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Bibliometric and trend analysis of the top 100 most-cited articles on lateral interbody fusion (LIF)

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Received: 17 March 2024 / Revised: 23 April 2024 / Accepted: 18 May 2024 © The Author(s), under exclusive licence to Springer-Verlag GmbH Germany, part of Springer Nature 2024

Abstract

Purpose: Lateral interbody fusion (LIF) is an increasingly popular minimally-invasive spine procedure. This study identifies notable trends in LIF literature and provides a detailed review of the bibliometric aspects of the top 100 most-cited articles. Methods: Articles were queried from the Web of Science database. Inclusion criteria consisted of peer-reviewed articles, full-text availability, and LIF focus. Network analysis including co-authorship mapping and bibliographic coupling were complemented by trend analysis to determine prominent contributors and themes. Analyses were conducted using VOSviewer and Bibliometrix (RStudio). Results: There has been a rapid increase in LIF publication and citation count since 1998. Leading journals were Spine (n=24), Journal of Neurosurgery Spine (n=22), and European Spine Journal (n=12). NuVasive funded the most publications (n=17), followed by DePuy Synthes Spine (n=4). The United States was the most represented country (n=81); however, trend analysis suggests a steadily growing international contribution. The most prolific author was J.S. Uribe (n=16), followed by a tie in second place by E. Dakwar and L. Pimenta (n=8). The most frequent keywords, "complication" (n=34), "surgery" (n=30), and "outcomes" (n=24), demonstrated a patient-centric theme. Conclusions: This bibliometric analysis provides in-depth insights into the evolution and trends of LIF over the last two decades. The trends and themes identified demonstrate the innovative, collaborative, and patientfocused characteristics of this subfield. Future researchers can use this as a foundation for understanding the past and present state of LIF research while designing investigations.

Keywords Bibliometrics · Lumbar · Lateral · Interbody · Fusion · Minimally-invasive

Introduction

Lateral interbody fusion (LIF) is a minimally invasive surgical procedure established due to the growing need for lumbar fusion surgery. The annual incidence of spinal fusion for degenerative disease and deformity has steadily risen in the United States, nearly tripling from 174,223 to 413,171 patients over 10 years (1998–2008) [1, 2]. The significant increase in incidence coincides with the broad implementation of LIF as a means of treating debilitating conditions of the lumbar spine [1].

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LIF involves exposing the lateral aspect of the lumbar spine through the retroperitoneum and psoas muscle [3]. A high fusion rate of approximately 97% has been reported in several studies evaluating LIF outcomes [4, 5], making it an efficacious procedure. Surgical exposure of the lumbar spine allows for the implantation of an interbody graft to maximize segmental lordosis, enhance fusion rates, and facilitate indirect nerve decompression [6–10]. By providing a large exposure of the disc space for interbody graft placement, the LIF approach precludes potential damage to the posterior spinal column and decreases the risk of bowel and vascular injury [11]. Several studies have associated LIF with decreased operative times, blood loss, and postoperative pain and concomitant decompression of nervous tissue [12, 13]. In addition, compared with other fusion procedures, rates of iatrogenic spinal instability, nerve root injury, and epidural fibrosis are reportedly decreased with LIF [6-10]. Given the widespread adoption of LIF to

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treat spine disorders, it is crucial to evaluate the quality of these clinical studies. Accordingly, the aim of this study is to summarize the myriad investigations for LIF procedures based on a review of journal publications since 1998. A bibliometric analysis was conducted on the 100 most cited articles discussing LIF procedures for spinal fusion to provide a detailed assessment of the current literature. Additionally, we provide a summary of select topics explored and the relevant article types present within the amassed literature.

Methods

A bibliometric strategy was utilized to analyze the literature on articles regarding LIF. Studies were queried using the Web of Science (WOS) database and sorted in descending order of citation number from inception to May 1st, 2023. Search terms in WOS included the terms "lateral interbody fusion"; "LLIF (lateral lumbar interbody fusion)"; "OLIF (oblique lateral interbody fusion)"; "ELIF, XLIF (extreme lateral interbody fusion)"; "DLIF (direct lateral interbody fusion)"; "pre-psoas"; and "trans-psoas". The initial search based upon these criteria yielded 362 peer-reviewed articles. These results were then sorted in descending order of citation number. Two independent reviewers (J.Z. and A.J.S.) evaluated articles for relevance to the topic, resulting in the top 100 most-cited articles on lateral instrumented fusion. Any reviewer conflicts regarding relevance were decided on by the senior author (T.C.).

Inclusion criteria for the current study were the following: (1) the primary topic (or major focus) of the article had to be lateral interbody fusion, (2) the primary or review article had to have full-text access available, and (3) the article had to be published by a peer-reviewed process with a journal indexed in WOS. Articles were excluded if the focus was not related to LIF, the article was abstract or poster only without a full-text manuscript available, or if the article was not published in a peer-reviewed journal. After implementing inclusion and exclusion criteria and reviewer consensus was attained on the top 100 articles, the following criteria were collected for each publication: article title, year of publication, first/senior author, institutions of authors, journal title, keywords, citation number, and country of publication. Descriptive statistics were captured using univariate analysis. Network analysis of author and keyword information was conducted using VOSviewer (Version 1.6.16) and Bibliometrix (R-Studio).

Results

Our analysis of the top 100 highest cited articles on lateral approaches to lumbar interbody fusion spanned a period of 22 years (Fig. 1). The oldest of these articles was published in 1998, the most recent was published in 2019, and the mean time since publication of an article on the list was 10.09 years.

The top ten articles in order of World of Science (WOS) citations are presented in Table 1. Information for all 100

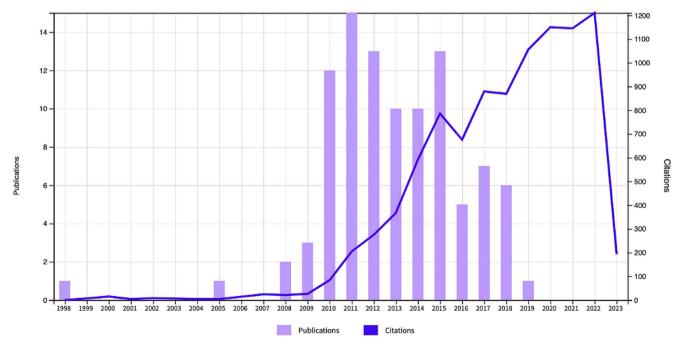


Fig. 1 The annual number of publications on lateral approaches to lumbar interbody fusion based on the 100 top cited articles (published between 1998 and 2019). Bar graph (purple) depicts publication count per year. Superimposed line plot (blue) depicts citation count over time

#	Authors		Source Title	Docu- ment Type	DOI	Times Cited, WoS Core	Times Cited, All Databases	Pub- lica- tion Year
-	Rodgers, WB; Gerber, EJ; Patterson, J	Intraoperative and Early Postoperative Complica- tions in Extreme Lateral Interbody Fusion An Analysis of 600 Cases	SPINE	Article	https://doi.org/10.1097/BRS.0b013e3181e1040a	302	336	2011
7	Oliveira, L; Marchi, L; Coutinho, E; Pimenta, L	A Radiographic Assessment of the Ability of the Extreme Lateral Interbody Fusion Procedure to Indirectly Decompress the Neural Elements	SPINE	Article	https://doi.org/10.1097/BRS.0b013e3182022db0	268	291	2010
ξ	Isaacs, RE; Hyde, J; Goodrich, JA; Rodgers, WB; Phillips, FM	A Prospective, Nonrandomized, Multicenter Evaluation of Extreme Lateral Interbody Fusion for the Treatment of Adult Degenerative Scoliosis Perioperative Outcomes and Complications	SPINE	Article	https://doi.org/10.1097/BRS.0b013e3182022e04	249	266	2010
4	Dakwar, E; Cardona, RF; Smith, DA; Uribe, JS	Early outcomes and safety of the minimally inva- sive, lateral retroperitoneal transpsoas approach for adult degenerative scoliosis	NEUROSURGI- CAL FOCUS	Article	https://doi.org/10.3171/2010.1.FOCUS09282	237	254	2010
Ś	Marchi, L; Abdala, N; Oliveira, L; Amaral, R; Coutinho, E; Pimenta, L	Radiographic and clinical evaluation of cage sub- sidence after stand-alone lateral interbody fusion Clinical article	JOURNAL OF NEUROSUR- GERY- SPINE	Article	https://doi.org/10.3171/2013.4.SPINE12319	228	263	2013
9	Youssef, JA; McAfee, PC; Patty, CA; Raley, E; DeBauche, S; Shu- cosky, E; Chotikul, L	Minimally Invasive Surgery: Lateral Approach Interbody Fusion Results and Review	SPINE	Article	https://doi.org/10.1097/BRS.0b013e3182023438	189	209	2010
2	Knight, RQ; Schwae- gler, P; Hanscom, D; Roh, J	Direct Lateral Lumbar Interbody Fusion for Degenerative Conditions Early Complication Profile	JOURNAL OF SPINAL DISORDERS & TECHNIQUES	Article	https://doi.org/10.1097/BSD.0b013e3181679b8a	188	206	2009
∞	Uribe, JS; Arredondo, N; Dakwar, E; Vale, FL	Defining the safe working zones using the mini- mally invasive lateral retroperitoneal transpsoas approach: an anatomical study Laboratory investigation	JOURNAL OF NEUROSUR- GERY- SPINE	Article	https://doi.org/10.3171/2010.3.SPINE09766	185	205	2010
6	Anand, N; Baron, EM; Thaiyananthan, G; Khalsa, K; Goldstein, TB	Minimally Invasive Multilevel Percutaneous Cor- rection and Fusion for Adult Lumbar Degenera- tive Scoliosis A Technique and Feasibility Study	JOURNAL OF SPINAL DISORDERS & TECHNIQUES	Article	https://doi.org/10.1097/BSD.0b013e318167b06b	181	198	2008
10	Fujibayashi, S; Hynes, RA; Otsuki, B; Kimura, H; Takemoto, M; Mat- suda, S	Effect of Indirect Neural Decompression Through Oblique Lateral Interbody Fusion for Degenera- tive Lumbar Disease	SPINE	Article	https://doi.org/10.1097/BRS.00000000000703	177	221	2015

 Table 2
 The top ten journals in order of number of publications contributed to the top 100 highest cited articles

#	Journal Title	Publication Count
1	Spine	24
2	Journal of Neurosurgery Spine	22
3	European Spine Journal	12
4	Journal of Spinal Disorders Techniques	9
5	Neurosurgical Focus	6
6	Clinical Orthopaedics and Related Research	4
7	Journal of Clinical Neuroscience	4
8	Scientific World Journal	4
9	Spine Journal	3
10	World Neurosurgery	3

articles is available in Supplemental Table 1, which depicts publications in order of total WOS citations (minimum = 50, maximum = 300, range = 250). In total, there were 9,803 citations, a combined H-index of 65, and an average citation count of 98.03 per article.

The top 100 articles were published across 17 journals (Table 2), with the top three being Spine (n=24), Journal of Neurosurgery Spine (n=22), and European Spine Journal (n=12). All 100 articles were published in English, and 11 countries were represented (Table 3). Of these, the United States accounted for the greatest number of publications (n=81), followed by Brazil (n=8) and Australia (n=6). Austria, France, and Thailand each contributed one article. Of the more than 160 institutions represented (Table 4), the top three were the University of South Florida (n=28), Duke University, (n=17), and the University of California San Diego (n=14).

Of the 391 total authors, 14 published more than five publications within the top 100 most cited articles, and are listed in Table 5. The most prolific was JS Uribe, currently at the Barrow Neurological Institute (AZ, USA) (n=16), followed by a two-way tie in second place (n=8) by E. Dakwar at the Cleveland Clinic Florida (FL, USA), and L. Pimenta, who has dual appointments at the Instituto de Patologia da Coluna (São Paulo, Brazil) and the University of California, San Diego (CA, USA). Finally, DA. Smith at the University

 Table 3 All 11 countries represented in the top 100 highest cited articles in order of total number of articles contributed

#	Country	Publication Count
1	United States of America	81
2	Brazil	8
3	Australia	7
4	Japan	5
5	Italy	4
6	People's Republic of China	3
7	Germany	2
8	South Korea	2
9	Austria	1
10	France	1
11	Thailand	1

of South Florida (FL, USA) was the third most prolific author (n=7). The average number of co-authors per document was 5.86, and the percent of international co-authorships was 15.15%

Table 6 depicts the funding sources responsible for financing at least two of the publications in the top 100 most cited articles. NuVasive funded the vast majority of these high-impact publications (n=17). DePuy Synthes Spine funded the second most (n=4), with Medtronic, the United

 Table 4
 The top ten institutes in order of number of publications contributed to the top 100 highest cited articles

#	Institution	Location	Publi- cation Count
1	University of South Florida	FL, USA	18
2	Duke University	NC, USA	11
3	University of California, San Diego	CA, USA	10
4	University of Miami	FL, USA	9
5	University of California, San Francisco	CA, USA	8
6	Instituto de Patologia da Coluna	SP, Brazil	7
7	Hospital for Special Surgery	NY, USA	6
8	Rush University	IL, USA	6
9	University of Pittsburgh	PA, USA	5
10	Barrow Neurological Institute	AZ, USA	4

Table 5 Authors with five or more articles in the top 100 highest cited

#	Author	Location	Publication Count
1	Uribe, JS	AZ, USA	16
2	Dakwar, E	FL, USA	8
3	Pimenta, L	CA, USA	8
		SP, Brazil	
4	Deukmedjian, AR	FL, USA	7
5	Smith, DA	FL, USA	7
6	Isaacs, RE	NC, USA	6
7	Marchi, L	SP, Brazil	6
8	Oliveira, L	FL, USA	6
9	Rodgers, WB	MO, USA	6
10	Coutinho, E	SP, Brazil	5
11	Kanter, AS	CA, USA	5
12	Okonkwo, DO	PA, USA	5
13	Wang, MY	FL, USA	5

Table 6	Funding	sources	with at	least	two	publications	in the	top	100
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#	Funding Source	Location	Publi- cation Count
1	NuVasive	CA, USA	17
2	DePuy Synthes Spine	MA, USA	4
3	Medtronic	MN, USA	3
4	National Institutes of Health	MA, USA	3
5	United States Department of Health Human Services	DC, USA	3
6	RTI Surgical	FL, USA	2
7	Stryker Spine	NJ, USA	2

States National Institutes of Health (NIH), and the United States Department of Health and Human Services (HHS) tied for third-most (n=3).

Citation analysis of these 14 most productive authors was also conducted, and is shown in Fig. 2a. The degree of connection between a given author to the other authors is given by total link strength (TLS). Of these 14 authors, the top five ranked by TLS were JS. Uribe (TLS=283, total citations=1486); E. Dakwar (TLS=175, total citations=920); L. Pimenta (TLS=157, total citations=882); DA. Smith (TLS=153, total citations=689); with L. Marchi tied with L. Oliveira for fifth, both with the same TLS and total citations (TLS=134, total citations=748). Each of these authors had links to every other, suggesting a robust network of collaboration.

A similar analysis was conducted for co-authorship between these 14 authors (Fig. 2b). In this case, a high TLS is indicative of the degree of significance of co-authorship. In this analysis, the total number of links was 30, and the top three authors in order of TLS were JS. Uribe (TLS = 34), L. Pimenta (TLS = 18), followed by a five-way tie between DA. Smith, AR. Deukmedjian, E. Dakwar, L. Oliviera, and L. Marchi (TLS = 17). Three distinct clusters of authors who engaged in close collaboration were generated (red, blue, and green), with the red and blue clusters demonstrating robust inter-collaboration. The fourth yellow cluster consisted of two authors who had only collaborated with each other.

Figure 3a depicts the 15 most common Keywords Plus terms extracted from the 100 highest cited articles, as well as their cumulative occurrences between 2005 and 2019. Keywords Plus terms are words or phrases algorithmically extracted from the titles of the cited references of a given article. The three most common keywords used were "complication" (n=34), "surgery" (n=30), and "outcomes" (n=24). A deeper analysis examining the change in the frequency of these top 15 keywords was conducted as well (Fig. 3b), again from 2005 to 2019.

Figure 3c depicts the results of a co-occurrence network analysis of all author keywords present ten or more times

across the 100 highest cited articles. The line connecting two keywords represents the co-occurrence of those words within the same article, and the degree of significance of this co-occurrence is given by the total link strength (TLS). In total, there were 29 items and 364 links between them. The top three author keywords in order of TLS were "complications" (TLS=231), "outcomes" (TLS=162), and "surgery" (TLS=152). Based on the interconnections between author keywords, four broad research domains (or clusters) were algorithmically generated and organized by color.

Discussion

In this study, we analyzed the top 100 most-cited articles on LIF, an increasingly popular neurosurgical technique. Our analysis provides insight on important trends and themes, as well as on the general direction the technique has been evolving in over the past two decades, to help guide future researchers and clinicians.

Over the 22 years the top 100 cited articles on LIF were published, there was a surge in publications occurring in the years 2010, 2011, and 2012 (Fig. 1). The final year in which more than ten articles were published was 2015, with an abrupt drop to five articles published in 2016. Interestingly, the top three publications, each cited more than 200 times, were all on the XLIF procedure. Additionally, when considering the most productive years together (2010 through 2012; n = 40), fully one quarter of the most cited publications were on this singular technique alone (n = 10), while all remaining articles were on LIF procedures more broadly. Furthermore, all but two of these XLIF articles were on postprocedure complications and outcomes. Taken together, it is reasonable to assume that the surge in high-impact LIF publications during this period could at least be partially attributable to the rise in popularity of the XLIF as a technique in the years following its initial description in 2006 [13]. This three year peak of LIF publications can thus be viewed as the field interrogating a new and promising technique. Along these lines, the subsequent drop observed after 2015 can be considered a plateau in research interest as the XLIF technique matured in the decade after its inception.

Of the top ten institutions in terms of contributions to the most cited articles (Table 2), nine are located in the United States, with the sole exception being the Instituto de Patologia da Coluna (IPC, Institute of Pathology of the Spine), a private spine practice in Brazil. The IPC is also the only private practice included in the top ten institutions. However, it is important to note that the medical director of the IPC, L. Pimenta, is also an Associate Professor at the University of California, San Diego, in the United States. Considering this, all ten of the top institutions are directly

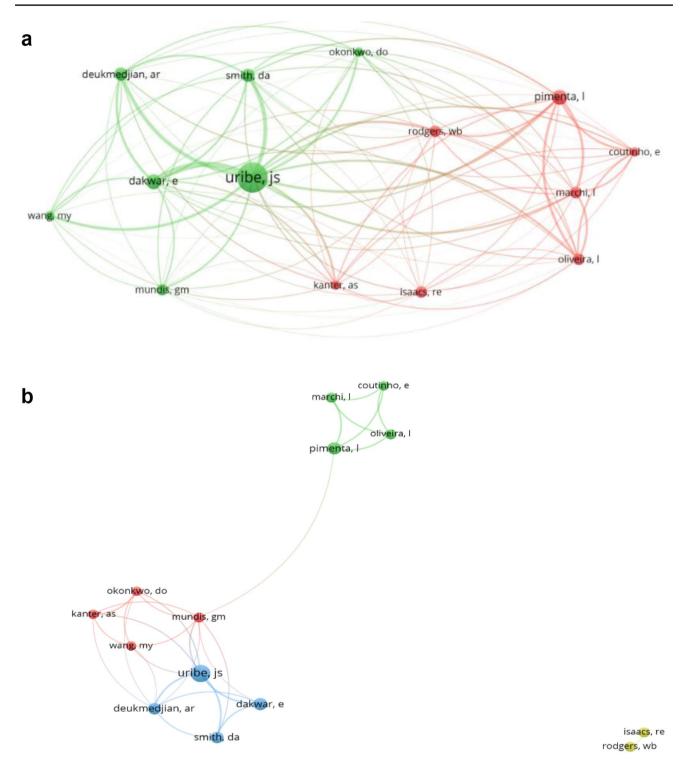


Fig. 2 a. Citation analysis of the most prolific authors. b. Co-authorship network of the most prolific authors

located or have strong ties to the United States. Specifically in the field of minimally invasive spine surgery, the United States has been a major driver of innovation for some time; accomplishments by United States institutions include the first reported use of a laparoscopic approach to lumbar discectomy [14, 15], and the first case series on the minimally-invasive resection of intradural spinal tumors [16].

These results correlate well with an analysis of the most productive countries (Table 3) — of the 11 nations represented in the most cited articles, the United States accounted

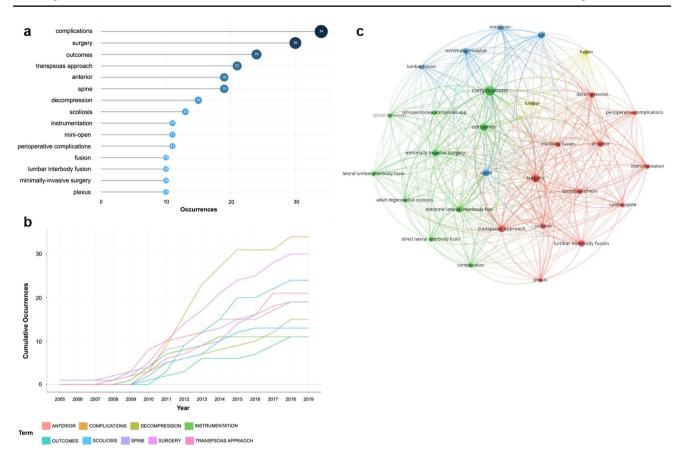


Fig. 3 a. The top 15 keywords plus organized by frequency. b. A graph depicting the change in frequency of the top 15 keywords plus over time. c. Author keyword co-occurrence network

for 81 of the 100 articles. These American institutions are well-distributed geographically, with the top three — University of South Florida, Duke University, and University of California San Diego - located in the south, southeast, and west coast of the country, respectively (Table 4). This suggests that while the United States has been driving the bulk of LIF research worldwide, within the country, no single institution or geographic region claims a monopoly. Many of these institutions are pioneers in LIF techniques. For instance, JS. Uribe at the University of South Florida published a seminal peer-reviewed article highlighting their novel technique of multilevel (>4) minimally invasive LIF for the treatment of scoliosis [17]. Duke University was the first to comprehensively review surgical outcomes and complications associated with the transforaminal approach for lateral interbody fusion [18]. University of California San Diego uses an innovative expandable technology to optimize fit between vertebral endplates [19].

This United States predominance in the field of LIF may be attributable to the funding opportunities available, as all seven of the funding sources that supported a minimum of two articles within the top 100, are based in the United States (Table 6). Nuvasive funded the most articles, which is consistent with their heavy involvement in the development of the XLIF procedure [13]. Additionally, with a mere six of the top 100 most cited publications funded by federal research organizations, this demonstrates a strong role of the private sector as a driver of LIF research efforts.

Given the important role the United States has played in the development of minimally-invasive spine techniques like LIF, it is the country that is most represented among LIF publications. It is also logical to assume some temporal lag in LIF research output from other countries, as it takes time for these Given the important role the United States has played in the development of minimally-invasive spine techniques like LIF, it is the country that is most represented among LIF publications. It is also logical to assume some temporal lag in LIF research output from other countries, as it takes time for these techniques to be validated and adopted, and for funding opportunities to arise and mature. Analysis over the 22 years covered shows a steady increase in the percentage of top cited publications from non-United States countries over time (Supp. Table 2). Of the seven most-cited articles published prior to 2009, there was only a single publication from a non-United States institution. In the ten years following, the percentage of publications from

non-United States institutions has been steadily increasing, from 17.50% between 2010 and 2012, to 32.40% between 2013 and 2015, to 47.30% between 2016 and 2019 (the most recent year in which a top 100 article was published). This data suggests that international LIF research has been gaining momentum over the past decades, and contributions to the field by country may become more diversified in the near future. This trend is additionally reinforced by analysis of the publishing journals, as of the ten journals that published at least three of the top 100 most cited publications, the European Spine Journal ranked third (Fig. 1b). While non-European institutions are not precluded from publishing in the European Spine Journal, it being the official journal of the Spine Society of Europe (EuroSpine) and accounting for a not insignificant proportion of the top cited articles, suggests rising research interest in the LIF technique.

Our citation analysis of these 14 most productive authors (Fig. 2a) showed a robust network of collaboration. Further investigation via co-authorship analysis (Fig. 2b) revealed four clusters. Of these, three of the four most productive authors (JS. Uribe, E. Dakwar, and DA. Smith) are all included in the same cluster (blue), indicating they collaborate the most often together. These authors all are/have been affiliated with the University of South Florida, which our analysis indicates as the most productive institution in terms of LIF research output.

Interestingly, co-authorship analysis shows that L. Pimenta, the remaining author of this top four, does not significantly collaborate with the other three, and is located in an entirely separate co-authorship cluster (green). This may be explained by the fact that the green cluster heavily consists of authors from the University of São Paulo in Brazil. L. Pimenta is also the only author within this cluster who has a link with another cluster (red), which may be explained by his dual appointment at the University of California, San Diego. This geographic connection is reiterated by the single link this author has with GM. Mundis of the red cluster, who is affiliated with the Spine Fellowship Program and the Scripps Green Hospital, both located in San Diego. As expected, each of the top three most prolific authors has contributed significantly to the LIF field. Both JS. Uribe's and DA. Smith's research works were some of the first to describe surgical outcomes and complications of the lateral retroperitoneal transpsoas approach [20, 21]. E. Dakwar's research at large focuses on the anatomical course of nerves and ligaments relevant to LIF procedures [20, 22]. L. Pimenta leveraged diagnostic imaging to evaluate the efficacy of several types of LIF procedures [23, 24].

The top three most common keywords revealed through keyword analysis (Fig. 3a) were "complication", "surgery", and "outcomes". These words suggest a theme of patientfocused research across these influential publications, one primarily concerned with the clinical results of LIF procedures. When analyzing the change in keyword frequency over time, our data revealed the steepest increase in frequency of "complication", the most common keyword, occurred over the same time period as the surge in publications discussed above (years 2010 through 2012), and seen in Fig. 1a. This is consistent with the notion that research interest in the safety and efficacy of the then-recent XLIF technique was a major driving force behind the high-impact LIF articles published during this most productive period.

Finally, the co-occurrence network analysis of author keywords (Fig. 3c) provides a deeper dive by generating clusters of highly-associated themes. The two most extensive clusters focused on: (i) broad surgical themes (main keywords: "surgery", "instrumentation", "decompression"; in red); (ii) specific, more recently developed surgical techniques, with a focus on minimal invasiveness and outcome (main keywords: "complications", "extreme lateral interbody fusion"; "direct lateral interbody fusion"; "lateral lumbar interbody fusion"; in green). This cluster data thus reiterates the top two most common keywords as depicted in Fig. 3a.

Limitations

There are some limitations in our study that warrant further discussion. First, each database used in our study has variations in citation numbers, which may influence the compilation and ranking of these top-cited articles. Second, our analysis focused only on articles published in English, thereby excluding potentially important works in other languages and limiting the comprehensive representation of our study. Additionally, an important limitation lies in the omission of the pivotal paper by Ozgur et al. [13], detailing the inception of the XLIF technique, as the WOS database was unable to retroactively add this article. However, given the early date of publication and the evolution of the field since this seminal work, we believe its inclusion would not have significantly altered our projections on current trends and future directions of the field. Finally, our analysis focused on only the top 100 articles, which, while not exhaustive, aims to highlight the most impactful developments and trends within the field in a concise manner while minimizing redundancy. We encourage future bibliometric studies to consider these limitations to ensure an even more comprehensive overview.

Conclusion

In conclusion, this bibliometric analysis provides valuable insights into the evolution and trends of LIF over the last two decades. Our study affirms the dominance of the United States in this specific neurosurgical research field, although we also highlight the exciting growth of international contributions. This development, evidenced by the steady increase in non-United States articles and the emergence of European Spine Journal as a significant publisher of influential LIF papers, suggests that there may be a broader global participation in the LIF research landscape in the future. Additionally, we have identified key institutions, authors, and funding sources pivotal to the growth of this field, as well as highlighted a robust network of collaboration among authors, particularly within the United States. Moreover, our study underscores the patient-centric research focus within the top-cited LIF literature, with "complications" and "outcomes" emerging as central themes. Future researchers can use these trends as a foundation for understanding the past and current state of LIF research while designing their own investigations.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s10143-024-02464-3.

Author contributions Material preparation, data collection and analysis were performed by J.Y.Z., B.E., and A.J.S. The first draft of the manuscript was written by J.Y.Z., B.E., R.J.J.C., G.P., and Z.A. Manuscript editing and final approval was conducted by M.T.C., A.J.S., and T.C. All authors contributed to study conception, design, and revision of previous versions of the manuscript. All authors read and approved the final manuscript.

Funding No funds, grants, or other support was received for this study.

Data availability No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate This bibliometric study does not contain any patient identifiers, and as such, no IRB approval or patient consent was required.

Competing interests The authors declare no competing interests.

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