



# Analysis of Preoperative CT Scan Can Help Predict Technical Failure of Endovascular Treatment of TASC C-D Aortoiliac Chronic Total Occlusions

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**Title : Analysis of pre-operative CT-scan can help predict technical failure of endovascular treatment of TASC C-D aorto-iliac chronic total occlusions**

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**Short running title :** Predictors of failure of aortoiliac recanalization

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29 **Keywords :** TASC C-D, aortoiliac chronic total occlusions, predictors, iliac rupture, technical

30 failure

31 **Conflicts of interest :** none

32

33

## ABSTRACT

*Aims* : To evaluate if features of occlusion analyzable on pre-operative CT-scan could predict risks of technical failure or iliac rupture of endovascular treatment of TASC C-D aorto-iliac chronic total occlusion (CTO). *Methods and results* : All patients treated by endovascular techniques for a TASC C-D aorto-iliac CTO between 2009 and 2016 were included (107 patients, 148 iliac arteries). We evaluated the location of the occlusion and the importance of the arterial calcifications. For this factor, patients were divided into 3 groups : the *Black occlusion group* (BO) with mild or no calcifications, the *white occlusion group* (WO) with moderate no protrusive calcifications and the *white protrusive occlusion group* (WPO) with heavy endoluminal calcifications. Technical failure occurred in 11 iliac arteries and per-operative iliac rupture in 6. The location in the external iliac artery (EIA) is the most significant risk factor of technical failure in univariate (OR = 9.93;p = 0.0012) and multivariate analysis (OR = 15.26;p = 0.0006). The presence of heavy endoluminal calcifications is a further significant risk factor (OR = 13.88;p = 0.0365). Rupture rate was comparable between the 3 groups. *Conclusions* : Pre-operative CT-scan can predict risk of technical failure but not of iliac rupture.

**Keywords** : TASC C-D, aortoiliac chronic total occlusions, predictors, iliac rupture, technical failure

## INTRODUCTION

Despite TASC II recommendations,<sup>(1)</sup> and because of good outcomes in several large studies,<sup>(2-4,6)</sup> endovascular treatment is now the first choice for complex aorto-iliac occlusions in high-volume centers with high technical success (> 90 %) and very low major per-operative complications including iliac rupture (< 5 %).<sup>(5-7)</sup> But the risk of technical failure and the fear of per-operative iliac rupture, especially in heavily calcified lesions limit the widespread use of this technique. Predictors of failure have been studied for patency and clinical outcomes for TASC C-D aorto-iliac occlusions.<sup>(8-10)</sup> To the best of our knowledge, anatomic risks factor for technical failure or per-operative rupture have been studied for superficial femoral and popliteal arteries and for coronary disease but not for aortoiliac arteries.<sup>(11)</sup> Oddly, predictors of technical failure and per-operative complications have been studied recently for transbrachial or transradial accesses but not for femoral accesses.<sup>(12-13)</sup> Yet, for the endovascular treatment of aorto-iliac TASC C-D chronic total occlusion (CTO), transbrachial access alone cannot be sufficient because of the diameter of the stent used, the necessity of kissing stent. Moreover, contrary to coronary occlusive disease,<sup>(14-17)</sup> for peripheral arterial disease there is no precise score analyzing the complexity of lesions. Most technical failures are associated with failure to cross the occlusion or for re-entry in the arterial lumen. In the TASC II classification,<sup>(1)</sup> diffuse multiple stenosis in the iliac artery is TASC D whereas short occlusion of external iliac artery (EIA) is TASC B. For endovascular treatment, the short occlusion of EIA is more technically difficult. Moreover, this classification does not take into account the degree of calcifications of aorto-iliac lesions. Thus, this classification seems relatively unsuitable to select between open surgical repair and endovascular treatment as highlighted by Ohana et al. in 2013 for superficial femoral artery occlusions.<sup>(18)</sup> Moreover, as was well demonstrated for coronary disease,<sup>(17)</sup> comparison between open surgery and endovascular treatment of aorto-iliac occlusive disease is also

difficult because patients included can be relatively different (TASC D lesions are very heterogeneous),<sup>(1)</sup> and series are heterogeneous including stenosis and occlusions, including femoro-popliteal segments.<sup>(2,5,7)</sup>

Technical success is very high (> 90 %) but for chronic total occlusion (CTO), failure persists despite the use of re-entry devices and antegrade approach.<sup>(17-21)</sup> Even if it is thought that heavily calcified lesions are more at risk for this complication, this has never been clearly defined.<sup>(5)</sup>

The aim of this study was to evaluate anatomic predictors of technical failure and per-operative iliac rupture of endovascular treatment of TASC C-D aorto-iliac CTO with a detailed analysis of pre-operative CT-scan.

## **MATERIALS AND METHODS**

### *STUDY DESIGN AND PATIENT SAMPLE*

This is a single-center retrospective analysis of a prospective cohort. All patients treated in our department by endovascular techniques for an aorto-iliac CTO TASC C-D between December 2009 and June 2016 were analyzed. Patients with no pre-operative CT-scan, with stenosis and no CTO and with an acute or subacute ischemia were excluded. We included 148 iliac arteries from 107 patients. All CT-scan were analyzed by 2 surgeons independently (NDS and AM); in case of discordance, the CT-scan was reviewed jointly. Mean age was 62 years (SD 51-73). The indication for treatment was claudication in 104 limbs (70,3 %), rest pain in 28 limbs (18,9 %) and tissue loss in 16 limbs (10,8 %). Patients were TASC C in 32 cases and TASC D in 75 cases. Baseline patient characteristics are given in Table I. Detailed lesions are described in Table II.

The study has been performed according to the principles of the Declaration of Helsinki and approval has been obtained from ethic committee of the hospital.

#### *CTO EVALUATION*

We analyzed 2 characteristics of CTO: the location and the extension of the CTO on the aorta or iliac artery and the degree of calcifications of the aorta and iliac arteries (Figure 1). For this characteristics, we divided CTO into 3 groups: the black occlusion group (BO) was defined by the presence of mild non-protrusive calcifications or the complete absence of calcifications in the total lesion length; the white occlusion group (WO) was defined by moderate calcifications of more of 50 % of the arterial circumference but little or no protrusive into the arterial lumen; the white protrusive occlusion group (WPO) was defined by the presence of heavy endoluminal arterial calcifications of more of 50 % of the arterial lumen.

Each iliac artery was analyzed separately.

#### *ENDOVASCULAR PROCEDURE*

The procedures were performed by a team of experienced vascular surgeons in a surgical theater using a recent generation mobile C-arm. A detailed description of our technique has been previously published.<sup>(21)</sup> For external iliac artery (EIA) occlusions that involve the common femoral artery (CFA), a superficial femoral puncture was performed if possible; if not, an antegrade approach using the contralateral femoral access was used.<sup>(22)</sup> CFA lesions were treated as described in the TECCO study.<sup>(23)</sup> In case of failure by a retrograde approach, all patients had an antegrade approach by contralateral femoral access or by the brachial access. No re-entry device was used.

#### *ENDPOINTS*

The primary endpoint was the technical failure rate defined by the impossibility to cross the lesion or to re-entry in the true lumen. Secondary endpoint was the per-operative iliac rupture rate defined by an extravasation of contrast agent in angiogram. For these two endpoints, each iliac artery was analyzed separately.

#### *STATISTICAL ANALYSIS*

Means with standard deviations were presented for continuous data and counts with percentages for categorical data. Groups were compared using Fisher's exact or Wilcoxon test as appropriate. Univariate and multivariate logistic regression models were performed to identify separately any independent predictors of technical failure and per-operative iliac rupture. Values of  $p < 0.05$  were considered statistically significant. All analyses were performed using R Core Team Software (version 3.1.0, R Foundation for statistical computing, Vienne, Austria)

#### **RESULTS**

Occlusions were located in the external iliac artery (EIA) in 37 cases (25 %), in the common iliac artery (CIA) in 41 cases (27.7 %), in both the external and the common iliac artery (BIA) in 42 cases (28.4 %), and in the on aortic bifurcation (AB) in 14 cases (18.9 %). There were 66 iliac arteries (44.6 %) in the BO group, 45 (30.4 %) in the WO group and 37 (25 %) in the WPO group. In 70 patients and 83 iliac arteries (56.1 % of the total number of cases), an antegrade access was attempted because of failure of the retrograde access, including 58 brachial accesses (39.2 %). For 93 iliac arteries (62.8 %), recanalization were subintimal. The interpretation of CT-scan were concordant between the 2 surgeons in 90 % of cases.

#### *TECHNICAL FAILURE*



Technical failure occurred in 11 iliac arteries (7.4 % of cases). Technical failures were impossibility to reentry in all the cases despite the use of antegrade and retrograde approach. Cases with technical failure were comparable to those without with regard to all baseline characteristics. Technical failure differed according to CTO location ( $p = 0.001$ ), it was more frequent when CTO was located in the EIA ( $p = 0.001$ ), and less frequent when CTO was located in CIA ( $p = 0.035$ ; Table III)

In univariate analysis, the location of the CTO in the EIA was the only factor significantly associated with technical failure ( $OR = 9.93$ ;  $p = 0.0012$ ; Table III). In multivariate analysis, after adjustment on age and renal failure, the location of the occlusion on EIA was also significantly and strongly associated with technical failure ( $OR = 15.26$ ;  $p = 0.0006$ ). The presence of heavy endoluminal calcifications (WPO group) was a further risk factor of technical failure in comparison with the WO group ( $OR = 13.88$ ;  $p = 0.0365$ ; Table IV).

#### *PER-OPERATIVE ILIAC RUPTURE*

Per-operative iliac rupture occurred in 6 iliac arteries (4 %). Four ruptures were successfully treated with a cover stent; the 2 other ruptures led to the death of the patient.

There was no risk factor significantly associated with per-operative iliac rupture in univariate model (Table V). There were 3 per-operative iliac ruptures in the BO group, 2 in the WO group and 1 in the WOP group ( $p = 0.881$ ). The occlusion of both the external and the common iliac artery was more frequently found in the per-operative iliac rupture group, although this difference was not significant ( $p = 0.282$ ).

#### **DISCUSSION**

To the best of our knowledge, this is the first study to analyze specifically anatomic predictors of technical failure and per-operative iliac rupture of endovascular treatment of TASC C-D

176 aorto-iliac CTO. The main risk factor for technical failure identified by this study was the  
177 location of the CTO in the EIA. This can be explained by occlusive disease that can extend  
178 into the common femoral artery (CFA). In such cases, the arterial access is difficult.  
179 Superficial femoral artery puncture could be necessary and the proximity of the CTO leads to  
180 a lack of “push”. For these cases, the antegrad approach seems really indispensable for us. We  
181 make this antegrade approach for all cases, we don’t try retrograde recanalization. But for the  
182 antegrade approach, the necessity of re-entry in CFA or more distal artery can be difficult and  
183 controversial. However, we have previously published good results for stenting of CFA and  
184 its bifurcation<sup>(22)</sup> and these results were confirmed by a recent multicenter randomized  
185 study.<sup>(23)</sup> If there is an appropriate landing zone in the CFA, results are good but if there is  
186 lesions of the bifurcation, it will be more complicated and results are worse. For these cases,  
187 hybrid surgery seems to be very interesting. Moreover, it appears important to obtain good  
188 results to use large diameter of stents in iliac arteries. If the CFA is of good diameter and with  
189 no important lesion, there is no problem but in the contrary, there is a risk of incomplete  
190 opening of the distal stent or even a risk of rupture of the CFA. So for all these reasons,  
191 hybrid surgery can be used with acceptable midterm results.<sup>(24)</sup>

192 The study shows that the degree of calcifications, especially endoluminal calcifications, is  
193 associated with technical failure. In many series, CTO and heavy calcified lesions are  
194 excluded.<sup>(25,26)</sup> However, because most technical failures result in the impossibility to cross  
195 the lesions or for re-entry in the true lumen, the degree of arterial calcifications is cited as a  
196 risk factor for technical failure in several studies but is not scientifically proven.<sup>(5,12,19,25)</sup> A  
197 similar situation is found for per-operative iliac rupture.<sup>(5,7)</sup> Despite vascular calcifications  
198 having been extensively studied,<sup>(26,27)</sup> their clinical implications for aortoiliac CTO remain  
199 unknown. For coronary occlusive disease, several risk scores have been published.<sup>(14-16)</sup>  
200 However, for peripheral arterial disease, the characterization of lesions is less well defined.

201 For example, Diehm et al. in 2008 published a largely undefined classification,<sup>(28)</sup> and in  
202 2015, Peripheral Academic Research Consortium (PARC) published a semi-quantitative  
203 classification but endoluminal calcifications were not studied.<sup>(29)</sup> For our statistical analysis  
204 about the role of calcifications, we decide to adjust on age and renal failure because these  
205 criteria have been described as risk factor of calcifications.<sup>(30)</sup> We don't adjust on diabetes  
206 because for diabetes, calcifications concern more infra-inguinal disease.<sup>(31)</sup>

207 An interesting aside is that in the present study that included complex lesions, technical  
208 success was high despite re-entry devices not being used. We believe that such devices are  
209 interesting but relatively dangerous in case of re-entry in the abdominal aorta. The  
210 complication rate is about 4.3 % while lesions treated are less severe and mostly infra-  
211 inguinal lesions.<sup>(19,20)</sup> Moreover, in a recent large study, technical success with the use of re-  
212 entry device was similar to that reported herein.<sup>(19)</sup> Heavy calcifications remains risk factor  
213 for technical failure despite the use of these devices.<sup>(19,20)</sup>

214 In our experience, the main trick to obtain good technical success is to try to make  
215 intraluminal recanalization. Indeed, the main explanation for failure is the impossibility to re-  
216 entry, particularly in the aorta. To make intraluminal recanalization, we use a straight and  
217 rigid catheter immediately to prevent the guidewire from leaving the wall. We direct the guide  
218 with the catheter to progress in the lumen. But in some cases, the occlusion is too hard and the  
219 intraluminal crossing impossible. In such cases, the other trick to obtain technical success, is  
220 to rapidly use antegrad approach. In the beginning of our experience, we try with a retrograde  
221 approach for a long time. Actually, we try few minutes and rapidly we make the antegrad  
222 approach. For all these procedures, we install the patient with an upper arm (generally the left)  
223 in the surgical field as well as the 2 femoral accesses. If cross over is possible, we try and if  
224 not we use the brachial access.

For per-operative iliac rupture, we did not identify risk factors. Per-operative iliac rupture occurred similarly in the 3 CTO groups, which may suggest that heavily calcified lesions should not be specifically excluded from endovascular treatment on the basis of this criterion alone, but requires further investigation in large multicenter international studies.

## *LIMITATIONS*

A general limitation of the study is that it was based on a single center. However, the cohort was prospective, and this design ensured exhaustive recruitment leading to a homogeneous and well defined population, but which was relatively small. This did not adversely affect the evaluation of technical success, but precluded meaningful conclusions as to iliac rupture.

Another aspect to consider is the semi-quantitative evaluation of arterial calcifications used herein. With specific 3D-reconstruction imaging software, quantitative analysis of arterial calcifications is possible but such software is not widely available to the vast majority of surgical teams. Although semi-quantitative, this classification is more precise than that described in guidelines published by Diehm et al. in 2008.<sup>(28)</sup> This is more similar of a further classification, published recently by the Peripheral Academic Research Consortium (PARC) with more the analysis of endoluminal calcifications.<sup>(29)</sup>

Another point to note is that we did not analyze specifically the length of lesions as a risk factor for technical failure, however among the 11 such cases in the present study, there were 3 BIA occlusions but 8 EIA occlusions, which suggests that longer lesions were not more technically difficult. Furthermore, the diameter of the vessel was not considered, but it is reported that in case of CTO this can be underestimated with pseudostenosis and lead to biased interpretation.<sup>(32)</sup> Moreover, recanalization are often subintimal so arteriel diameter can't really affect technical failure.

Finally, as the event rate is too low, it is impossible to generate a robust model.

250    **CONCLUSION**

251    This study shows anatomic predictors of technical failure of endovascular treatment of aorto-  
252    iliac TASC C-D CTO. Open surgery could be discussed in first choice in patients with these  
253    risk factors especially in low-volume centers in order to avoid endovascular failure and its  
254    medico-economic consequences.

255

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- 343
- 344

345 **FIGURE LEGENDS**

346 Figure 1 : Pre-operative CT-scan. (A) WO group (B) BO group, (C) WOP group

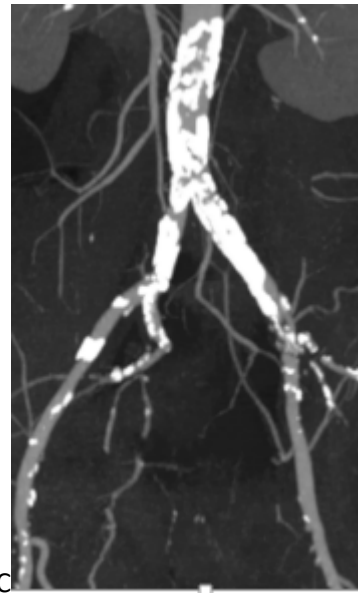
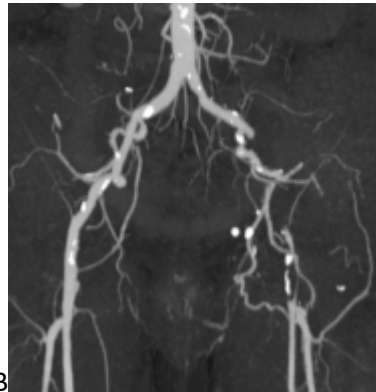


Table 1: Baseline Patient and Lesion characteristics<sup>a</sup>

	<i>Total population, n = 107</i>
<i>Mean Age, years</i>	<i>62 (11.2)</i>
<i>Sex, male</i>	<i>86 (81.9)</i>
<i>Current smoker</i>	<i>61(57)</i>
<i>Former smoker</i>	<i>31(28,9)</i>
<i>Diabetes</i>	<i>26 (24.3)</i>
<i>Hypertension</i>	<i>66 (62.9)</i>
<i>Dyslipidemia</i>	<i>53 (50.5)</i>
<i>Obesity (BMI &gt;30)</i>	<i>10 (9.5)</i>
<i>Renal failure (GFR &lt; 60 ml/min)</i>	<i>8 (7.6)</i>
<i>Previous aorto-iliac surgery</i>	<i>28 (26.7)</i>
<i>Endovascular</i>	<i>24 (22.4)</i>
<i>Open surgery</i>	<i>4 (4.3)</i>
<i>Claudication</i>	<i>104 (70,3)</i>
<i>Critical limb ischemia</i>	<i>44 (29,7)</i>
<i>Rest pain</i>	<i>28 (18,9)</i>
<i>Tissue loss</i>	<i>16 (10,8)</i>
<i>TASC</i>	
<i>C</i>	<i>32 (29.5)</i>
<i>D</i>	<i>75 (70.5)</i>

<sup>a</sup>Continuous data are presented as the means ± standard deviation;

Categorical data are presented as the counts (percentage).

Abbreviations: BMI, body mass index, GFR glomerular filtration rate,

TASC: Trans-Atlantic Inter-Society Consensus

Table 2. Detailed lesions according to TASC II classification






Type of lesions	N =
	26
	19
	11
	37
	14

Table 3: Technical failure<sup>a</sup>

	no n = 137	yes n = 11	p-value <sup>b</sup>
Age, years	61.98 (11.53)	62.64 ( 6.30)	0.601
CTO group			
BO	55 (40.1%)	5 (45.5%)	0.148
WO	46 (33.6%)	1 (9.1%)	
WOP	36 (26.3%)	5 (45.5%)	
Location of occlusion			0.001
AB	28 (20.4%)	0 (0.0%)	
BIA	39 (28.5%)	3 (27.3%)	
EIA	29 (21.2%)	8 (72.7%)	
CIA	41 (29.9%)	0 (0.0%)	
Smoking			0.802
never	15 (10.9%)	1 ( 9.1%)	
previous	44 (32.1%)	2 (18.2%)	
current	78 (56.9%)	8 (72.7%)	
Diabetes			1
no	101 (73.7%)	9 (81.8%)	
insulino-dependant	8 (5.8%)	0 (0.0%)	
non insulino-dependant	28 (20.4%)	2 (18.2%)	
Hypertension			0.337
Dyslipidemia	70 (51.1%)	7 (63.6%)	0.537
Obese (BMI > 30)	14 (11.3%)	0 ( 0.0%)	1
Renal failure (GFR < 60 ml/min)	9 ( 6.6%)	1 ( 9.1%)	0.55
Previous aorto-iliac surgery			0.265
no	90 (72.0%)	4 (57.1%)	
endovascular	29 (23.2%)	2 (28.6%)	
open surgery	6 ( 4.8%)	1 (14.3%)	
Claudication	119 (90.2%)	8 (72.7%)	0.109
BIA occlusion	39 (28.5%)	3 (27.3%)	1
AB occlusion	28 (20.4%)	0 (0.0%)	0.125
EIA occlusion	29 (21.2%)	8 (72.7%)	0.001
CIA occlusion	41 (29.9%)	0 ( 0.0%)	0.035
WPO group	36 (26.3%)	5 (45.5%)	0.178
WO group	46 (33.6%)	1 ( 9.1%)	0.174
BO group	55 (40.1%)	5 (45.5%)	0.758

<sup>a</sup>Continuous data are presented as the means  $\pm$  standard deviation; Categorical data are given as the counts (percentage).

<sup>b</sup>Fisher's exact test for categorical data and Wilcoxon test for continuous data

Abbreviations: AB, aortic bifurcation; BIA, both iliac arteries; BMI, body mass index; BO, black occlusion; CIA, common iliac artery; EIA, external iliac artery; GFR, glomerular filtration rate; WO, white occlusion; WPO, white protrusive occlusion.



Table IV. Predictors of technical failure from the multivariate model

Characteristics	Odds Ratio	95 % CI	p
Age	0.99	0.91 to 1.07	0.82
Renal failure	1.24	0.06 to 11.26	0.86
EIA lesion	15.27	3.59 to 87.77	0.0006
BO group	4.03	0.54 to 85.12	0.2361
WPO group	13.88	1.63 to 328.52	0.036

*Abbreviations : BO, black occlusion; CI, confidence interval; EIA, external iliac lesion; WPO, white protrusive occlusion*

Table V. Table 5. Per-operative iliac rupture

	no n = 142	yes n = 6	p-value <sup>a</sup>
Age, years			
Calcifications			0.881
group			
BO	57 (40.1%)	3 (50.0%)	
WO	45 (31.7%)	2 (33.3%)	
WPO	40 (28.2%)	1 (16.7%)	
Location of occlusion			0.282
AB	28 (19.7%)	0 (0.0%)	
BIA	38 (26.8%)	4 (66.7%)	
EIA	36 (25.4%)	1 (16.7%)	
CIA	40 (28.2%)	1 (16.7%)	
Antegrade access recanalization	77 (54.2%)	4 (66.7%)	0.69
intraluminal	55 (38.7%)	0 (0.0%)	0.178
subintimal	80 (56.3%)	6 (100.0%)	
smoking			0.704
no	16 (11.3%)	0 (0.0%)	
previous	45 (31.7%)	1 (16.7%)	
current	81 (57.0%)	5 (83.3%)	
diabetes			1
no	105 (73.9%)	5 (83.3%)	
Insulino- dependant	8 (5.6%)	0 (0.0%)	
non insulino- dependant	29 (20.4%)	1 (16.7%)	
hypertension	88 (62.0%)	3 (50.0%)	0.676
dyslipidemia	75 (52.8%)	2 (33.3%)	0.427
Obese (BMI > 30)	14 (11.2%)	0 (0.0%)	1
Renal failure (GFR < 60 ml/min)	10 (7.0%)	0 (0.0%)	1
Previous aorto- iliac surgery			0.315
no	91 (71.7%)	3 (60.0%)	
endovascular	30 (23.6%)	1 (20.0%)	
open surgery	6 (4.7%)	1 (20.0%)	
claudication	121 (88.3%)	6 (100.0%)	1

<sup>a</sup>Continuous data are presented as the means  $\pm$  standard deviation; Categorical data are given as the counts (percentage).

<sup>b</sup>Fisher's exact test for categorical data and Wilcoxon test for continuous data

Abbreviations: AB, aortic bifurcation; BIA, both iliac arteries; BMI, body mass index; BO, black occlusion; CIA, common iliac artery; EIA, external iliac artery; GFR, glomerular filtration rate; WO, white occlusion; WPO, white protrusive occlusion.