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The Misti Gold bio-oncotic gel filled breast prosthesis: an acceptable alternative to silicone?

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SUMMARY. **Concern about the use of silicone gel as a filler for breast prostheses has stimulated interest in other materials. We have evaluated the Misti Gold prosthesis which contains a "bio-oncotic" gel of low molecular weight Polyvinylpyrrolidone (PLASDONE 24AUK). Our experience of its use in breast augmentation is that the aesthetic results obtained with retromammary placement are inferior to those obtained from a silicone gel filled prosthesis. Nonetheless there are theoretical advantages for its use which will need to be considered in the light of recent regulatory decisions.**

It is estimated that 110,000 women undergo breast augmentation for aesthetic purposes worldwide each year (Carr, 1989). Until the recent ruling by the Federal Drug Administration (FDA) (Calman, 1992) the vast majority received silicone gel filled prostheses, since these had been found to give superior results to the original saline filled prostheses.

The major clinical problem with all breast prostheses had been the unacceptable encapsulation rate, however this has been addressed in part by the development of texturing of the siloxane shell (Coleman *et al.*, 1991; Ersek, 1991).

Recent public and FDA concern about the safety of silicone, the problems of radio-opacity during mammography and the effects of silicone leakage on the reticulo-endothelial and immune systems have now focused attention on alternative filling materials for the shell.

The Misti Gold prosthesis (Bioplasty Inc. St Paul Mn USA) uses the same standard textured siloxane shell as their Misti prosthesis, but filled with low molecular weight Polyvinylpyrrolidone (LMW PVP) instead of silicone gel.

PVP is not a new agent, being widely used in the 1950's as an intravenous plasma expander, and is found today as a binding and palliation agent in many drugs and foodstuffs.

LMW PVP has many theoretical advantages over both silicone gel and saline as a filling material (Table 1).

Table 1 Potential advantages of using Plasdone 24AUK (LMW PVP)

* Iso-osmotic and bio-inert
* Rapid excretion in the urine
* Superior X-Ray transmission
* Highly lubricant

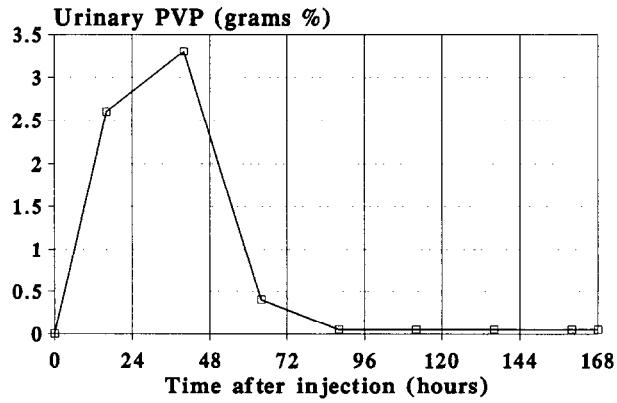

Fig. 1

Figure 1—Urinary excretion curve of LMW PVP in New Zealand White Rabbit after subcutaneous injection. The volume injected was proportional to two 370 cm^3 prostheses in a 55 kg woman. Histological examination at 7 days showed no evidence of PVP within the soft tissues or reticulo-endothelial system. [Data from Bioplasty Inc.]

1. It is osmotically balanced (290 milliosmols pH 7.3) and bio-inert so that traumatic shell rupture should not provoke either anaphylactic or physiological shock.
2. It is of low molecular weight (less than 20000) and is readily and rapidly excreted through the renal glomerulus in the event of leakage (Fig. 1).
3. It has superior X-ray transmission to both silicone and saline, which may be of benefit in subsequent mammography.
4. It is a good lubricant, reducing the risk of "fold-flaw fracture" which is thought to explain the high deflation rate of saline filled prostheses.

The Misti Gold is considerably more expensive (170%) than a standard Misti prosthesis and we therefore undertook a review of patients who had undergone augmentation with this prosthesis to assess the early results and complications.

Patients and methods

11 patients underwent bilateral breast augmentation for aesthetic purposes between November 1990 and April 1991. Patients were selected who required no additional procedures to the breast, had given informed consent for the prosthesis and were otherwise fit (American Society of Anesthesiology grade I).

All patients underwent surgery under general anaesthesia as an inpatient with a single surgeon (RS), assistant (HL) and anaesthetist using a standard transaxillary approach. Peri-prosthetic vacuum drains (Prevac wound drainage system, Arthrodax, Ross-on-Wye, UK) were placed and no prophylactic antibiotics given.

Twelve of the prostheses were inserted in the retropectoral plane and ten in the retromammary position according to clinical need and patient preference. Prostheses ranged in size from 240–320 cm^3 and were of the fillable version. About 40 cm^3 of LMW PVP was instilled into the shell before insertion, the remainder being inserted when the prosthesis was in position.

For all patients evidence of immediate, early and late complications was sought. Specific attention was paid to intra-operative difficulties with prosthesis handling and insertion, and to any local complications such as bleeding, haematoma, infection, delayed wound healing and undue pain.

All patients were assessed at post-operative consultation by the same observer (RS). Objective measures of outcome were made for symmetry by measurement and appearance, contour irregularities (shell wrinkles) by direct vision and palpation. Capsular contracture was assessed using the Baker scale (Baker, 1981).

Subjective outcome measures included the texture and feel of the augmented breast for "naturalness" and overall patient and surgeon satisfaction. Data were obtained by direct enquiry and patient responses to the two measures compared to ranges: "very abnormal" to "like a normal breast" and "very dissatisfied" to "very pleased". Surgeon responses were recorded independently of patient responses but were not blinded. A specific response to describe the unusual feel of some of the breasts was added (*vide infra*).

Results

Complications

The incidence of complications is shown in Table 2. There was initial difficulty with the filling mechanism with the first two patients which was overcome with experience and by warming the sachet of gel to reduce its viscosity. One patient developed a postoperative haematoma which was evacuated on day 7. She went on to develop a unilateral Baker grade IV capsule. No other patient had early evidence of significant encapsulation (Grades III or IV).

Aesthetic outcome

Table 2 also shows the results of objective and subjective assessment by the surgeon. All unsatisfactory results were due to the appearance of visible wrinkles in the prosthesis beneath the skin and/or an unnatural "crepitus-like" feeling to the prosthesis, a little like that obtained by indenting a table tennis ball (Fig. 2). Patient satisfaction with the results was high (10/12) despite some being aware themselves of these abnormalities.

One patient has since had additional gel instilled and one patient has requested their removal because of anxiety about their safety, despite assurance that they did not contain silicone gel.

Table 2 Complications of Misti Gold prostheses when placed in the retropectoral or retromammary plane

Complication	*Retropectoral (n = 12)*	*Retromammary (n = 10)*
Difficult filling	1	1
Haematoma	1*	0
Infection	0	0
Capsule (Grade III or IV)	1*	0
Unsatisfactory feel (edges or wrinkles)	1	6

*: same prosthesis.

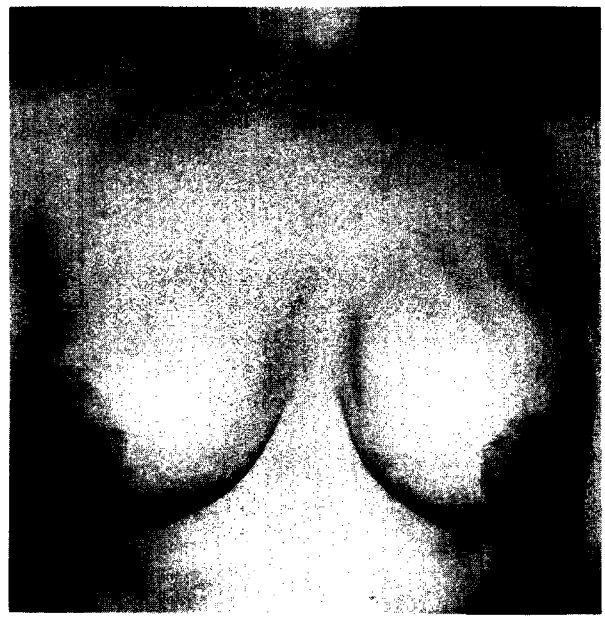

Fig. 2

Figure 2—Result 18 months after retromammary placement of 320 cm^3 Misti Gold prosthesis. Note the visible corrugations in the upper quadrants. Some improvement was obtained subsequently by instillation of extra gel into the shell.

Discussion

The Misti Gold bio-oncotic gel filled breast prosthesis addresses many of the concerns raised by silicone gel filled prostheses and early experience worldwide suggests a low encapsulation rate (Unpublished data: Cranstone 1992) consistent with other prostheses with textured shells.

PVP has been in use in humans topically, enterally,

subcutaneously and intravenously for many years with no reported severe complications when used at this molecular weight. One patient who received multiple subcutaneous injections with *high* molecular weight PVP went on to develop Dupont-Lachapelle disease (Cutaneous thesaurismosis) (Robinson *et al.*, 1990).

The *low* MW PVP used in the Misti Gold is readily excreted by the kidney without metabolism, and is less likely to accumulate in the reticulo-endothelial system than silicone, nor to form palpable masses that may mimic tumours. Whilst there is no controlled evidence that the improved radiolucency of PVP reduces the chance of masking changes on mammography, the increased visualisation of the breast tissue must be considered beneficial (Beisang *et al.*, 1991).

Thus on theoretical grounds the Misti Gold fulfils the criteria for an optimal prosthesis for use in the retromammary position.

We believe that the unsatisfactory aesthetic outcome when it is used in this site results from the increased fluidity of LMW PVP at body temperature compared to that of silicone gel. This allows the PVP to flow away from the superior edge of shell with gravity, leaving wrinkles in the shell at the point where the subcutaneous breast tissue is least, and an empty shell to palpate beneath the skin. Similar complaints have been made in the past about saline filled prostheses.

In July 1991 a pre-filled version of the Misti Gold prosthesis was released which contained additional LMW PVP to attempt to overcome this problem; however, both versions were withdrawn in November 1991 when the FDA did not allow Bioplasty to file for product approval. The FDA cited inadequate length of patient follow-up and criticised promotional publicity which claimed unproven clinical mammographic benefit. The company are currently seeking approval to relaunch the prosthesis.

Our findings suggest that the additional cost and sub-optimal results of the Misti Gold in its current form when used as a retromammary prosthesis outweigh the potential benefits over silicone gel filled prostheses. However with the latter under critical scrutiny and having lost public confidence in some markets, the Misti Gold may need to be viewed in a new light for both retromammary and retropectoral use.

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