Relationship Between Thickness of Calcium on Optical Coherence Tomography and Crack Formation After Balloon Dilatation in Calcified Plaque Requiring Rotational Atherectomy

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Background: Target lesion calcification is known to influence percutaneous coronary intervention. We evaluated the effects of rotational atherectomy (RA) and subsequent balloon angioplasty on calcified coronary lesions using optical coherence tomography (OCT).

Methods and Results: Thirty-seven calcified lesions in 36 patients were treated with RA followed by balloon angioplasty and stent implantation. In all patients, serial OCT images obtained after RA, after balloon angioplasty, and after stent implantation were analyzed at 1-mm intervals. The arc and thickness of the calcium component were measured after RA. The formation of calcium cracks was assessed after balloon angioplasty. A total of 625 segments were analyzed. The formation of calcium crack after balloon angioplasty was associated with greater stent cross-sectional area (7.38 ± 1.92 vs. 7.13 ± 1.68 mm², $P=0.035$) as well as greater lumen gain (3.89 ± 1.53 vs. 3.40 ± 1.46 mm², $P<0.001$). Segments with calcium cracks after angioplasty had a larger median calcium arc (360° , IQR, $246\text{--}360^\circ$ vs. 147° , IQR, $118\text{--}199^\circ$, $P<0.001$) and a thinner calcium thickness (0.53 ± 0.28 vs. 1.02 ± 0.42 mm, $P<0.001$) than those without. The optimal thresholds of calcium arc and calcium thickness for the prediction of cracks were 227° and 0.67 mm, respectively.

Conclusions: Larger calcium arc and thinner calcium thickness were associated with formation of calcium crack. Presence of calcium crack was the important determinant of optimal stent expansion. (*Circ J* 2016; **80**: 1413–1419)

Key Words: Calcified plaque; Optical coherence tomography; Rotational atherectomy

The recent introduction of drug-eluting stents (DES) has substantially reduced restenosis rates.^{1,2} DES are thus frequently used in complex lesions associated with calcified stenosis in the current percutaneous coronary intervention (PCI) era.³ Target lesion calcification, however, is known to influence PCI. The adverse effects of target lesion calcification include the inability to cross or dilate a coronary stenosis with PCI devices such as balloons or stents. Stent underexpansion is a known risk factor for stent restenosis or stent thrombosis.^{4,5} Complex calcified coronary lesions are thus associated with worse outcome after stent implantation, even in the DES era.^{6,7} Rotational atherectomy (RA) facilitates delivery or expansion of PCI devices in complex calcified lesions. Practical guidelines recommend the use of RA for the preparation of

heavily calcified lesions that cannot be crossed by a balloon or adequately dilated before stenting.⁸

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Until recently, structural changes in the vessel wall during PCI were assessed in vivo on angiography^{9,10} or intravascular ultrasound (IVUS).^{11,12} Several studies have demonstrated the potential utility of IVUS for the treatment of calcified lesions. Mintz et al reported that IVUS of target lesion calcification might be useful for modifying the revascularization strategy.¹³ Similarly, Roy et al showed that RA was used more often in lesions treated with IVUS-guided PCI than in those treated with angiographic-guided PCI, which may contribute to reducing

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Figure 1. Frequency domain-optical coherence tomography (FD-OCT) analysis. (A) Minimal lumen area (dotted circle), calcium arc (double-headed pink arrow), and minimal calcium thickness (double-headed blue arrow) measured on OCT after rotational atherectomy. (B) The presence of cracks (arrowhead) was also assessed after balloon angioplasty.

DES thrombosis and repeat revascularization.¹⁴ The ability of IVUS to quantitatively evaluate calcified plaque, however, is limited because ultrasound signals are reflected by the surface of calcium components. Optical coherence tomography (OCT) is an optical analogue of IVUS that can visualize calcium components with less signal attenuation,¹⁵ enabling full delineation of superficial calcium components in the arterial wall.¹⁶

The aim of this study was to clarify the relationship between lesion characterization after RA and the mechanisms of lumen enlargement after adjunctive balloon angioplasty followed by stent implantation in complex calcified coronary plaque evaluated using sequential frequency domain-OCT (FD-OCT).

Methods

Subjects

This study was a prospectively planned observational study of calcified coronary plaque requiring PCI. Consecutive patients with complex calcified coronary lesions requiring RA with OCT guidance were screened for eligibility at Yokohama City University Medical Center. We excluded patients with cardiogenic shock, heart failure, or serum creatinine >2.0 mg/dl in the absence of hemodialysis. Patients with restenotic lesions, chronic total occlusion, or left main lesions, and those in whom adequate OCT images could not be obtained were also excluded from this study. Written informed consent was obtained and the ethics committee of the university approved the study. From October 2011 through May 2015, a total of 37 calcified coronary plaques (37 vessels) in 36 patients with coronary artery disease were studied prospectively. Lesions in all patients were treated with RA, followed by adjunct balloon angioplasty with subsequent stent implantation. Clinical history, cardiovascular risk profile, and current medication were obtained on hospital chart review. Estimated glomerular filtration rate (eGFR) was calculated using the Modification of Diet in Renal Disease formula, and chronic kidney disease was defined as eGFR <60 ml/min/1.73 m².

Study Protocol

PCI was performed via the radial or femoral approach using a 7-Fr or 7.5-Fr guiding catheter. Baseline coronary angiogra-

phy was performed after i.v. bolus injection of 6,000–7,000 IU of heparin and i.c. isosorbide dinitrate (2.0–2.5 mg) to prevent coronary artery spasm. After careful manipulation of the guidewire, additional i.c. isosorbide dinitrate (2.0–2.5 mg) was administered, and pre-PCI OCT evaluation was attempted if the catheter was advanced distal to the culprit lesion. After the pre-PCI intracoronary imaging attempt, the guidewire was replaced by a 0.009" 300-cm wire (RotaWire™, Boston Scientific, Natick, MA, USA) with the use of a microcatheter. RA was performed with a Rotablator™ (Boston Scientific) at a rotational speed of 200,000 r.p.m., using a pecking motion, avoiding a decrease in the rotational speed of the burr $>5,000$ r.p.m.¹⁷ The burr size was selected to achieve a burr/vessel ratio of 0.5–0.7. During RA, heparin, verapamil, and nitroglycerin were given i.c. from the tip of the Teflon sheath, and a temporary pacemaker wire was inserted to prevent hemodynamic compromise due to bradycardia during RA if the target vessel was the right coronary artery. After RA, balloon angioplasty was performed using a non-compliant balloon dilated to 12–20 atm. If an indentation was seen in the balloon, additional RA or dilatation with a higher pressure (up to 26 atm) was considered, and then stent implantation was performed. Maximal balloon pressure and maximal balloon size were recorded. Pre-PCI OCT was possible in only 14 cases because of the lesion severity, but subsequent serial OCT assessment was performed in all 36 cases.

OCT

OCT was performed before RA (when possible), immediately after RA, after plain old balloon angioplasty (POBA), and after stent implantation. All OCT was performed as FD-OCT (C7 or C8 XR Imaging System; St. Jude Medical, St. Paul, MN, USA). A 2.7-Fr OCT catheter (Dragonfly or Dragonfly JP; St. Jude Medical) was advanced distal to the lesion, and automated pullback was performed with contrast injection through the guiding catheter. OCT images were recorded and analyzed using the OCT console. The pullback speed was 20 mm/s for Dragonfly and 18–36 mm/s for Dragonfly JP.

Angiography

All angiograms were analyzed with a computer-assisted, auto-

Table 1. Baseline Characteristics

	n=36
Age (years)	71.1±10.4
Male	25 (69)
Coronary risk factors	
Diabetes	19 (53)
Hypertension	29 (81)
Dyslipidemia	21 (58)
Current smoker	7 (19)
Chronic kidney disease	22 (61)
Hemodialysis	9 (25)
Clinical presentation	
Acute coronary syndrome	14 (39)
Stable angina pectoris	22 (61)
Medication	
Aspirin	36 (100)
Thienopyridine	36 (100)
β-blocker	21 (58)
ACEI/ARB	18 (50)
Calcium channel blocker	17 (47)
Statin	30 (83)
Oral hypoglycemic agents	10 (28)
Insulin	5 (14)

Data given as mean±SD or n (%). ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker.

mated edge-detection algorithm (Medis) by an angiographer blinded to the clinical and OCT findings, using quantitative coronary angiography (QCA) measurements. Reference diameter, minimal lumen diameter, and percent diameter stenosis were determined on QCA. The outer diameter of the contrast-filled catheter was used for calibration, and QCA analysis was conducted from the single-best-available projection with the least foreshortening and the most severe stenosis.

OCT Analysis

OCT measurements were performed using commercially available offline analysis software (ILUMIEN OPTIS, St. Jude Medical). The calcium component was detected on OCT using validated criteria.¹⁸ The same anatomic image slices were analyzed after RA, after POBA, and after stenting. By using one or more reproducible axial landmarks (eg, the proximal or distal side branch or calcium itself) and the known pullback speed of 20 mm/s, identical cross-sectional slices on serial studies could be identified for comparison. Each plaque was measured at 1-mm intervals along a calcified lesion as long as the arc of the calcium was >60°. All OCT images were analyzed by 2 independent investigators who were unaware of the clinical presentations. Plaque morphology was qualitatively evaluated, and the cross-sectional images (arc, thickness of the calcium component, lumen area, final stent area, and minor and major axis stent diameters in each segment) were quantitatively measured by an individual with no knowledge of the clinical presentation (Figure 1A). Calcium thickness was measured at the thinnest part, excluding the outer 30° segment at both edges of the calcium arc in each cross-sectional image. Plaque morphology was assessed for the presence of cracks in the calcium component, which were defined as discontinuity of the luminal surface in the calcium component (Figure 1B). The following quantitative measurements were obtained: (1) calcium arc after RA (°); (2) minimal calcium thickness after RA (mm);

Table 2. Angiographic Findings

	n=37
Target vessel	
Left anterior descending	30 (81)
Left circumflex artery	2 (5)
Right coronary artery	5 (14)
Lesion calcification	
Mild	2 (5)
Moderate	12 (32)
Severe	23 (62)
QCA analysis	
Reference diameter (mm)	2.48±0.54
Minimal lumen diameter (mm)	0.94±0.43
%DS	61.8±15.4
Procedural characteristics	
Number of rotablator	1.25
Final burr size (mm)	1.64±0.13
Burr/artery ratio	0.69±0.13
Maximal balloon diameter (mm)	2.92±0.36
Maximal balloon pressure (atm)	19.2±3.8
Maximal stent diameter (mm)	3.14±0.36
Maximal stent pressure (atm)	17.3±4.2

Data given as mean±SD or n (%). %DS, percent diameter stenosis; QCA, quantitative coronary angiography.

(3) lumen area after RA (mm²); (4) final stent area (mm²); (5) lumen gain (mm²)=final stent area-lumen area; and (6) symmetry index=minimal stent diameter/maximal stent diameter.

Statistical Analysis

Statistical analysis was performed with PASW Statistics 22.0 (SPSS, Chicago, IL, USA). Qualitative data are presented as n (%). Normally distributed, continuous variables are given as mean±SD and were compared using Student's t-test. Continuous variables with skewed distributions are expressed as median (IQR) and were compared using Mann-Whitney test. Intraobserver and interobserver agreements were assessed using Bland-Altman analysis and correlation coefficients. To determine the optimal threshold for the calcium arc and calcium thickness for the prediction of calcium cracks after balloon dilatation, receiver operating characteristic (ROC) curve analysis was performed. The cut-off point was defined as the greatest sum of the sensitivity and specificity estimates. For all analyses, P<0.05 was considered to indicate statistical significance.

Results

Reproducibility of Data

We assessed the reproducibility of the OCT findings in a random sample of 30 cross-sectional images. OCT images were reviewed separately by 2 independent observers blinded to the clinical findings. Intraobserver variability was 0.06±0.10 mm for calcium thickness, 5±31° for calcium arc, and 0.02±0.05 mm² for lumen area. Interobserver variability was 0.08±0.13 mm for calcium thickness, 18±41° for calcium arc, and 0.01±0.06 mm² for lumen area. Correlation coefficients were high for repeated measurements of the arc, thickness of the calcium component, and lumen area by the same observer (r=0.926, 0.950, and 1.000, respectively) as well as for measurements by 2 different observers (r=0.879, 0.924, and 0.999, respectively).

Table 3. FD-OCT Analysis			
	Crack (n=307)	No crack (n=318)	P-value
After RA			
Lumen area (mm ²)	3.49±1.58	3.73±1.66	0.06
Calcium arc (°)	360 (246–360)	147 (118–199)	<0.001
Calcium thickness (mm)	0.53±0.28	1.02±0.42	<0.001
After stenting			
Final stent area (mm ²)	7.38±1.92	7.13±1.68	0.035
Lumen gain (mm ²)	3.89±1.53	3.40±1.46	<0.001
Symmetry index	0.81±0.07	0.81±0.07	0.39

Data given as mean±SD or median (IQR). FD-OCT, frequency domain-optical coherence tomography; RA, rotational atherectomy.

Patient Characteristics

Baseline patient characteristics are summarized in Table 1. Nineteen patients (53%) were diabetic, and 22 patients (61%) had chronic kidney disease, including 9 patients (25%) who were receiving hemodialysis.

Angiography

The quantitative angiographic findings are listed in Table 2. Twenty-eight lesions were treated with a single burr, and the other 9 lesions were treated using 2 burrs. Final burr size was 1.5 mm in 16 lesions and 1.75 mm in 21 lesions. All lesions were treated with adequately sized balloons and stents with high inflation pressure.

OCT

A total of 625 segments were analyzed in the 37 lesions. Calcium

cracks were observed in 307 segments (49%) in 32 patients (86%). We divided the segments into 2 groups according to the presence or absence of calcium cracks after balloon angioplasty (before stent implantation): the crack group ($n=307$) and the no crack group ($n=318$). The formation of calcium crack after balloon angioplasty was associated with greater stent area as well as with greater lumen gain (7.38 ± 1.92 vs. 7.13 ± 1.68 mm², $P=0.035$; and 3.89 ± 1.53 vs. 3.40 ± 1.46 mm², $P<0.001$, respectively; Table 3). The crack group had a larger median calcium arc (360° , IQR, 246–360° vs. 147° , IQR, 118–199°, $P<0.001$) and a thinner calcium thickness (0.53 ± 0.28 vs. 1.02 ± 0.42 mm, $P<0.001$) than the no crack group.

In 14 lesions in which pre-PCI OCT assessment was available, we evaluated the percent change in lumen volume: lumen volume (after RA)–(baseline)/lumen volume (baseline)×100. Mean percent change in lumen volume was 11.7%.

Figure 3. Representative sequential frequency domain-optical coherence tomography (FD-OCT) images. (A) Pre-procedural angiography showed severe narrowing with calcification in the proximal left anterior descending artery. (C–H) Serial FD-OCT images obtained at the same cross-section (red line). (C) Pre-PCI OCT showed heavily calcified plaque with a minimal calcium thickness of 0.97 mm (double-headed arrow). (D) After rotational atherectomy with a 1.5-mm burr, the calcium thickness measured 0.93 mm, with evidence of calcium removal. (E) After additional atherectomy with a 1.75-mm burr, the calcium thickness became 0.67 mm. (F) Adjunctive balloon angioplasty with a 2.5-mm balloon did not create a crack within the calcium, but (G) additional angioplasty with a 3.0-mm balloon resulted in crack formation (arrowhead). The final (B) angiogram and (H) OCT image after stent implantation showed optimal results with adequate stent expansion without malapposition.

Cut-Offs of Predictors for Calcium Crack

On ROC curve analysis, we identified the optimal thresholds for the prediction of calcium cracks after balloon angioplasty. The best cut-off for the calcium arc for the prediction of calcium cracks was $>227^\circ$ (sensitivity, 81.0%; specificity, 81.9%; area under the curve [AUC], 0.884; 95% CI: 0.858–0.910, $P<0.001$; **Figure 2A**). The calcium thickness that best predicted calcium cracks was <0.67 mm (sensitivity, 73.1%; specificity, 77.8%; AUC, 0.827; 95% CI: 0.795–0.859, $P<0.001$; **Figure 2B**). The incidence of calcium cracks after POBA in segments with both a calcium arc $>227^\circ$ and calcium thickness <0.67 mm was 86.9%. Representative images of sequential FD-OCT are given in **Figure 3**.

Lesion-Based OCT Analysis

To minimize the effect of interactions between calcium fragil-

ity and longitudinal distribution of calcified plaque, we also analyzed the 50 lesions from 36 patients. Cross-sectional images of the minimal lumen area site after RA within the calcified plaque were used for analysis. If the maximal lumen area between the tandem lesions was >4 mm², we analyzed both proximal and distal minimal lumen area site independently. Of those, calcium crack was observed in 28 lesions (56%). On ROC curve analysis, the optimal thresholds of the calcium arc and calcium thickness for the prediction of calcium cracks were $>240^\circ$ (sensitivity, 96.4%; specificity, 100%; AUC, 0.979; 95% CI: 0.964–1.00, $P<0.001$) and <0.77 mm (sensitivity, 70.3%; specificity, 82.1%; AUC, 0.869; 95% CI: 0.766–0.971, $P<0.001$), respectively.

Calcium Crack Location

In 28 segments with calcium cracks on lesion-based analysis,

we also assessed the crack location and thickness of calcium at the site. Cross-sectional images obtained after RA were precisely synchronized with those obtained after balloon dilatation, and the angle between the actual crack site after balloon dilatation and the site of minimal calcium thickness after RA, as referenced to the center of lumen, was measured. The mean calcium thickness at the crack site was 0.67 ± 0.23 mm. The mean angle between crack site and minimal calcium thickness site was $53 \pm 48^\circ$.

Discussion

The adverse effects of target lesion calcification may challenge DES delivery, expansion, and effectiveness.^{19–22} Recently, Kobayashi et al showed that the extent of target lesion calcification on OCT was associated with stent underexpansion.²³ Thus, complex calcified coronary lesions are associated with poorer outcome due to factors such as in-stent restenosis, even in the DES era.^{6,7,17}

RA uses a high-speed, rotating, diamond-coated, elliptical burr to ablate occlusive atherosclerotic material and thereby restore lumen patency.^{9,10} RA can adequately modify calcified plaques and facilitate stent delivery and expansion.^{6,24} RA has thus become an essential technique with growing importance in the current PCI era as increasingly complex patients and lesions are considered candidates for interventional therapy.

The mechanism and efficacy of RA with subsequent balloon angioplasty have been evaluated in several IVUS studies, which found that RA improves lumen dimensions by plaque ablation with little or no vessel expansion, leaving a significant residual cross-sectional narrowing.¹¹ Adjunct balloon angioplasty further improves lumen dimensions by vessel expansion and plaque dissection with little or no plaque compression.¹² Thus, the best approach to facilitate stent expansion in a complex calcified coronary lesion is to modify vessel wall compliance by partial removal of the calcium component via RA. In previous clinical trials, RA with smaller burr sizing (burr-to-artery ratio <0.7) reduces angiographic complications with similar angiographic success rates, as compared with more aggressive sizing (burr-to-artery ratio >0.7).^{25,26} RA for advanced calcified lesions may increase the risk of periprocedural myocardial infarction, which is a distinct disadvantage of excessive atherectomy for calcified lesions.^{22,27} Thus, RA fulfilling minimal requirements is an important strategy. In the present study, mean percent change in lumen volume after RA was 11.7%, which was lower compared with the previous IVUS study.^{11,12} This suggests that the best use of RA in the current era is for lesion modification before balloon dilatation to achieve optimal lumen enlargement after stent implantation in complex calcified lesion. The optimal endpoints of RA required to ensure successful outcomes of balloon angioplasty and subsequent stent implantation are thus warranted. To the best of our knowledge, this is the first study to use OCT to evaluate plaque characteristics related to calcium cracks after POBA. The present study indicated that RA might not be mandatory to achieve optimal stent expansion in lesions with minimal calcium thickness <0.67 mm, and extensive RA with the use of an oversized burr can be detrimental. In contrast, if the minimal calcium thickness is >0.67 mm after RA, the burr size can be upgraded to promote formation of calcium crack.

The present FD-OCT study confirmed that RA is an effective treatment for heavily calcified stenotic coronary arteries. Calcium cracks were observed in 49% of the segments in heavily calcified coronary lesions after balloon angioplasty and were associated with a favorable response to stent expansion.

Calcium cracks after balloon angioplasty were associated with a greater arc and a thinner minimal thickness of the calcium component. These features were important for creating calcium cracks by adjunctive balloon angioplasty. More than 3 decades ago, Waller described 3 potential mechanisms of lumen enlargement due to balloon angioplasty: (1) compression of soft plaque elements; (2) fracture of the plaque; and (3) stretching of the normal arterial wall or of the more elastic plaque elements.²⁸ Because RA did not influence the soft or elastic plaque components, fracture of the plaque or stretching of normal segments is considered the key mechanism for lumen enlargement in heavily calcified coronary lesions. Several IVUS studies have demonstrated that dissection planes caused by adjunctive balloon angioplasty after RA are often located within calcified plaque.^{11,12} This is in sharp contrast to balloon angiography alone, in which dissections typically occur at the junction of calcified and non-calcified plaques.²⁹ RA might weaken the structural integrity by ablating calcium and thereby increase the likelihood that the calcium itself will crack. It is reasonable that a minimal calcium thickness is associated with plaque frailty. The calcium arc was also an important factor contributing to lesion fragility. When the arc is wide and the lumen diameter is smaller than the balloon diameter, balloon inflation pressure directly pushes both edges of the calcified plaque, causing the solid mass to bend and eventually create a crack within the plaque. In contrast, when the arc is narrow, balloon inflation pressure acts as a force that stretches relatively elastic tissue. In the latter situation, the calcified deposit acts as a fulcrum for the barotrauma, and the edge of the deposit acts as a wedge in creating a cleavage plane.

We also demonstrated that calcium crack was not always created at the site with minimal thickness, but the calcium thickness was similar between the actual crack site and the minimal thickness site. The primary objective of plaque modification by RA in complex calcified coronary lesions is to cross and adequately dilate stenotic lesions by adjunctive balloon angioplasty and subsequent stent implantation. In the present study, the optimal cut-offs for the prediction of calcium cracks on ROC curve assessment were calcium arc $>227^\circ$ and calcium thickness <0.67 mm. Thus, if a calcified lesion assessed on OCT met these criteria at baseline, the probability of calcium cracks developing after POBA and of optimal stent deployment is considered likely without rotablation.

Although RA with subsequent DES implantation can achieve high success rates, previous studies have failed to show the effectiveness of RA-assisted PCI. In the ROTAXUS study, routine lesion preparation using RA did not reduce the late lumen loss of DES at 9 months, despite an initially higher acute lumen gain.³⁰ Therefore, balloon dilation with only provisional rotablation still remains the default strategy for complex calcified lesions before DES implantation. In this context, further OCT-guided studies are needed to more clearly demonstrate the potential benefits of RA-assisted PCI on long-term outcome, such as a reduced risk of in-stent thrombosis.

Study Limitations

This study had several important limitations. First, it was a single-center, retrospective analysis of a small number of patients. We did not include a control group (without RA) in the current analysis because we treated mild calcified lesions with balloon angioplasty and moderate-severe calcified lesions with RA before stent implantation. Therefore, a larger prospective multicenter study with well-defined clinical endpoints needs to be conducted to delineate potential differences in predictors and threshold of calcium cracking during various

strategies. Second, all lesions were treated using FD-OCT guided strategies, and the operators were not blinded to the serial morphological assessment of the calcified coronary plaque. Therefore, estimation of the thickness of calcium may have affected the subsequent strategy, including the selection of burr size or balloon size. Third, we used high-speed (200,000 r.p.m.) RA in this study, which might increase platelet activation and might impair coronary microcirculation.³¹ Fourth, pre-PCI OCT imaging could not be performed in all patients. Pre-PCI findings would have influenced post-OCI findings. Finally, all patients in this study were treated by RA, and OCT was mandatory after RA before balloon dilatation. Whether or not the present results can be translated to calcified lesions treated without RA remains to be elucidated.

Conclusions

FD-OCT is an effective technique for evaluating plaque characteristics in calcified coronary lesions. Larger calcium arc and thinner calcium thickness were associated with the formation of calcium crack after balloon angioplasty following RA. Segments with calcium cracks had a larger lumen gain and a greater stent cross-sectional area during PCI than those without. Measurement of calcium arc and thickness may promote the achievement of optimal PCI endpoints for subsequent balloon or stent dilatation.

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