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SEVEN-YEAR EXPERIENCE WITH THE DUMON PROSTHESIS

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SUMMARY

The Dumon stent (or Endoxane) designed in 1987 is flexible, multisized, studded, silicone prosthesis. This report describes the combined results of Dumon stent placement in Marseille, France (J.F. Dumon); Brescia, Italy (S. Cavaliere); Saint-Etienne, France (J.M. Vergnon); and Barcelona, Spain (P. Diaz).

The 4 teams have placed 1574 stents in 1058 patients through September 1994. All cases involved high grade stenosis of the tracheobronchial tree resulting from extrinsic compression or wall collapse due to loss of cartilagineous support. The locations were the trachea (54%), left main stem bronchus (21%), right main stem bronchus (18%) and miscellaneous (8%). The main indications were malignant tumors (677 patients; 926 stents), benign tracheal stenosis (263 patients; 419 stents), postsurgical bronchial stenosis after lung transplantation (15 patients; 36 stents), low grade malignant tumors (21 patients; 50 stents), and miscellaneous benign stenosis lesions (82 patients; 143 stents).

All stents were placed via the rigid bronchoscope. The mean number of stents per patient was 1.5 overall, 1.4 in patients with malignant lesions and 1.6 in patients with benign tracheal stenosis. The mean duration of stenting was 14 months for benign tracheal disease (longest 6.2 years) and 4 months for malignancy (longest 4.7 years).

Complications were uncommon, usually easily managed, and rarely life threatening. The main complications were migration (9.5%), obstruction by secretions (3.6%), and granulation (7.9%) Rare complications included airway ulceration, infection, septic shock, and aphonia. Secondary obstruction due to extrinsic compression of the prosthesis was never observed. Yearly evaluations are recommended. Based on our 7-year experience, we conclude that the Dumon stent represents an effective way to reestabilish a viable airway in patients with benign and malignant tracheobronchial disease.

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INTRODUCTION

The use of stents to replace lost cartilaginous support in the tracheobronchial tree is not a new idea. The earliest attempts involved surgical placement of a silicone tube in the trachea. The best known surgical prosthesis was the Neville stent (1). This device has been almost completely abandoned because of the high incidence of severe complications, namely: rupture of the anastomosis and infection.

Current stents can be divided into two main groups: tube stents with or without metallic reinforcement and wire mesh stents. The main tube stents are the Montgomery T-tube, Orlowski stent, Dumon stent, Hood stent, Freitag stent, and Novastent. The main wire mesh stents are the Gianturco stent, Wallstent and Palmaz stent. Tube stents are more difficult to insert than mesh stents but, unlike the latter, they can be removed. Wire mesh stents often generate granulomas. The Dumon stent was designed in 1987. Since that time, more than 10,000 Dumon endotracheal and endobronchial silicone stents have been sold. In this article we describe the experience of 4 teams using the Dumon stent.

MATERIALS AND METHODS

Description

The Dumon stent is a studded cylindrical tube made of soft silicone. To enhance flexibility and facilitate placement and removal, it has no metallic reinforcement. The studs are designed to prevent migration and limit contact with the mucosa. The outer surface of the stent is covered with a non-stick coating. To prevent granulomas from forming at the distal and proximal ends, the rims of each stent are polished to remove burrs. As shown in Table I, Dumon stents come in a variety of lengths and diameters. A radio-opaque model is also available.

Table I: Standard dimensions of the Dumon Stent.

Location	Diameter (mm)	Length (mm)
Trachea	16 15 14	40 50 60
Left Main Stem Bronchus	13 12 10	30 40
Right Main Stem Bronchus	12 10	20
Carina (Y)	15/13	40

Indications

The main indications for stenting are malignant tumors, tracheal stenosis, bronchial stenosis after sleeve resection or transplantation, and low-grade malignant tumors. Miscellaneous indications include benign stenosis due to tuberculosis, amyloidosis, radiotherapy, and bronchomalacia. The common feature in all cases is high-grade stenosis. In malignancy the usual mechanism is extrinsic compression since endoluminal growth can be controlled using laser resection. For tracheal stenosis the mechanism can be cicatricial stenosis or loss of cartilaginous support. The decision to place a stent is always made during therapeutic endoscopy if resection of an obstructing lesion or dilatation of a stenosis fails to achieve an adequate airway.

Placement Technique

Stent placement requires the use of a rigid bronchoscope. For proper stent selection, the diameter and length of the narrowing must be carefully measured. Diameter is assessed in relation to the barrel of the endoscope. Tissue resection should be performed before measurement. The length of the stenosis is determined by withdrawing the telescope from the distal edge to the proximal edge of the stenosis and measuring the amount of displacement from the rigid tube. The stent must fit snugly into the stenosis without excessive force on the airway walls and be 1 cm longer than the total length of the narrowing so that the stent overextends the stenosis 0.5 centimeters proximally and distally. Stent selection is the key to preventing migration.

The stent is best placed using the dedicated introducer corresponding to the diameter of the endoscope. Loading the stent into the introducer requires special care. The sent is lubricated with silicone spray and aspirated into the introducer tube through a special funnel accessory. It should never be forced into the introducer. Once the stent has been loaded, the bronchoscope is placed with its tip at the distal end of the stenosis and used as a conduit for the introducer tube. The stent is ejected as the bronchoscope is progressively withdrawn. Placement with the dedicated introducer avoids injury when the stent is passed through the vocal cords.

After ejection, the telescope is inserted and the position of the stent is verified. In most cases adjustment using gripping forceps is necessary. In this regard, it should be remembered that it is much easier to pull a stent up than to push it down so that it is preferable to err distally than proximally.

Post-placement care

In the immediate post-placement period, patients should perform inhalations with a large-drop saline aerosol spray 4 times a day. The number of inhalations can be gradually reduced until it is done only when congestion occurs.

Routine endoscopy is not necessary but we do recommend a yearly evaluation in cases of long-term placement. If symptoms should occur, stents can be located on plain film x-rays. We do not use radio-opaque stents because their lack of tranparency prevents observation of the mucosa during endoscopy and because addition of radiopaque material reduces the strength of the stent.

Decision-making during follow-up depends mainly on clinical signs. Persistent cough after stent placement suggests migration, especially if it is associated with gradual respiratory compromise. Fiberoptic bronchoscopy should be performed to check the position of the stent. Stents that are not in the proper position should be repositioned or removed. Sudden respiratory compromise is suggestive of obstruction. Aerosol inhalations should be performed and coughing should be induced. Fiberoptic bronchoscopy may be necessary to clear the obstruction if these measures fail. Progressive respiratory compromise is a symptom of granuloma formation or recurring stenosis above or below the stent. In this case, the stent should be removed and, after resection of endoluminal lesions, replaced with a longer model. Foul-smelling breath is a sign of colonization by bacteria or fungi and the stent should be changed.

Removal Technique

The Dumon stent can be easily removed with foreign body forceps. First the prosthesis is loosened by turning it 360°. Next, the upper rim is collapsed. Finally, the stent is jammed against the end of the bronchoscope and withdrawn. After removal, it may be necessary to resect adherent tissue that often develops around stents. Follow-up endoscopic examination should be performed on day 7 after stent removal.

RESULTS

Between 1987 and 1994, the 4 teams placed 1574 stents in 1058 patients. Overall, the mean number of stents placed per patient was 1.5. However, the number of stents used in patients with benign tracheal stenosis was greater than the number used in patients with malignant tumors (1.6 vs 1.4). This finding can be attributed not only to the fact that duration of placement is longer in patients with benign disease but also to the fact that stents can migrate as external compression subsides.

Table II: Indications for Stent Placement.

Indication	Patients	Stents
Malignant	677	926
Tracheal Stenosis	263	419
Bronchial Stenosis (transplant)	15	36
Mildly Malignant Tumors	21	50
Miscellaneous	82	143
Total	1058	1574

Site

Overall the most frequent location was the trachea (54%) followed by the left main stem bronchus (21%) and the right main stem bronchus (18%). However, as can be seen in Table III, for indications other than tracheal stenosis, the distribution of locations was more even-trachea: 38 %, left main stem bronchus: 28% and right main stem bronchus: 24 %. For malignant tumors only, the distribution was trachea: 40 %, left main stem bronchus: 23% and right main stem bronchus: 27 %

Table III: Site of Placement (1574 stents).

INDICATIONS	TR	LMSB	RMSB	LLLB	RLLB	TI	TR/B	Y
Malignant Tumors	375	212	246	10	3	22	40	18
Tracheal Stenosis	418	0	0	0	0	0	0	1
Low grade Malignant Tumors	19	23	5	1	0	0	2	1
Transplant	0	28	5	0	0	3	0	0
Miscellaneous	40	62	25	4	6	3	3	0
TOTAL	852	325	281	15	9	28	45	19

TR: Trachea, LMSB: left main stem bronchus, RMSB: right main stem bronchus, LLLB: left lower lobe bronchus, RLLB: right lower lobe bronchus, TI: tronchus intermedius, TR/MSB: trachea and main stem bronchus.

Duration

For cicatricial tracheal stenosis, the mean duration of placement was 1.2 years and the longest duration was 6.2 years. For malignant disease the mean duration of placement was 4 months and the longest duration was 4.7 years.

Complications

As shown in Table IV, the main complications were migration (9.5%), granuloma (7.9%), and obstruction by secretions (3.6%). The main symptoms of migration are persistent cough and dyspnea due to recurring stenosis. Migration is not life-threatening since the prosthesis remains open. Granulomas can occur at either end of the stent and cause progressive dyspnea. Obstruction by secretions leads rapidly to respiratory compromise.

Rare complications included: ulceration of the tracheal or bronchial wall, secondary tumor obstruction, infection, septic shock and aphonia. Ulceration can lead to hemorrhage, mediastinal perforation or esophago-bronchial fistula. Secondary tumor obstruction is always due to tumor progression above or below the stent rather than to compression of the stent. Infection is uncommon but purulent secretions or mycotic infection may require stent change after long-term placement. Complications were more frequent in patients with tracheal stenosis than malignant disease: 18.6% vs 6,0 % for migration, 17.2% vs 1.4% for granulomas, and 5.7 % vs 1.4% for obstruction (Table IV).

Table IV: Complications of stent placement (1574 stents). Number (%).

INDICATIONS	N* of stent	MGR	OBS	GRN	FIS	SSK	HEM	APH
Malignant Tumors	926	56 (6%)	9 (1%)	13 (1.4%)	1	1	1	1
Mildly Malignant Tumors	50	2 (4%)	2 (4%)	6 (12%)				
Miscellaneous	143	13 (9.1%)	10 (7%)	27 (18.9%)				1
Transplant	36	1 (2.8%)	11 (30.6%)	6 (16.7%)				
Tracheal Stenosis	419	78 (18.6%)	24 (5.7%)	72 (17.2%)				
TOTAL	1574	150 (9.5%)	56 (3.6%)	124	1	1	1	2

MGR: migration, OBS: obstruction, GRN: granuloma, FIS, fistula, SSK, septic shock, APH: aphonia.

Follow-up

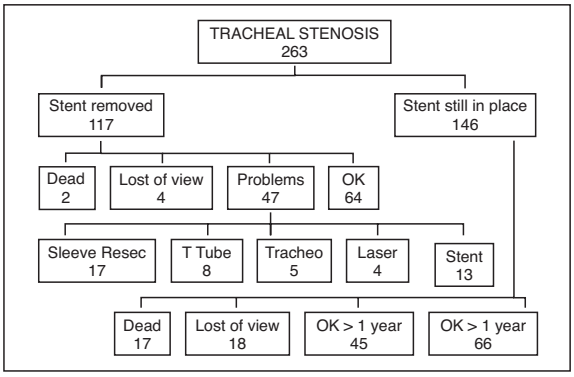
Stent placement was performed for malignant stenosis in 677 patients. A group of 262 patients died after a mean of 3 months. Another group of 207 patients (81 stent removed and 126 still in place) are still alive after a mean of 5 months (Table V). A third group of 211 patients was lost from follow-up.

Table V: Follow-up of malignant tumors (677 patients).

	Number of Patients	Mean (Days)	Mean (Months)
Dead	262	104	3
Removed	81	136	5
Still in place	126	144	5
Total	469	120	4
Lost from view	208		

Stent placement was performed for tracheal stenosis in 263 patients. Table VI sumarizes the complexity of follow-up after stenting in patients with tracheal stenosis. Stents have been removed in 117 patients without recurrence in 64 (54.7%). Further treatment was necessary due to recurrence after removal in 47 patients. Sleeve resection was perfomed in 17 patients, t-tube placement in 8, tracheotomy in 5, further laser resection in 4, and placement of another stent in 13. Of the remaining 6 patients, 4 have been lost from follow-up and two have died. Stents are still in place in 146 patients. A group of 66 patients have had the stent for more than one year with a maximum of 6.2 years. This high proportion of prolonged placements along with the fact that 17 patients died attests to the extremely critical condition of these patients. Excluding the 18 patients that were lost from follow-up, the remaining 45 cases are too recent to know the outcome (less than 1 year).

Table VI: Follow up of tracheal stenosis (263 patients).



DISCUSSION

The Dumon stent was designed to resist compression. Its cylindric form provides a vault effect by which compressive forces are distributed evenly. No of cases secondary obstruction due to extrinsic compression was observed in our experience. Metallic reinforcement that diminishes the dynamics of clearance is not needed. Flexibility facilitates placement and removal, improves tolerance, and preserves clearance of secretions. The studs on the outer surface of the stent prevent migration and reduce mucosal ischemia by limiting contact with the wall. A wide range of sizes and diameters is available so that stenting can be limited to the stenotic zone. Minimizing the length of the stent is also a factor in maintaining clearance and enhancing tolerance. The rims of each stent are polished to remove burrs and reduce the risk of granuloma, It is unnecessary and unwarranted to cut a Dumon stent before placement. The disadvantages of the device are the relative thickness of its wall which reduces the diameter of the lumen, the need for rigid bronchoscope to achieve placement, and the need for careful sizing. Stent removal is usual after one year in patients with benign disease and may be necessary in case of complications in patients with malignant disease or if the stent is no longer necessary.

There is a wide range of indications for stent placement, including bronchial stenosis after lung transplantation (2% of indications in our series), tracheal stenosis (27%) and malignant tumors (62% including mildly malignant). Miscellaneous indications account for the remaining 9%: benign stenosis due to tuberculosis, amyloidosis, radiotherapy stenosis after surgery and bronchomalacia. The common feature in all cases is high-grade stenosis.

Malignant tumors are the main indications and stent placement has become an indispensable tool for patients with malignant external compression. The complication rate is low and the need for surveillance is minimal. Quality of life is greatly improved. For tracheal stenosis, the second commonest indication, the benefit is less clear-cut. The complication rate is high. However, in our experience, the success rate was 69% including 24% of patients who are recurrence free at one year after stent removal.

The flexible silicone Dumon stent was designed based on experience with the Montgomery T-tube (2,3,4,5). An effective stent needs to be easy to insert and remove, comfortable for the patient while maintaining an effective airway, and have minimal complications. Although we have an obvious preference for this device, our

experience in more than 1000 patients (more than 1500 stents) demonstrates that our stent meets these requirements for most indications.

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