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Experience with the Mentor Contour Profile Becker-35 expandable implants in reconstructive breast surgery*,**

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Summary *Introduction:* Round expander-implants (Beckers 25 and 50) and anatomical expander-prostheses filled with firm cohesive gel (McGhan Style 150) are established choices for single-stage expander breast reconstruction. Because of their drawbacks we selectively adopted the anatomical Becker-35 expander-implant filled with soft cohesive gel from January 2005.

Patients and methods: All patients undergoing reconstructive breast surgery using the Contour Profile® Becker-35 expandable implant over a two-year period were retrospectively reviewed with respect to indication, implant sizes, inflation details, complications and outcomes.

Results: 36 patients, mean age 48.9 years ($r = 14–69$), received 39 anatomical Becker-35 expanders (three bilaterally). Three quarters of these implants (29) were used for immediate breast reconstruction while the remainder were equally divided between delayed postmastectomy reconstruction (5) and correction of congenital breast asymmetry (5). Half of the patients had simultaneous latissimus dorsi myocutaneous flap coverage of the implants.

The median numbers of inflations and deflations needed to achieve the target expansion size and shape were 3 ($r = 0–7$) and 0 ($r = 0–4$), respectively. The mean time from expander insertion to completion of reconstruction was 4.6 months ($r = 0–13$ months). Four patients required surgical intervention for haematoma, implant infection, severe capsular contracture, and palpable rippling. Additionally there were three injection port adjustments, giving a 20% overall revisional surgery rate (8/39 breasts) after a median follow-up of 20 months ($r = 6–38$ months). Four implants (10%) developed significant but asymptomatic rippling. The significant

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capsular contracture rate was 21% (8/39 breasts), which was related to chest wall radiotherapy.
Conclusion: In this short-term study, the Becker-35 expander was successfully used for single-stage prosthetic breast reconstruction with an incidence of early complications comparable to alternative prostheses. Although it has expanded the range of implants available to the breast surgeon, its exact role in reconstructive breast surgery has yet to be established.

Prosthetic reconstruction is a popular technique for post-mastectomy breast reconstruction because of its apparent simplicity.[1,2] It is accomplished as either a single-stage or two-stage procedure. Single-stage reconstruction employs either a fixed volume implant or a bi-lumen adjustable gel-saline prosthesis. Fixed volume implants have, however, limited application (in the absence of flap coverage) for single-stage reconstruction. In contrast, expandable implants, also referred to as permanent expanders, are more popular.[3–7] Since 1996 these have been available in either the round (Beckers 25 and 50) or the anatomical (McGhan Style 150) varieties. The round expandable implants have a number of drawbacks including excessive fullness of the upper poles, unnatural rounded shape, poor lower pole projection, and a reportedly high revisional surgery rate.[8] On the contrary, the only available anatomical expandable implant (McGhan Style 150) prior to the Becker-35 was not designed for overinflation or injection port removal.[5,7] It also possessed a firm cohesive gel and was prone to frequent in-situ torsion of the injection ports.[5,7]

The Mentor Contour Profile Becker-35 expander (Figure 1) was launched onto the market in 2004 to address some of these problems and those inherent in the earlier generation Beckers 25 and 50. Like these traditional round Beckers, the Becker-35 is a bi-lumen implant with identical injection ports and fill tubes. However, like the McGhan Style 150 expander, it is teardrop shaped with almost identical dimensions to those of the short height variety (Figure 1); but its outer compartment contains soft cohesive silicone gel. These features are said to allow preferential expansion of the lower pole and provide for 25% overexpansion of the implant (Mentor Medical Systems Manufacturer's Information Leaflet). The former enables the implant to closely mimic the natural breast shape. The drawbacks of the existing single-stage expanders could therefore be theoretically circumvented by this new expandable implant. On this basis, the senior author (CMM) selectively adopted the Becker-35 expander for single-stage prosthetic breast reconstruction and correction of congenital breast deformities when a permanent expander was indicated.

Figure 1 Contour Profile Becker-35 Expandable Implant illustrating the inner saline filled compartment and long fill tube with a large injection port.

As there are no published series of the Becker-35 prosthesis, we decided to review our experience with this implant to evaluate its possible roles. The following is a review of our early experience in patients receiving Mentor Contour Profile Becker-35 expanders.

Patients and methods

Patients undergoing prosthetic breast reconstruction with the Mentor Contour Profile Becker-35 expander by a single surgeon (CMM) over a two-year period (January 2005 to December 2006 inclusive) were retrospectively reviewed. Only those with a minimum follow-up period of six months were included. Data were collected about the specific indication for the implant, expander size, inflation volumes, number of postoperative inflations and deflations, time taken to achieve final volume, aesthetic outcomes and complications.

Operative technique

In latissimus dorsi flap reconstructions, the expander was sandwiched between the latissimus dorsi and pectoralis major muscles. In prosthesis-only reconstructions, the expander was inserted in the standard subpectoral position[1] with the lower one-third of the implant in a largely subcutaneous position. If axillary dissection was performed the pocket included the fascia overlying the serratus anterior to prevent lateral implant displacement. The expander port was positioned in the deep subcutaneous tissues 5–7 cm inferolaterally to the breast mound[9] contrary to the recommendation of others.[10] Two suction drains (submuscular and subcutaneous) were placed and the wound was closed in two layers with monocryl sutures.

Selection of expander

The size of the expander used was based on the pre-operative width and height of the contralateral breast in conjunction with the intra-operative mastectomy weight. An implant one size larger than predicted was used when the patient had significant ptosis while a one size smaller

Table 1 Reconstruction profile

	Implant only	Implant + LD flap	Breasts
Immediate reconstruction	13	16	29
Delayed reconstruction	4	1	5
Total	17	17	34

implant was used in patients undergoing lastissimus dorsi implant reconstruction. The intra-operative dimensions of the mastectomy pocket were also taken into consideration thereby introducing a degree of flexibility in selecting the size.

Inflation protocol

Following expander placement on-table inflation never exceeded 50—100 mls of saline so as to not put undue tension on the wound. Further inflation of the expander was commenced two weeks postoperatively with subsequent visits once every one or two weeks. Inflation was stopped after achieving 25% overexpansion or when a symmetrical result had been obtained. In patients scheduled for postoperative radiotherapy the inflation protocol was accelerated so as to be completed just before the radiotherapy planning (six weeks following surgery). Where indicated, deflation was performed to achieve symmetry but no sooner than three months after the last inflation.

Results

Over the 24-month period, 36 patients, mean age 48.9 years ($r = 14—69$), received 39 anatomical Becker expanders (three bilaterally). Three quarters of the implants (29) were used for immediate breast reconstruction while the remainder was equally divided between delayed postmastectomy reconstruction (5) and correction of congenital breast asymmetry (5). Half of the patients had simultaneous latissimus dorsi myocutaneous flap coverage of their implants (Table 1). The most frequently used nominal implant sizes were 460 mls and 565 mls ($r = 195—685$ mls) (Figure 2).

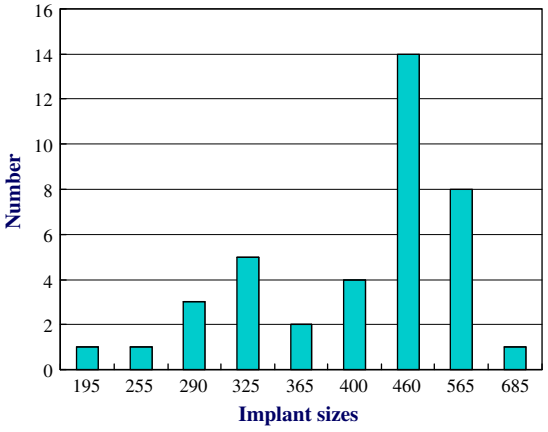


Figure 2 Bar chart showing the different sizes of implants used in the study.

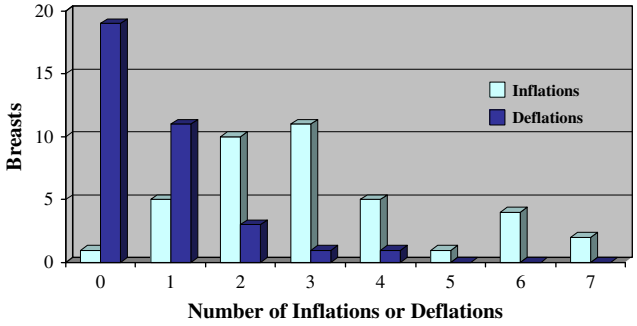


Figure 3 Number of breasts requiring a given number of inflations and deflations to achieve target breast shape and size.

The median follow-up was 20 months ($r = 6—38$ months). The median numbers of inflations and deflations needed to achieve the target expansion size and shape were 3 ($r = 0—7$) and 0 ($r = 0—4$), respectively. Of the 25 patients with implants in-situ for more than six months, 72% (18) have not required deflation to achieve the desired breast size and shape (Figure 3). The mean time from expander insertion to completion of reconstruction was 4.6 months ($r = 0—13$ months). This excludes the time taken for adjuvant therapy (Figure 4).

The complications recorded were eight cases of severe capsular contracture (Baker III/IV), six instances of rippling, of which four were significant but asymptomatic and three injection port problems (Table 2). Four patients required surgical intervention for haematoma (1), implant infection (1), severe capsular contracture (2), and palpable rippling (1). Additionally there were three injection port adjustments (Table 2) (Figure 7), giving a 20% overall revisional surgery rate (8/39 breasts).

Severe capsular contracture was the most common complication in this series (Table 2). This is a time dependent event and so far has developed in seven patients representing eight implants equally divided between implant only and LD-implant reconstruction types. All the seven patients who developed capsular contracture had received either postoperative radiotherapy (6) or previous radiotherapy (1). Interestingly, six out of nine patients

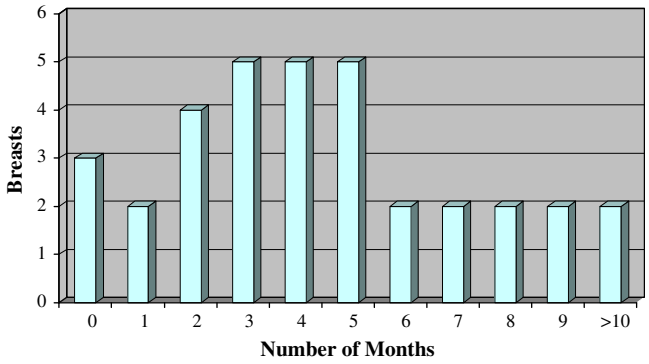


Figure 4 Duration of the inflation/deflation cycle for each breast, excluding the time taken for adjuvant therapy. Average cycle 4.6 months.

Table 2 Complications following Becker-35 expander insertion ($n = 39$ implants)

Capsular contracture	8 (21%)
Rippling	4 (10%)
Injection port rotation (adjustment)	3 (8%)
Infection (removal)	1 (3%)
Haematoma (expander exchange)	1 (3%)
Reoperation	8 (20%)

receiving adjuvant postoperative radiotherapy went onto develop severe contracture. Most patients were happy with the cosmetic outcomes. A representative example of our commonest use of the Becker-35 expander (immediate reconstruction in conjunction with a latissimus dorsi flap) is shown in Figure 5.

Discussion

Single-stage expander breast reconstruction has a number of advantages (Table 3). Patients only have to undergo one operation and the target expansion size and shape can be readily adjusted by subsequent inflations and deflations. When anatomical expandable implants are used for this purpose, they also provide a more natural shape to the reconstructed breast (Figure 6) by allowing preferential expansion of the lower pole.[3,5,7] The Becker-35 expander is thought to achieve this by virtue of the contour shaped inner saline lumen being tethered to the outer shell and being predominantly sited in the lower region of the implant (Figure 1). Like other textured expanders, they are said to enable more complete expansion by decreasing the amount of capsular contraction and resisting expander migration.[1,11–13]

The Becker-35 anatomical expandable implants can be overinflated (by up to 25%) postoperatively with subsequent deflation 3–6 months later in order to achieve symmetry and a degree of ptosis. Expansion of the implants was usually continued to 25–50% beyond the target size. The patient was then usually left in this overinflated shape to allow the expanded skin and capsule to settle. The use of overexpansion to produce a larger skin envelope and allow a subsequent greater degree of ptosis is well established for round expanders.[3,14,15] This technique also gives patients some control over the final breast sizes.[3,4,16–18] In contrast, in our series, most patients did not require the 25% over-inflations to achieve their desired shape. Furthermore, approximately half of the patients were content with the breast shape when size symmetry had been achieved and declined the offer for overinflation. Interestingly, very few inflations were required to achieve the final results as shown by the low number of inflations (average 3.1) needed to reach the target expansion size and shape. This figure compares favourably with the 3.05 reported by McGeorge's

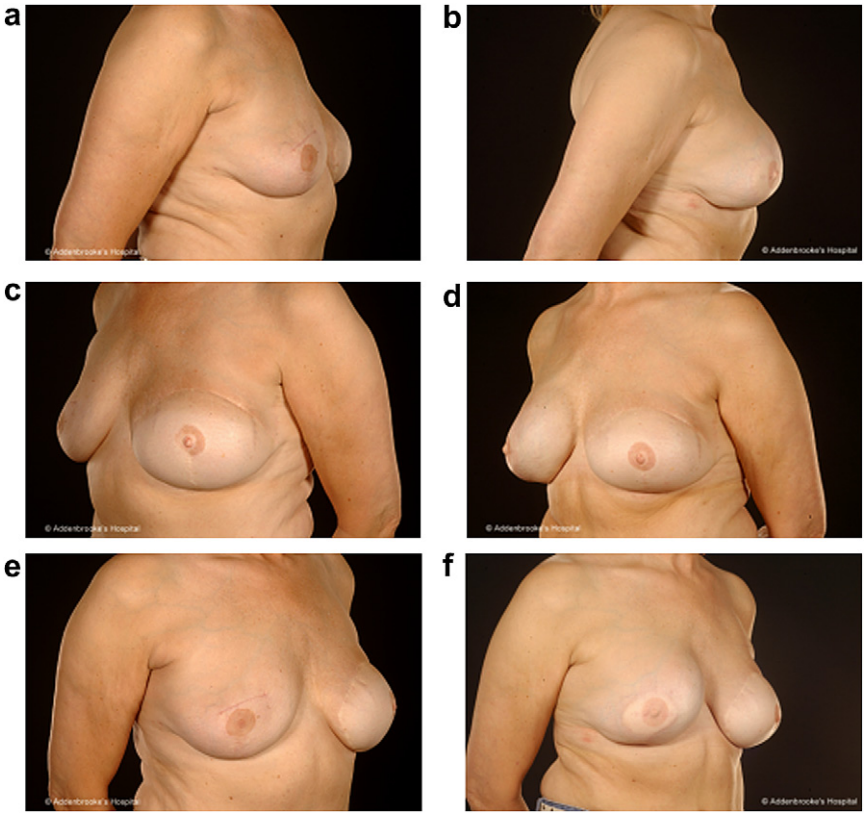


Figure 5 This 55-year-old woman with a previous left free TRAM flap delayed breast reconstruction presented with a contralateral breast cancer six years later (a,c,e). She requested an immediate breast reconstruction with was undertaken with a latissimus dorsi flap and a Becker-35 expander. Her postoperative appearances at eight months (b,d,f) are satisfactory after two inflations only. No deflation was necessary.

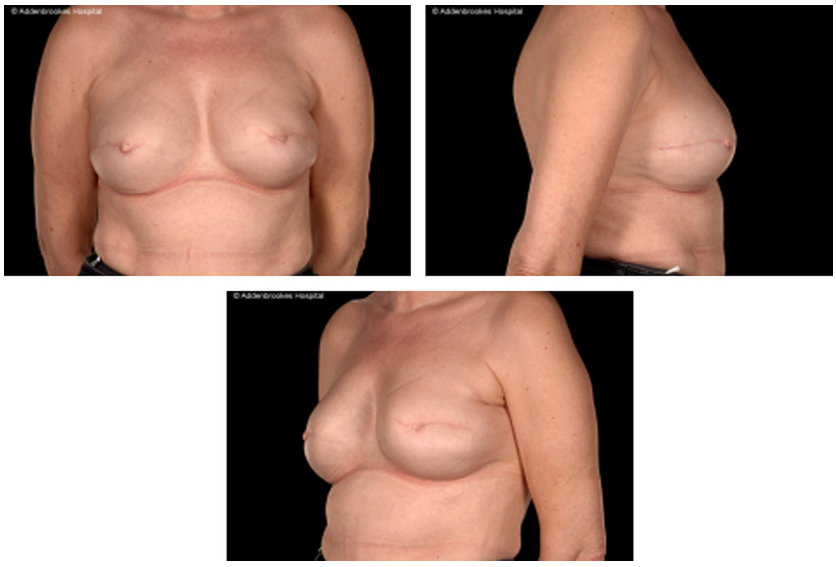


Figure 6 This 53-year-old woman underwent bilateral mastectomies for bilateral breast cancer and immediate implant only breast reconstruction with Becker-35 expanders. She subsequently underwent bilateral nipple reconstruction. Her postoperative appearances at 11 months post breast reconstruction are shown.

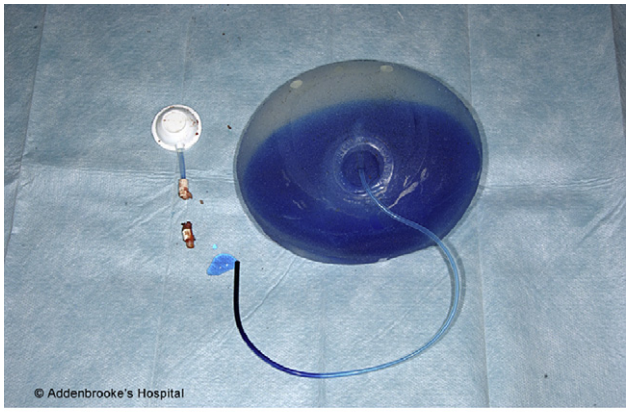
group with the McGhan Style 150 expanders.[5] Of the 25 patients with implants in-situ for more than six months, almost 3/4 did not require deflation to achieve the desired breast size and shape (Figure 2). This is a new finding and possibly a unique advantage for the Becker-35 expandable implant not previously reported for other expanders. It may be a function of the breast shape of the implant. Besides these advantages of the new Becker expander, it shares a number of disadvantages with the traditional Beckers (Table 3).

The round Becker expanders have been reported to have low rates of trans- and post-expansion capsular contracture around 5—10%.[16,17,19] This contrasts with our study finding of 7 cases of significant capsular contracture (20%), all in patients who had received either postoperative or previous radiotherapy. Six out of nine patients receiving adjuvant postoperative radiotherapy went on to develop severe contracture. Despite the small patient numbers these findings support the conclusion of others that irradiating breast expanders postoperatively is a major factor in the development of capsular contracture,[20—23] whether they are temporary or permanent. Noticeable rippling is another undesirable complication of prosthetic breast reconstruction. It tends to form on the medial side of the breast and inferolaterally. It was largely asymptomatic but was commented on by a number of patients in our study. However, only one of the patients requested that her Becker-35 expander be exchanged for another prosthesis type on account of the unacceptable visible and palpable rippling. We suspect that the cause of the noticeable rippling may be due to the design of the implant as the Becker-35 only contains 35% silicone gel, whereas the McGhan Style 150 expander has almost 50% gel. In addition to such problems with the breast mound, the Becker injection port constituted another source of concern. Injection port problems constitute a minor reconstructive complication but occasionally require surgical repositioning in order to continue the expansion (Figure 7). It has been reported that the injection ports of permanent expanders can be difficult to place satisfactorily and are prone to undergo 180° rotation, especially when the micro- rather than the macro- dome is used.[24] Fortunately, the Becker-35 injection port is available in two sizes and we tended to use the smaller size for the thin patients and bigger size for the larger patients to avoid difficulties of localisation subsequently. Removal of the port however was not found to be as easy as that for the round Beckers although this was only a subjective clinical impression.

A potential problem with anatomical devices is in-situ malrotation. We, however encountered no incidences of this in our series possibly because of the textured nature of the implant surface. This risk can be further minimised by exact pocket dissection, drain placement to avoid fluid accumulation and placement of a binder above the breast to maintain implant position for 3—4 weeks postoperatively and the use of textured surface prostheses.[12,13,25,26]

Table 3 Advantages and shortcomings of Becker-35 expandable implants

Advantages of Becker-35	Disadvantages of Becker-35
● Adjustable	● Noticeable rippling
● Single-stage breast reconstruction	● Relatively low percentage of gel compared to McGhan Style 150 or Becker 50
● Anatomical breast shaped	
● Injection port can be removed if required (not integrated)	● Injection port subjectively more difficult to remove than previous Becker
● May avoid need for overinflation or deflation	● Difficult to judge the ideal size of prosthesis based on breast width and weight



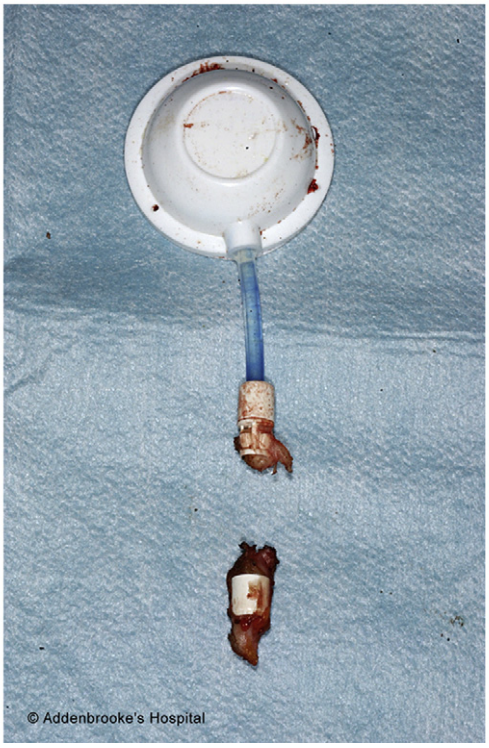


Figure 7 Intra-operative photograph of an injection port whose fill tube was found to have detached from the connector with an ingrowth of scar tissue. This had prevented expander inflation. It was attributed to a technical error, possibly clamping of the tube with a haemostat at the time of reconstruction.

Although at present after a relatively short follow-up 80% of Becker-35 implants are still in-situ, the longevity remains to be determined. This is especially because the Canniesburn group has reported a low long term 'durability' with round Beckers.[8] Our data are promising but it remains to be seen whether they will withstand the test of time better than their round counterparts.

In this short-term study, the Becker-35 expander was successfully used in patients undergoing breast surgery for a variety of indications with an incidence of early complications comparable to alternative prostheses. It may achieve satisfactory breast shape without the need for overinflation. Although these preliminary data are encouraging and the Becker-35 prosthesis has expanded the range of implants available to the breast plastic surgeon, its exact role in reconstructive breast surgery remains to be defined.

Conflict of interest

None.

Funding source

No study sponsors or any other party(s) were involved in the funding of this work.

Ethical statement

Investigations or any such activities pertinent to producing this study were carried out to a high ethical standard.

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