSI is the quickest growing technology in the last 5 years. Unicompartmental knee arthroplasty produces the most patents per year. Navigation arthroplasty did not match the recent growth in overall activity and activity in the other

Table 2
Top Performing Patent Codes.

Technology Cluster	Total Patents	Total as %
Generic	2287	29.20
Component	1478	18.87
Material	1207	15.41
Instruments	981	12.53
Modularity	570	7.28
Navigation	537	6.86
Custom	459	5.86
Unicompartmental	160	2.04
Trial	153	1.95