



CLINICAL EVALUATION AND RADIOGRAPHIC EVALUATION PULPOTOMIZED PRIMARY POSTERIOR TEETH RESTORED WITH PREFABRICATED STAINLESS-STEEL AND ZIRCONIA CROWNS

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ABSTRACT

Objectives This clinical study was directed to evaluate the clinical and radiographic success of Stainless-steel crowns versus zirconia crowns on primary molars. **Subjects and methods:** A total of ten children with twenty pulpotomized primary mandibular molars were involved and categorized into 2 groups; Group I; pulpotomized primary molar teeth restored with zirconia crowns and Group II; pulpotomized primary molar teeth restored with Stainless-steel crowns. The clinical and radiographic evaluations were conducted at baseline, 1-, 3-, and 6-months intervals utilizing the Scoring system. **Results:** The results of this study showed that was no statistically significant difference between proximal contact areas, marginal adaptations, and restoration failure scores in the two groups at baseline, 1, 3, and 6 months. Stainless Steel crown group showed statistically significantly higher mean OHI scores than the Zirconia crown group at 1 and 6 months. Stainless Steel crown group showed statistically significantly higher mean GI scores than the Zirconia crown group at 3 and 6 months. After 6 months, 70% of the Stainless-Steel crowns showed acceptable clinical and radiographic criteria compared to 100% of the Zirconia crowns. **Conclusions:** Zirconia crowns demonstrated better gingival health than the stainless- steel crowns group. Zirconia crowns can be used as a safe esthetic alternative for stainless steel crowns with successful clinical outcomes.

KEYWORDS: Pulpotomy, Stainless-Steel, Zirconia, marginal adaptations

INTRODUCTION

Dental caries is the most prevalent disease, especially in children. If left untreated, caries has the potential to substantially degrade tooth structure and result in the need for one or more tooth surface restorations^(1,2). Restoration of pulpotomized primary molars is a common technique in paediatric dentistry offices⁽³⁾. Since pulpotomized teeth are more likely to fracture due to the large loss of tooth

structure, one goal of dental materials research is to select the optimum restorative material for the restoration of these teeth. In order to sustain the remaining tooth structure and endure masticatory stresses, the restoration must be strong and long-lasting. In this situation, using crowns to restore primary teeth provides many benefits over using traditional restorations like amalgam, including greater lifespan, simplicity of use, and reduced restorative microleakage⁽³⁾.

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The prefabricated stainless-steel crown (SSC), which protects the main tooth from fracture, reduces the chance of leaking and ensures a biological seal, has been demonstrated to be the restoration of choice or the “gold standard” for many years. Additionally, the SSCs are inexpensive and less reliant on the insertion technique. Unfortunately, parents routinely oppose stainless-steel metal crowns for cosmetic grounds ⁽⁴⁾.

Prefabricated paediatric zirconia crowns (ZCs) with great aesthetic qualities, durability, and reduced fabrication time have recently been presented by manufacturers. These ZCs will please parents, children, and dentists alike. However, due to their erroneous measurements and costly costs, these crowns prevent youngsters from having an aesthetically pleasing smile and prevent their usage in clinics ⁽⁴⁾.

Major failure was defined as the absence of clinical effectiveness. Additionally, it can be described as a composite index of symptoms and signs that point to the diagnosis of periradicular periodontitis or irreversible pulpitis and include signs and symptoms such as pain, pulp infection, dental abscesses, and any periradicular pathology that is visible on radiographs. Therefore, to create affordable prefabricated crowns that can be utilized as a final treatment for primary teeth, this study evaluated the clinical success of prefabricated stainless steel and zirconia crowns.

SUBJECTS AND METHODS

Study Design

A split-mouth, parallel design, randomized, non-blinded prospective controlled clinical trial.

Study Setting and Population

The involved patients were selected from the outpatients of Clinic the Pedodontics and Oral Health, Faculty of Dental Medicine (Cairo – boys), Al-Azhar University. All clinical and follow-up

procedures were carried out at the Pedodontics and Oral Health Department of the Faculty of Dental Medicine (Cairo – boys), Al-Azhar University.

Eligibility criteria of the study^(5,6)

Inclusion criteria

At the beginning we choose patients with pulp-treated primary molars are indicated for restoration with crowns and patients with deep caries are indicated for pulpotomy. The most important criteria is the choice of patients with two contralateral carious primary molars in the same arch, the teeth to be included should be fully erupted and have functional occlusion with at least one opposing tooth.

Finally the crowned molar must be in contact with at least one adjacent molar medially with the primary first molar and/or laterally with the permanent first molar (standard for posterior crowns). Besides parents and patients acceptance and cooperation should be taken.

Exclusion criteria:

We will exclude the children whose parents refused to participate in the study and the children with another systemic disease can affect their immunity or cooperation.

In addition to the primary molars whose radiographic examination reveals a widening of the periodontal space and the presence of radiolucent image on the root furcation and/or apices.

If there are internal or external resorption. Finally primary molars with evidence of periodontal disease, primary molars in infra-occlusion and primary molars with root resorption of more than a third of the radicular length, we can add to this criteria mobile tooth indicated for extraction.

Ethical Consideration: Ethical Committee of the Faculty of Dental Medicine (Cairo, Boys), Al-Azhar University with Ethical Approval No (EC Ref No. 613/3511).

Patient Consent

The study's goal of this clinical trial was explained to the children and their parents, and they both signed an informed consent form before participating.

Sample Size

Based on the previous study of Prabhu et al ⁽⁶⁾, a power calculation of sample size indicated that a minimum of 10 children per group were required to detect a significant difference between groups. The effect size ($df=9.726$) and the required sample size were calculated for a 95% confidence interval and a power of (0.4606).

Subject Grouping:

In all patients, each tooth of the pair (two contralateral primary carious mandibular molar teeth in the same arch) was restored with one of the two tested crowns as the following:

Group I: Prefabricated zirconia crown ($n=10$).

Group II: Prefabricated stainless-steel crown ($n=10$).

Intervention

Pulpotomy^(5,7)

All teeth were prepared after performing local anesthesia of 3% Mepecaine with 1:100.000 epinephrine. All caries were removed after local anesthetic was administered, and coronal access was made with a sterile No. 330 high-speed bur with water spray to reveal the pulp chamber.

A sterile spoon excavator was utilized for coronal pulp amputation.

For the purpose of achieving hemostasis, a sterile cotton pellet moistened with distilled water was placed over the pulp stumps. The molar was removed from the trial if bleeding persisted for longer than 5 minutes. Using a sterile cotton pellet,

formocresol was administered for three to five minutes. (Figure 1)

The pulp stumps were covered with a strengthened zinc oxide eugenol base after the cotton pellet was removed. The primary molars must be covered with a rubber dam for pulpotomy therapy, and high-viscosity glass ionomer cement must then be used for restoration.

Crown Preparation

Before beginning molar reduction, a suitable crown size should always be chosen with Zirconia NuSmile Try-In Crowns or SSCs ⁽⁵⁾, Regardless of the type of crowns that were used, all enrolled teeth were prepared according to NuSmile's instructions "preparation guide" as follows ^(5,7) :

Removal of 1-2 mm from the occlusal surface following the natural occlusal contours, opening the interproximal contacts and reducing the entire clinical crown by 20-30% (or 0.5-1.25 mm), the resulting preparation was parallel to slightly converging occlusally, the preparation margin should be carefully extended and refined to a feather edge approximately 1-2 mm subgingivally with a thin, tapered diamond, to avoid tearing up tissue when doing subgingival tooth changes, a thin, narrower diamond bur should be used, checking that no undercuts or subgingival ledges remain, to ensure no undercuts or subgingival ridges are remaining about 1-2 mm subgingivally on every location, the anticipated edge should be polished to a feather edge and Finally, line and point angles were removed to allow all preparation regions to be slightly rounded, all line angles of the prepared tooth should be rounded (Figure 1) ,the teeth should be clean of saliva, blood, or debris and control gingival hemorrhage,crowns should be held firmly in place until cement self-sets. Then, the residue was cleaned up (Figure 1).

Check occlusion: if a crown is in high occlusion, the opposing teeth may be adjusted as necessary.

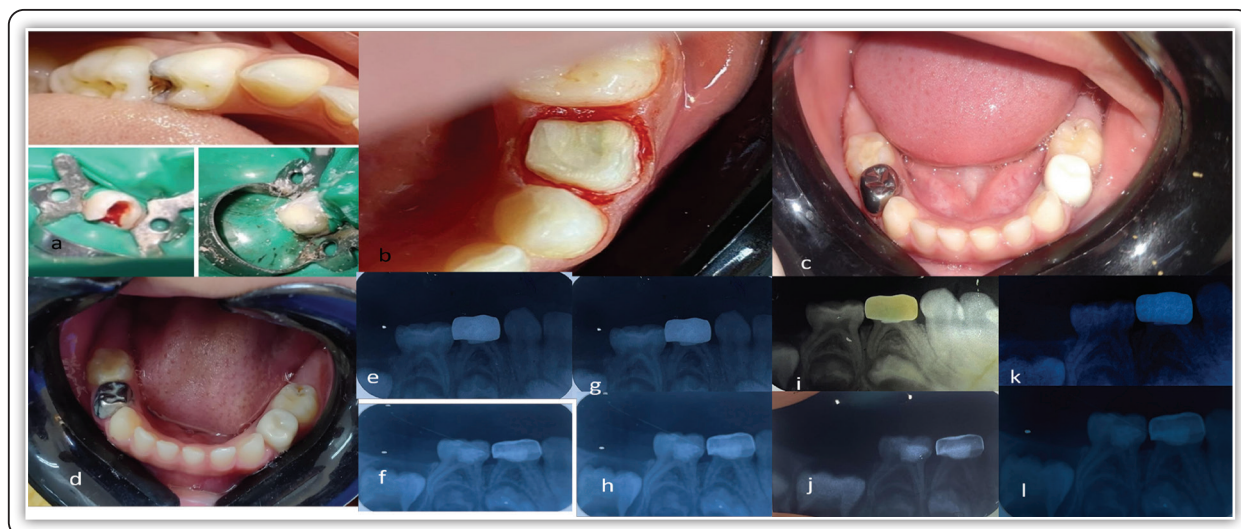


FIG (1) (a) Pulpotomy procedures for primary mandibular molar, (b) Primary mandibular molar preparation, (c) Child with cemented Zirconia crown and SSC, (d) After 6 month, (e and f) Immediately, (g and h) 1 month, (I and j) 3 months, and (k and l) 6 months

Allocation

Primary mandibular molars that were prepared first were allocated to prefabricated ZCs; 1 to 2 weeks later, the contralateral primary mandibular molar of the same pair was restored by an SSC⁽⁷⁾. All crowns were cemented with conventional glass ionomer cement.

Follow-up visits were scheduled for one month, three months, and six months utilizing the Scoring system. Figure (1). (5) When a patient did not respond to contact from the researchers or missed an appointment, a follow-up examination was rescheduled after one to two weeks

Post-operative assessment: Clinical evaluation^(5,8)

After the cementation of the crown, the clinical evaluation was recorded with the following parameters: Proximal contact area: for posterior teeth, between first and second primary molars (mesial point) and between second primary molars and first permanent molars if erupted (distal point), for anterior teeth between incisor and lateral, All these points were recorded as intact or open by passing a dental floss. Crown marginal adaptation was measured with the dental probe at four points:

mesial, middle, distal buccal walls, and middle lingual walls and was reported as either good with sealed margins or poor when the explorer detected an open margin. Crown margins were considered poor when at least one point was opened. Restoration failure was measured according to the United States Public Health Service (USPHS) by assessing it with both the naked eye and dental- led curing light.

Oral Hygiene Index (OHI) and radiographic bone health for the study tooth and control tooth were measured. Parameters affecting GI and interproximal bone levels were measured. The OHI was estimated by running the side of an explorer over the buccal surface of the treated molar.

The gingival index (GI) was measured for the restored tooth. The GI was measured by passing an explorer tip gently within the sulcus mesial, distal, buccal and lingual surface of each crown.

Radiographic periodontal evaluation

Patients were evaluated in four stages: immediately after cementation, one month, 3 months, and 6 months. Radiographic evaluation was done using a periapical radiograph.

The periapical radiographs were placed on the X-ray viewer and the height of the interdental bone was measured from the crest of the interdental bone to the cemento-enamel junction (CEJ).

Data management and analysis

Statistical analysis was performed using a commercially available software program (SPSS Chicago, IL, USA). Numerical data were described as mean and standard deviation or as median and range as appropriate according to the normality of the data using tests of normality (Shapiro-Wilk test). Data were compared using the Mann-Whitney U test (for 2 groups) depending on normality. Friedman's test was used to study the changes by time in each group. Wilcoxon signed-rank test with Bonferroni's adjustment was used for pair-wise comparisons between the time periods when Friedman's test is significant. Qualitative data were presented as frequencies (n) and percentages (%). Chi-square test was used to compare between the two groups. The level of significance was set at $P < 0.05$. All tests were two-tailed.

RESULTS

Both groups recorded the same age means and standard deviation (mean \pm SD) value (6 ± 0.67). This is because this study was designed as a split-mouth study, so, the same patient received both treatments of ZCs and SSCs one on the right side and the other on the left side. Both Groups have the same number and percentage of 7 (70%) and 3 (30%) treated male and female children respectively. This is because this study was designed as a split-mouth study, so, the same patient received both treatments of ZCs and SSCs one on the right side and the other on the left side.

Clinical evaluation

Proximal contact areas

At the baseline, 50% of the ZCs group showed

intact points compared to 60% of the SSCs group. The chi-square statistic is 0.202. The P-value is 0.6530. The result is not significant at $P \leq 0.05$. However, after 1 month, 60% of the ZCs group showed intact points compared to 70% of the SSCs group. The chi-square statistic is 0.219. The P-value is 0.6392. The result is not significant at $P \leq 0.05$. But, after 3 months and 6 months, 100% of the ZCs and SSCs groups showed intact points with no pen points. The results of Friedman's test were used to study the changes by time in each group and found that there was no statistically significant difference ($P > 0.05$) between the changes by time in each group (ZCs or SSCs).

Marginal adaptation

At the baseline, 80% of the ZCs group showed well-sealed margins compared to 90% of the SSCs group. The chi-square statistic is 0.392. The P-value is 0.531. The result is not significant at $P \leq 0.05$. However, after 1 month, 3 months and 6 months, 80% of the ZCs and SSCs groups showed well-sealed margins. The results of Friedman's test were used to study the changes by time in each group and found that there was no statistically significant difference ($P > 0.05$) between the changes by time in each group (ZCs or SSCs).

Restoration failure

At the baseline, after 1 month, and 3 months 100% of the ZCs and SSCs group showed high durability, with no cracks or chips. However, after 6 months, 90% of the ZCs showed high durability, with no cracks or chips compared to 100% of SSCs groups showed well-sealed margins. Only one zirconia crown was chipped after 6 months of follow-up with a percentage of 10%. The results of Friedman's test were used to study the changes by time in each group and found that there was no statistically significant difference ($P > 0.05$) between the changes by time in each group (ZCs or SSCs).

TABLE (1) The results of comparison between the two groups:

		ZCs	SSCs	p-value
Gender	Age	6± 0.67	6± 0.67	1 Ns
	Male; n (%)	7 (70%)	7 (70%)	1 Ns
	Female; n (%)	3 (30%)	3 (30%)	
Proximal contact areas	Baseline; no (%)	5 (50%)	6 (60%)	0.6530 ns
	1 month; no (%)	6 (60%)	7 (70%)	0.6392 ns
	3 months; no (%)	10 (100%)	10 (100%)	NC
	6 months; no (%)	10 (100%)	10 (100%)	NC
P0		0.173 ns	0.382 ns	
Marginal adaptations	Baseline; no (%)	8 (80%)	9 (90%)	0.531 ns
	1 month; no (%)	8 (80%)	8 (80%)	NC
	3 months; no (%)	8 (80%)	8 (80%)	NC
	6 months; no (%)	8 (80%)	8 (80%)	NC
P0		0.173 ns	0.382 ns	
Restoration failure	Baseline; no (%)	10 (100%)	10 (100%)	NC
	1 month; no (%)	10 (100%)	10 (100%)	NC
	3 months; no (%)	10 (100%)	10 (100%)	NC
	6 months; no (%)	9 (90%)	10 (100%)	Nac

Gingival index (GI)

At the baseline, the ZCs and SSCs group showed no gingival inflammation. However, after 3 months and 6 months, the Mann–Whitney U test results showed that ZCs showed significantly better gingival index measures than SSCs, with low gingival inflammation responses. the changes by time in each group and found that there was no statistically significant difference ($P>0.05$). The Wilcoxon signed-rank test results showed a statistically significant difference between the baseline time and the other follow-up times (1,3, and 6 months), however, no statistically significant difference between the 1,3, and 6 months follow-up periods.

Oral hygiene index (OHI):

At the baseline, the ZCs and SSCs group showed no debris. However, after 1 month and 6 months, ZCs showed significantly better oral hygiene index measures than SSCs, with low debris retention. the changes by time in each group and found that there was no statistically significant difference ($P>0.05$) However, the SSCs group showed a statistically significant difference between the changes in the oral hygiene index measures over time. The Wilcoxon signed-rank test results showed a statistically significant difference between the baseline time and the other follow-up times (1,3, and 6 months), however, no statistically significant difference between the 1,3-, and 6-months follow-up periods.

TABLE (2) The results of comparison between the two groups

		ZCs		SSCs		P
OHI	Baseline	0.00	0.00	0.00	0.00	1
	1 month	7.6	0.69	13.4	0.96	0.031*
	3 months	8.2	0.82	12.8	0.97	0.073ns
	6 months	7.3	0.63	13.7	0.78	0.010*
	0.104 ns		0.001*			
GI	Baseline	0.00	0.00	0.00	0.00	1
	1 month	8.4	0.84	12.6	1.50	0.086ns
	3 months	7.6	0.99	13.4	1.32	0.023*
	6 months	6.5	1.05	14.5	0.87	0.001*

Radiographic evaluations

At the baseline, 100% of the ZCs and SSCs groups showed normal (non- resorbed) interproximal bone. However, after 1 month, 100% of the ZCs group showed normal (non- resorbed) interproximal bone compared to 90% of the SSCs group. But, after 3 months, 100% of the ZCs group showed normal (non-resorbed) interproximal bone compared to 80% of

the SSCs group. Conversely, after 3 months, 100% of the ZCs group showed normal (non-resorbed) interproximal bone compared to 70% of the SSCs group. The results of Friedman's test were used to study the changes by time in each group and found that there was no statistically significant difference ($P>0.05$) between the changes by time in each group (ZCs or SSCs).

TABLE (3) The results of comparison between radiographic periodontal evaluation in the two groups:

		ZCs	SSC	p
Radiographic periodontal evaluation	Baseline; no (%)	10 (100%)	10 (100%)	NC
	1 month; no (%)	10 (100%)	9 (90%)	NAN
	3 months; no (%)	10 (100%)	8 (80%)	NAN
	6 months; no (%)	10 (100%)	70 (70%)	NAN
		1 ns	0.774 ns	

DISCUSSION

One of the most crucial operations in dental offices is the final restoration of anterior and posterior primary teeth that have had pulp treatment. Full coronal restoration is one method that is being used more frequently to treat pulpotomized primary teeth⁽⁹⁾. Other options are available as well, but each involves sacrifices and has a different clinical performance⁽⁴⁾. Therefore, the aim of this study was directed to evaluate the clinical success of two types of prefabricated full coronal restoration during restoring the pulpotomized primary molars.

SSC has long been thought to be the ideal way to restore primary molars with severe carious lesions⁽⁷⁾. But the parents' desire for restorations that seem as natural as their own teeth led to the invention of metal-free covering⁽⁵⁾. Therefore, Zirconia crowns, an aesthetic prefabricated crown, have recently been suggested by various manufacturers⁽⁷⁾.

The findings of this present study showed that maintaining intact contact between teeth for the ZCs and SSCs was statistically non-significant at the baseline and after 1 month, however, the open contact points disappeared at 3 months and 6 months. This finding may be because the mesial drafting of teeth could result in closing the open contact point. This is because after the application of a crown, the mesial point may shift mesial when the tooth is evaluated for follow-up care, but the distal point will remain intact^(4, 9).

The results of this present study showed no statistically significant differences in proximal contact points at the baseline (after cementation), after 1 month, 3 months, and 6 months for both tested crowns. These results agreed with the results of Donly et al. (2018)⁽¹⁰⁾, who reported no differences in proximal contact points (mesial and distal) between the steps, before preparations and after 6 months, 12 months, and 24 months of follow-up. Also, Abdulhadi et al (2017)⁽¹¹⁾, also reported 60 posterior ZCs and SSCs with no differences after 3 months, 6 months, and 12 months of follow-up.

Moreover, the results of this present study showed that the marginal integrity for the ZCs and SSCs was statistically non-significant at the baseline, however, the marginal integrity has no statistically significant change with time. The improper marginal integrity was due to the use of ZCs or SSCs with larger sizes as teeth needed with no clinical problems from producing new contact points.^(9,12) However, the results of this present study disagreed with the results of Hanafi and Altinawi (2020)⁽⁹⁾, who reported that all Zirconia crowns had poor marginal adaptation. However, the results of the current study agree with the results of Holsinger et al. (2016)⁽¹²⁾ who concluded that zirconia crowns have a good margin of 86% after 20 months of follow-up.

Restoration failure with ZCs and SSCs was scored with high durability, with no cracks or chips after 6-months. Only one ZC was chipped after 6 months. The current study was consistent with the results of Abdulhadi et al (2017)⁽¹¹⁾ which also reported no cracks or fractures after 12 months of follow-up with 60 posterior ZCs. Also, the results of a study by Holsinger et al. (2016)⁽¹²⁾ showed that 96% of 44 anterior EZ-Pedo survived with no fractures after 20 months of follow-up.

Another study by Abuelniel and Eltawil's (2018)⁽⁵⁾ found that both of the crown materials used in this study (Zirconia and SSCs for posterior teeth) had a success rate of 100% after a 12-month follow-up period, meaning that there were no chips, cracks, or fractures in any of the crowns.

Despite the patients' and their parents' oral hygiene recommendations. However, there were varying degrees of plaque accumulations across the two groups that were discovered during follow-up visits. Less plaque accumulated in the Zirconia crowns group over the course of the follow-up periods. However, a statistically significant difference between the two groups showed that the SSCs group had higher values for the plaque index. These results agreed with the results of Abuelniel and Eltawil's (2018)⁽⁵⁾ and Maclean et al.

(2007)⁽¹³⁾ who concluded that the SSCs group had higher values for the plaque index in comparison with the ZCs.

The current study's findings show that the SSC group had a statistically significantly higher mean OHI score than the Zirconia crown group after one and six months. This may be related to Zirconia crowns' highly polished, smooth surfaces, which prevented plaque buildup and associated gingival discomfort.⁽¹⁴⁾ Also, Walia et al. (2014)⁽⁸⁾ revealed that Zirconia crowns on primary anterior teeth demonstrated excellent gingival health in another investigation.

The current study's findings show that the SSC group had a statistically significantly higher mean GI score than the ZCs group after 3 and 6 months. This may be related to Zirconia crowns' highly polished, smooth surfaces, which prevented plaque buildup and associated gingival discomfort.⁽¹²³⁾ Additionally, according to Sharaf and Farsi (2004)⁽¹⁵⁾, primary dentition stainless steel crowns and significant proximal caries have been linked to aberrant alveolar bone resorption, especially when there is inadequate crown crimp, length, contour, position, and cement left in the gingival sulcus. Furthermore, Maclean et al. (2007)⁽¹³⁾ believed that incorrectly shaped metal borders and adhesive remnants in the sulcus in the case of SSCs were the main aggravating factors to the gingiva, leading to further plaque buildup and ensuing gingival inflammation.

The results of this present study revealed that the SSCs group showed inter- proximal bone resorption of (90%, 80%, and 70%) compared to 0% of the Zirconia crowns at 1, 3, and 6 months respectively. However, there was no statistically significant difference between the two groups or between the tested periods. These results agreed with the results of Abuelniel and Eltawil's (2018)⁽⁵⁾ who concluded that the SSCs have aberrant alveolar bone resorption. Furthermore, primary dentition stainless steel crowns and significant proximal caries have been linked to aberrant alveolar bone

resorption, particularly when there is insufficient crown crimp, length, contour, position, and cement left in the gingival sulcus, according to Sharaf and Farsi (2004)⁽¹⁵⁾.

CONCLUSIONS

Within the limitations of this in vivo study the following can be concluded zirconia crowns demonstrated better gingival health than the stainless- steel crowns group. Zirconia crowns can be used as a safe esthetic alternative for stainless steel crowns with successful clinical outcomes.

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