Investigation

Clinical and patient-level predictors of procedure and tooth survival after direct pulp capping

Nihan Gencerliler, MPH; Kelly Terlizzi, MS; Heather T. Gold, PhD; Asgeir Sigurdsson, DDS, MS; Lorel E. Burns, DDS, MS

ABSTRACT

Background. Historical reports of unpredictable outcomes associated with vital pulpal therapies, particularly direct pulp capping (DPC), have contributed to clinicians' skepticism of the procedure. Contemporary reports highlight more predictable outcomes of vital pulpal therapies, inclusive of DPC. There is a dearth of reported patient-centered outcomes of these procedures.

Methods. Insurance claims were used in an observational, retrospective cohort study to evaluate outcomes of DPC performed on permanent teeth. Statistical analyses included Kaplan-Meier survival estimates and Cox proportional hazards regression. Log-rank tests were used to evaluate unadjusted differences in survival. Cox proportional hazard regression was used to evaluate the adjusted hazard of adverse event occurrence.

Results. The analytic cohort included 4,136 teeth from 3,716 patients. DPC procedures were identified in public-payer (85.5%) and private-payer (13.4%) insurance claims databases. After DPC, procedure survival rate was 83% and tooth survival rate was 93% during a mean follow-up time of 52 months. Molar tooth type, same-day permanent restoration placement, and amalgam restoration type were significant positive predictors of procedure (DPC) survival. Age was not a statistically significant predictor of procedure survival after controlling for tooth type, gender, time to restoration, and restoration type. Nonmolar tooth type and younger age were significant positive predictors of tooth survival after DPC. Failures were most likely to occur within the first year.

Conclusions. DPC has favorable patient-centered outcomes and contributes to long-term tooth survival.

Practical Implications. The favorable patient-centered outcomes of DPC bolster calls to consider cost-effectiveness and access to care for endodontic procedures.

Key Words. Pulp capping; dental; analyses, survival; outcomes, patient-relevant; analysis, insurance claims.

JADA 2024:155(8):699-707
https://doi.org/10.1016/j.adaj.2024.05.014

The vitality of the dental pulp may be compromised by means of the presence of a deep caries lesion, traumatic dental injuries, and subsequent iatrogenic restorative interventions used to manage these conditions.[1] Strategies to preserve pulp vitality are ultimately aimed at prolonged retention of the natural dentition.[2-4] These strategies include vital pulpal therapies, inclusive of selective caries removal techniques; indirect pulp capping; direct pulp capping (DPC); and pulpotomy procedures.[5] This range of clinical procedures allows for the engagement of the following dental clinicians, with varied training, to preserve pulp vitality: general dentists, pediatric dentists, and endodontists.

Historical reports of unpredictable outcomes associated with vital pulpal therapies, particularly DPC, have contributed to clinicians' skepticism of the procedure.[6,7] It has been suggested that this skepticism has led to more invasive procedures, such as root canal therapy, to be considered as a more predictable treatment alternative in cases of pulpal exposure,[8,9] especially in cases when root development is complete. However, advancements in biomaterials, increased biological

This article has an accompanying online continuing education activity available at: http://jada.ada.org/ce/home.

understanding of the dental pulp, and louder calls to consider cost-effectiveness and access to care in clinical decision making have led to refocused attention on vital pulpal therapy procedures in the global endodontic community. Position statements published by the European Society of Endodontology in 2019[5] and the American Association of Endodontists in 2021[10] highlighted the predictable outcomes for vital pulpal therapy procedures. The statements emphasized the need for the use of aseptic techniques, enhanced visualization facilitated by means of magnification, disinfection protocols, and enhanced coronal seals facilitated by means of the use of calcium silicate materials to achieve predictable outcomes.

Although some guidelines and position statements have advocated for avoidance of pulpal exposure through selective caries removal,[5,11] other position statements and reports of clinicians' practice patterns suggest that complete caries removal is often preferred, even if pulpal exposure results.[10,12-15] Phenomena other than caries that may result in vital pulp exposure include mechanical injury and dental trauma. In the case of pulpal exposure, DPC is the most minimally invasive of the vital pulpal therapies and the most accessible to a wide range of clinicians. Furthermore, DPC has been described as a more cost-effective alternative to root canal therapy after pulpal exposure of an asymptomatic tooth.[16,17]

Reports of DPC treatment success range from 59% through 84% at 2 through 3 years.[18] Results of a survival analysis after DPC, conducted in Germany, showed a 72% procedure survival rate and a 96% tooth survival rate after 3 years of follow-up.[19] Progressive failures after DPC have been reported at follow-up times of increasing duration.[6,18,20] In a 2022 scoping review of systematic reviews reporting the outcomes of vital pulpal therapy published from 1990 through 2020, investigators identified that treatment outcomes were reported inconsistently in the literature.[21] Clinician-centered outcomes, such as treatment success ascertained through clinical and radiographic examinations, were used considerably more often than patient-centered outcomes.[22,23] Although objective in approach, clinician-centered outcomes do not always align with the most prioritized patient-reported outcomes.[23] The most critical patient-centered outcomes after endodontic treatment have been determined to be pain relief and tooth survival.[24] However, tooth survival has been reported in fewer than 20% of studies on vital pulpal therapy.[21] In addition, the need for further intervention after endodontic treatment has also been determined to be a core outcome for assessment.[24]

Our aim was to evaluate the outcome of DPC procedures performed on permanent teeth in real-world settings, with a focus on the patient-centered outcomes of procedure survival and tooth survival.

METHODS

In our retrospective cohort study, we included patients who had undergone at least 1 DPC procedure in the permanent dentition and had at least 1 year of continuous dental insurance enrollment after the date of the identified DPC procedure. Treatments were excluded from the study if the dental encounter for DPC was missing an associated tooth number or there was no evidence of placement of a permanent restoration after the DPC procedure. This study was approved by New York University School of Medicine's institutional review board (s22-01301).

Data sources

Data were sourced from electronic insurance claims and enrollment databases of the New York State Medicaid program and the Massachusetts Center for Health Information and Analysis (CHIA). Access to the data was arranged through data use agreements approved by CHIA and the New York University Health Evaluation and Analytics Laboratory. The New York State Medicaid database included encounters that occurred from 2006 through 2019. The database from CHIA provided all-payer (public and private insurance) claims collected from health insurance payers licensed to operate in the Commonwealth of Massachusetts. CHIA release Version 7.0, included the years 2013 through 2018.

ABBREVIATION KEY

CHIA: Center for Health Information and Analysis.
DPC: Direct pulp capping.

Variables

The final analytic data set contained the following variables: unique patient identifier, patient gender, patient age at date of treatment, state of residence (New York, Massachusetts), insurance type (private or public payer), dates of patient enrollment and disenrollment in insurance, date of

Table 1. Sample characteristics, stratified according to tooth type.

SAMPLE CHARACTERISTIC	OVERALL (n = 4,136)	TOOTH TYPE			P VALUE*
		Anterior (n = 514)	Premolar (n = 925)	Molar (n = 2,697)	
Age Group, Y, No. (%)					
≤19	1,403 (33.9)	193 (37.5)	131 (14.2)	1,079 (40.0)	
20-40	1,671 (40.4)	139 (27.0)	488 (52.8)	1,044 (38.7)	< .001
≥41	1,062 (25.7)	182 (35.4)	306 (33.1)	574 (21.3)	
Follow-Up Time (Mo), Mean (SD)	52.9 (35.9)	54.6 (37.1)	52.7 (36.4)	52.7 (35.4)	.538
Gender, No. (%)					
Female	2,360 (57.1)	†	†	1,542 (57.2)	
Male	1,742 (42.1)	†	†	1,133 (42.0)	.052
Other	34 (0.8)	†	†	22 (0.8)	
Permanent Restoration Placement, No. (%)					
Same date as direct pulp capping	3,642 (88.1)	441 (85.8)	828 (89.5)	2,373 (88.0)	.112
After date of direct pulp capping	494 (11.9)	73 (14.2)	97 (10.5)	324 (12.0)	
Permanent Restoration Type, No. (%)					
Amalgam	1,500 (36.3)	5 (1.0)	366 (39.6)	1,129 (41.9)	
Composite	2,552 (61.7)	497 (96.7)	546 (59.0)	1,509 (56.0)	< .001
Cuspal coverage	84 (2.0)	12 (2.3)	13 (1.4)	59 (2.2)	

* *P* values reflect results of χ^2 test between sample characteristic and tooth type. † Suppression of the value would result in disclosure of a cell size < 11.

DPC treatment, tooth number treated with DPC, tooth type (ie, anterior, premolar, or molar), type and date of permanent restoration placement after DPC, and type and dates of adverse events after the DPC procedure. Adverse events after DPC procedures were defined as root canal therapy or tooth extraction.

Current Dental Terminology codes[25] were used to identify the following dental procedures in the electronic insurance claims: direct pulp cap (D3110), permanent restorations (D2000-D2999); initial root canal therapy (D3310, D3320, and D3330), and tooth extraction (D7140 and D7210). The time to placement of a permanent restoration was calculated and defined as the number of days from the date of the DPC procedure (D3110) until the date the permanent restoration was placed (D2000-D2999).

Analysis

Data analysis was completed using SAS, Version 9.4 (SAS Institute) and R, Version 4.0 (R Core Team) software.

A DPC procedure was considered to have survived until the occurrence of an initial adverse event (subsequent root canal therapy, tooth extraction). Tooth survival after DPC was assumed until the occurrence of tooth extraction. Patients, and thus DPC cases, were considered lost to follow-up at a lapse in the patient's insurance enrollment status of more than 90 days. The calculated time to placement of a permanent restoration after DPC was dichotomized into the following categories: same date as DPC or after the date of the DPC procedure. Age at the time of DPC was transformed into a categorical variable and the following age groups were used: 19 years and younger, 20 through 40 years, and 41 years or older. Kaplan-Meier survival estimates were calculated annually for the study period for both procedure (DPC) and tooth survival. Kaplan-Meier curves and log-rank tests were used to evaluate unadjusted differences in survival according to tooth type, time to permanent restoration, restoration type, and age group. A Cox proportional hazards model was used to evaluate the adjusted hazard of adverse event occurrence after DPC capping procedures controlling for age group, gender, tooth type, placement of permanent restoration, and permanent restoration type. Another Cox proportional hazards model was used to evaluate the hazard of tooth extraction after DPC capping procedures controlling for age, gender, tooth type, placement of permanent restoration, and permanent restoration type. Robust SEs were used in the

Table 2. Procedure and tooth survival after direct pulp capping.

FOLLOW-UP TIME, Y (MO)	NO. AVAILABLE FOR ANALYSIS AT TIME OF FOLLOW-UP	PROCEDURE (DIRECT PULP CAPPING) SURVIVAL, % (95% CI)	TOOTH SURVIVAL, % (95% CI)
1 (12)	3,820	92.14 (91.33 to 92.97)	97.29 (96.80 to 97.89)
2 (24)	2,678	88.84 (87.86 to 89.84)	95.64 (95.00 to 96.28)
3 (36)	2,074	86.45 (85.33 to 87.59)	94.59 (93.86 to 95.33)
4 (48)	1,500	84.63 (83.40 to 85.88)	93.43 (92.57 to 94.29)
5 (60)	1,047	82.30 (80.88 to 83.75)	91.46 (90.37 to 92.56)
6 (72)	720	81.06 (79.51 to 82.65)	90.38 (89.15 to 91.64)
7 (84)	431	79.11 (77.27 to 80.99)	88.60 (87.12 to 90.11)
8 (96)	290	77.99 (75.94 to 80.10)	88.03 (86.45 to 89.63)
9 (108)	207	77.99 (75.94 to 80.10)	87.75 (86.10 to 89.44)
10 (120)	139	76.64 (74.14 to 79.23)	86.34 (84.23 to 88.51)

Cox proportional hazards models to account for person-level clustering resulting from including multiple DPC procedures performed in a single patient in the analysis. A 2-sided statistical significance level (α) of .05 was used for all analyses.

RESULTS

A total of 4,710 teeth treated with DPC procedures during the study period were identified. After applying the exclusion criteria, the final analytic sample included 4,136 unique teeth from 3,716 patients treated with DPC procedures. Of these DPC procedures, 85.5% were from public-payer insurance claims (New York, Massachusetts) and 13.4% were from private-payer insurance claims (Massachusetts). Mean (SD) patient age was 29.8 (16.1) years (median, 28 years; interquartile range [IQR], 16-41 years). Mean (SD) number of teeth treated per patient was 1.1 (0.3) (median, 1; IQR, 1-1). The characteristics of the final study sample at the tooth level, overall, and according to tooth type are described in Table 1.

The distribution of permanent restoration type after DPC procedures was 61.7% composite, 36.3% amalgam, and 2.0% cuspal coverage. A permanent restoration was placed on the same day as the DPC procedure in 88.1% of cases.

The overall survival rate of the DPC procedure was 83.2% over a mean observation period of 52.1 months (median, 42 months; IQR, 26-71 months). For the 694 teeth (16.8%) that experienced procedure (DPC) failure, 405 (58.4%) had initial root canal therapy and 289 (41.6%) were extracted as the initial adverse event. Tooth survival over the mean observation period was 92.9%. DPC procedure survival and tooth survival are reported at annual follow-up times up to 10 years (Table 2) and as Kaplan-Meier curves (Figure). Procedure failures were most likely (48.8%) to occur within the first year after DPC.

In the unadjusted survival analyses, female gender ($P = .042$), age 20 through 40 years ($P = .010$), molar tooth type ($P < .001$), same-day permanent restoration placement ($P < .001$), and amalgam restoration type ($P < .001$) were significant positive predictors of DPC procedure survival. For the outcome of tooth survival, 19 years and younger ($P < .001$) and permanent restoration placement the same day of DPC ($P < .001$) were significant positive predictors.

In the adjusted analysis of procedure survival after DPC, the multivariable Cox proportional hazards model indicated that molar tooth type, same-day permanent restoration placement, and amalgam restoration type were significant positive predictors of procedure survival (Table 3). Molars treated with DPC had 23% lower odds of experiencing an adverse event compared with anterior teeth (reference; adjusted hazard ratio [aHR], 0.77; 95% CI, 0.61 to 0.97), after controlling for age, gender, time to permanent restoration, and restoration type. When permanent restorations were placed at any time after the date of DPC, the odds of procedure failure doubled (aHR, 2.05; 95% CI, 1.64 to 2.44). Composite and cuspal coverage restorations were associated with 1.45 and 4.22 times the odds of failure, respectively, compared with teeth restored with amalgam restorations after DPC (composite aHR, 1.45; 95% CI, 1.20 to 1.75; cuspal aHR, 4.22; 95% CI, 2.90 to 6.14). Patient age

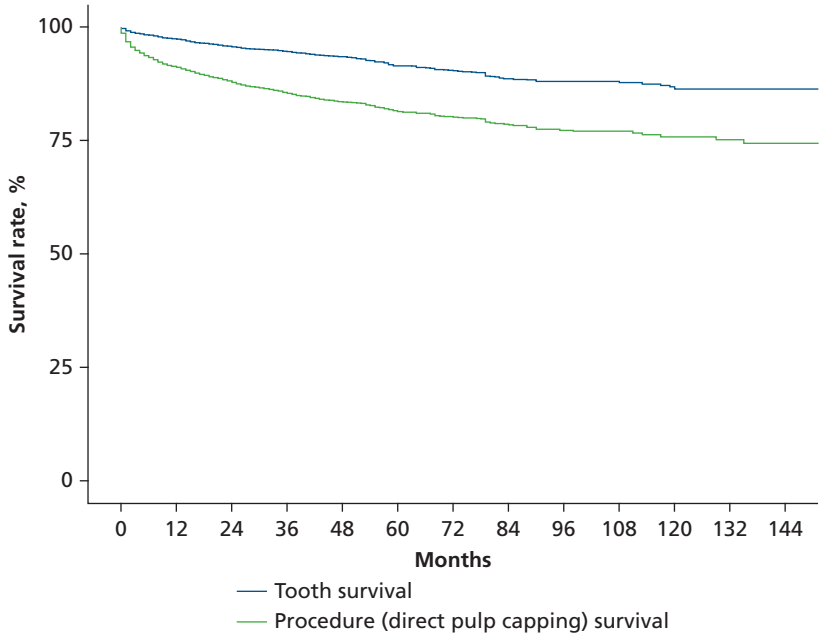

Figure. Kaplan-Meier curves of procedure and tooth survival after direct pulp capping.

Table 3. Adjusted hazard ratio estimates from multivariate Cox proportional hazard analysis of procedure survival after direct pulp capping (DPC).

VARIABLE	ADJUSTED HAZARD RATIO (95% CI)	*P* VALUE*
Gender [Reference: Female]		
Male	0.86 (0.73 to 1.02)	.069
Other	0.15 (0.02 to 1.09)	.061
Age Group, Y [Reference: ≤ 19]		
20-40	0.94 (0.76 to 1.15)	.534
≥ 41	1.22 (0.98 to 1.50)	.065
Tooth Type [Reference: Anterior]		
Premolar	0.99 (0.76 to 1.29)	.896
Molar	0.77 (0.61 to 0.97)	.024
Permanent Restoration Placement [Reference: Day of DPC Procedure]		
After date of DPC	2.05 (1.64 to 2.44)	< .001
Permanent Restoration Type [Reference: Amalgam]		
Composite	1.45 (1.20 to 1.75)	< .001
Cuspal coverage	4.22 (2.90 to 6.14)	< .001

* *P* value corresponds to test of the null hypothesis that adjusted hazard ratio = 1.

was not statistically significant after controlling for tooth type, gender, time to permanent restoration, and restoration type.

In the adjusted analysis of tooth survival after DPC, the multivariable Cox proportional hazards model indicated that nonmolar tooth type (ie, anterior and premolar) and younger age were significant positive predictors of survival (Table 4). In contrast with the unadjusted log-rank analysis, where tooth type was not a significant predictor of tooth survival, in the adjusted analysis molars treated with DPC were almost 2 times more likely to undergo extraction compared with anterior teeth (reference) (aHR, 1.97; 95% CI, 1.29 to 3.01) when age, gender, time to permanent restoration, and restoration type were controlled for. In addition, time to permanent restoration

Table 4. Adjusted hazard ratio estimates from multivariate Cox proportional hazard analysis of tooth survival after direct pulp capping (DPC).

VARIABLE	ADJUSTED HAZARD RATIO (95% CI)	*P* VALUE*
Gender [Reference: Female]		
Male	0.89 (0.70 to 1.14)	.370
Other	†	Not applicable
Age (Continuous)	1.03 (1.03 to 1.04)	< .001
Tooth Type [Reference: Anterior]		
Premolar	1.14 (0.71 to 1.81)	.593
Molar	1.97 (1.29 to 3.01)	.002
Permanent Restoration Placement [Reference: Date of DPC Procedure]		
After date of DPC	0.67 (0.42 to 1.06)	.090
Permanent Restoration Type [Reference Amalgam]		
Composite	1.26 (0.98 to 1.62)	.076
Cuspal coverage	1.18 (0.46 to 3.05)	< .001

* *P* value corresponds to test of the null hypothesis that adjusted hazard ratio = 1. † Unable to estimate adjusted hazard ratio due to small sample size and lack of extraction events in this group.

placement was no longer a significant predictor of tooth survival after adjusting for covariates. Age exhibited a linear relationship with tooth survival when checking model assumptions and was consequently included as a continuous variable. With regard to age, each additional year was associated with a 3% increase in the hazard of tooth extraction (aHR, 1.03; 95% CI, 1.03 to 1.04).

DISCUSSION

In this observational, retrospective cohort study, we evaluated dental insurance claims and enrollment data with the aim of reporting generalizable, patient-centered outcomes of DPC. Procedure survival and tooth survival after DPC were the specific outcomes of interest.

After pulp exposure, DPC is the simplest and most conservative treatment option for preserving pulp vitality and maintaining the natural dentition. Furthermore, the broad applicability of the DPC procedure is supported by the findings of our study, which indicated that DPC is performed in patients across the lifespan. In alignment with previously published findings, we found that DPC was performed predominately on multirooted teeth.[19] This is clinically relevant due to the fact that more invasive procedure alternatives to DPC, such as root canal therapy, performed on multirooted teeth are more expensive[15] and more technically challenging to complete. Therefore, this finding has access-to-care implications, which may be considered when contemplating the application of DPC procedures in the attempt to maintain natural dentition. For example, a lack of insurance coverage, in general or for specific procedures, may be a barrier to accessing oral health care for some patients. In our study, insurance coverage for dental procedures varied according to state of residence, patient age, and tooth type.

Our study's findings support previous reports that DPC is a predictable procedure.[18,19] After 3 years, the DPC procedure survival rate was 86% and tooth survival rate was 95%. Procedure survival remained greater than 80% for the first 6 years after DPC. Tooth survival, identified as the most critical outcome measure for endodontic treatment,[23] was greater than 90% 6 years after DPC. In agreement with other studies, the results of our study indicated that DPC procedure failures are most likely to occur within the first year after treatment.[26,27] When DPC procedures failed, the first adverse event was root canal therapy for 58% of cases and tooth extraction for 42% of cases. Although the reported incidence of tooth extraction immediately after DPC failures may seem high, these findings should be contextualized with the sequence of events after failure of the treatment alternative of root canal therapy in mind. Endodontic outcomes studies have reported that after failure of initial root canal therapy, the most common initial adverse event is tooth extraction.[28,29] Thus, despite the possibility of requiring further interventions, teeth treated with DPC may be

retained for a longer period due to the postponement of more invasive treatments. The high incidence of tooth extraction immediately after the failure of initial endodontic procedures may be an indication of tooth restorability for these cases, an indication of the value patients or clinicians place on maintaining the natural dentition, or may reflect barriers in access to care for endodontic treatment.

The outcomes reported in our study can be compared with outcomes reported in a German study with similar methodology published in 2016 (ie, 72% DPC procedure survival rate and 96% tooth survival rate after 3 years).[19] Although the tooth survival findings between these 2 studies are similar, there is an almost 10% difference in the survival rates of the DPC procedure between the 2 studies. One potential explanation for this difference in procedure survival may be differences in clinical technique applied in the United States compared with those in Germany. It is more likely, however, that nuanced methodological differences between the 2 similarly designed studies account for the discrepancy. For example, we only included DPC cases with evidence of placement of a permanent restoration, while permanent restorations placed subsequent to DPC were not mentioned in the German study.[19]

Some factors that have been reported to be associated with the success of vital pulpal therapies, and endodontic treatments more broadly, were evaluated in our study. The influence of patient age on the outcomes of DPC has been reported inconsistently.[30-33] After controlling for tooth type, gender, time to permanent restoration, and restoration type, patient age was not a statistically significant predictor of the outcomes of DPC procedures. However, age was a significant predictor of tooth survival after DPC. As patient age increased, tooth extraction was significantly more likely after DPC failure. For comparison with the German study,[19] the results of our unadjusted analysis must be used. When covariates such as tooth type and restoration placement are not controlled for, categorical age is a significant predictor of both procedure and tooth survival after DPC. Consistent with the German study,[19] age did not have a linear association with DPC procedure survival in our study. Our findings on tooth survival after DPC were in direct contrast to those from the German study,[19] in which increased age was associated with lower rates of tooth extraction after DPC failure. Beyond age, tooth type, time to placement of a permanent restoration, and type of permanent restoration were significantly associated with the outcomes of DPC procedures in our study. Adjusted analyses revealed that DPC procedures performed on molars were less likely to fail, but when failure of DPC procedures did occur, molars were more likely to be extracted than other tooth types. Tooth type has not been consistently reported to be a significant prognostic factor for the outcomes of DPC procedures in studies with smaller sample sizes,[31-34] but in reviews of the vital pulpal therapy literature, researchers have suggested there has been limited analysis of the effect of tooth type.[35-37]

Our findings on tooth extraction after the failure of DPC procedures are consistent with those of other studies reporting increased rates of extraction in molars after failure of endodontic treatment.[28] In our study, the increased risk of extraction after failed DPC for molars may be an indication of access to care for more complex endodontic procedures, such as root canal therapy. The hypothesis of limited access to care for endodontic procedures is particularly likely in our study, as most of the DPC claims (86%) came from public-payer insurance databases. Root canal therapy for permanent molars in patients older than 20 years was not a consistently covered benefit during the study period, a reflection of state-level policy during the study period.[38,39] A variable that clinicians may control when performing DPC is time to placement of a permanent restoration. Our findings agree with previous studies that a minimal time span between DPC and placement of a permanent restoration is a strong predictor of successful outcomes[33,34,40] and support the American Association of Endodontists' position statement that urged immediate placement of a permanent restorative material after vital pulpal therapy.[10] The rate for placement of cuspal coverage after DPC was low in our study (2%). We hypothesized that this may reflect clinicians' decisions not to place cuspal coverage restorations on teeth with procedures (DPC) that have been viewed with skepticism historically or that teeth requiring cuspal coverage were more likely to be selected for more invasive treatments, such as root canal therapy, on pulpal exposure. Alternatively, this low incidence of cuspal coverage placement after DPC could be a reflection of access-to-care considerations for these restoration types and a reflection of covered insurance benefits. When cuspal coverage restorations were placed, the DPC procedures were more than 4 times more likely to fail. This may be an indication of the preoperative status of the pulp in these cases, or a reflection of the amount of injury caused to the pulp in preparation for these restoration types.

The findings of our study are not without limitations. The primary limitation is one that applies to other outcome studies using administrative claims; that is, the nonclinical nature of the data. Thus, it is not possible to assess the preoperative status, aseptic clinical technique, biomaterials of the pulp capping agents used, or clinical symptoms experienced as a result of treatment failure. Although the nonclinical nature of these data must be considered, in all vital pulpal therapy studies, even those in which clinical data are used, the measurement of pulpal health is a limitation.[35,41] Furthermore, it is possible that data were missing, resulting from events that may not be captured in the claims. This could potentially lead to an overestimation of procedure or tooth survival and an inflated suggestion of patient-centered outcomes in our study. Ultimately, the large sample size reported in our study allowed for sufficient power to report statistically significant findings and potentially increased generalizability compared with outcome studies in which cases are limited to those completed in academic settings. The focus on patient-centered outcomes in our study addressed a gap in the vital pulpal therapy literature, identified by researchers in a 2022 scoping review.[21]

CONCLUSIONS

DPC has favorable patient-centered outcomes and contributes to long-term tooth survival. Failures are most likely to occur within the first year. Molar tooth type, same-day placement of a permanent restoration, and amalgam restoration type were significant positive predictors of DPC procedure survival. Nonmolar tooth type and younger age were significant positive predictors of tooth survival after DPC. ■

DISCLOSURE

None of the authors reported any disclosures.

Ms. Gencerliler is an assistant research scientist, Department of Endodontics, College of Dentistry, New York University, New York, NY.

Ms. Terlizzi is an analyst, Health Evaluation and Analytics Laboratory, New York University, New York, NY.

Dr. Gold is a professor, Department of Population Health, New York University Langone Health, New York, NY.

Dr. Sigurdsson is a professor and the chair, Department of Endodontics, College of Dentistry, New York University, New York, NY.

Dr. Burns is an assistant professor, Department of Endodontics, College of Dentistry, New York University, New York, NY. Address correspondence to Dr. Burns, Department of Endodontics, College of Dentistry, New York University, 345 E 24th St, New York, NY 10010, email lorel.burns@nyu.edu.

The views expressed here are those of the authors and do not necessarily reflect the position or policy of the New York State Department of Health. Examples of analysis performed within this article are only examples. They should not be used in real-world analytic products.

This study was funded by grant 78302 awarded to New York University from the Robert Wood Johnson Foundation's Harold Amos Medical Faculty Development Program (principal investigator: Dr. Burns). The content is solely the responsibility of the authors and does not necessarily represent the official views of the Robert Wood Johnson Foundation.

ORCID Numbers. Nihan Gencerliler: https://orcid.org/0000-0002-8269-5437; Kelly Terlizzi: https://orcid.org/0009-0001-5354-8518; Heather T. Gold: https://orcid.org/0000-0002-5896-0499; Asgeir Sigurdsson: https://orcid.org/0000-0002-6911-8248; Lorel E. Burns: https://orcid.org/0000-0002-7420-5418. For information regarding ORCID numbers, go to http://orcid.org.

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