

# Direct Implantation of Intracoronary Stents

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The original idea for the use of intraluminal splints, i.e. the precursors of intracoronary prostheses (stents) in medicine, is found in the writings of the famous medical philosopher and writer, Alexis Carrell. The first application on an experimental level was carried out by the distinguished radiologist Dotter in 1964, while the honour of the first coronary artery stent implantation, in 1987, belongs to U. Sigwart and J. Puel<sup>1</sup>. In the 90s, the use of stents in coronary vessels, peripheral vessels and carotids increased impressively, in parallel to the use of interventional percutaneous techniques for managing problems that were within the surgeons' scope.

The implantation of stents accounts for a 60-80% of all interventional revascularization techniques (PCI). Their predominance over conventional angioplasty and other techniques, i.e. the so-called "alternative techniques" (various types of atherectomy-rotablator, DCA etc.), is due to clear and specific causes. The multi-center, randomized Benestent II<sup>2</sup> and Stress<sup>3</sup> studies have clearly demonstrated the superiority of stents over conventional angioplasty. In «difficult» lesions, such as total occlusions (TOSCA)<sup>4</sup>, grafts<sup>5</sup>, and other complex, high risk lesions (Epistent)<sup>6</sup>, the use of stents is superior to any other technique. In addition, the results of atherectomy, either rotational (Rotablator) or directional (DCA), are significantly improved when the use of such techniques is followed by stent implantation. Finally, the fact that there is no special train-

ing required, beyond the knowledge of simple angioplasty, and the replacement of anticoagulants by ticlopidine<sup>7</sup>, have reinforced the range of their application.

As expected, research in this field progressed significantly and its results evolved fast, both in the purely technical field and in the field of their application. Thus, there are currently more than 35 stents in use. (not necessarily of different types, since some of them differ only in name), and more than 50% of the annually published studies in the field of interventional cardiology are stent-related. Improvements which originated from research resulted in the development of stents of a smaller profile, greater flexibility and advancement potential, and firm attachment on reliable, high-pressure balloons. As a consequence of the above, their implantation is successfully attempted at a rate higher than 95% in a wide range of lesions (elongated lesions, small vessels, bifurcated lesions), even through 6F catheters via the femoral and radial artery.

## Direct stenting

Direct stenting (DS), i.e. placement of stents without predilatation, occurred as a natural consequence of the above improvements<sup>8</sup>. Standard procedure is known to include predilatation of the lesion using a balloon, typically of a smaller size than the reference vessel, followed by stent placement and quite often over-dilatation using another balloon. The benefits of

direct stenting are obvious; reduction of total procedural time, radiation time, contrast agent quantity and, hence, of cost, since at least one –and often two eballoon(s) are saved. The currently limited bibliography shows that this method may be applied to 30-40% of the total scheduled implantation cases (primary stenting)<sup>9,10,11,12,13</sup>. Most of the studies are retrospective and observational. They investigate direct safety and effectiveness of the method, and clinical results during the first month<sup>14</sup>. All studies suggest that the method is safe and successful at a rate >95%, and major coronary vascular events (MACE) in the first month do not differ from those of other studies, where implantation was performed using predilatation. There are also two small prospective studies which examine the safety and effectiveness of two particular types of stents exclusively, and the MACE after six and nine months. Among the above studies, it is worthwhile mentioning the one conducted at the Mayo Clinic<sup>15</sup>, due to its large study population and comparative content.

The study analyzed 777 patients who had undergone direct stenting, as compared to 3,716 patients where implantation was preceded by predilatation. There were no differences, both in direct and long-term results, between the two groups. The «direct» group used fewer wires, balloons and contrast agents,

while a cross over of only five patients in this group to the other group was required. The assumption of potential reduction of restenosis in the DS case was not confirmed in any study to date. This assumption was supported by the theoretical view that predilatation always converts a stable plaque to an unstable one, through the rupture and tearing it causes, and exposes its thrombogenic elements into blood circulation, a fact that constitutes the primary core of subacute thrombosis and a restenosis feature as well. Following predilatation, a dissection is often caused, so deep that it leads to acute occlusion, which requires emergency stent placement (bailout). DS ensures a somehow controlled implantation without dissection of the atheromatous plaque, but through its direct «burying» and without further damage to the already damaged endothelium.

Our original experience is consistent with the international<sup>16</sup> one. In the first fifty serial cases (Tables 1, 2, 3), accounting for about 1/3 of the total scheduled implantations during that period, 4% of them failed while CPK was tripled over the baseline in one case only. Both groups showed similar hospitalization times, since they shared similar clinical courses. After having accumulated enough experience, we now try DS even in the most complex lesions, such as type C, hence currently applying the method in over 50% of the cases. In order for the method to be safe and effective, we should be very careful in the selection of both the lesions and the materials.

**Table 1.** Clinical and angiographic features.

	Group A	Group B	P
<b>Gender (M/F)</b>	42/8	44/6	NS
<b>Age (years)</b>	59.2±9.8	62.0±10.3	NS
<b>MI history</b>	16 (32%)	18 (36%)	NS
<b>Unstable angina</b>	18 (36%)	24 (48%)	NS
<b>Ejection fraction &lt;40%</b>	7 (14%)	10 (20%)	NS
<b>Target vessel</b>			
<b>LAD</b>	25 (50%)	28 (56%)	NS
<b>LCx</b>	9 (18%)	5 (10%)	NS
<b>RCA</b>	11 (22%)	9 (18%)	NS
<b>SVG</b>	5 (10%)	8 (16%)	NS
<b>Lesion type</b>			
<b>A</b>	10 (20%)	9 (18%)	NS
<b>B1</b>	30 (60%)	34 (68%)	NS
<b>B2</b>	10 (20%)	7 (14%)	NS
<b>C</b>	–	–	

Group A: Conventional stenting.

Group B: Direct stenting.

### Guiding catheter

The catheter with the greatest back-up is selected, but also that with an adequate inner diameter to allow withdrawal of the intact stent, in case of access failure. The use of a 6F guide has well established local advantages, and, in this case, it also facilitates deep catheterization of the orifice due to its small outer diameter, thus increasing the implantation potential in difficult cases. On the other hand, in case of failure, the possibility of stent detachment from the balloon and stent loss is increased due to its relatively small inner diameter. The opposite applies for 8F catheters. In our laboratory, we use 7F catheters in the majority of cases, taking the middle route.

As regards catheter type, there is a greater concern in lesions located in the circumflex artery, particularly when its origin is at a large angle from the stem. AL2, EBU or Voda have proven to be appro-

**Table 2.** QCA and IVUS measurements prior stenting.

	QCA			IVUS			
	LRD	MLD	%	MLD	MLS	VS	%
<b>Group A</b>	3.3±0.5	1.3±0.4	62±6	1.5±0.5	2.1±1.2	11.2±4.6	82±7
<b>Group B</b>	3.1±0.4	1.2±0.4	64±8	1.4±0.4	1.9±0.9	10.8±5.1	79±8
<b>P</b>	NS	NS	NS	NS	NS	NS	NS

- LRD: Lumen reference diameter, MLD: Minimum lumen diameter, %: % stenosis, MLS: Minimum lumen surface, VS: Vessel surface, QCA: Angiography, IVUS: Intracoronary ultrasonogram.

appropriate choices. For difficult lesions in the right coronary artery, AL2 can be used. Also, in the case of shallow take-off of the above artery, multipurpose 6F can be safely immersed as required, offering excellent support.

### Guide wires

In cases where a severe tortuosity precedes the stenosis, or the stenosis is found in an angled part of the vessel, the use of extra support wires is required, in order to achieve straightening (Figure 1A, 1B, 1C). The disadvantage of these wires is that their hardness renders them traumatic and difficult to steer. For this reason, a safe practice is to access the lesion with a soft wire and then, if «transferring» of the stent through this wire is not feasible, making use of the hard one. Finally, recent types (such as ATW by Cordis) combine the above advantages, having a soft tip and a hard body.

### Stents

In the DS case, the ideal stent is the one with the lowest profile, providing the best attachment to the

balloon, which in turn should be a high-pressure type and have good advancing properties. There are no comparative studies showing the most appropriate one. In the two above mentioned small studies conducted on the same type of stents, Jostent<sup>17</sup> by Jomed and Multilink<sup>18</sup> by ACS were successfully used. We have used many types of stents in our laboratory, but more often we used AVE by Medtronic AVE and Bx Velocity by J & J.

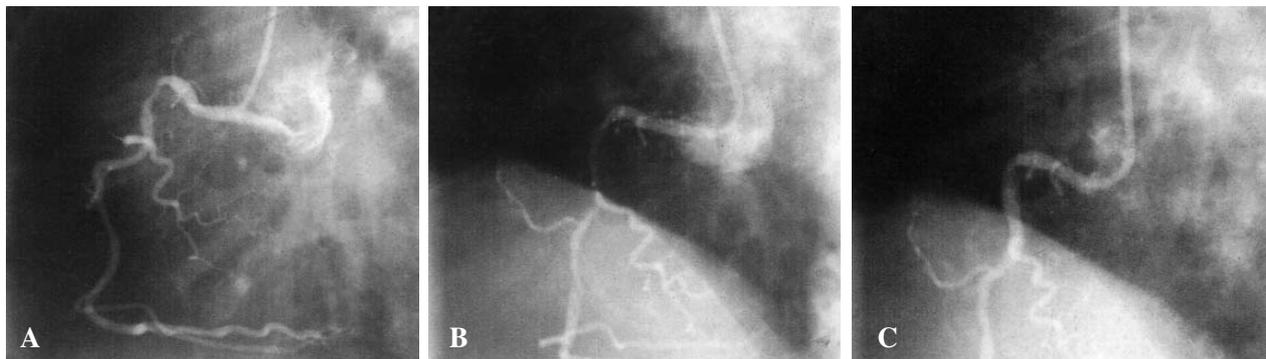
### Selection of lesions

All studies, without exception, state that DS is tried on carefully selected lesions. Typically, the selection or exclusion criteria are not described in detail. There is, however, a trend to rule out distally located elongated lesions, highly angled lesions and lesions preceded by significant tortuosity. Fairly calcified lesions and total occlusions are also excluded and B2 and C type lesions are in general avoided, but not totally excluded. In smaller vessels, i.e. with reference diameter less than 2.7mm, direct stenting is problematic since a significant lesion corresponds to a Minimal Lumen Diameter (MLD) less than 1mm. In recent total or subtotal occlusions, such as in AMI<sup>19</sup>, unstable angina or subendocardial MI, direct stenting does not constitute a contra-indication. On the contrary, it is recommended (if feasible), on the grounds that it avoids thrombus breakdown that usually occurs with unstable syndromes and caused by predilatation, hence potentially causing an increase in myocardial enzymes by peripheral embolisms<sup>20</sup>. However, in order for the technique to be feasible, upon passing the guide wire and administration of nitrate, it is required to delineate the continuation of the vessel at least using TIMI I flow. The same applies for the rationale of the application of the method on grafts, where the risk of peripheral embolisms, particularly on degenerated ones, is

**Table 3.** QCA and IVUS measurements after stenting.

	QCA		IVUS		
	DLD	RS	DLD	MPS	MPS/VS
<b>Group A</b>	2.3±0.3	1.0±0.1	1.9±0.3	7.4±1.8	0.66±0.11
<b>Group B</b>	2.2±0.4	0.9±0.2	1.8±0.4	8.0±1.6	0.74±0.19
<b>P</b>	NS	NS	NS	0,07	NS

- DLD: Direct lumen dilatation, RS: Residual stenosis, MPS: Minimum prosthesis surface, MPS/VS: Minimum prosthesis surface / Vessel surface. QCA: Angiography, IVUS: Intracoronary ultrasonogram.



**Figure 1.** Direct stenting of a critical right coronary artery lesion located in a very tortuous and angulated proximal segment.

**A.** Selective angiography of the right coronary artery pre intervention.

**B.** Passage of an extra support wire through the lesion after deep intubation of an Amplatz Right II guiding catheter, which resulted in straightening of the vessel and facilitated the procedure.

**C.** Final result after stent implantation.

high<sup>21</sup>. Finally, restenotic lesions seem to be fairly susceptible to the method, given the well established fact that they do consist of soft and compressible - not hard and calcified - material.

#### Other problems during stenting

We refer to problems that rarely occur and pertain to accurate and full stent deployment. Failure to dilate the balloon and, therefore, failure to even partially place the stent, is related either to a defective balloon, which is unrelated to predilatation, or to the existence of a particularly hard, calcified lesion. In the latter case, the balloon may break while passing through the hard lesion, or dilatation may be impossible due to hardness. The literature and our experience gained on over 200 DS lesions suggest that no case of failure is attributed to dilatation failure. In the above material, we may note five cases of relatively early balloon rupture below 10 atm, while an over-dilatation was required using another balloon for 10% of the cases. These rates are similar to those for the predilatation method. Another, infrequent but existing, problem is related to the accurate placement of the stent. It occurs when the minimal lesion diameter (MLD) is almost equal to the profile of the stent, which entails non-delineating of the vessel continuation and therefore hinders full coverage of the lesion. This problem is managed through intracoronary administration of sufficient quantities of nitrates, marking of reference points (side branch, bend of the vessel, calcification etc), and finally using a longer stent. This of course does

not lead to systematic use of longer stents, since we know that with predilatation we often distend points beyond the stenosis that we are forced to cover.

#### Failure parameters algorithm

As already mentioned, most research work deals with the safety and effectiveness of the method in a carefully selected number of lesions. This selection has a clearly empirical character and differs among researchers. Normally, the more complex lesions (B, C) we include, the higher total rate with DS we achieve. At the same time, however, we increase the number of failures, and potential complications. The experience of the operator by all means constitutes a significant factor, both for the selection of the lesions and for the effectiveness of the method. However, the existence of clinical and angiographic parameters must be investigated, which, either individually or combined together, predict the failure potential of the implantation in a direct manner. There is a study in progress under the guidance of the Cardiology Clinic of the University of Ioannina which leads towards that direction. In particular, this is tried directly in all lesions where we have decided the implantation of a stent, i.e. without preselection. The only exclusion refers to chronic total occlusions. The parameters recorded are: the type of lesion by ACC/AHA, the site by GUSTO, angulation, tortuosity, calcification, MLD, length, reference diameter, stent length and diameter and flow by TIMI. The purpose of the study is, therefore, to create an algorithm from the above parameters, which will predict

the possibility of unsuccessful direct stenting. Furthermore, a sub-study monitors the deployment of the directly placed stents through intracoronary ultrasonograms (IVUS). Using this technique, which is more sensitive than angiography (QCA) successful placement criteria are evaluated, both fully and relatively to the predilatation group. An early analysis of a small sample shows that there is no difference between the two groups<sup>22,23</sup>.

## Conclusion

Due to the increasing cost of medical services combined with the aging of the population, and hence the inability of the social security organizations to effectively respond, implementation of every new diagnostic or therapeutic method is now required to be placed under financial control as well. This means that the average annual cost of the new method shall be assessed for each symptom-free patient (cost effectiveness ratio), and compared to the respective cost of the older method. In this case, cost savings are obvious. What needs to be done is to prove –beyond any reasonable doubt– that the safety and effectiveness of direct stenting does not differ from that for the predilatation method, and to determine the rate and the features of the lesions for which the application of the method is successful and safe. We hope that our study will contribute to the achievement of this objective.

## References

1. Sigward U, Puel J, Mirkovitch V, Kappenberger L: Intravascular stents to prevent occlusion and restenosis after transluminal angioplasty. *N Engl J Med* 1987; 316: 701-706.
2. Serruys P, Jaegare P, Kiemeneki F, et al: A comparison of balloon expandable stent implantation with balloon angioplasty in patients with coronary artery disease. *N Engl J Med* 1994; 331: 489-495.
3. Fischman D, Leon M, Baim D, et al: A randomized comparison of coronary stent placement and balloon angioplasty in the treatment of coronary artery disease. *N Engl J Med*, 1994; 331: 495-501.
4. Buller CE, Dzavik V, Carere RG, Mancini GB, Barbeau G, Lazzan C, et al: Primary stenting versus balloon angioplasty in occluded coronary arteries: the Total Occlusion Study of Canada (TOSCA). *Circulation*. 1999; 100: 236-242.
5. Savage M, Douglas J, Fisman D, et al, for the Saphenous Vein De Novo Trial Investigators: Stent placement compared with balloon angioplasty for obstructed coronary bypass grafts. *N Engl J Med* 1997; 337: 740-747.
6. Topol EJ, Mark DB, Lincoff AM, Cohen E, Burton J, et al: Outcomes at 1 year and economic implications of platelet glycoprotein IIb/IIIa results from a multicenter randomized trial. EPISTENT Investigators. *Evaluation of Platelet IIb/IIIa Inhibitor for stenting*. *Lancet*, 1999; 354: 2019-2024.
7. Colombo A, Hall P, Nakamura S, et al: Intracoronary stenting without anticoagulation accomplished with intravascular ultrasound guidance. *Circulation* 1995; 91: 1676-1688.
8. Figulla HR, Mudra H, Werner GS, et al: Direct Coronary Stenting without Predilatation: A New Therapeutic with a Special Balloon Catheter Design. *Cathet Cardiovasc. Diagn.* 1998; 43(3): 245-252.
9. Briguori C, Sheiban I, De Grigorio J, Anzuni A, Di Mario C, Colombo A, Direct coronary stenting without predilatation. *J Am Coll Cardiol*, 1999; 34(7): 1910-1915.
10. Chan AW, Carere RG, Solankhi N, Dodek A, Webb JG: Coronary stenting without predilatation in a broad spectrum of clinical and angiographical situations. *J Invasive Cardiol*, 2000; 12: 275-279.
11. Herz I, Assali A, Solodky A, Simcha Brandes NS, Buto N, Teplizky I, et al: Coronary stenting without predilatation (SWOP): applicable technique in everyday practice. *Catheter Cardiovasc Interv* 2000; 49(4): 384-388.
12. Hamon M, Richardeau Y, Licluse E, Sabatier R, Agostini D, Filmont JE, Grollier G, Potier JC: Direct coronary stenting without predilatation in acute coronary syndromes. *Am Heart J*, 1999; 138: Pt 1,55-9.
13. Bolte J, Diefenach C, von Olshausen K: Coronary stent implantation without preliminary dilatation. *Z Kardiol* 1998; 87 (9): 707-714.
14. Martinez Elbal L., Ruiz Nodar JM, Zueco J, et al: Direct coronary stenting versus stenting with predilatation: Immediate results of a multicenter, Prospective Randomized Study. The DISCO trial. ESC 2000, Abstract 1516.
15. Wilson SH, Berger PB, Mathew V, Bell MR, Garrat KN, Rihal CS, et al: Immediate and late outcome after direct stent implantation without balloon predilatation. *J Am Coll Cardiol* 2000; 35 (4): 937-943.
16. Triantis G, Sionis D, Stefanidis J, Sassalos K, Achtypis D, Papanikolaou K: Direct stenting-Single center experience. *Interventional Cardiovascular Therapeutics Athens 2000; May 27-7, Athens Greece (Abstracts)*.
17. Oemrawsingh PV, Scalij MJ, Srimahachota S, Jukema JW, Brusckhe AV: Clinical and angiographic outcome of stent implantation without predilatation using the Jostent Flex stent. *J Invasive Cardiol*, 2000; 12(4): 187-193.
18. Pentousis D, Guerin Y, Funck F, Zheng H, Toussaint M, Corcos T, et al: Direct stent implantation without predilatation using Multilink stent. *Am J Cardiol* 1998; 82: 1437-1440.
19. Herz I, Assali A, Solodky A, Shor N, Ben-Gal T, Adler Y, et al: Coronary stent deployment without predilatation in acute myocardial infarction: a feasible, safe, and effective technique. *Angiology* 1999; 50(11): 901-908.
20. Shutte D, Potgietter L, Moir K: Coronary stenting without Predilatation in Acute Coronary Syndromes. *J Interv Cardiol* 2000; 13: 161-166.
21. Sabatier R, Hamon M, Mahmoudi A: Gould Direct Coronary Stenting Reduce No Reflow Stent Implantation in Acute Coronary Syndromes? A Randomized Study. ESC 2000, Abstracts 1519.
22. Triantis G, Sionis D, Stefanidis I, Achtypis D, Sassalos K, Papanikolaou K: Is the deployment of intraluminal stents affected by the absence of predilatation? Announcement at the Panhellenic Cardiology Conference, Athens, November 2000.
23. Chevalier B, Glatt B, Guyon P, et al: Cost effectiveness of Direct Coronary Stenting. *Eur Heart J* 1999; 20 Suppl. P2698: 504.