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A Systematic Scoping Review of Patient-specific Devices in Operative Management of Scaphoid Nonunion

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Abstract

Scaphoid nonunion is a complication that occurs in 5-10% of patients who sustain an acute scaphoid fracture. There is no superior method for managing scaphoid nonunion that has been established in the current literature. The use of patient specific devices has been explored as a way to improve surgical management of scaphoid nonunion. 3D printing has made the production of patient specific devices more accessible. CT and MRI images can be used to model devices such as anatomic models and surgical guides. In this review we aim to discuss the current evidence for the use of patient specific devices for managing chronic scaphoid nonunion and demonstrate their different uses. A scoping review of peer-reviewed literature, existing patent applications, and grey literature was performed. Although the current research has demonstrated some possible benefits such as reduction in surgical time and accuracy of restoration of anatomy, further investigation with comparative studies is required to make conclusions about the superiority of these techniques over standard freehand techniques.

Take-Home Points

Patient-specific devices (PSDs) are increasingly used in complex fracture management for planning, intraoperative modeling, and jig creation and as custom implants.

Three-dimensional printing (3DP) implemented in the management of acute scaphoid fractures has been shown to improve patient and surgeon outcomes.

There is limited evidence on scaphoid nonunion, despite the increased operative difficulty associated with deformity correction and poor vascular supply.

This review showed that the use of PSD resulted in accurate radiological outcomes and suggests that it may also reduce operating time and improve clinical results for scaphoid nonunion surgery; however, a lack of comparative studies weakens these conclusions, and further investigation is required to determine if they play a role in current management of scaphoid nonunion.

Introduction

Scaphoid fractures are the most common fracture of the carpus, accounting for approximately 70% of all carpal bone fractures[1]. Scaphoid nonunion is a common complication of scaphoid fractures, occurring in 5% to 10% of cases despite appropriate management[2,3]. The increased risk of scaphoid nonunion is attributed to several factors including delayed or missed diagnosis and the scaphoid's tenuous blood supply to the proximal pole, which flows retrograde and is vulnerable to disruption during acute fracture[4,5]. Unstable fractures of the scaphoid waist may fall into a humpback deformity due to opposing flexion forces on the distal fragment and extension forces on the proximal fragment[5,6]. The result is altered biomechanics which can result in degenerative changes in the wrist known as scaphoid nonunion advanced collapse and decreased range of motion and strength[6]. Surgical management of scaphoid nonunion aims to improve functional outcomes by restoring anatomy,

M. Roberts (primary author), S. Lee (reviewing and editing), A. Allen (corresponding author, writing, reviewing and editing), J. Bloor (data collection and extraction), E. Whiteside (research strategy, reviewing and editing), R. Nicol (reviewing and editing), V. Shridhar (idea conception and review), P. Burey (funding acquisition and reviewing), T. Shelley (funding acquisition and reviewing), C. Wall (writing, reviewing and editing).

Disclosure: The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (http://links.lww.com/JBJSOA/A852).

with rigid fixation and compression of the fracture[7]. There is no established superior method of surgical fixation in scaphoid nonunion with multiple techniques reported in the literature[8].

The past decade has seen increased interest in the use of patient-specific guides (PSGs) and patient-specific implants (PSI) in orthopedic surgery, collectively referred to here as patient-specific devices (PSDs)[9,10]. PSGs are primarily used during preoperative planning of complex procedures to limit radiation exposure and reduce operating time[11,12]. PSI aim to improve the fit and load distribution of implants while reducing the inefficiency and costs associated with sizing implants intraoperatively[13,14].

Three-dimensional printing (3DP) or additive manufacturing (AM) has made the use of point-of-care manufacturing in surgery more accessible[15]. 3DP uses computer software to transform medical images, such as computer tomography (CT) or magnetic resonance imaging (MRI), into Standard Triangle Language (STL) files[16]. STL files are digitally manipulated to produce the desired model with applications including anatomic modeling, surgical planning, precision prosthetics, permanent implants, or tissue fabrication[17,18].

3DP has been implemented in the management of acute scaphoid fractures to produce custom surgical guides, anatomic models, and patient-specific total prostheses[19-21]. A recent systematic review reported that when compared with using standard freehand techniques, PSD can improve accuracy of reduction, reduce radiation exposure, and reduce operating time in acute scaphoid fixation[19]. No such systematic review exists for scaphoid nonunion, despite the increased operative difficulty associated with deformity correction and poor vascular supply.

The aim of this study was to review the use of PSD in the operative management of chronic scaphoid nonunion.

Materials and Methods

Overview

A scoping review was conducted in accordance with the Joanna Briggs Institute System for the Unified Management, Assessment, and Review of Information (JBI SUMARI) methodology for scoping reviews[22]. The Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) was used to present the search data (Fig. 1)[23]. Included studies are presented in tables.

Search Strategy

The search strategy was designed to identify both published and unpublished studies. A three-step search strategy was used. First, an initial limited search of MEDLINE (PubMed), CINAHL (EBSCO), Web of Science (Clarivate), and ScienceDirect (Elsevier) was undertaken to identify articles on the topic. The text words contained in the titles and abstracts of relevant articles and the index terms used to describe the articles were used to develop a full search strategy for MEDLINE, CINAHL, Web of Science, and ScienceDirect (see Supplemental Information Appendix 1). The reference list of all included sources of evidence was screened for additional studies. Patents were searched using lens.org. Theses and dissertations were searched using the ProQuest database. In addition, a Google search was conducted, using the keyword "conference", limiting the results to include PDF and PowerPoint files only.

No publication time limits were imposed.

Articles were determined eligible for inclusion if they discussed PSD in surgical management of scaphoid nonunion, including, but not limited to, PSI, PSG, and anatomic models. All article types were included, including dissertations, conference abstracts, and patents.

Articles were excluded if they were written in a language other than English, if they focused on acute scaphoid fracture management, if no clinical outcomes were reported, or if they discussed computational models of scaphoid fixation.

Data Extraction

All identified citations were collated and uploaded into EndNote 20 (Clarivate Analytics), and duplicates were removed. Remaining articles were imported into JBI SUMARI (JBI, Adelaide, Australia)[24]. Screening and data extraction were completed by two independent reviewers (M.R. and J.B.) using a modified PRISMA Extension for Scoping Reviews (PRISMA-ScR) checklist. The data extracted included author details, participant demographics, data variables, critical appraisal, synthesized results, discussion, and limitations. Nonrandomized studies were appraised with the Methodological Index for Non-Randomized Studies to assess quality[25]. A score of ≤8 was considered poor quality, a score of 9 to 14 was considered moderate quality, and a score of 15 to 16 was considered good quality for noncomparative studies. Cutoff points of ≤14, 15 to 22, and 23 to 24, respectively, were used for comparative studies.

Results

Study Selection

From the initial search, 505 articles were identified after duplicates were removed. At the title and abstract screening stage, 474 articles were excluded. A total of 32 articles were sought for retrieval with one unable to be sourced in English despite having a translated title and abstract. The remaining 31 articles were screened in full text, with 19 excluded as outlined in Fig. 1. Reviewers M.R. and J.B. extracted all data from the remaining 12 articles.

Article Characteristics

The scoping review identified 10 articles from 10 peer-reviewed journals. All articles were published since 2005, with 11 being published after 2015, reflecting an increase in interest and research into PSD for the management of scaphoid nonunion. Two articles were reported in BMJ Case Reports, and 2 were published in The Journal of Hand Surgery. Five journal articles were published in various surgical journals. One was published in a broad interdisciplinary journal, Injury.

The first authors of included journal articles represented six countries, most commonly Japan (3), United States (2), and Switzerland (2). The remaining first authors were from Austria, China, and Italy. All first authors were affiliated with either orthopedic (7) or plastic surgery (3) departments. Journal

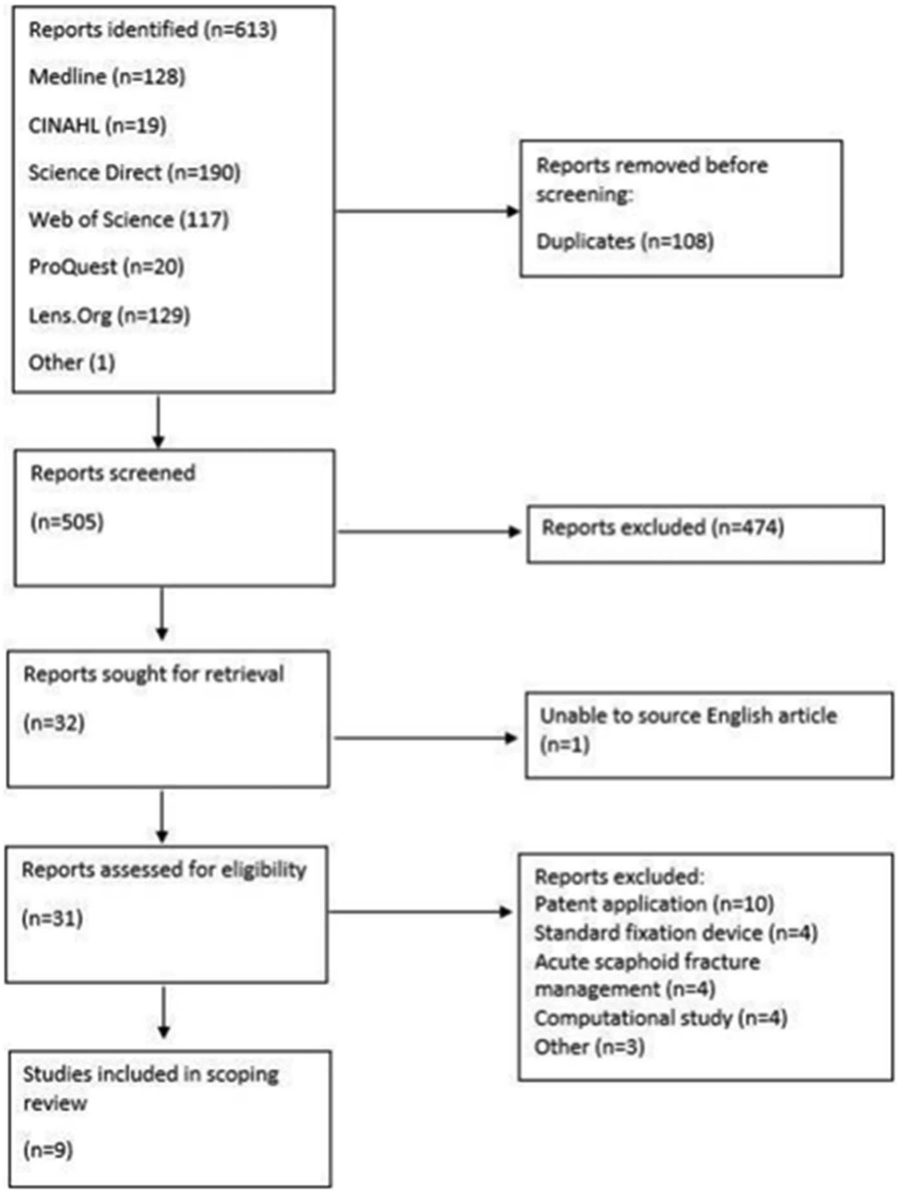

Fig. 1

Summary of search results.

article types included four case reports, two retrospective cohort studies, two narrative reports, a prospective cohort study, and a single randomized control trial (RCT). The extracted results of these articles are summarized in Table I; for full results, see Supporting Information: Appendix 2.

Seven journal articles were assessed for quality, excluding the two narrative reports. Three noncomparative articles were graded as poor quality, and two were graded as moderate quality. The two comparative articles were graded as moderate quality. Full tabulated assessment is available in Table S2 in Supporting Information: Appendix 3.

A meta-aggregate flowchart was used to summarize key findings (Table II). PSDs in scaphoid nonunion were used preoperatively as planning models, intraoperatively as guides for reduction and fixation, and as PSI. The results of these PSDs were measured radiographically and clinically. A visual illustration of these PSDs is shown in Fig. 2 in the chronological order of publication. Radiographic outcomes demonstrated good accuracy of reduction, with bony union being demonstrated across all articles. Clinical measurements including pain scores and ROM all improved across the articles presented. This is in comparison with articles which demonstrated no variation between PSD and routine care of using a freehand technique to perform a standard bone graft and internal fixation[26-28]. Two articles reported a significant reduction in operating time[20,29].

TABLE I Summary of Results

First Author	Year	Country	Journal	Design	Device	Participant Criteria
Haefeli et al.[32]	2015	Switzerland	*Journal of Hand Surgery (European Volume)*	Experimental study, case report	Intraoperative, reduction template	Donor cadaver; scaphoid nonunion with humpback deformity
Houdek et al.[32]	2016	United States	*Techniques in Hand and Upper Extremity Surgery*	Narrative report, case report	Intraoperative, model for graft harvest	Scaphoid nonunion with avascular necrosis of the proximal pole
Oki et al.[29]	2021	Japan	*MBJ Case Reports*	Case report	Intraoperative, model for plate	Scaphoid nonunion with volar flexion deformity
Schweizer et al.[29]	2016	Switzerland	*Journal of Hand Surgery*	Prospective cohort study	Intraoperative, reduction guide	Scaphoid nonunion in waist or junctional fracture greater than 6 months postinjury
Taylor and Iorio[31]	2017	United States	*Journal of Reconstructive Microsurgery*	Narrative report	Intraoperative, model for graft harvest	Scaphoid nonunion with avascular necrosis
Schmidt et al.[27]	2020	Austria	*Injury*	Narrative report	Intraoperative, model for fracture reduction and graft harvest	Post-traumatic pseudoarthrosis with an avascular proximal pole
Yin et al.[20]	2020	China	*Journal of Orthopaedic Translation*	Randomized control trial	Intraoperative, surgical guide for fixation	Scaphoid nonunion with no to minimal displacement as diagnosed on CT

Discussion

This scoping review has demonstrated that PSDs are gaining popularity in the management of scaphoid nonunion around the world. PSDs are used for preoperative planning, as intraoperative models or guides for fixation, and as PSI. With the range of methodologies reported, there is no significant evidence for any single practice. The included studies report that PSDs are noninferior to standard surgical practices with possible improvement in accuracy of anatomic reduction and decreased operating time when compared with standard freehand techniques. The reviewed studies have not demonstrated superiority of PSD in producing increased rates of bone union or improved postoperative clinical outcomes, only that their use is not inferior compared with freehand techniques.

Anatomic reduction is important when surgically addressing scaphoid nonunion as it is an independent factor affecting the rate of union postoperatively[30]. A scaphoid fracture with malalignment has a 9.5 times reduced probability of uniting, and nonunion is associated with increased pain and decreased ROM and grip strength[30]. The results of this scoping review demonstrate accurate reduction across the articles with the use of PSD.

The recent rise of AM in orthopedics has led to several large cohort studies and RCTs investigating the use of 3DP. Wong et al. reviewed RCTs of 3DP PSG across upper limb, lower limb, and spinal injuries. A total of 21 RCTs demonstrated beneficial outcomes of shorter operating time, reduced blood loss, and reduced fluoroscopy use[31]. This reinforces our results demonstrating that PSDs are noninferior to standard management. Schweizer et al. showed that using 3DP PSG to define alignment when reconstructing scaphoid nonunions had a significant improvement in the accuracy of restoration of anatomic alignment compared with not using a PSG[29]. This study did not discuss clinical patient outcomes. The lack of high-quality comparative studies in this scoping review limits the conclusions that can be drawn. Despite

TABLE II Aggregated Findings of PSD Use in Scaphoid Nonunion

Key findings of PSD use	Elaboration	References
PSD used preoperatively and intraoperatively and for management of scaphoid nonunion	PSG used in osteotomy and fixation of scaphoid nonunion	20,29,32
	PSI modeled using patient contralateral wrist and database-derived radiographic images	26,29,32
	Anatomic models used for intraoperative graft modeling	26-31
Radiographic outcomes	Improved accuracy of bony alignment postoperatively compared with the preoperative stage	26,29,33
	Bony union achieved was equal to standard care	26,29,32,33
Reduction in operating time with patient-specific guides	Using a patient-specific guide resulted in a significant reduction in surgical time compared with when a guide was not used	20,29
No significant difference in clinical outcomes when compared with standard fixation	Improvement of clinical scores was observed postoperatively in both standard care and patient-specific devices	20,29,33
	Improvement of range of movement postoperatively in both standard care and patient-specific devices	27

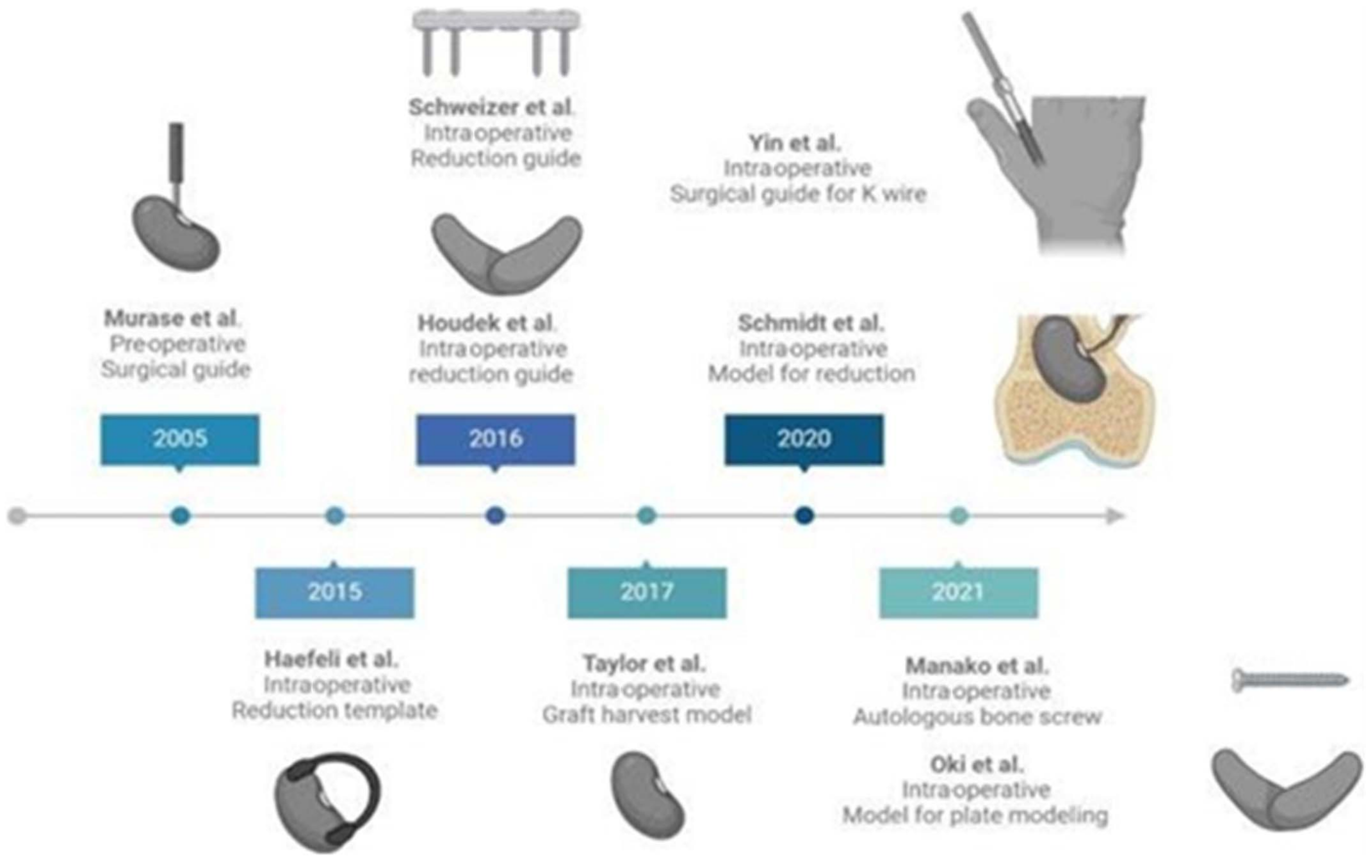

Fig. 2
Visual illustration of the types of PSDs in scaphoid surgery. PSDs = patient-specific devices.

3DP PSG demonstrating benefit in other areas of the body, we are not able to generalize this to the scaphoid without further research, and it is not yet possible to say whether 3DP PSG should be incorporated into standard surgical practice. This is an avenue for further investigation given the promising results in other areas of the body[31]. There are a number of possible applications for PSG in the surgical management of scaphoid nonunion, including, but not limited to, guides for osteotomy creation and alignment restoration, and PSI modeled on patients' contralateral scaphoids and as anatomic models for intraoperative reference for surgeons to accurately restore alignment[26,29,32].

Our results can also be compared with studies assessing PSD use in acute scaphoid fracture management. A 2023 review by Li et al.[19] investigated the use of 3DP in treating acute scaphoid fractures. They discussed PSD use in preoperative planning, including PSG for fracture reduction. Similar outcomes were reported, with improved accuracy of reduction and reduced operating time (Li et al., 2023). Two notable comparative studies have examined the utility of PSG in management of acute fractures. Salabi et al. designed a 3DP PSG to guide percutaneous fixation of acute undisplaced scaphoid waist fractures based on high-resolution CT scans[33]. They used the guide for introduction of a Kirschner wire over which a cannulated screw was placed for definitive fracture fixation and compared this with freehand wire insertion. Postoperative CT scans were performed to compare the actual and ideal screw placement and trajectory. They concluded that the scaphoids fixed with the PSG had more accurate screw placement. This was a cadaver study, and therefore, clinical significance of this conclusion could not be assessed. DeWolf et al. also performed a cadaver study that compared accuracy of Kirschner guide wire placement for screw fixation of acute scaphoid fractures[34]. They found no significant difference in the accuracy of wire placement between the PSG and freehand groups. They also found that using their PSG reduced surgical time and intraoperative radiation exposure when compared with freehand wire placement. A study by Jew et al. used a 3D-printed model for surgical planning for fixation of acute scaphoid fractures[35]. This study had a small sample size and no comparator. They reported that the printed models were useful for preoperative planning and are likely more useful for complex fractures. Despite this, we cannot conclude that it contributes to better outcomes compared with traditional techniques without further comparative studies. Another application that has been explored is scaphoid replacement with custom titanium-printed implants; however, this is still in an experimental phase[36].

Another factor that must be considered with this new technology is its economic impact. To our knowledge, a cost-benefit analysis of 3DP PSG in the management of scaphoid nonunion has not been performed. Numerous variables must be considered in evaluating the cost-effectiveness of this new technology, including the cost of raw materials, printing costs, access to 3D printers, preoperative planning time and dedicated imaging, and surgical time differences. The costs of PSG production are dependent on the sort of guide being produced, the material used, and the printer required. This should be considered when designing future PSDs to minimize healthcare costs while optimizing patient safety. A study by Schweizer et al. produced a 3DP PSG that costs $300 USD[29]. Other studies have referenced a range of production costs between $4 and $500 USD[37]. This wide range demonstrates the need for further individual cost benefit analysis as part of the development of new devices before recommending them instead of the current standard of care. This will require extensive follow-up of patients both with and without use of 3DP devices postoperatively to explore the full financial impact through measures such as return to work, rate of revision surgery, and extent of healthcare follow-up required[18,37].

The strengths of our study include its methodological rigor and the breadth of data sources included. We acknowledge that our results are limited by a lack of comparative studies. We did not include other emerging technologies in scaphoid fracture management including computer-assisted fixation. Patent applications are evidence of a company's interest in a field, but they do not include data regarding effectiveness, and hence, we are unable to comment on the results of PSI.

Conclusion

There is growing interest in the use of PSD in the management of scaphoid nonunion. However, higher-quality comparative studies are required to demonstrate the efficacy of these devices. Most PSDs reported in the literature were anatomic models for preoperative planning and intraoperative graft modeling. There is a paucity of evidence for PSD in reducing these complex fractures and facilitating fixation. Further research with comparative studies is required before changes to current practice can be proposed.

Appendix

eA Supporting material provided by the authors is posted with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJSOA/A853). This content was not copyedited or verified by JBJS. ■

Note: Sustainable Industry Manufacturing for Long-Term Ecosystems (SIMPLE) Hub Regional Research Collaboration (RRC) grant, Department of Education, Australian Government.

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