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Reusable and Disposable Adipose Cannulas: History, Costs, Concerns.

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Reusable and Disposable Adipose Cannulas: History, Costs, Concerns

Summary

Liposuction (the removal of unwanted adipose, or fat, tissue from the body) and autologous fat transfer (the transfer of fat from one region of a patient's body to another) represent nearly $1 billion of the plastic and cosmetic surgery procedures conducted in the United States (2006). This figure is much higher when non-board certified plastic and cosmetic surgeons who also perform these procedures are considered (e.g., dermatologists, dentists, etc.). By and large, most of these procedures are elective surgery such that insurance does not provide coverage. These procedures are almost entirely paid for by patients. These procedures almost always require the use of devices referred to as "cannulas" to remove and/or transfer fat tissue. Cannulas consist of a hub that connects with a syringe or suction device, and a long, blunt-end tube with ports or holes on the sides near the closed, blunt end where the fat enters and/or leaves the tube. By and large, the vast numbers of adipose cannulas used in these procedures are reusable in nature, that is, they are used on multiple patients over many years. Prior to each use, reusable adipose cannulas are cleaned, sterilized and stored to, hopefully, prevent cross-contamination (bacterial or virus, for example) between patients. The cleaning typically involves washing/scrubbing the cannulas with chemicals to remove remaining tissue, and then the cannulas are sterilized using high-temperature steam (autoclaving). The chemical wash is often diluted and disposed of through the plumbing system of the facility where the procedure is conducted. However, despite these efforts, cases of cross-contamination using reusable adipose cannulas have been reported, with the first such cases in the United States reportedly occurring in California. An alternative to reusable adipose cannulas, i.e., disposable adipose cannulas, are one-time use only devices which packaged and sterilized and then are disposed-of following the adipose removal or injection procedure. These devices are disposed-of in the same accepted manner as other disposable medical devices such as syringes and needles – in general, they are incinerated by regulated organizations, with no pollutants entering the environment (the non-contaminated residue ash remaining from these devices is often placed in land-fills). Both types of cannula devices are regulated for commercialization by the United States Food and Drug Administration; however no regulations or laws exist which set forth the number of times that a reusable adipose cannula can be used; the number of patients that reusable adipose cannulas can be used upon before being discarded and replaced; or the number of years that reusable adipose cannulas can be used by a physician before they must be discarded and replaced. Patients are rarely if ever informed that the reusable adipose cannula being utilized for a procedure has been used on other patients, the number of previous patients a particular cannula has been used upon, or the number of years that a particular reusable adipose cannula has been utilized. Although the number of cases of contamination are low, the issue surrounding this information is considered important to be provided to patients in that these procedures require the insertion of a previously-used medical device into the body of the patient, and because these procedures are elective in nature and not covered by insurance (and therefore represent an often significant out-of-pocket expense to the patient or care-giver).

Liposuction Background

The medical practice of removing excess adipose (fat) tissue from localized areas of the body has existed since 1921, when a French physician, Charles Dujarrier, attempted to remove subcutaneous fat using a uterine curette on a dancer's calves and knees. Unfortunately, a tragic result occurred due to injury of the femoral artery of this patient, leading to amputation of one of the dancer's legs. The practice essentially went dormant with intermittent use (and often less than desirable results) for about 55 years, when the modern era of localized fat removal began.

In 1976, two brothers working in Rome, Arpad and Giorgio Fischer, published results of their work describing the development and use of a blunt-ended hollow cannula equipped with suction to remove fat tissue from localized areas of the body. The use of suction and cannulas enabled large amounts of fat to be removed from the abdomen and other areas through incisions which were very small compared to traditional surgical incisions. It was after the success of this approach that the term “liposuction” began to be used to describe the procedure. The cannulas were smaller and less aggressive in design than the uterine curettes that had been previously used. The tips of the cannulas were blunt or rounded, and the holes or "ports" were on the side of the cannula shaft, rather than on the end. This design approach allowed for a much more even removal of fat, with far less trauma to the tissues.

Liposuction procedures began in the United States in the late 1970’s. Dr. Julius Newman, a cosmetic surgeon, and his associate Dr. Richard Dolsky, a plastic surgeon, are credited with having taught the first American course on liposuction in Philadelphia in 1982. The first live surgery workshop was reportedly held in Hollywood, California, in June 1983 under the direction of the American Society of Cosmetic Surgeons and the American Society of Liposuction Surgery.

In 1987, Dr. Jeffery Klein reported on his development of tumescent anesthesia to be used in conjunction with liposuction. This innovation involved infiltration of a large volume of saline, plus a dilute solution of lidocaine with epinephrine, into the area of fat tissue to be removed, which allowed more extensive liposuction exclusively by local anesthesia. Tumescent anesthesia revolutionized the field of liposuction for all specialties. It has been suggested that the tumescent technique has been the key to the safety and accuracy of modern liposuction, and has been recognized throughout the world for its importance. Even more important was the impact that the tumescent technique had on the safety of liposuction because the technique eliminated the need for general anesthesia, which allowed for the procedures to be performed outside of a hospital setting. In addition to the patient being awake, in control of their own breathing and other bodily functions, and being able to constantly communicate with the surgeon, bleeding was dramatically reduced.

While some specialties continue to perform liposuction in a hospital-based setting, surgeons have clearly shown that tumescent liposuction is safe as an office-based outpatient surgical procedure. The vast majority of these procedures are conducted in non-hospital settings.

Applicable Procedures

There are two primary medical procedures that involve the use of adipose cannulas: liposuction and micro lipo-injection (or "autologous fat transfer").

In general, liposuction procedures involve the removal of large quantities of fat tissue, with the overall objective usually being reshaping or contouring the shape of the body. In these procedures, the fat that is removed is properly discarded. Autologous (which in this context means the donor and recipient are the same person) fat transfer is a relatively recent innovation. Fat is living tissue and as such, it can be moved from one area of a patient's body and transferred to another area to act as a "filler." The filler is the patient's own living tissue, and patients who may be allergic to other types of fillers or approaches, or those that prefer not to have an artificial filler used on their bodies, may prefer use of their own fat in procedures where fillers or other similar approaches are used.

For example, with respect to the aging face, it was previously assumed that as the aging process continues, the skin of the face becomes more flabby or loose. It has now been recognized that wrinkle formations and hollow areas of the face associated with aging are in large part due to loss of facial fat tissue. With aging, fat can disappear from the cheek bones, mid face, chin, and lips, and can accumulate in the jaw-line and neck. Fat has been used as a filler in almost all regions of the face where wrinkles and hollow areas result, or to enhance the features of the face. The hands are another region where the effects of aging can lead to a reduction in fat content. Fat has also been used to reduce the impact of these wrinkles as well. Fat can and has been used for breast augmentation, or to "smooth" deformations caused by implants that have changed or lost their shape over time. Reasons beyond cosmetic objectives exist for autologous fat transfer procedures, such as trauma, acne scarring, and HIV infection (some HIV medications can also lead to facial fat loss).

Fat transfer can involve as much "art" as it does medical skill. The fat to be transferred can not simply be injected into an area of the body where filling or plumping is desired. Rather, significant skill must be utilized to contour the transferred fat so that it can achieve the desired objectives, rather than simply "clump" in an area. In autologous fat transfer procedures, fat is removed from a fatty area of the body (generally the stomach, thighs or buttocks), cleaned (in some cases the physician will allow the removed fat to "stand" in the syringe so that liquids, such as blood, and other materials separate from the fat prior to re-injection; in others, the fat is centrifuged to aid in the process of separating the fat from other materials within the fat), and then layered in the areas requiring it by re-injection, such as the face or the hands. Because fat is a living tissue, the transferred fat graft can take root in the new area and persist. As with the original fat, over time the transferred fat can also disappear. However, transferred fat can last for significant periods of time. It is noted that care is exercised in the handling of the fat in these procedures. Tearing or ripping of the fat cells during removal and re-injection can kill fat cells, and such cells by definition can not take root in the new area.

Because the incision site for these procedures is generally quite small (owing to the small size of the cannula), the injection sites heal with virtually no visible scar.

Cost

By and large, almost all liposuction and autologous fat transfer procedures are categorized as "elective surgery." As such, in almost all such cases, these procedures are not covered by insurance, and must be 100% paid for by the patient. These procedures are most often associated with human patients, but a market is beginning to grow for liposuction on pets (such as dogs and cats) as well as rejuvenation procedures on certain types of animals (horses, for example; fat cells contain stem cells and procedures now exist for the removal of fat from race horses, treatment of the removed fat, and then reinjection of materials derived from the fat into, for example, the tendons of a race horse). The total costs associated with any particular procedure can and will vary depending upon the specific procedure being conducted; the skill, experience and reputation of the physician (or veterinarian); the location of the physician's surgical suite or hospital; as well as other factors.

In general, for human patients, the costs can range anywhere from a few thousand dollars per procedure, to tens of thousands of dollars. According to the American Society of Plastic Surgeons, in 2006, nearly $900,000,000 was spent on liposuction procedures, and nearly $75,000,000 was spent on autologous fat transfer procedures in the United States. However, this figure is just for board certified plastic and cosmetic surgeons. Other medical professionals (dermatologists, dentists, ear, nose and throat specialists, etc.) are increasingly performing these procedures, such that the actual expenditures for these procedures are believed to be much higher.

Adipose Cannulas

Design

The adipose cannulas used in these procedures are generally the same in terms of design: a hub that attaches to the end of a syringe (or to a suction machine), and a cannula tube having a blunt or rounded end with holes or ports on the sides of the cannula near the blunt or rounded end. For liposuction procedures, the cannulas are usually larger in diameter and longer in length; for autologous fat transfer, the cannulas tend to have much smaller diameters and lengths. In general, reusable adipose cannulas are made of stainless steel, while disposable adipose cannulas can be made of stainless steel (for the cannula) and sturdy plastic or plastic and rubber for the hub. While physicians may have preferential differences between reusable and disposable adipose cannulas, essentially the use and results are the same with these devices (anecdotal reports suggest that recovery times may be reduced with disposable adipose cannulas, presumably due to the fact that the device has not been previously used).

Cannula Cost

The costs of the adipose cannulas vary. For reusable adipose cannulas used for liposuction, these devices can cost anywhere from about $150.00 to about $300.00 per cannula. For autologous fat transfer, reusable micro cannulas can cost anywhere from about $150.00 to about $275.00 per cannula. For disposable adipose cannulas used for liposuction, these devices can cost anywhere from about $20.00 to about $25.00 per cannula. For autologous fat transfer, disposable micro cannulas can cost anywhere from about $15.00 to about $25.00 per cannula.

Cleaning and Sterilization

Reusable adipose cannulas must be cleaned and sterilized after each procedure. In general, the cannulas are washed or bathed in a cleaning solution (to help in the removal of fat that may stick to the interior walls of the cannula), a brush is inserted into the cannula to scrub the inside (to further clean and remove excess fat stuck thereto) and then sterilized in an autoclave machine (an autoclave is a pressurized, steam heated vessel that is intended to kill, for example, any bacteria or viruses that may exist on the cannula in an effort to sterilize the reusable adipose cannula).

The cleaning solution contains human tissue removed from the cannula. These solutions are often diluted and then disposed via the drainage system of the facility where the procedure is conducted (usually via a sink in the facility). At the point where the reusable cannula is eventually discarded, it is often incinerated via specialized facilities that incinerate (burn) the device and reduce the device to non-contaminated ash; pollutants are not released into the atmosphere via specialized filtration systems, and the remaining, non-contaminated residue ash (referred to as "cake") is safely discarded in land fills. Based on guidelines of the Association for the Advancement of Medical Instrumentation, the cost to set-up and the monthly labor/material charges associated with cleaning medical instruments is estimated to be about $6,200.00 or about $1,550 per week. Depending on the number of reusable cannula devices cleaned each week, the cleaning costs are also part of the overall cost associated with using the devices – for example, if there are 100 instrument cleanings per week, the average cleaning cost per instrument is $15.50.

Disposable adipose cannulas by definition are not cleaned after each use. As with any disposable medical product used in a surgical setting (such as a disposable needle or disposable syringe, garments, gauze, etc.), after use, the disposable adipose cannula is placed in a specialized container and usually incinerated along with other similar devices discarded from surgical procedures. As with the reusable cannulas, the incinerated disposable devices are destroyed by specialized organizations that handle hazardous medical waste, with no pollutants being released into the atmosphere, with the remaining non-contaminated residue ash (cake) being discarded in land fills.

Whether by intention or lack of awareness, a built-in incentive exists for using reusable cannulas for multiple times because with each use, the per-procedure cost of the reusable cannulas decreases, even though the cleaning costs remain fixed. For example, for a reusable cannula that costs $200, if it is used 10 times on 10 patients, the per-use cost is $20.00, plus the associated cleaning costs (for example, $15.50 per use assuming 100 instrument cleanings per week) for a total of $35.50 per use. If the instrument is used 100 times on 100 patients, the per-use cost is $2.00, plus the associated cleaning cost, for a total of $17.50 per use. If it is used 200 times on 200 patients, the per-use cost decreases to $16.50.

In general, the more that a reusable cannula is used, the lower its overall cost to the doctor.

For disposable cannulas, the costs are fixed based upon the cost of the device, plus a minimal disposal/incineration cost (these vary in that often the organizations who destroy such devices; because these organizations incinerate any and all materials used in a surgical procedure, the cost

per disposable cannula is difficult to calculate – however, overall, this cost is comparatively small compared with the cleaning costs associated with reusable cannulas.)

While some may question if there are cost savings between one type of device and another, others recognize that "in the end, disposables are no more expensive than reusable instruments," based upon the amount of time doctors and their staffs save by not having to reprocess (i.e. clean and sterilize) reusable instruments.

Regulations Regarding Sale and Use

Adipose cannulas are medical devices and therefore subject to regulatory approval by the United States Food and Drug Administration prior to commercialization. There are no laws or regulations regarding the length of time that reusable adipose cannulas can be used before they are disposed, nor are there laws or regulations regarding the number of patients that may be treated using the same reusable adipose cannula before they are disposed.

The length of time and number of patients for which a reusable adipose cannula applies is essentially left to the recommendation of the manufacturer, and to the discretion of the physician based upon the physician's knowledge of the continuing utility of a reusable adipose cannula (i.e., is the device still in "good" working order); the experience level of the physician with respect to the device; and the predilections of the physician in terms of intangibles (i.e., some may have a pre-determined number of times that they may use a device before replacing it; others may simply use the device until it has reached a point where it is no longer practical to use the device). Because no laws or regulations exist as to how many times a reusable adipose cannula may be used before it must be replaced or the number of different patients it can be used upon before it must be replaced, there is almost a built-in incentive to use these devices as often as possible before they are replaced, or before it becomes impractical to continue using them, simply to reduce the fixed costs associated with these devices per procedure.

Reusable Adipose Cannula Issues

Because a reusable adipose cannula by definition can be used on numerous patients over a series of years, any improper cleaning, sterilization or storage of the device can lead to potential problems such as cross-contamination or infection based upon the accidental transfer of bacteria or viruses from one patient to another. The cleaning and sterilization of a reusable adipose cannula is different from most other reusable surgical or medical instruments (such as for example the types used by dentists) because (1) fat is "sticky" and thus will have a tendency to adhere to these devices, and (2) unlike almost any other surgical instrument, the material being excised, that is, fat, must go *through the inside* a very small device (as opposed to being on the outside of the device such as would be the case with, for example, tissue on a

dental instrument) such that it is impossible and impractical to examine the inside of the device after each use to determine if it has been thoroughly cleaned. In the case of almost every other type of surgical instrument, the device making contact with tissue or other material can be examined because such material will almost always be on the *outside* of the device. The stickiness issue becomes an even greater one because the nature of cleaning the inside of a cannula (for example, scraping with a brush after soaking in a chemical cleaning solution, followed by autoclaving) can cause divots, crevices and other indentations within the cannula where fat can subsequently adhere. Another key reason why cleaning a reusable cannula is different and more complicated than other types of medical devices is that the holes where the fat enters the device or leaves the device is on the *side* of the cannula, with the end of the cannula being closed. Therefore, washing does not involve traditional flushing where solutions can be thrust through the device and exit an open end; rather, the solutions must circulate through the cannula and exit the side of the cannula, thus potentially leaving residue at the tip or along the interior surface.

Whatever residual fat tissue that might be left in the cannulas can harbor bacteria and viruses which are much smaller in size than even the smallest piece of fat tissue that might adhere to the inside of the cannula. However, this issue is not restricted to the potential cross-contamination between patients.

It is also a practical issue.

The insertion of a medical device into the body of a patient can take on a very personal, "comfort zone" aspect. In short, many (if any) patients are not informed that reusable adipose cannulas have been inserted into the bodies of other patients, or used to remove the fat of other patients, or to transfer the fat of another patient. While some patients may not object to this information particularly when informed of the cleaning, sterilization and storage processes employed before the reusable adipose cannula is utilized to perform their procedure, other patients might strongly object to having such a personal procedure conducted using instruments that have previously been used on other patients. Providing such relevant information as to the number of patients and the time of use of any reusable adipose cannula as well as the cleaning, sterilization and storage procedures used thereon, and the fact that alternative devices exist (that is, disposable, one-time use only adipose cannulas) can only help to enhance the comfort level of the patient or patient-guardian, and further enhance the physician-patient relationship. Disclosure of such information to a patient is never a negative. It is in fact essential for a truly informed consent.

Beyond the "comfort-zone" issue, the potential for infection in these procedures does exist.

Other countries have recognized risks associated with reusable medical devices in general. The National Coordinating Committee on Therapeutic Goods, Australia, noted in 2004 that:

> "Medical devices, particularly instruments, are often replaced only when they are beyond repair. Consequently, older, superseded medical devices may remain in circulation long after new, redesigned instruments have been purchased. Decommissioning superseded medical devices <u>that are difficult to clean</u> could assist in reducing the public health risks associated with these types of medical devices." (Emphasis added.)

In addition certain diseases are caused by materials which can be impervious to standard cleaning and sterilization techniques. Prion diseases, which include the human form referred to as Creutzfeldt-Jacob

syndrome (CJD) and the bovine form referred to as bovine spongiform encephalopathy (mad cow disease) are caused by proteins referred to as prions. The human form of the disease is believed to be caused by the exposure to prions associated with mad cow disease. The infectious agent of prion diseases resists conventional sterilization and decontamination methods on stainless steel surfaces. Indeed, it has been noted that:

> Because Mad Cow/CJD prions can withstand temperatures of approximately 1,000˚ F, the era of being able to adequately sterilize reusable medical/dental surgical instruments with current technology such as an autoclave is now past. We are calling for new universal sterile health precautions and policies requiring that ALL invasive medical, surgical, and dental instruments and devices may be used one time, and one time only, after which they must be discarded safely and appropriately. (Emphasis supplied; "ALL" capitalized in original).

Furthermore, even after cleaning and sterilization, residue (presumably human protein or fat) can remain within a reusable adipose cannula, and while not considered a "contaminant" such residue can accidentally be transferred from one patient to another.

Although statistically small, there are cases where, despite cleaning, cross-contamination has been associated with the use of reusable adipose cannulas.

The first official report to the United States Centers for Disease Control and Prevention (CDC) of surgical-site infections (SSI) caused by rapidly growing microbacteria (RGM) following liposuction or liposculpture occurred in early 1998; these incidents were all reported from Caracas, Venezuela. The CDC noted that SSI caused by RGM following aesthetic surgical procedures (such as liposuction or liposculpture, that is, autologous fat transfer) "is rare." Nonetheless, regardless of being "rare," such cases do exist and have occurred in California.

For example, the CDC reported from California (2002) that among 82 patients who underwent liposuction performed by a single practitioner in a 6-month period, 34 (41%) developed cutaneous abscesses. A bacterial organism identified as *Mycobacterium chelonae* was shown to be the source of the abscesses. A detailed retrospective cohort study that included interviews with former employees and statistical analysis of risk factors indicated that inadequate sterilization and rinsing of surgical equipment with tap water were likely sources of mycobacterial contamination. This was the first reported outbreak a hospital-acquired bacterial infection to occur in association with liposuction in patients in the United States, and as noted, these cases occurred in California.

While the introduction of the tumescent anesthesia approach allowed for the vast majority of these procedures to be conducted outside of a hospital setting and in physician offices or clinics, this, too, may increase the cause for concern over potential infections:

> Data recently published by the Journal of the American Medical Association show that infections from just one type of bacteria -- methicillin-resistant Staphylococcus aureus (MRSA) -- kill about twice as many people in the U.S. as previously thought. The finding is based on lab tests, not on what hospitals report. If the same methodology were used to

quantify deaths from all hospital infections, the death toll would likely be much larger than 100,000.

These infections are caused largely by unclean hands, inadequately cleaned equipment and contaminated clothing that allow bacteria to spread from patient to patient. In a study released in April, Boston University researchers examining 49 operating rooms at four New England hospitals found that more than half the objects that should have been disinfected were overlooked by cleaners. (Emphasis added).

Hospitals used to routinely test surfaces for bacteria, but in 1970 the CDC and the American Hospital Association advised them to stop, saying testing was unnecessary. The CDC still adheres to that position despite a 32-fold increase in MRSA infections. CDC officials say that lab capacity should be reserved for tests on patients.

Testing surfaces is so simple and inexpensive that it's used routinely in the food industry. Is it more important to test for bacteria in meat processing plants than in operating rooms?

The organization that accredits most hospitals, the Joint Commission, usually visits a hospital every three years. The commission emphasizes hand hygiene, but that's not enough. As long as hospitals are inadequately cleaned, doctors' and nurses' hands will become recontaminated seconds after they are washed, whenever they touch a bacteria-laden surface.

Joint Commission accreditation is no guarantee that a hospital is sanitary. An April 2007 study showed that 25% of California hospitals deemed unsanitary by state investigators responding to complaints had been accredited by the Joint Commission within the previous year.

Physicians' offices are not inspected at all. Most physicians are required to take a yearly course on infection precautions, but there is no follow-up to ensure they adhere to them or maintain clean offices. Patients' privacy concerns and cost issues may stand in the way of regularly inspecting doctors' offices, but when serious hygiene infractions are suspected, state health authorities should act decisively. **In many states, health departments and state medical boards are under criticism for putting a physician's livelihood ahead of patient safety**. (Emphasis supplied).

Nobody denies the right of any physician to make a living through the practice of their medical skills.

By the same token, neither should patients be denied access to relevant information that allows the patient, in consultation with his or her physician, to be fully informed about information that allows the patient to make a more reasoned and informed decision about a medical procedure to be performed on the patient. It is the patient's body. It should be the patient's choice.

Conclusion

Regardless of whether the reusable adipose cannula has been properly cleaned, sterilized and stored, most patients, if any, are ever informed that in the case of reusable adipose cannulas, the devices may have been used on many different patients over the course of several years. Regardless of whether or not cross-contamination issues may or may not be significant, this issue should be viewed in the context of full disclosure for patients, based upon a "comfort zone" perspective – once a patient or patient-guardian has been informed as to the number of different patients and the number of years that the reusable adipose cannula has experienced, as well as the cleaning, sterilization and storage procedures used on that cannula, it may be the case that the patient will not be concerned as to the reusability of the cannula. By further informing the patient or patient-guardian that an alternative exists in the form of disposable adipose cannulas, the patient or patient-guardian is able to make a more informed decision as to what type of device that they prefer to be utilized in their procedure. This, then, enhances the communication and knowledge-awareness process between the patient and physician.

Full disclosure between a physician and the patient can never be detrimental.

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