

For those ostomates (ostomists) who require the use of some form of external collection device upon the abdomen with which to isolate and or contain their unimpeded stomal effluents, the use of these pouches or bags is a well known and established protocol.

All ostomy collection devices should satisfy the three **C** requirements:

Containment

Control

Camouflage

Lately, questions have arisen concerning alternative strategies for abdominal stoma and effluent management, namely the “COP” or Continent Ostomy Port.

If one subtends all arguments about how best to manage effluent with the principle of unimpeded luminal flow*, then one has to be wary of the allure of continent options. To date, there has not been an effective and long lasting strategy to effluent diversion that does not include compromises. The question is: Does one compromise appearance or function?

External collectors without any interference with effluent flow compromise appearance.

Internal reservoirs that retard or impede effluent flow compromise function as do devices inserted into the stoma.

*Ref: W.M.Bayliss and E.H.Starling published their paper "Movements and Innervation of the small intestine" (*J.Physiol.* XXIV: 98-143, 1899), in which they formulated the "Law of the Intestine".



External Pouching Approach

- Long and safe history
- Many iterations over many decades
- Manufacturers: from dozens to the Big Three
- Design merging into Groupthink
- Room for improvements
- Differentiation desirable

2

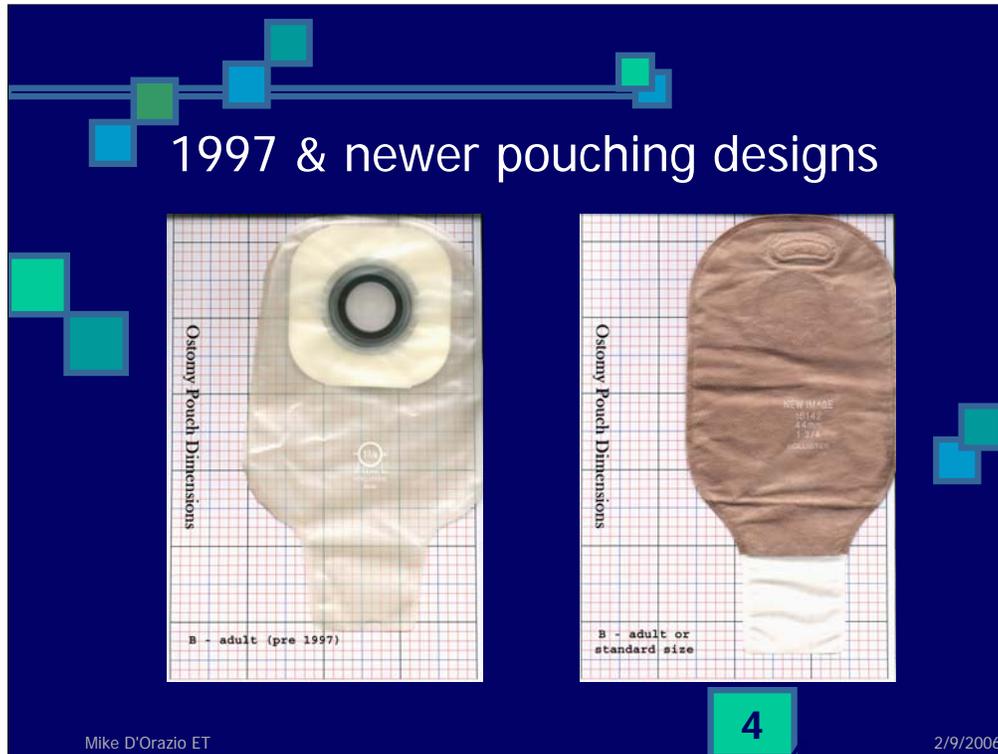
Mike D'Orazio ET 2/9/2006

A search, albeit incomplete, of the US patent files will reveal an historical permutation of ostomy collection devices and related artifacts:

Inventor / Item	Patent #	Date
1. Clare Artificial Anus Apparatus	1217567	1917
2. Cras Colostomy Appliance	1656328	1928
3. Koenig Colostomy Appliance	2048392	1936
4. Diack Colostomy Bag	2054535	1936
5. Geisler Colostomy Appliance	2129054	1938
6. Gricks Colostomy Apparatus	2154202	1939
7. Perry Colostomy Cup	2205270	1940
8. Carhart Colostomy Device	2294537	1942
9. Fenwick Colostomy Protector	2327514	1943
10. Marsan Colostomy Protector	2314724	1943
11. Fenwick Colostomy Pan	2380740	1945
12. Perry Stoma Receiver	2496175	1950
13. Ardner Colostomy Protector 2544579	2544579	1951
14. Van Hove Colostomy Receptacle	2549649	1951
15. Ginsburg Colostomy Apparatus	2595934	1952
16. Perry Stoma Receiver	2638898	1953
17. McConnell Colostomy Unit	2656838	1953
18. Fenton Device for Mounting Fecal Pouch	2818069	1957
19. Orowan Enterostomy Appliance	3100488	1963
20. Marsan to Hollister Sealing Pad for..	3302647	1967
21. Marsan Sealing Ring or Pad for...Pouch	3713445	1973
22. Neumeier Enterostomy Appliances	3964485	1976
23. Chen et al Ostomy Adhesive	4253460	1981



Davol Rubber Company reusable rubber drainable pouch on the left (1940s vintage)
Coloplast disposable drainable ostomy pouch (Ileo B) on the right (1970s vintage)



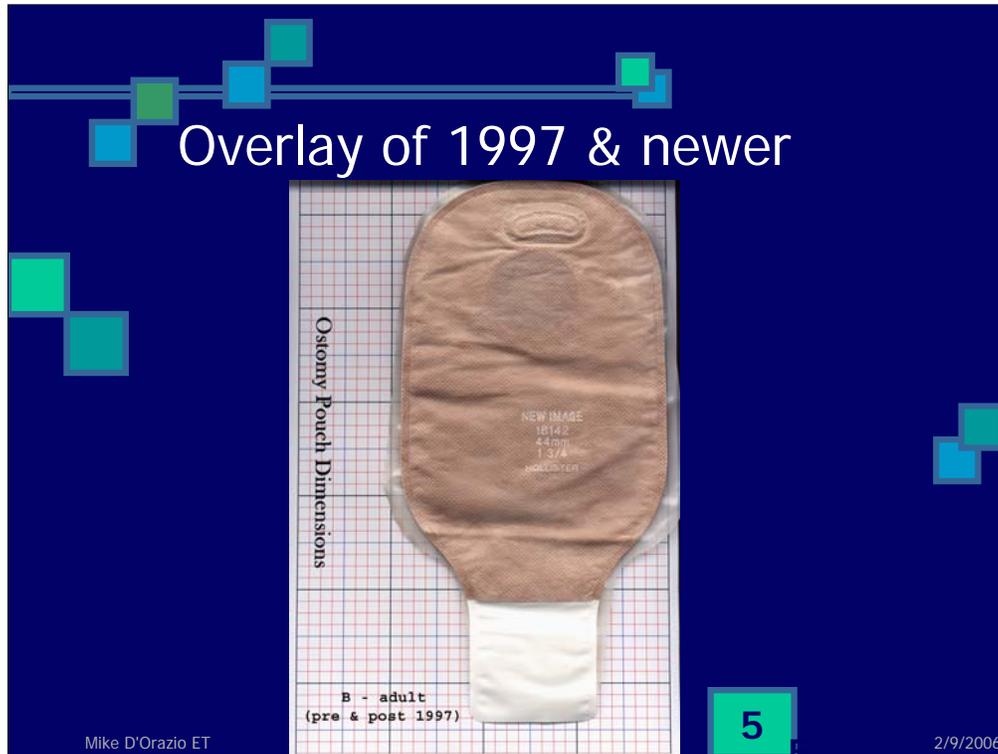
Hollister pre-1997 drainable & disposable pouch on the left (touted as 770 ml volume capacity) and referred to as adult size.

Hollister post-1997 drainable & disposable pouch on the right (touted as 625 ml volume capacity) and still referred to as adult size.

From about this time forward, the major ostomy pouch manufacturers in the US have adopted similar pouch design and volume configurations. In effect, there are no distinguishing shape or size features among the competitors. Groupthink has set in!

The irony lost in this observation is that in 1981 when Squibb launched its SurFit two-piece pouching system it set the trend for pouch shape and size that the other two players eventually mimicked. Squibb, the newcomer on the block, took the ostomy marketplace by storm and the former leaders merely mimicked Squibb's game plan by gradually adopting similar wafer technologies and bag shapes and sizes. Squibb did not give much thought to its own initial bag configuration, except to differentiate itself from the extant competitors' offerings.

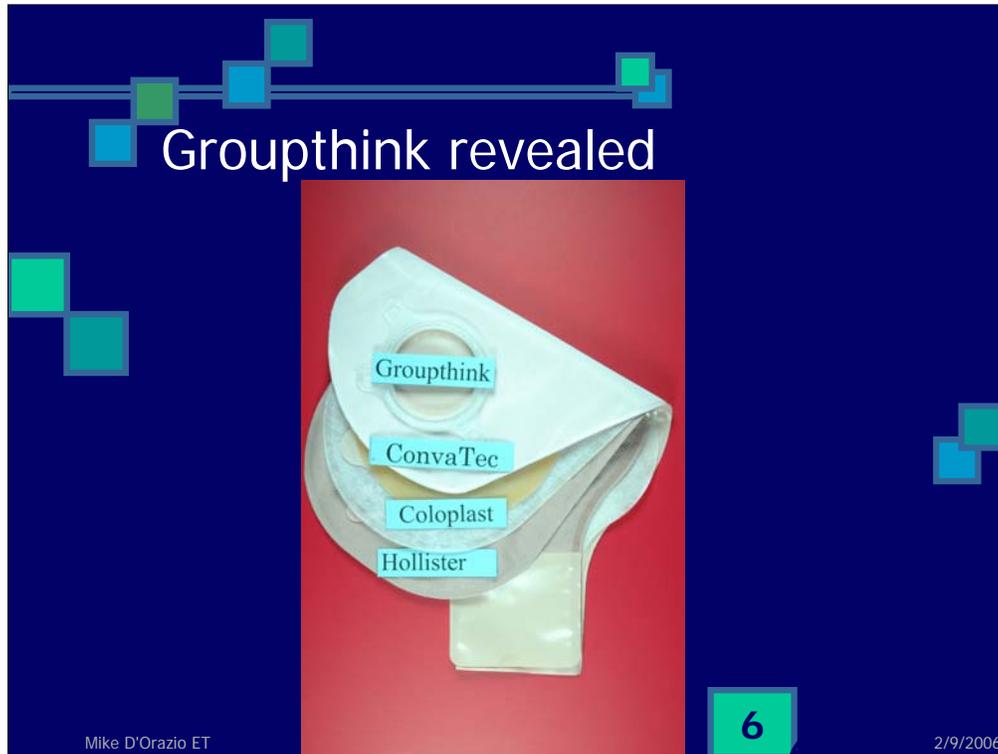
Sometimes, mimicking the competition, in an attempt to recoup ground, can backfire.



Reduced volume capacity of pouches induces more frequent emptying, whereas greater volume capacities permit less frequent need to empty, if ostomate so desires.

A smaller capacity pouch can not be made larger, however a larger capacity pouch can be treated as smaller. Frequency of pouch emptying is determined by effluent output rates and patient emptying preferences.

Put another way, you can not use volume capacity that is not there, however you can choose to do so if it is there.



Voila!! Flattery run aground!

Of late, since the late 1980s and mid 1990s, the big three ostomy pouch manufacturers have converged in the size and shape parameters of their pouches. In effect, their pouches share the same egg-shaped or jelly bean look, with no discernible difference in volume capacities among the standard or adult drainable pouches.

It begs the question: Why?



Photo taken in the mid 1980s.

All pouches are of adult or standard size

Hollister, ConvaTec and Coloplast are represented.



Pouches, previously unladen, are now filled with 150cc of water and allowed to distort or sag under their own loads.

Observe the degree of downward deformation or distortion the pouches undergo.

Also note the bulging or balling of the contents along the lower portions of the filled pouches – in effect, the walls of the pouches have distorted quite a bit from their unladen flat profile.

That is, except for one notable exception, the Coloplast Ileo B pouch with the blue & white striping pattern along the upper right corner of photograph.

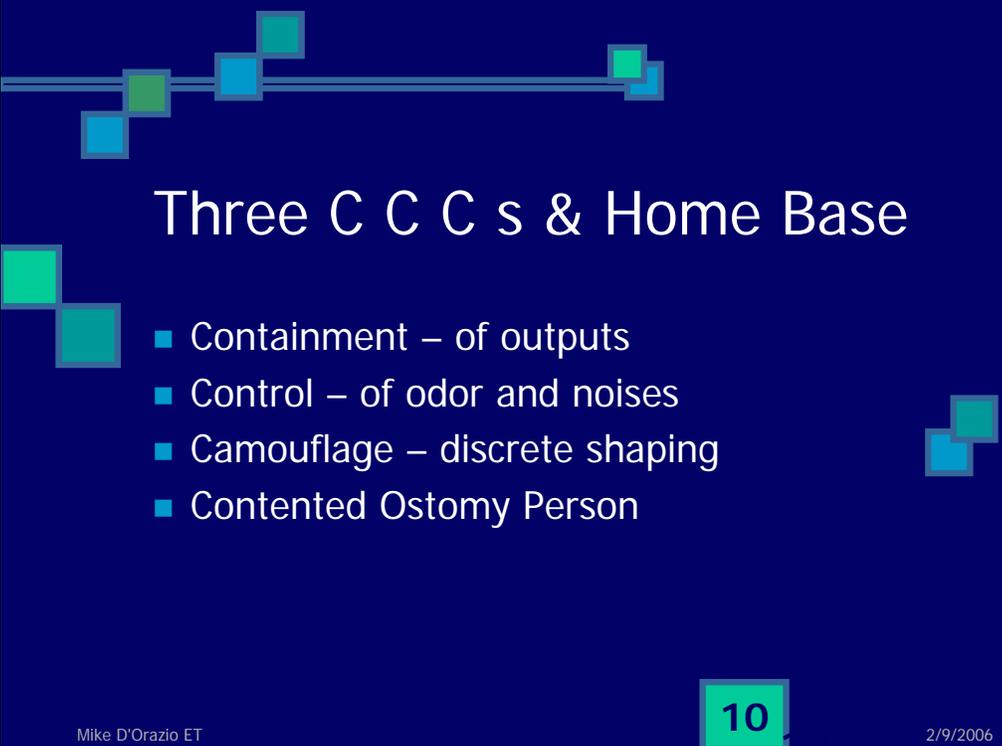
The purpose of this photo exercise is to reveal the flimsy characteristics of the pouch film or wall materials commonly employed by all the manufacturers today – even Coloplast has succumbed to the flimsy pouch film material. Their Ileo B pouch has not been made or available since the 1980s.



Series of photos that reveals the pouch distortion experienced by an ileostomate.

The weight and liquid nature of the effluent converging at the bottom of the pouch causes the pouch to act as a bola or swinging bolus, not unlike the weight at the bottom of a pendulum, that impinges upon the genitals.

Because the pouch film or walls are not “sturdy” enough to avoid distortion under load, the weighted contents of the pendulous bag are now bulging in appearance and threatening delicate body parts. There is a loss of any flattering profile once the effluent begins to fill the bag.



Three C C C s & Home Base

- Containment – of outputs
- Control – of odor and noises
- Camouflage – discrete shaping
- Contented Ostomy Person

Mike D'Orazio ET

10

2/9/2006

The Triad & COP

- ASS
- SPD
- PPP
- COP (contented ostomy person)

Mike D'Orazio ET

11

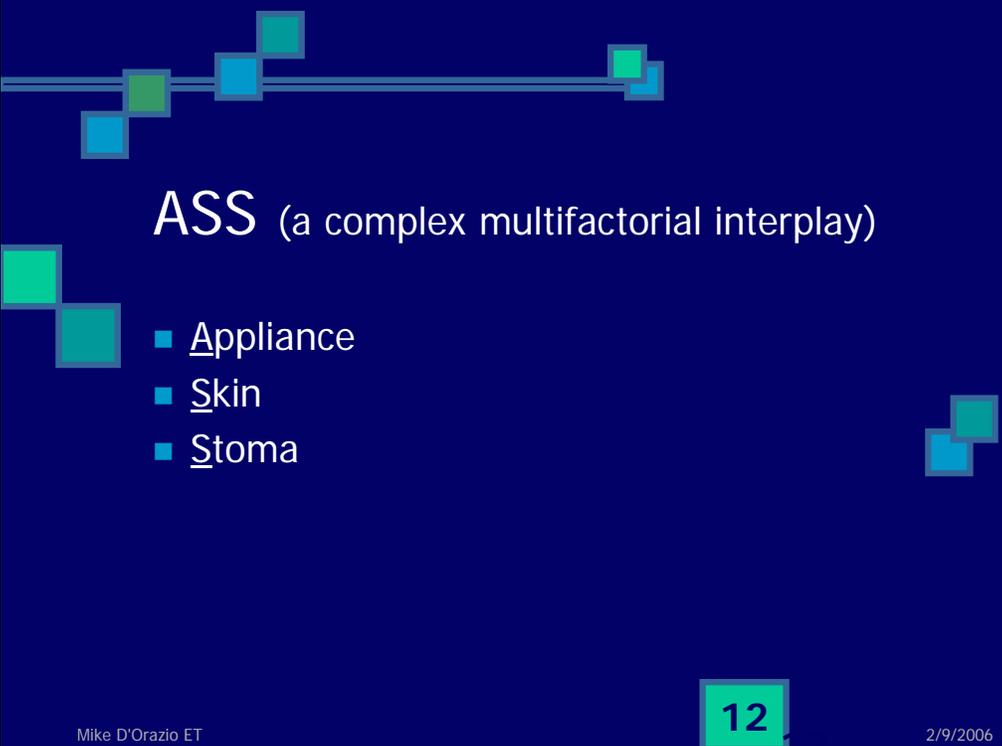
2/9/2006

The overall success of ostomy management rests with achieving and maintaining the triad. For decades, surveys and research papers have periodically addressed the quality of life (QoL) outcomes or shortcomings of incontinent ostomy management. There are many players involved with the rehabilitation of ostomates – surgeons, nurses, other caretakers, manufacturers and payers with varying degrees of competencies and interests.

I submit that we have not always done a very good job of it. Too many stomas are still poorly placed and constructed, even when they are elective. Too many post surgical caretakers are lacking the insights and skill sets to effectively, consistently and efficiently teach and correct for failed management strategies both in the short and long term periods. How else do you explain the prevalence of management problems with established ostomies? Some clinicians have been lured into the mantra of patient driven choice when deciding when and how much to intervene in or override patient decisions. The concept of comparative advantage or professional standing escapes their understanding of their unique roles and duties as fiduciary agents working on behalf of the patient. Manufacturers have been asked to assist in the ongoing rehabilitation needs of the ostomate. In some instances manufacturers have taken the initiative to co-opt some of the roles of the ET practitioners. Whether or not this was and is a good thing remains to be seen – I suspect it is not a good thing. In either case, taking the heat off the clinicians has enabled some of the clinicians to further abrogate their knowledge and practice responsibilities.

In the rush to correct the shortcomings of poor ostomy outcomes new innovations and ideas are proffered. The thrust to shift paradigms is rampant in some sectors of our society. Perhaps, we should step back and ask if we are offering the essential care and teaching or fine tuning that more readily addresses the shortcomings.

Human nature and human wants are quite complex and enduring concepts that make it difficult to achieve consistent and straightforward remedies for a whole host of life threatening and altering challenges. Nevertheless, one should not necessarily scurry about looking for innovative solutions or alternatives to straightforward shortcomings. Adaptation and adjustment to serious threats or outcomes, like ostomy, takes time and consistently applied and appropriate remedies. Fine tuning is often more useful than radical makeover.

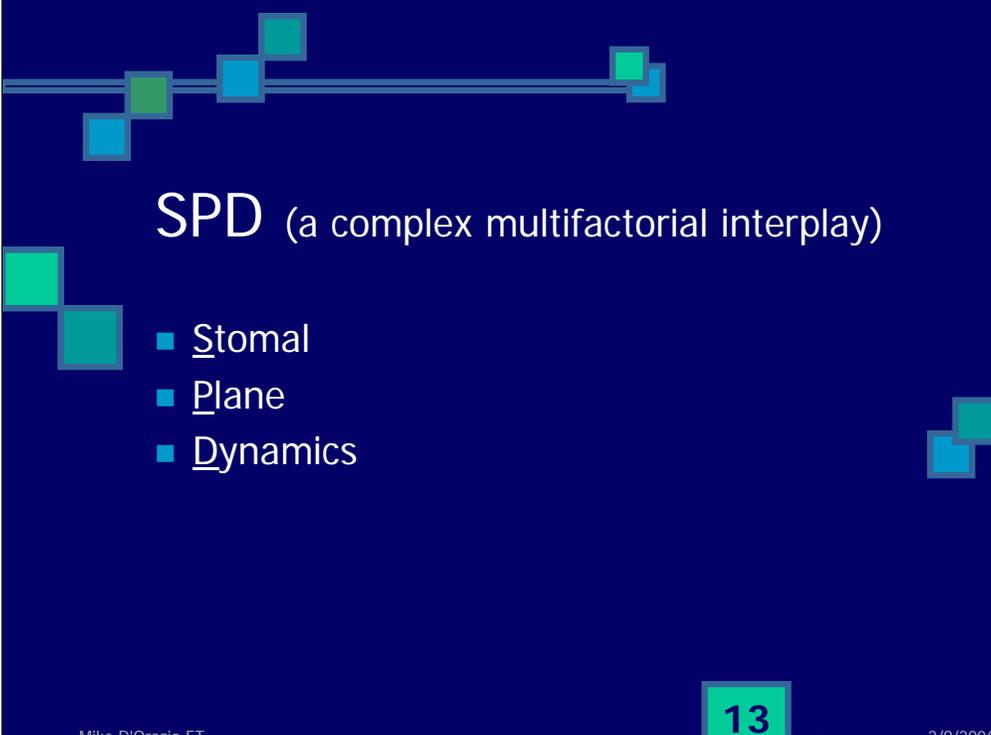


ASS (a complex multifactorial interplay)

- Apliance
- Skin
- Stoma

12

Mike D'Orazio ET 2/9/2006

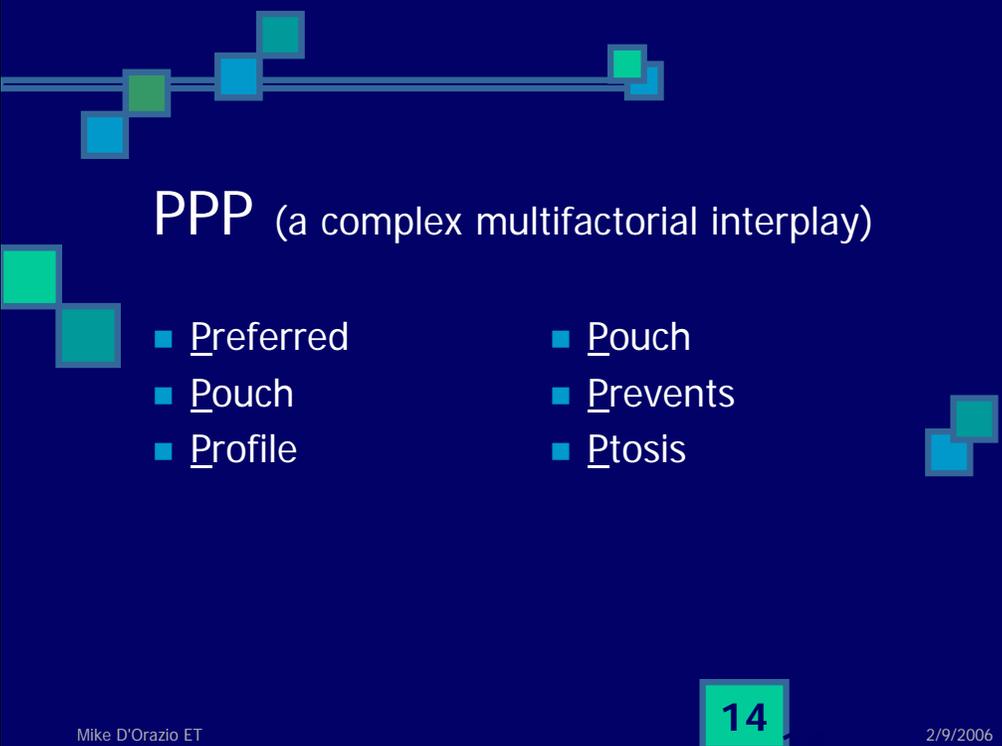


SPD (a complex multifactorial interplay)

- Stomal
- Plane
- Dynamics

13

Mike D'Orazio ET 2/9/2006



PPP (a complex multifactorial interplay)

- Preferred
- Pouch
- Profile
- Pouch
- Prevents
- Ptosis

14

Mike D'Orazio ET

2/9/2006

$\Sigma (ASS + SPD + PPP) = COP$

- Successful pouching system contributes greatly to a contented ostomy person
- Pareto optimality also achieved
- Achieving three bases (ASS + SPD + PPP) of successful ostomy management leads to a home run

Mike D'Orazio ET 15 2/9/2006

It should also be noted that numerous and apparently conflicting medical papers have been published that deal with the quality of life (QoL) issues of ostomy and non-ostomy diversions (IPAA, etc).

The American medical and surgical literature presumes that an ostomy outcome is significantly less desirable and therefore more likely to adversely affect QoL than a restorative proctocolectomy procedure (IPAA, etc). In contrast European reports show a more balanced perspective.

The best reading on these apparent contradictions is to realize that most patients prefer to be free of the symptoms and threats that serious bowel disease entails. If the physician or surgeon leans toward IPAA then that is what the ignorant patient will prefer. If the choice of ostomy or IPAA is offered, with the same degree of neutrality about risks, long term and short term, during and after the operation, then most patients will still opt for a non-ostomy outcome. The overarching motive for all surgical candidates is to not be seriously mutilated in appearance and function - for anybody contemplating surgery this is a no-brainer, even if it fails to consider the law of unimpeded effluent flow.

In fact, it is not uncommon to find patients with IPAA's or other internal reservoirs who persevere through prolonged and sometimes horrific and repeat complications and surgeries; who persist in preserving their non-ostomy lifestyles and very reluctantly succumb to an incontinent ostomy when all else fails.

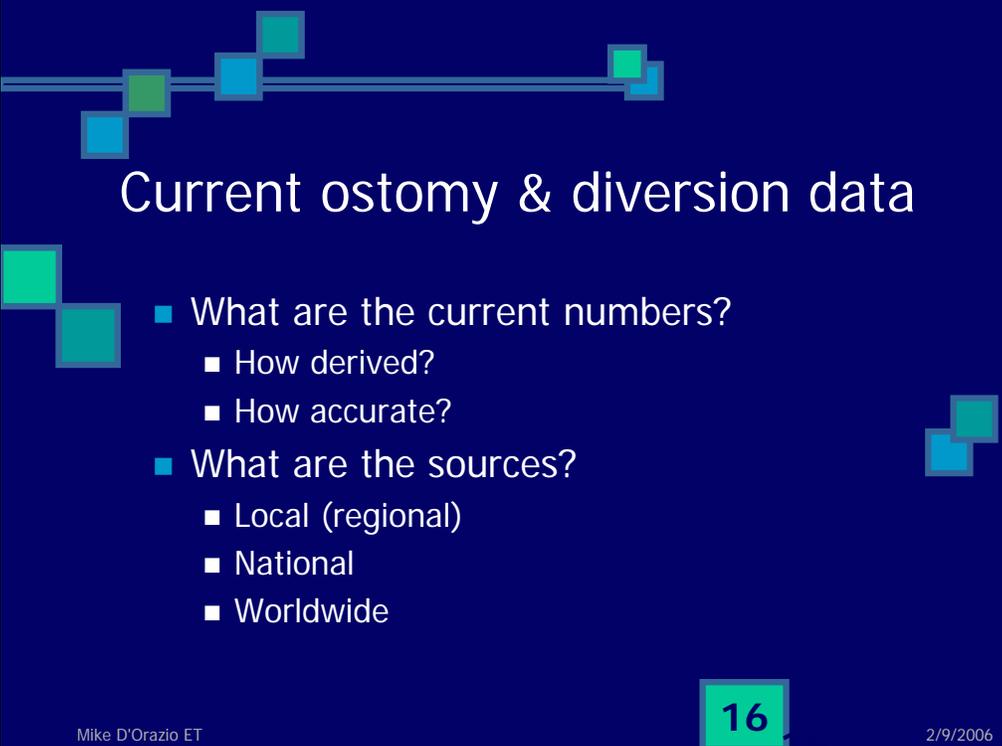
These same patients will, after a short period of adjustment to ostomy, come to realize that the ostomy is not all that troubling and fearful, even as their lifestyle is now more compromised secondary to the previous surgeries and increasing loss of bowel.

For decades, when incontinent ostomies were the only suitable recourse recommended by surgeons, the greatest majority of ostomates did quite well adapting and adjusting to life with an ostomy.

The long term outcomes of internal reservoirs have yet to be fully realized, but an a priori impression is that perverting the essential nature or unidirectional and unimpeded flow of the bowel and urinary tracts is inviting risks that may be greater than with an unimpeded ostomy.

Surgeons are doers and love a challenge! Nature is not a doer and is enough of its own challenge!

The rhetorical question remains: Why do we keep forgetting or ignoring basic physiological principles?



Current ostomy & diversion data

- What are the current numbers?
 - How derived?
 - How accurate?
- What are the sources?
 - Local (regional)
 - National
 - Worldwide

Mike D'Orazio ET

16

2/9/2006

For several decades the number 750,000 was touted as the extant population of ostomates among the US population. Not sure how this number came about, however, it had taken on a life of its own and was repeatedly used in the UOA & American Cancer Society (ACS) literature.

Given the trend away from permanent abdominal stomas, incontinent or otherwise, I suspect that the true count is much less than the 750,000 number.

What currently is not known is the rate of creation of new abdominal stomas, whether temporary or permanent, incontinent or otherwise, anywhere in the world.

Among potential and accurate local sources for arriving at reasonably accurate outcomes during specified time periods (annually) would be the operating rooms at hospitals that perform ostomy surgeries.

Another potential source for annual ostomy creations would be the WOCN or similar groups; however, the chance for data collection error may be greater since these group practitioners are not necessarily in attendance in the OR at every ostomy creation.

Perhaps the lay ostomy associations could be solicited for their membership data, however this too would not be representative of the full count since many ostomates escape the radar of the lay groups.

Achieving an accurate picture

- Reliance upon historical antecedents?
- Data sources:
 - Operating reports
 - WOCN
 - Lay groups
 - Surgeons
 - Governmental agencies
 - Private entities

Mike D'Orazio ET 17
2/9/2006

Private entities refers to those companies or entities that are in the business of capturing a range of health related data - IMS Health comes to mind here since they are actively doing an ostomy survey in Europe and the USA.

www.imshealth.com

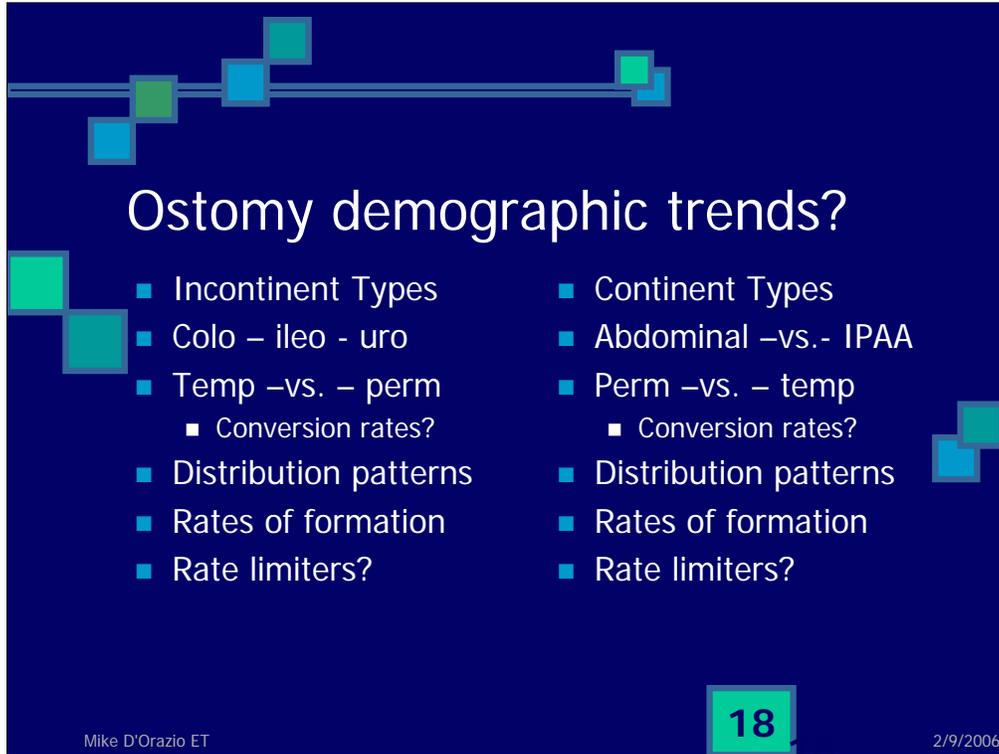
Stoma Patient Audit*: Comprehensive, pan-European database monitoring ostomy appliance market share in patient number terms at point of discharge from hospital, allowing users to predict future trends in overall community market share.

From the IMS Hospital division

IMS
Plymouth Meeting Executive Campus
660 W. Germantown Pike
Plymouth Meeting PA 19462-0905
USA
Tel: 1 (610) 834 5000

"Dadson, Sue (Sittingbourne)" <SDadson@uk.imshealth.com>

"Stoma Patient Audit is an on going project which has been running for over 20 years in GB and Europe and the US project has been running since the middle of 2003."



Ostomy demographic trends?

- Incontinent Types
- Colo – ileo - uro
- Temp –vs. – perm
 - Conversion rates?
- Distribution patterns
- Rates of formation
- Rate limiters?

- Continent Types
- Abdominal –vs.- IPAA
- Perm –vs. – temp
 - Conversion rates?
- Distribution patterns
- Rates of formation
- Rate limiters?

18

Mike D'Orazio ET 2/9/2006

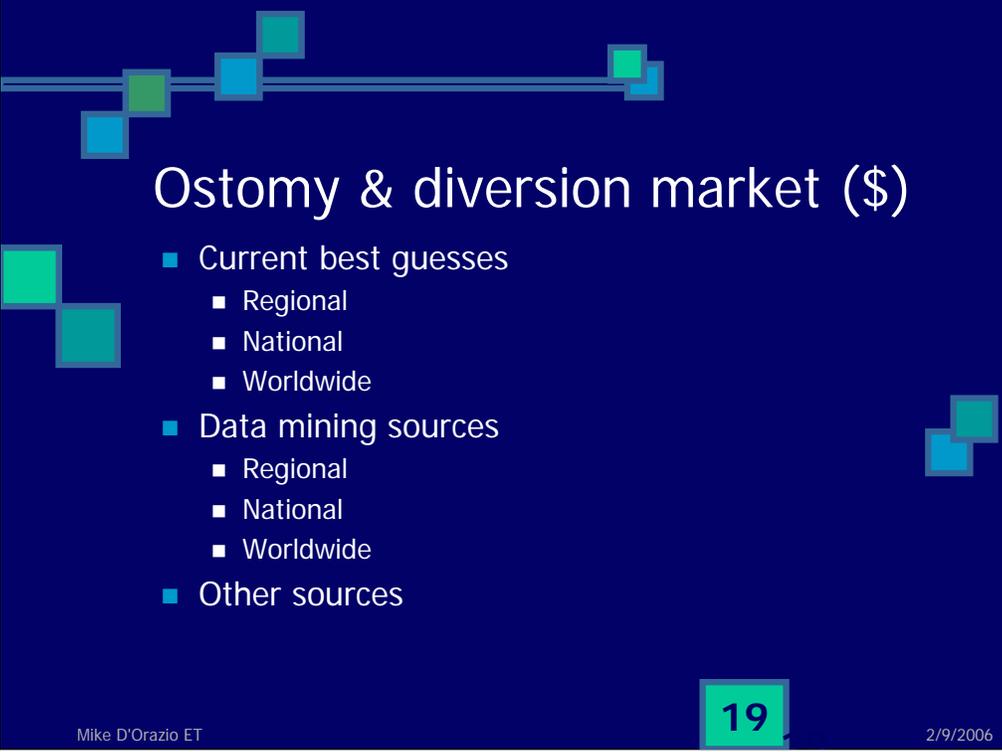
The notion of conversion rates refers to the situations whereby permanent or temporary ostomies change status for a host of reasons, planned or otherwise.

Distribution patterns refer to the locales (continents, countries, regions, states, cities, locales, hospitals, etc...) where ostomies are created and the percentage of ostomy types.

Rates of formation address the frequency each type of ostomy is created annually, semiannually, quarterly, etc...

Rate limiters attempt to identify those circumstances, innovations, discoveries, etc. that would alter the incidence rate of any abdominal ostomy type. For example, the emergence of the continent abdominal stoma procedures, as popularized by Kock and Barnett, have had a limiting effect upon the numbers of incontinent abdominal ostomies created. In like fashion the variations of continent urinary procedures have also impacted the outcomes of traditional incontinent abdominal urinary ostomies. Another example would be the introduction of the IPAA procedures which further reduced the numbers of abdominal ileostomies, incontinent or continent.

Another example of a rate limiter is the failure rate of non-ostomy procedures that result in ostomy creation, whether temporary or permanent.



Ostomy & diversion market (\$)

- Current best guesses
 - Regional
 - National
 - Worldwide
- Data mining sources
 - Regional
 - National
 - Worldwide
- Other sources

Mike D'Orazio ET

19

2/9/2006

Some have touted a range between \$USD1.0 to 3.0 billion.

This arena of speculation is up for grabs and self serving speculation.

Most likely the primary ostomy products manufacturers can shed the most accurate light on the numbers.

However, the manufacturers can only reasonably address product costs (sales) while the larger costs of ostomy creation, care and management expenses are spread among other venues.

Growth initiatives

- Blockbusters - revolutionary
- Steady improvements – “evolutionary”
 - The play on the word “evolutionary” is intentional
- Revisiting continent ostomy devices
 - 1980s to 1990s showed a spate of interest in such devices
 - Were interests sidelined by IPAA?

20

Mike D'Orazio ET 2/9/2006

The blockbuster concept has an enduring appeal. Dreamers and innovators are the lifeblood of progress. In like fashion charlatans and fakers also troll the arenas of desperation and turmoil. Sometimes serendipity propels progress. Even eureka moments can give rise to useful discoveries.

However, in spite of the best intentions and strongly held beliefs, meaningful progress and innovative strategies must be pursued without adversely affecting patient well being. The medical history is replete with evidence of risks-benefits scenarios. The long view, by its very nature, is not an instantaneous moment of insight. Long term outcomes of any new or innovative technique or device will be revealed eventually. In the short run, pioneers and innovators struggle to sway the marketplace. However, what are their culpabilities when the passage of time reveals the harms that may also arise from their enthusiasms?

When I was first presented with the necessity of an ileostomy, at the tender age of 20 years, I pleaded strongly for an alternative – an artificial replacement or a transplanted colon. I was told these options did not exist. After the ostomy, and with the onset of sore peristomal skin secondary to faulty post operative care, I begged for the skin nerves to be cut so I may be free of the pain from stool leakage. Again, I was told this was not feasible. Eventually, someone got it right and my ostomy care improved with better teaching and management skills.

The lessons I take away from my own early experiences are that understanding the changeable functions of the human body and integrating reasonable solutions to problems can help greatly in allowing one to adapt and adjust to life with an ostomy.

Lure of "COP" (Continent Ostomy Port)

- Who or what prompted interest?
- How do you see its potential?
- How committed are you to it presently?

Mike D'Orazio ET

21

2/9/2006

The concept of an ostomy occlusion device is not a new one. There was a spate of activity in this area during the decade of the 1980s preceding the emergence of the IPAA.

Animal and human trials on occlusive stoma devices were typically of short duration (weeks to months) and with mixed results. While some investigators touted the efficacy of doing this procedure others expressed concerns about the changing bacterial flora secondary to the stasis effects. In order to achieve success the bowel had to undergo a period of accommodation to progressive dilatation or distension that was highly variable and painful. Those studies on dogs or piglets were less revealing about the visceral or somatic complaints of pain as found in the human populations.

As late as 1995 a multi center study from Italy utilizing the Conseal foam plug revealed limited applicability for ileostomized patients. Perhaps Coloplast could shed further light on this outcome?

An aborted trial in the early 1980s by J&J found that the only ileostomy patients able to tolerate the port without early symptomatic distress were those patients who already had a significant amount of prestomal dilatation secondary to a narrowed stomal tract. For many of the patients, the unusual angulations of the bowel proximal to fascial planes presented additional significant challenges for the port's placement and function.

"COP" explored

- Seductive concept
- Gamut of human responses:
 - From rejection to desperation
- How does it work
- Learning curve?
- On whom will it work?

22

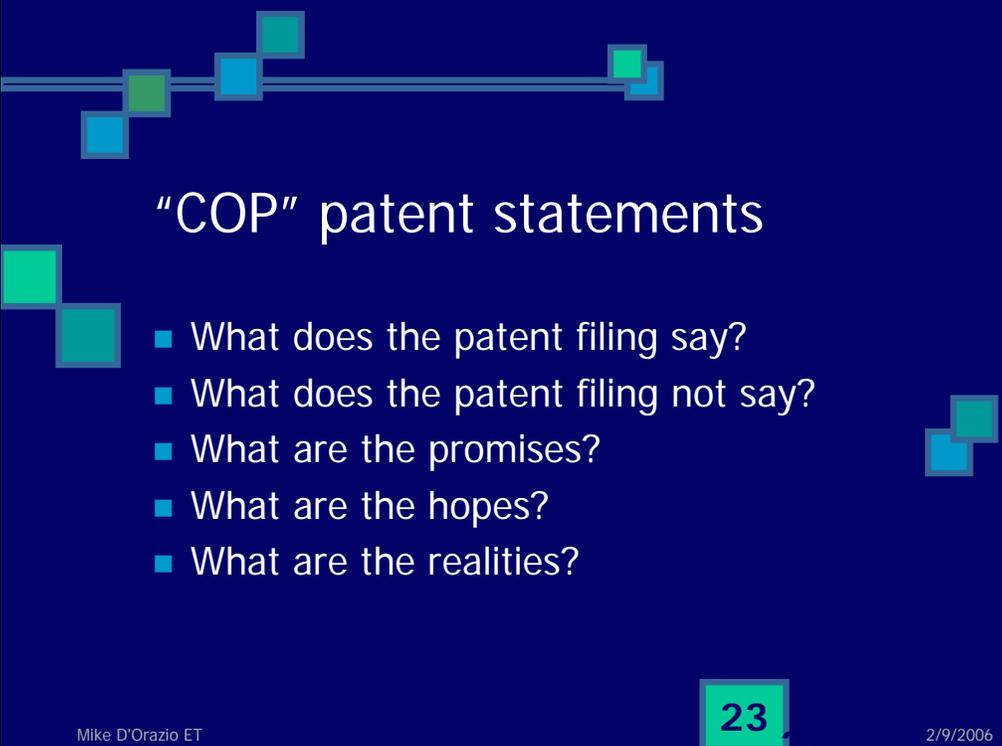
Mike D'Orazio ET 2/9/2006

Learning curve:

- ❖ Who is going to teach the COP concept?
- ❖ How will suitable candidates be selected, and by whom?
- ❖ How long will it take to master the learning and teaching of the COP
- ❖ Where will the teaching take place?
- ❖ Who will pay for the teaching?

On whom will it work:

- ❖ Colostomies – all types?
- ❖ Ileostomies – all types?
- ❖ Urostomies – all types?
- ❖ Contraindications:
 - ❖ Long stomas?
 - ❖ End versus loop stomas?
 - ❖ Angular stomal tracts?
 - ❖ Adhesions?
 - ❖ Strictures – stenoses?
 - ❖ Etc...?



"COP" patent statements

- What does the patent filing say?
- What does the patent filing not say?
- What are the promises?
- What are the hopes?
- What are the realities?

23

Mike D'Orazio ET 2/9/2006

Because an idea or concept is patented does not mean that it is useful or doable.
The patent files are loaded with ideas and concepts that do not pan out as intended.

"COP" Culpabilities (?)

- Perforation
- Bleeding
- Obstruction
- Infection
- Stasis
- Inflammation
- Pain
- Toileting anxiety
 - From sit-flush-forget
 - To how-when-where
- Toilet tethering
- Selection conflicts
- Expectation conflicts
- Blame transference
 - From practitioners
 - To manufacturers

24

Mike D'Orazio ET

2/9/2006

Unlike physicians and surgeons, who typically obtain permission to perform their non-guaranteed procedures, product manufacturers are at greater legal risk should things go awry – implicit and explicit warranty of merchantability. Medicine / surgery is still accorded greater leeway when it comes to accountability – in large measure because society accepts the notion that it is as much art as it is science. A trusted patient-doctor/health worker relationship helps to buffer the health profession from animus when things do not work out as initially planned or desired.

Well meaning and skillful surgeons can promise their patients the moon and still get away with only a meteor fragment as the end result. But, let a manufacturer's product cause harm, directly or otherwise, and the wrath of the legal profession will be brought to bear much sooner.

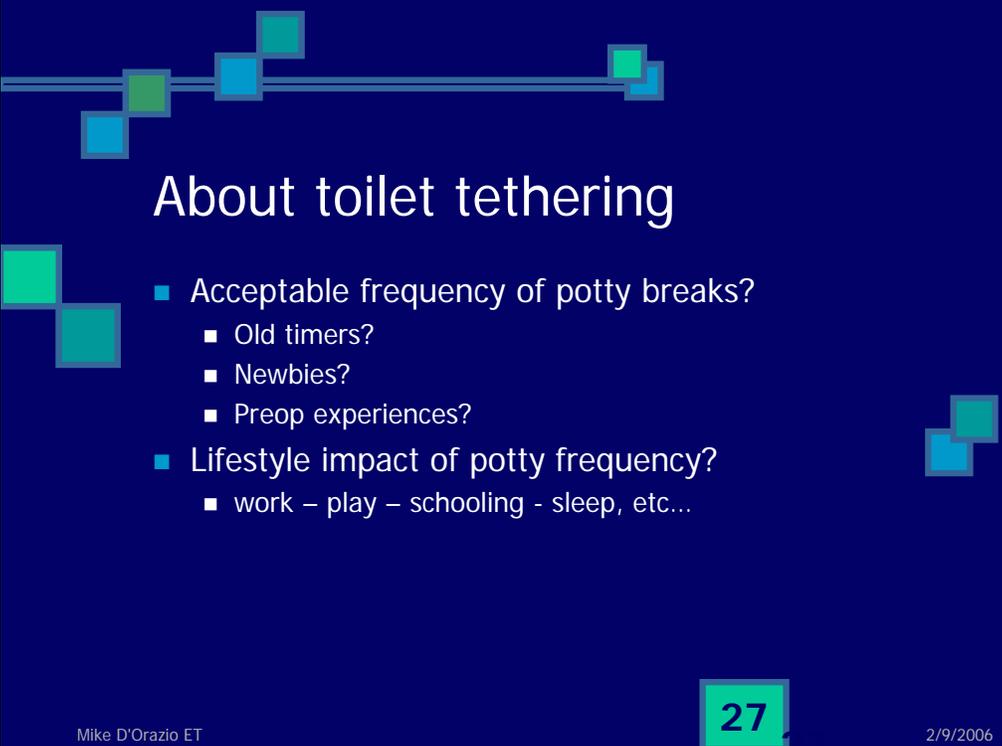
The more invasive the device the greater the legal jeopardy. Current ostomy collection devices are rated as class one objects under C.F.R. guidelines. Internal ports would likely require at least a class two rating, with a commensurate increase in risk profiles.

About toileting & ostomy patterns

- How often does one modify their potty routine?
- Explain the range of reactions to threatened potty integrity.
- Explain the adjustment reactions to threatened potty.
- Explain the accommodation/resolution processes to altered potty via ostomy.
- Explain the reluctance to modify altered ostomy potty.
- Explain the quest for alternative ostomy potty routines.

Altered potty routines

- Acceptable stool handling techniques?
- Acceptable stool disposal techniques?
- Acceptable potty time management?
- Cultural attitudes toward potty behaviors?
- Cultural responses to altered potty?
- Economics of altered potty?
- Environmental impacts of altered potty?



About toilet tethering

- Acceptable frequency of potty breaks?
 - Old timers?
 - Newbies?
 - Preop experiences?
- Lifestyle impact of potty frequency?
 - work – play – schooling - sleep, etc...

27

Mike D'Orazio ET

2/9/2006

Prima facie principles
abiding by well ordered schemes of Mother Nature

- Small intestinal tract
 - No parking or stopping to smell the bacteria
 - Absorption and transport
 - Unidirectional flow - to the cecum
- Ureter(s)
 - No parking or stopping to smell the bacteria
 - Transport only
 - Unidirectional flow to the bladder

Mike D'Orazio ET 28 2/9/2006

W.M.Bayliss and E.H.Starling published their paper "Movements and Innervation of the small intestine" (*J.Physiol.* XXIV: 98-143, 1899), in which they formulated the "Law of the Intestine".

A stimulus within the intestine, i.e., the presence of food, initiating a band of constriction on proximal side and relaxation on distal side. This results in a peristaltic wave.

and

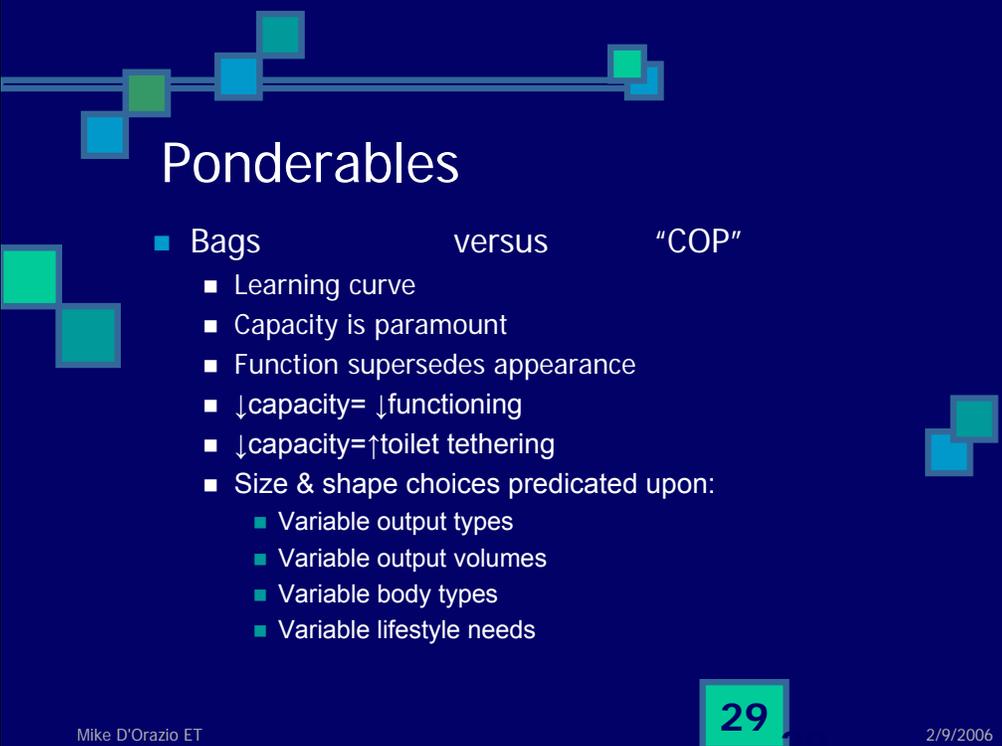
Local stimulation of the gut produces excitation above and inhibition below the excited spot. These effects are dependent on the activity of the local nervous system, also called the enteric nervous system (ENS).

In general, Bayliss & Starling's discoveries of revolutionary and rudimentary physiological properties, have held up under repeat scientific scrutiny.

One should always be mindful of the way the human body has operated for many thousands of years.

When contemplating remedies for failed organ functions, one should not lose sight of the normal operative behavior of the healthy organ.

In the case of the bowel and urinary tracts, the concept of unimpeded luminal and unidirectional (cephalad to caudal) flow of effluent is a prima facie fact that should not be ignored or dismissed when attempting to correct for an underlying disease or injury.



Ponderables

- Bags versus "COP"
 - Learning curve
 - Capacity is paramount
 - Function supersedes appearance
 - ↓capacity= ↓functioning
 - ↓capacity=↑toilet tethering
 - Size & shape choices predicated upon:
 - Variable output types
 - Variable output volumes
 - Variable body types
 - Variable lifestyle needs

Mike D'Orazio ET

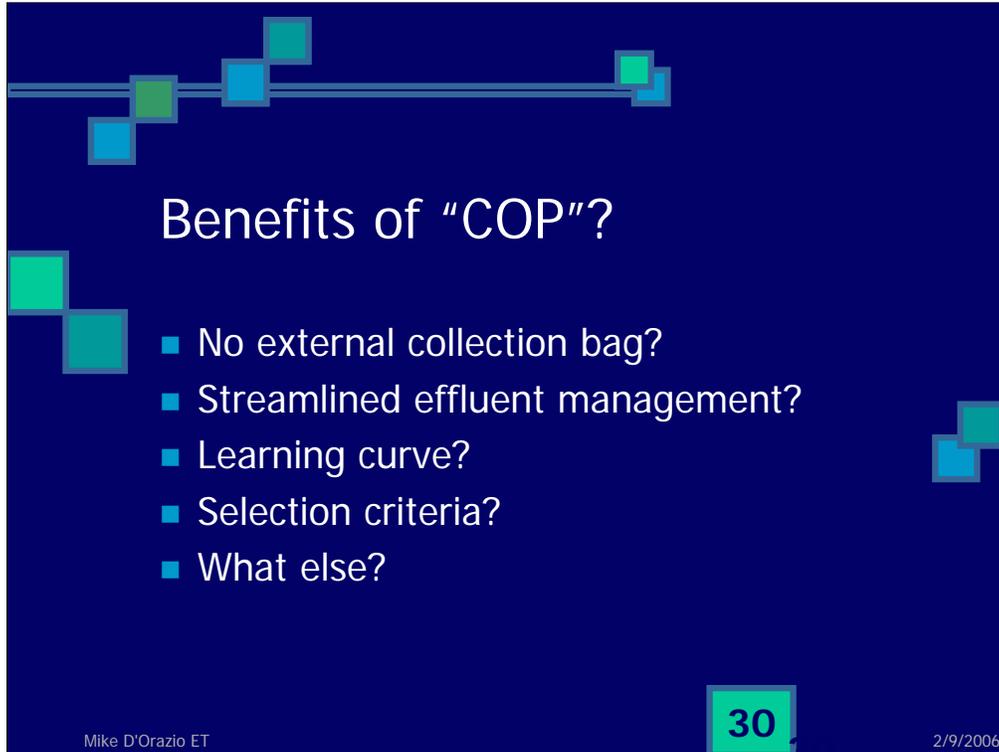
29

2/9/2006

Capacity:

What is the likely tolerable capacity of the distended bowel (lumen) versus a filling bag?

What is the likely frequency rate of emptying a bag versus accessing the port for drainage?



Benefits of "COP"?

- No external collection bag?
- Streamlined effluent management?
- Learning curve?
- Selection criteria?
- What else?

Mike D'Orazio ET

30

2/9/2006

According to the patent filing claims, the use of a collection pouch is still considered when the port is opened for release of the non gaseous effluent. What will a patient have gained if a pouch is still required with the COP? Into what kind of a receptacle will the effluent be contained?

Current continent ileostomates (Kock or Barnett types) use a catheter to drain the internal reservoir, while at times finding the need to flush out the contents. What will COP candidates use to evacuate their stoma should the need arise?

How does one effectively select suitable numbers of COP candidates who do have adhesions or the risks for post operative adhesions, especially when the reported incidences for post op intraabdominal adhesions is conservatively placed at 60%?

Typically, the diagnoses of adhesions and related sequelae are made only after obstructive episodes arise and other causative entities are ruled out.

Risks of "COP"

- Stasis outcomes
- Trauma outcomes
- Jilted performance expectations
- Selection criteria pitfalls
- Learning curve
- What else?

Mike D'Orazio ET

31

2/9/2006

What percentage of COP clients are likely to experience exacerbated intestinal distension complaints secondary to the port precipitating or prolonging an obstructive episode? Put another way, is the port likely to induce an obstructive process in those patients who have adhesions, but who have yet to experience intestinal obstruction?

Does the potential exist for the port to contribute to a closed loop obstruction, wherein a segment of obstructed bowel arises between an adhesive stricture or kink and the port?

Has anyone addressed the luminal stasis risks, with its associated bacterial overload and transmural migration of organisms, with the use of the COP?

What of patients with functional gastrointestinal disease/disorder (FGID) or irritable bowel syndrome (IBS) or residual / recurrent Inflammatory bowel disease (IBD)? Many ostomates, not afflicted directly with cancer or diverticular disease, may still be afflicted with some of these entities.

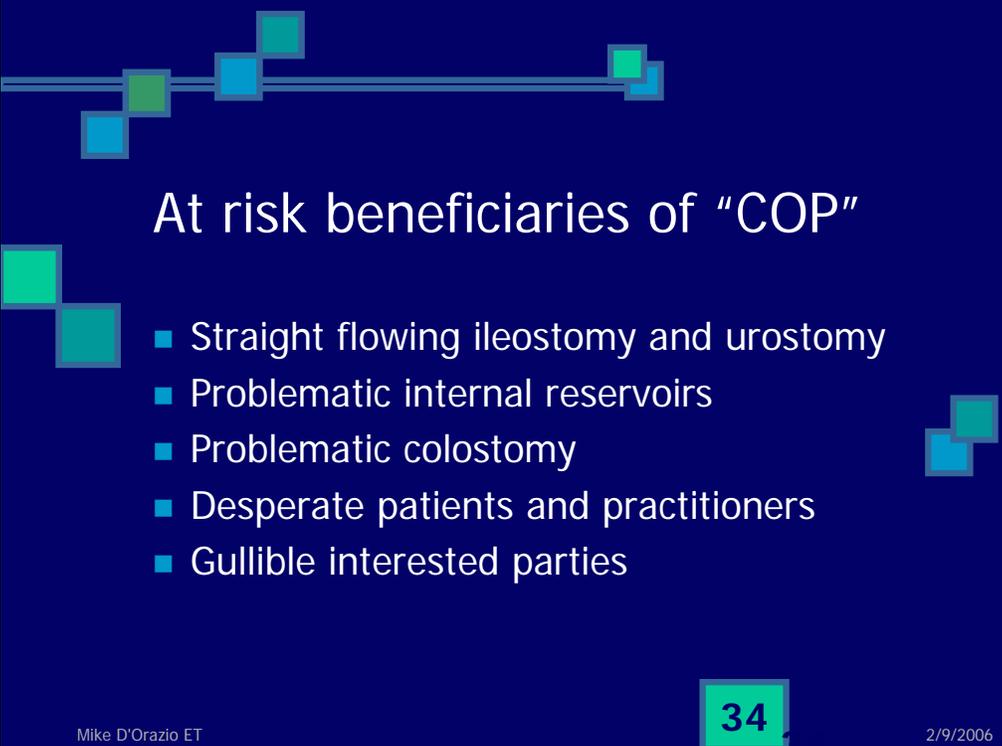
What is the expected duration of wear or insertion for the port? What criteria are utilized to determine the safety profile and use guidelines for the COP?

Liability transfer

- Surgical attempts, via internal reservoirs, to obviate the need for external effluent storage collectors place the surgeons at risk for mishaps.
- What risks are “inherited” by manufacturers as they attempt to supplant surgically derived internal storage devices with a COP?

Likely "COP" beneficiaries

- "Some" colostomates
- Perhaps some internal reservoirs with abdominal stomas
- Some ileostomates?
- Who else?



At risk beneficiaries of "COP"

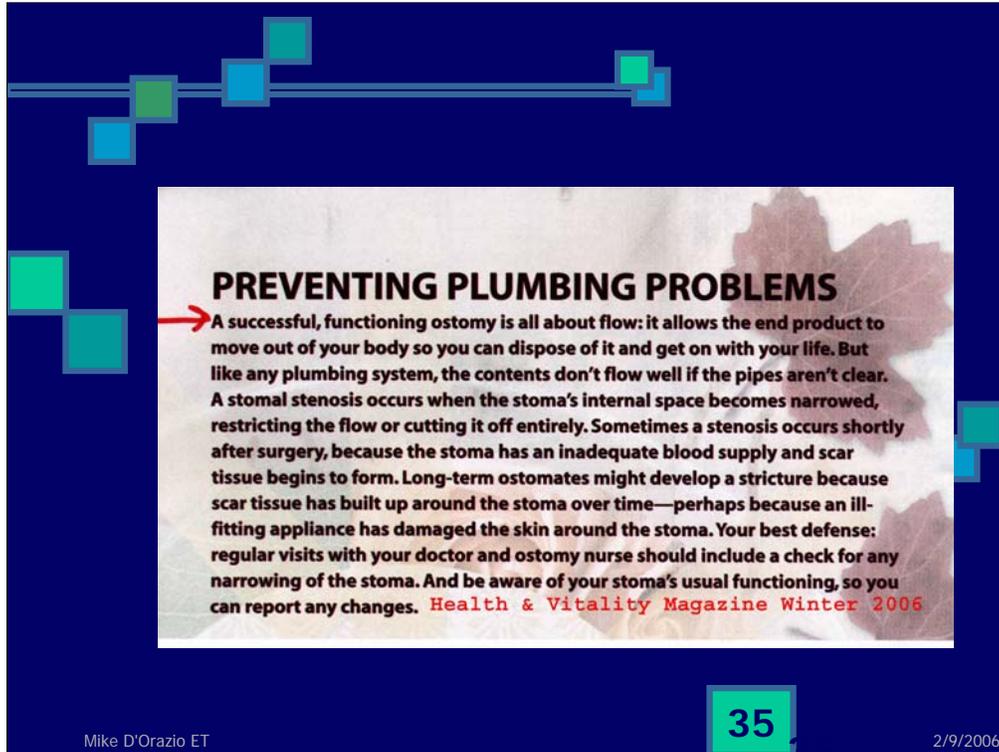
- Straight flowing ileostomy and urostomy
- Problematic internal reservoirs
- Problematic colostomy
- Desperate patients and practitioners
- Gullible interested parties

34

Mike D'Orazio ET 2/9/2006

The port now impedes luminal free flow.

Internal reservoirs at risk for pouchitis and or bacterial overload are likely poor candidates for COP.



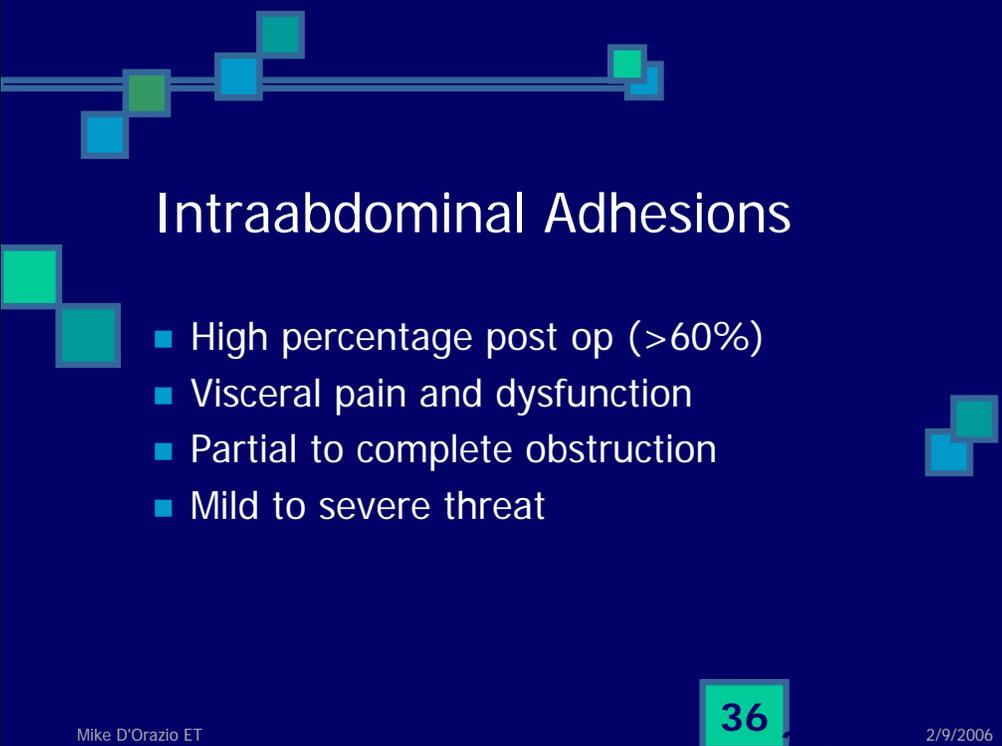
PREVENTING PLUMBING PROBLEMS

→ A successful, functioning ostomy is all about flow: it allows the end product to move out of your body so you can dispose of it and get on with your life. But like any plumbing system, the contents don't flow well if the pipes aren't clear. A stomal stenosis occurs when the stoma's internal space becomes narrowed, restricting the flow or cutting it off entirely. Sometimes a stenosis occurs shortly after surgery, because the stoma has an inadequate blood supply and scar tissue begins to form. Long-term ostomates might develop a stricture because scar tissue has built up around the stoma over time—perhaps because an ill-fitting appliance has damaged the skin around the stoma. Your best defense: regular visits with your doctor and ostomy nurse should include a check for any narrowing of the stoma. And be aware of your stoma's usual functioning, so you can report any changes. *Health & Vitality Magazine Winter 2006*

35

Mike D'Orazio ET 2/9/2006

ConvaTec's consumer magazine gets it right in the first sentence.



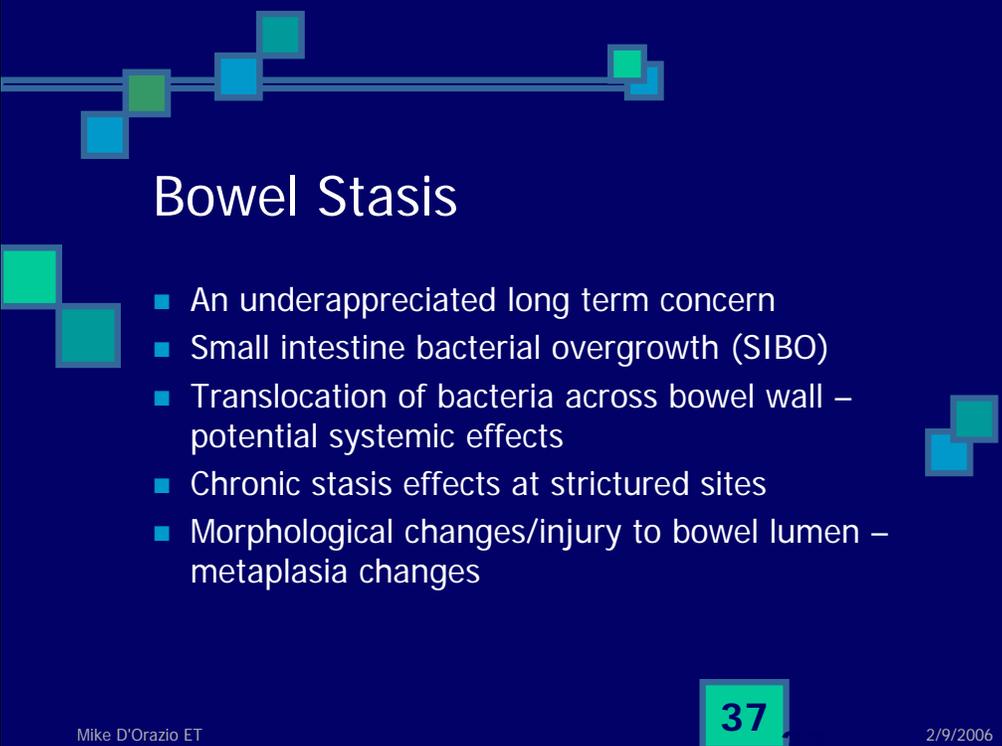
Intraabdominal Adhesions

- High percentage post op (>60%)
- Visceral pain and dysfunction
- Partial to complete obstruction
- Mild to severe threat

36

Mike D'Orazio ET

2/9/2006



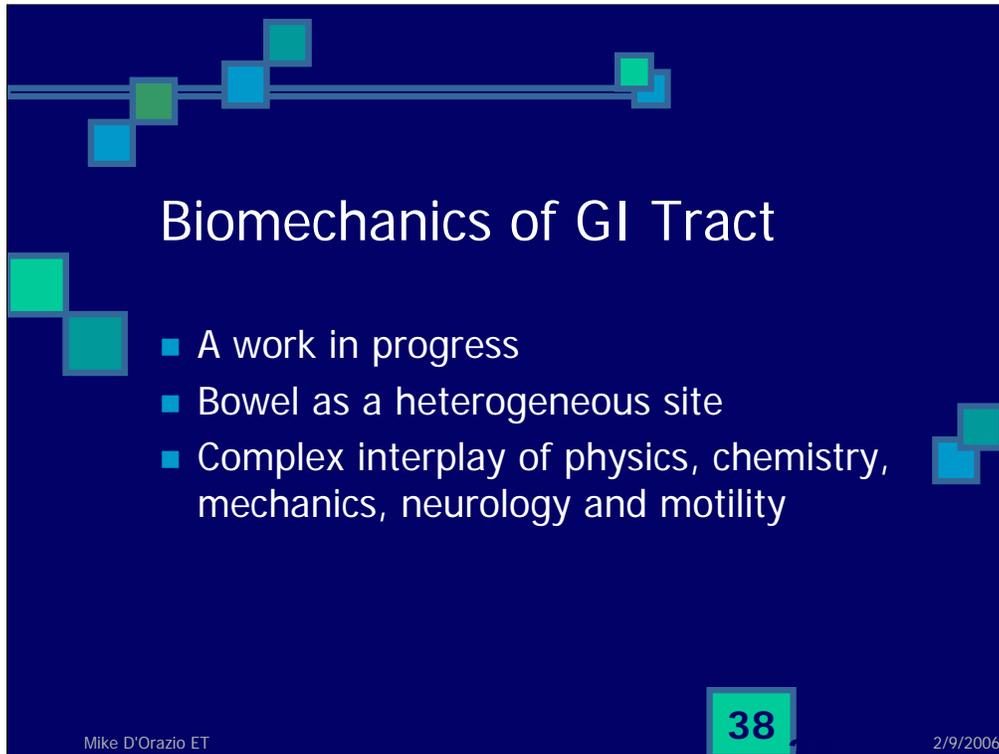
Bowel Stasis

- An underappreciated long term concern
- Small intestine bacterial overgrowth (SIBO)
- Translocation of bacteria across bowel wall – potential systemic effects
- Chronic stasis effects at strictured sites
- Morphological changes/injury to bowel lumen – metaplasia changes

37

Mike D'Orazio ET

2/9/2006



Biomechanics of GI Tract

- A work in progress
- Bowel as a heterogeneous site
- Complex interplay of physics, chemistry, mechanics, neurology and motility

38

Mike D'Orazio ET 2/9/2006

Book: Biomechanics of the Gastrointestinal Tract
Author: Hans Gregersen
Publisher: Springer-Verlag, London
Date: 2003
ISBN: 1852335203

“It is reasonable to assume that more or increasingly complex geometries of the GI tract occur secondary to abdomino-pelvic surgeries resulting in bowel and or bladder resections, reconnections, repositionings, ostomy creation and internal reservoirs. A case in point is the high incidence of postoperative adhesions found and or experienced status post ostomy related surgeries. Another case in point is the incidence of narrowing, stricturing or stenosing of segments of bowel post surgical and radiation interventions and from disease processes.” MLD, 2006

Consider the following

Pseudo obstruction	Pain	Variable device lengths	Variable device diameters
Customized inflation	Adhesions history	strictures, etc...	Luminal angulations
Changing weight	Dietary habits	Accommodation period	Accommodation capacitance
Learning curves	Stasis effects	Institutional knowledge	Long term efficacy

39